



OKLAHOMA
State Department
of Health

Test Directory

Oklahoma State Department of Health
Public Health Laboratory
4615 W. Lakeview Rd
Stillwater, Oklahoma 74075
Telephone: (405) 564-7750
Fax: (405) 900-7611

Email: PublicHealthLab@health.ok.gov

Website: <https://oklahoma.gov/health/locations/public-health-laboratory>

Federal Tax ID: 736017987
CLIA Number: 37D0656594

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LABORATORY INFORMATION

Hours of Operation

Monday – Friday, 8:00 am - 5:00 pm (Central Time)

The OSDH Public Health Laboratory (PHL) may be reached by email at PublicHealthLab@health.ok.gov. The general email address is monitored by PHL team members that will make sure the inquiry will be answered by the correct service area within two business days. Typical inquiries relate to supply requests, courier information, and providing copies of test results. It is also possible to ask technical questions about specific tests, specimen collection, storage and shipping, and patient test result availability and interpretation.

The OSDH PHL is closed on Official State Holidays:

- New Year's Day
- Martin Luther King, Jr. Day
- President's Day
- Memorial Day
- Independence Day
- Labor Day
- Veterans Day
- Thanksgiving
- Christmas

Generally, when a holiday falls on a non-workday — Saturday or Sunday — the OSDH will be closed on Monday (if the holiday falls on Sunday) or Friday (if the holiday falls on Saturday). For specific dates see [State Holidays \(oklahoma.gov\)](http://stateholidays.oklahoma.gov).

Contacts

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Website: <https://oklahoma.gov/health/locations/public-health-laboratory>

Federal Tax ID: 736017987

Licensure and Accreditations

The OSDH PHL has CLIA (Clinical Laboratory Improvement Amendments) certification through CMS (Centers for Medicare & Medicaid Services).

Each laboratory is required to verify that reference laboratories utilized by the laboratory are CLIA'88-certified for high-complexity testing in the applicable specialty/subspecialty for which testing services are sought. This requirement can be satisfied by obtaining copies of current CLIA certificates from each reference laboratory utilized by the referring laboratory. Since the OSDH PHL serves as a reference laboratory for County Health Departments and other institutions, we have made available a current copy of our CLIA certificate (#37D0656594) at the [OSDH PHL website](#) (see Public Health Laboratory/Test Directory) to allow submitting sites to comply with this regulation. If the OSDH PHL forwards submitted specimens to a reference laboratory for additional testing, there is no requirement for the submitting site to obtain verification of CLIA-'88 certification from those reference laboratories; submitting laboratories may rely on our accreditation to ensure compliance with this regulation.

SPECIMEN COLLECTION

Kits/Supplies

The OSDH PHL provides the following collection kits/supplies free-of-charge to OSDH County Health Department sites through the Inventory Supply System:

- Enteric Bacteria kit (Cary-Blair Transport Medium)
- TB/Sputum Culture kit
- Virus Transport Medium kit (Remel M4RT Tube)
- Pertussis kit
- Aptima Urine Specimen Transport Tube (USTT)
- Aptima Multitest Swab Specimen Transport Tube (MSSTT)
- SST Tubes (Serum Separator Tubes)
- Newborn Screening and PKU Monitoring Form (ODH #450)
- Specimen Biohazard Bags
- Absorbent for Specimen Bags
- Disposable Nasopharyngeal Swabs
- Parafilm
- 22"x24" Reclosable Bags
- 2-Label for Lab Requisitions
- Clear Wet Prep Tubes
- Child/Adult Sickle Cell Screening kit (ODH #485)

The following kits are offered to private clinics and hospitals (fees apply as indicated); check with the OSDH Warehouse at (405) 444-6494 during regular business hours, email janeti@health.ok.gov or michaelxa@health.ok.gov, or submit a Laboratory [Supply Order Request](#) (see details below) to arrange shipment:

- Enteric Bacteria kit (Cary-Blair Transport Medium) (\$18.00)
- TB/Sputum Culture kit (\$17.00)
- Virus Transport Medium kit (Remel M4RT Tube)
- Pertussis kit

Collection kits for Newborn screening and PKU monitoring (ODH #450 Newborn Screening Form) and adult/child hemoglobinopathy (sickle cell) screening (ODH #485 Child/Adult Sickle Cell Screening Kit) are available to birthing centers, County Health Departments, and other healthcare providers at no cost.

Supplies are shipped Monday through Thursday.

Instructions for Specimen Collection

Instructions for specimen collection are provided in the description of individual tests within this Test Directory. Further specifics regarding specimen collection can be obtained from technical staff of the OSDH PHL.

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All specimens must be collected, labeled, transported, and processed according to procedures indicated in this Test Directory and/or kit instructions. Prior to collection of the specimen, review the appropriate container type, specimen volume, storage and shipping conditions, and any other special handling requirements needed for optimum analysis. If the guidelines for these processes are not met, the specimen may be rejected or the test results compromised.

To ensure correct patient and specimen identification at the point of collection, personnel involved in the collection of specimens must confirm the patient's identity by checking at least two patient identifiers prior to collection of a specimen, e.g., an inpatient's wristband may be checked for name and unique hospital number or an outpatient's name and birth date may be used. The patient's identity should be verified by asking the patient to identify themselves when it is practical to do so.

Standard precautions to protect against exposure to infectious diseases should always be followed, and barrier protections applied whenever specimens are obtained from patients.

Labeling Specimens

The primary specimen container/tube must be labeled with at least two patient-specific identifiers (i.e., patient name, date of birth, medical record number, barcode, lab number, or other unique code). Note that use of the patient's name alone on the specimen is inadequate to uniquely identify the specimen. Other information may also be required on the specimen container/tube depending on individual test requirements. Some test kits have labels supplied for labeling specimen containers/tubes, otherwise use computer-generated or other labels available at the submitting site. Note that microscope slides submitted for identification purposes (e.g., malaria speciation) are considered primary specimen containers and must be labeled appropriately.

Submissions by Oklahoma County Health Departments:

1. Place unique laboratory barcode label on container/tube. Caution: Do not cover the manufacturer's expiration date on container/tube. Position label such that the level of blood in the tube is visible.
2. Ensure barcode label on container/tube matches the barcode label on test requisition form prior to submission.



3. Other information may need to be placed on container/tube depending on individual test requirements; refer to collection instructions for specific test.

Submissions by Other Sites:

1. Record patient's full name or other patient identifier, and date of birth on container/tube. Use a computer-generated label, if available.
2. Ensure information on the container/tube matches that on the test requisition form prior to

submission.

3. Other information may need to be placed on container/tube depending on individual test requirements; refer to collection instructions for specific test.

If multiple labels are used on a specimen, the last applied label will be used as the primary method of identification. It is good practice to place new specimen labels immediately beneath the name/identifier of the patient as it appears on the previous label such that the names/identifiers on both labels can be read.

For instructions on labeling collection kits for newborn screening and PKU monitoring (ODH #450 Newborn Screening Form) and adult/child hemoglobinopathy (Sickle Cell) screening (ODH #485 Child/Adult Sickle Cell Screening Kit), see the Newborn Screening (NBS) Panel section of this Test Directory.

TEST REQUESTS

Rabies

Rabies specimens are no longer accepted or processed at the OSDH PHL. Animal specimens to be tested for rabies should be submitted to the Oklahoma Animal Disease Diagnostic Laboratory (OADDL) of the OSU College of Veterinary Medicine, located at 1950 W Farm Rd, Stillwater, OK 74078. OADDL can be contacted by telephone at (405) 744-6623. If you suspect a case of human rabies, immediately contact the OSDH Disease and Prevention Services at (405) 426-8710. In emergent situations, the specimens may be delivered to local county health departments for courier transport to OADDL.

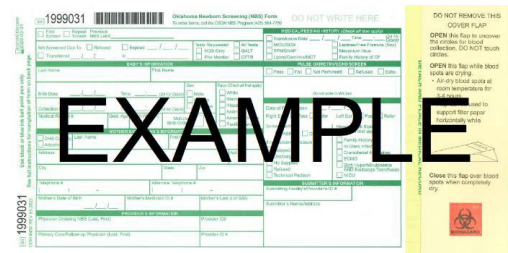
Test Requisition Forms

All patient specimens submitted to the OSDH PHL for testing must be accompanied by an appropriately completed test requisition form. Submitters should use a test requisition form appropriate for the specimen being submitted:

- [Oklahoma State Department of Health - Lab Request](#)
This form is used for submission of patient specimens/isolates other than those associated with newborn screening, PKU monitoring, or child/adult sickle cell screening. OSDH County Health Department sites are able to pre-populate this form electronically within the OSDH PHOCIS system; other sites can access this form at the OSDH PHL website.
- [Online Laboratory Requisition Form ODH #419](#)
This form is used when access to the PHOCIS/PHIDDO system is not set up, such as when submitting for a Community Based Organization (CBO).
- **Laboratory Requisition Form Printable ODH #419LRN**
This form is used to order tests of select agent. If access of this form is needed, please contact the PHL email at PublicHealthLab@health.ok.gov or OSDH Infectious Disease Service at (405) 426-8710.

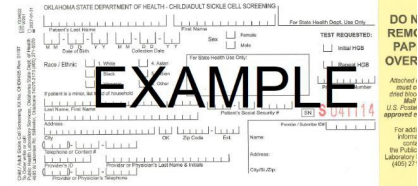
Newborn Screening Form ODH #450

This form is used for submission of specimens for newborn screening and PKU monitoring, and can be ordered from the OSDH PHL Client Services Department at (405) 564-7750; also, see [Kits/Supplies](#) section of this Test Directory.



- **Sickle Cell Screening Form ODH #485**

This form is used for screening of children/adults for sickle cell disease and can be ordered from the OSDH PHL Client Services Department at (405) 564-7750; also, see [Kits/Supplies](#) section of this Test Directory.



Test requisition forms for patient testing must be completed in their entirety and contain the following information (CLIA Regulation 42 CFR 493.1241) prior to submission:

- Patient's name or unique patient identifier (e.g., MR#);
- Patient's sex;
- Patient's DOB;
- Test(s) to be performed;
- Source of the specimen, when appropriate;
- Date and, if appropriate, time of specimen collection;
- Name and address or other suitable identifiers of the authorized person requesting the test, and if appropriate the individual responsible for using the test results, OR name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life-threatening laboratory results or panic or alert values;
- Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

Note: Information provided on the test requisition form will be cross-referenced with information appearing on the last placed label on the specimen container/tube.

All patient-specific identifiers (i.e., patient name, date of birth, MR#, or other unique number or code) provided on the test requisition form must match exactly those provided on the specimen container/tube; any discordance will result in the specimen being deemed unsatisfactory for testing. Therefore, if the name on the requisition is spelled differently from that on the specimen (even by a single letter), it will be deemed unsatisfactory for testing. If a patient's initials rather than full name are provided on the primary specimen container and the full name is provided on the test requisition, it will be deemed unsatisfactory for testing. Also, even if one patient-specific identifier is concordant between the requisition and specimen but another identifier is discordant, the specimen will be deemed unsatisfactory for testing. The PHL may contact the submitter to resolve such discrepancies in the identifiers provided on the test requisition and specimen.

Also, if other information (e.g., sex, DOC, time of collection) is discordant between the specimen container/tube and test requisition form that potentially affects the acceptability of the specimen, the submitter will be contacted for clarification.

Obvious inconsistencies between multiple labels on the same specimen container/tube will result in the specimen being deemed unsatisfactory for testing.

Information provided on the test requisition may be changed; however, the PHL will not change any information that is provided on a specimen. A corrected requisition form or other suitable documentation must be provided by the submitter before the specimen can be accepted for testing.

For instructions on completion of ODH #450 Newborn Screening Form (for newborn screening and PKU monitoring) and ODH #485 Child/Adult Sickle Cell Screening Form (for adult/child sickle cell screening), see Newborn Screening (NBS) Panel section of this Test Directory.

Verbal Requests

The OSDH PHL does not accept verbal requests for initial testing; however, it does accept verbal requests for add-on testing to previously submitted specimens, as appropriate (see Add-on Test Requests section below).

Add-on Test Requests

Additional testing may be added subsequent to submission of an original test request, if volume of the original submitted specimen is adequate. Requests for add-on testing may be received verbally, but must be followed with a written request within 30 days of the verbal request. All verbal requests for add-on testing require test order 'read-back' to ensure accuracy. Additional testing may be delayed in the absence of a written request. A test report will not be issued for any additional requested testing in the absence of a written request.

STAT Requests

STAT testing is performed only on specimens to determine outbreak status as deemed necessary, and on all credible bioterrorism threat cases. STAT testing requests require notification and approval of the OSDH PHL prior to submission of the specimen.

Medico-legal Test Requests

The OSDH PHL does not perform medico-legal testing.

Test Cancellations

Testing can only be cancelled by the original submitter of the specimen. This can be done verbally or in writing. A report will be issued indicating cancellation of the test.

Referral Testing

When indicated, the OSDH PHL will refer specimens to specific reference laboratories for additional testing. Test results from reference laboratories will be reported to submitting sites by the OSDH PHL.

Specimens submitted to the OSDH PHL for referral to another laboratory for testing (i.e., passthrough testing), including the Centers for Disease Control and Prevention (CDC), requires prior notification and approval by the OSDH PHL. Such specimens should be submitted using the reference laboratory's test requisition form, and collected, labeled, stored and shipped as instructed by the reference laboratory.

Specimens referred by OSDH PHL to a reference laboratory for testing should be submitted using OSDH PHL's test requisition form, and collected, labeled, stored and shipped as instructed by the OSDH PHL. It is the responsibility of the OSDH PHL to include any additional paperwork required by the reference laboratory and to ensure that the collection, labeling, storage and shipping requirements communicated in the OSDH PHL's Test Directory and by OSDH PHL staff are compliant with the requirements of the reference laboratory for that specific test.

Prior to submitting specimens to a reference laboratory, the OSDH PHL will obtain a copy, or have on-hand a copy, of the current CAP accreditation and/or CLIA certificate of the reference laboratory to verify that the reference laboratory is CLIA-'88 certified for testing in the applicable specialty/subspecialty.

SPECIMEN STORAGE AND SHIPMENT

Following collection, specimens must be appropriately pre-processed and stored (as necessary) then packaged and shipped to ensure that they arrive at the OSDH PHL in a satisfactory state for testing. All packages of specimens should be accompanied by a Specimen Shipping Manifest. For detailed information on appropriate pre-processing, storage, packaging and shipping of samples for submission to the OSDH PHL for testing, refer to the individual test descriptions in this Test Directory. Some general guidance on these topics is provided below.

Blood Tubes, CSF, Urine, Culture Tubes, Sputum, and Stool Specimens

1. Specimens must be packaged in a securely sealed, water-tight, *primary* container appropriate for the specimen being collected (e.g., blood tube, UPT tube, screw-capped plastic tube, etc.). This primary container must be appropriately labeled.
2. The primary container must be placed in a *secondary* container (zip-lock plastic biohazard bag) that is capable of being closed to form a water-tight seal.
 - The secondary container should contain an absorbent material (e.g., paper toweling or gauze) of sufficient volume to absorb the complete fluid contents of the primary container in case of leakage/breakage of the primary container.
 - OSDH PHL personnel will not open biohazard bags containing specimens that have leaked or broken during transit. If the specimen can be identified without opening the biohazard bag, a report will be issued to the submitter to inform them that the specimen will not be tested. If such specimens cannot be identified, a report will not be generated; therefore, submitting facilities should check their Specimen Referral Log at appropriate intervals to ensure test results have been received accordingly, and contact the OSDH PHL if results have not been received in the expected timeframe.
3. Multiple samples (except Aptima samples tubes for CTGC testing) may be placed in a single *secondary* container but:
 - The total volume of samples in one *secondary* container must not exceed 50 mL.
 - Sputum samples (for tuberculosis testing), stool samples (for enteric testing), and samples for virus isolation testing should be separated from all other sample types; each specimen type should be packaged separately.
 - When possible, package specimens by test type requested, (e.g., all Syphilis in one

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- bag, all HIVs in one bag, etc.).
- Specimens that require specific transporting conditions (ambient, refrigerated or frozen) must be packaged and shipped separately. It is strongly encouraged to mark the outside of the bag of all *secondary* containers with “Transport at Room Temperature”, “Transport Refrigerated” or “Transport Frozen”. If such specimens are sent via the OSDH PHL-contracted courier, the courier must be informed that the specimens are to be transported refrigerated on ice packs or frozen on dry ice, as appropriate. Alternatively, samples may be packed in insulated boxes containing cold packs at refrigerated temperatures (for samples requiring refrigerated temperatures during shipping) or with sufficient frozen ice packs or dry ice (for samples that should remain frozen during transport) and given to the courier. Samples that should be transported frozen should be placed directly on frozen ice packs or dry ice to keep them frozen. Do not place specimens that should be transported at refrigerated temperatures directly on frozen ice packs; place cardboard or other insulator between ice packs and these specimens.
 - When shipping frozen specimens over long distances, it is best to use a combination of dry ice and frozen gel ice-packs; the gel ice-packs will remain frozen for a day or two after the dry ice has dissipated.
4. Requisitions should be placed in the outer pocket of the plastic biohazard bag. Do not wrap requisitions around individual specimens. Fold requisition such that the test request faces outward and can be read through the bag.

Newborn Screening, PKU Monitoring and Sickle Cell Screening Forms

For instructions on storage and shipping of collection kits for newborn screening, PKU monitoring, and adult/child hemoglobinopathy (sickle cell) screening, see Newborn Screening (NBS) Panel section of this Test Directory.

Courier Service

The OSDH PHL contracts with a courier service to pick-up specimens from OSDH County Health Departments and other sites for delivery to the central laboratory located in Stillwater. Courier pickup occurs on a regular schedule Monday through Friday for most sites (weekend pick-up of newborn screening specimens occur at most birthing facilities). Requests for non-scheduled specimen pickups must have prior approval; email PublicHealthLab@health.ok.gov or call the OSDH PHL at (405) 564-7750. Pick-up occurs at approximately the same time each workday for an individual site. Specimens collected after the designated pick-up time will be picked-up from the site on the following workday. Specimens should not be held for batch pick-up. Accordingly, testing of these specimens will not begin until the day following pick-up, at the earliest. Such delays in testing should be considered especially when scheduling specimen collection from patients on Fridays; if the specimen is not picked-up on Friday, pick-up will be delayed until Monday and testing will not occur until Tuesday, at the earliest. For newborn screening specimens picked-up on weekends, testing begins on Monday or the next work day. Similar provisions should be made for holiday closings of the OSDH PHL. Specimens should be stored appropriately from the time of collection to the time of delivery to the OSDH PHL.

Other Delivery Methods

The OSDH PHL-contracted courier is the preferred method for delivery of specimens to the OSDH PHL; however, specimens can also be transported directly to the OSDH PHL via private courier, commercial courier (e.g., FedEx, UPS), or USPS. Note: these alternative services will not be able to deliver specimens to the OSDH on weekends.

Shipping Regulations

For shipping specimens, specimens should be packaged and labeled in compliance with applicable state, and federal, and international regulations covering the transport of clinical specimens and etiologic agents/infectious substances. Specific rules and regulations set forth by the U. S. Department of Transportation ([eCFR :: 49 CFR 173.196 – Category A infectious substances](#), Category A infectious substances and part 173.199, Category B infectious substances) should be followed in order to ensure safe transport of potentially infectious substances.

A Category A infectious substance is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. *A Category B infectious substance* is an infectious substance that does not meet the criteria for inclusion in Category A.

According to [Guidance on regulations for the transport of infectious substances 2021-2022 \(who.int\)](#), the proper designation for shipment of Category A substances is “UN 2814 – Infectious Substance, Affecting Humans” and that for Category B substances is “UN 3373 – Biological Substance, Category B”.

If samples are transported by air, the International Civil Aviation Organizations (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods should be followed. The International Air Transportation Association (IATA) provides shipping procedures based on ICAO instructions for shipping hazardous materials by air. These can be found in packing instructions 620 for Category A infectious substances and packing instructions 650 Category B infectious substances. Contact the OSDH PHL at PublicHealthLab@health.ok.gov for additional information regarding shipping regulations.

SPECIMEN RECEIPT AT OSDH PHL

Specimen Rejection

Specimens will be rejected for the following reasons:

- Inappropriate specimen (e.g., type; patient age; patient gender);
- Inappropriate specimen container or collection device/media;
- Insufficient volume for analysis (i.e., QNS);
- No or illegible patient name or other unique identifier on specimen container;
- No or illegible patient name or other unique identifier on requisition form;
- Inability to match at least one unique identifier between the test requisition form and the specimen container due to absence or illegibility of others;
- No test requisition form;
- Inability to determine address or submitter ID for submitting laboratory/clinic (may be able to obtain information by inquiry, if missing);

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- Expired collection device/kit;
- Specimen received outside of timeframe appropriate for testing;
- Specimen handled improperly subsequent to collection (e.g., improper temperature during specimen shipment; specimen container leaked, broke or otherwise compromised during shipping);
- Laboratory accident (e.g., spilled sample during accessioning);
- Other reasons as outlined in the individual test descriptions of this Test Directory.

All specimens deemed unsatisfactory for testing will have a final report generated stating the reason.

Missing Information

When any of the following information is missing from the test requisition form or specimen container, or is otherwise illegible or unclear (e.g., orders are non-specific or non-standard), the submitter will be contacted by the OSDH PHL, as appropriate:

- Patient's name
 - Date of birth (DOB);
 - Time of birth (NBS only);
 - Date of collection (DOC);
 - Time of collection (TOC) (NBS only; and only if less than one day difference between date of birth and date of collection);
 - Sex assigned at birth (not required for NBS unless 2nd tier CAH testing is required);
 - Address of submitter;
 - Test requested;
 - Source of specimen, if appropriate.
- OSDH PHL will contact the submitters via phone call (which will be documented) and the submitters will be requested to send the needed information to OSDH PHL (PublicHealthLab@health.ok.gov) and ASR (OSDH.ASR@health.ok.gov) within 7 days of receipt of specimens. Specimens with missing information will be held for 7 days or until they have exceeded the appropriate time for testing, whichever is shorter. If missing information is not received from the submitting site within 7 days, the specimen will be deemed unsatisfactory for testing and reported as *“Unsatisfactory: information requested, not received”*.

Referred specimens for enteric bacteria testing with missing information and for which requested information is not received, will be tested by the OSDH PHL and test results will be communicated to the OSDH Infectious Disease Division for epidemiological purposes only. The submitter will receive a final report that indicates *“Unsatisfactory for testing”* and will not receive test results from OSDH PHL.

TEST REPORTS

Issue of Test Reports

Reports are issued via fax and/or US Mail to the submitting facility/healthcare provider using the information provided on the test requisition form. Submitters must complete a Facsimile Permission Form prior to receiving reports by fax. To sign-up for this service, call the PHL at (405) *Last revised 12-1-2023*

564-7750.

OSDH County Health Departments are able to retrieve patient test reports directly using the PHOCIS system.

Newborn Screening results are accessible to authorized healthcare providers through the *Newborn Screening Results* web-based portal. To sign-up for this service, call the PHL Client Services Department at (405) 564-7750.

Some critical test results may be reported by telephone to authorized clients (facilities/healthcare providers). Critical results for newborn screening will be timely communicated to OSDH NBS follow-up team to contact providers. All results conveyed by telephone require “read-back” confirmation by party receiving.

It is preferred that patients or legal representatives return to the submitter for test results. However, reports may be available upon request if the appropriate documentation received listed in the *Patient Access to Laboratory Test Results* section below.

Changes to Information on Test Reports

Corrections to test reports, subsequent to original issue of test results to the submitter, may be made by the OSDH PHL, as appropriate. The Corrected Report will indicate the information being changed (i.e., with explicit indication of “from” and “to”) and the need for the change, as appropriate. A request will be made to the submitting facility for the original report to be returned to the OSDH PHL or for it to be destroyed by the submitting facility.

Changes to information presented in a test report may be made at the request of an authorized individual from the submitting facility. Please, call the OSDH PHL at (405) 564-7750 and ask to speak to the supervisor of the laboratory responsible for performing the test. Verbal requests for changes to information provided on test reports must be followed by a written request within 30 days. A report will not be issued on such specimens until a written request from the submitting facility is provided to the OSDH PHL. The laboratory supervisor and/or Client Services Department will provide the necessary forms for completion by the submitter in order to fulfill such requests. Requests for changes in demographic information following issue of a test report will result in issue of a Corrected Report; the information being changed (with explicit indication of “from” and “to”), the person requesting information to be changed, and date/time of the request will be indicated on the Corrected Report. A request will be made to the submitting facility for the original report to be returned to the OSDH PHL or for it to be destroyed by the submitting facility.

The OSDH PHL will perform minor demographic errors for patient name but will not change the identity of the patient unless test requisition information incorrectly entered into the LIMs system or specimen container has been misinterpreted by OSDH PHL staff during data entry or a typographical error occurs.

Patient Access to Laboratory Test Results

On February 6th, 2014, the Centers for Medicare & Medicaid Services (CMS) published a final rule that amended both the Clinical Laboratory Improvement Amendments (CLIA) and the Health Insurance Portability and Accountability Act (HIPAA) in order to provide patients with direct access to laboratory test results. Under the final rule, laboratories that operate as covered entities under

HIPAA are required to provide individual patients, or their representatives, with laboratory test results for those tests performed by the laboratory upon the patient's request.

The OSDH PHL in Stillwater is unable to provide laboratory test results directly to individuals presenting at this location. Patients, or their legal representatives, may obtain copies of their laboratory test reports for testing performed at the OSDH PHL by presenting at the County Health Department or other health care facility where medical care was provided. The patient, or their legal representative, will be asked to complete an [ODH 206 Oklahoma Standard Authorization](#), provide a photo ID and/or authorization code prior to release of laboratory test results.

Alternatively, patients, or their legal representatives, can contact the OSDH PHL at (405) 564-7750 to obtain laboratory test reports through the mail or electronically. A patient, or their legal representative, may request laboratory test results performed by the OSDH PHL by completing a [Request to Release Lab Test Results](#).

BILLING

CPT Coding

The OSDH PHL has provided CPT codes for testing that it performs for guidance purposes only. These codes reflect our interpretation of the coding requirements. CPT coding is the sole responsibility of the billing party. Individual facilities should contact the OSDH PHL for information regarding testing methodology and the local Medicare carrier for clarification, as appropriate.

ONSITE TEST LIST

Individual tests that are performed in the PHL in Stillwater are listed alphabetically in the subsequent pages. Be aware that individual tests may be named differently than expected, and keywords have been provided in the title in some instances. If you are having difficulty finding the specific test, try searching the document for keywords.

Bordetella – PCR

Use: For the diagnosis of pertussis syndrome (whooping cough) in children with consistent epidemiological and clinical features of disease. Also, appropriate for adults with persistent cough in whom *Bordetella pertussis* infection is suspected.

Methodology: This assay targets three insertion sequences, IS481, pIS1001 and hIS1001 of *Bordetella* spp. Using real-time, multiplexed PCR. *B. pertussis* or *B. parapertussis*-positive cases are reflexed to a second PCR that targets the *ptxS1* gene that encodes the S1 subunit of pertussis toxin. Presence/absence of combinations of these sequences allows for differentiation between *B. pertussis*, *B. parapertussis* and *B. holmesii*. While this test may detect *B. bronchiseptica*, it cannot differentiate it from other *Bordetella* spp. CDC recommends *B. pertussis* culture concurrently.

Clinical Significance: Pertussis is an upper respiratory tract infection caused by *B. pertussis* bacteria. It is a serious disease that can cause permanent disability in infants, and even death. In previously vaccinated children and adults in whom immunity has waned, symptoms can be mild or absent. Since adenovirus, parainfluenza viruses, CMV, *Mycoplasma pneumoniae*, and *Chlamydia pneumoniae* can also cause pertussis-like coughing, rapid and accurate diagnosis is needed to guide therapy.

Further background information, fact sheets, statistics and educational resources may be found at the OSDH Infectious Disease Services [website](#).

Specimen Type: • Nasopharyngeal swab (with flexible, fine-shaft and nylon, rayon or Dacron tip)

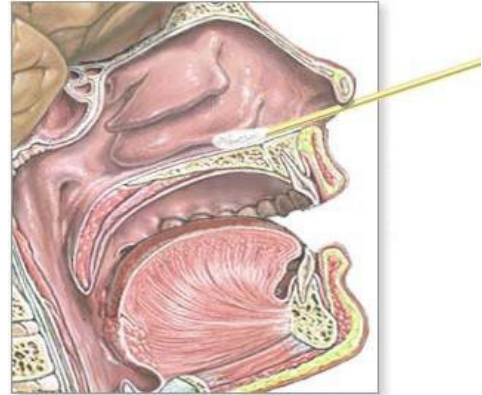
Minimum Volume/Size: Swabs: 1 or 2

Container: Regan Lowe transport media (provided by OSDH PHL)

Collection: Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false laboratory test results. Training in specimen collection is highly recommended due to the importance of specimen quality.

Tip: If the patient is seated for the procedure, have the patient sit with their head against a wall since patients have a tendency to pull away during the procedure.

1. Label a Regan Lowe transport media tube with patient's name and date of collection.
2. If the nasal passages have a large amount of mucous, ask the patient to blow their nose before collecting specimen.
3. With the thumb of one hand, gently elevate the tip of the patient's nose, then gently insert NP swab into a nostril.
4. Guide the swab straight back (not upwards), along the floor of the nasal passage until it reaches the posterior wall of the nasopharynx; the distance from the nose to the ears gives an estimate of the distance the swab should be inserted.



Note: Do not force the swab – if an obstruction is encountered during insertion, try the other nostril.

5. Rotate the swab by firmly brushing against the nasopharynx several times.
6. Hold it there for a few seconds then with a rotating motion gently remove it.
7. Place swab immediately into Regan Lowe transport media, positioning the swab about half way into media.
8. Break-off or cut excess shaft of swab so that tube can be capped.
9. Place tube in plastic biohazard bag and insert completed requisition form in outer pouch of the bag.

Special Instructions:

- Specimens should be collected as early as possible in infection, preferably within 3 days of onset of clinical symptoms. Optimal sensitivity of detection occurs during the first 3 weeks of cough.
- Incubate NP swabs at ambient temperature for 18-24 hours prior to shipping at refrigerated temperature (2-8°C) or ship immediately at ambient temperature.
- Contact OSDH Infectious Disease Services at (405) 426-8710 regarding all suspected *Bordetella pertussis* cases.
- It is extremely important to record date of onset, date of collection (DOC) and physician contact information on requisition form.

Shipping:

Refrigerated at 2-8°C (alternatively, ship immediately at ambient temperature); must be received within 7 days from DOC

- Common Causes for Rejection:**
- Incorrect transport media
 - Incorrect collection device, e.g., cotton or calcium alginate swab
 - Incorrect shipping temperature
 - NP swab not submerged/present in transport media
 - Specimen received > 7 days after DOC
 - Other criteria as outlined in Specimen Rejection section of this Test Directory

Turn-around Time: Within 5 working days from receipt

Normal Value (Reference Range): Bordetella Not Detected

Reportable Results:

- Bordetella Not Detected
- Bordetella pertussis Detected
- Bordetella parapertussis Detected
- Bordetella holmeii Detected; can't rule out B. pertussis co-infection
- Bordetella pertussis and B.parapertussis Detected
- Bordetella pertussis and B.holmesii Detected
- Indeterminate

Interpretation: Specimens that are positive for IS481 and *ptxS1* indicate presence of *B. pertussis*, those positive for pIS1001 and *ptxS1* indicate presence of *B. parapertussis*, and those with IS481 and hIS1001 products indicate *B. holmesii*. Dual infections of *B. pertussis* and *B. parapertussis* are indicated when IS481, pIS1001 and *ptxS1* are detected.

Limitations/ Interferences: A negative result does not preclude the presence of Bordetella spp. Infection. The results of this test should not be used as the sole basis for diagnosis or patient management decisions. Positivity of this test may be variable following treatment.

Cotton swab; Calcium alginate swab (shown to inhibit PCR); Wooden-shaft swab

CPT Code: 87801

Notes: This is a laboratory-developed test; performance characteristics have been validated and determined to be suitable for diagnostic purposes by the OSDH PHL. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Carbapenem-resistance Testing (Antibiotic Resistance Laboratory Network – ARLN)

Use: Confirmation and characterization of carbapenem-resistant *Enterobacteriaceae* (CRE), *Pseudomonas aeruginosa* (CRPA), and *Acinetobacter* spp. (CRA) isolates from Oklahoma healthcare facilities for epidemiological purposes. These tests are intended as an aid for infection control of carbapenem-non-susceptible organisms in healthcare settings. They are not intended to guide or monitor treatment for carbapenem-non-susceptible bacterial infections.

Per the [Oklahoma Administrative Code, Title 310 Chapter 515-1-8](#), pure isolates of these organisms shall be sent to the OSDH Public Health Laboratory for additional characterization, typing or confirmation within two (2) working days (Monday through Friday, state holidays excepted) of final identification or diagnosis.

Methodology: *Enterobacteriaceae* and *P. aeruginosa* isolates are initially subjected to MALDI-ToF-mass spectrometry and/or biochemical testing to confirm species. Successfully identified isolates subsequently undergo a variable combination of Modified Carbapenemase Inactivation Method (mCIM) to confirm phenotypic carbapenem resistance, Antimicrobial Sensitivity Testing (AST) using a broth microdilution method (Sensititre™ System) and molecular detection of KPC, NDM, VIM, IMP and OXA-48 antimicrobial resistance genes (Cepheid Xpert® Carba-R IVD), according to CDC's *Guidance for Testing CRE and CRPA in State and Local Public Health Laboratories*. *Acinetobacter* spp. Isolates are referred directly to the Antimicrobial Resistance Laboratory Network (ARLN) Regional Laboratory or CDC for detection of KPC, NDM, VIM, IMP, and OXA variant genes.

Clinical Significance: Carbapenemase-producing *Enterobacteriaceae*, *P. aeruginosa* and *Acinetobacter* spp. Are a growing public health concern. They are often resistant to all beta-lactam agents and can be co-resistant to multiple classes of other antimicrobial agents. Identifying isolates that produce carbapenemase and classifying the kind of carbapenemase present is important in preventing their spread.

Further background information, fact sheets, statistics and educational resources may be found at the OSDH Infectious Disease Services website.

Specimen Type:

- Pure isolate of confirmed or suspected carbapenem resistant *Enterobacteriaceae* grown for 18-24 h on Trypticase Soy Agar with 5% Sheep's Blood (BAP).
 - It is recommended that isolates are restricted to *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, and *Enterobacter* spp. That are resistant to imipenem, meropenem, or doripenem (each with MICs of ≥ 4 $\mu\text{g}/\text{mL}$), or ertapenem (≥ 2 $\mu\text{g}/\text{mL}$) by standard susceptibility testing methods.

- Pure isolate of confirmed or suspected carbapenem-resistant *P. aeruginosa* that is resistant to imipenem, meropenem or doripenem by standard susceptibility testing methods (MIC \geq 8 μ g/mL). Muroid CRPA isolates should be excluded
- Pure isolate of confirmed or suspected carbapenem-resistant *Acinetobacter spp.*
 - It is recommended that isolates are restricted to *Acinetobacter baumannii* or *A. baumannii* Complex that are resistant to imipenem, meropenem, or doripenem (each with MIC of \geq 8 μ g/mL) by standard susceptibility testing methods.
- Pure isolate of confirmed or suspected organism that exhibits pan-resistance to all tested carbapenems by standard antimicrobial susceptibility methods.

Minimum Volume/Size: Minimum of 1 plate, visible growth

Container: Petri plate

Collection: Primary specimens should be collected according to the submitting institution's standard procedure.

Special Instructions:

- Submit isolates on a BAP or MacConkey agar plate.
- Per [What to Report \(oklahoma.gov\)](http://www.ok.gov) (OAC 310:515-1-8), specimens must be submitted within two (2) working days (Monday through Friday, State holidays excepted) of final identification or diagnosis.
- Incubate all isolates in appropriate atmosphere for 18-24 hours prior to shipping.
- MDRO Submission Form must be completed and submitted in addition to the standard Laboratory Requisition Form (ODH #419); form can be accessed at [OSDH Public Health Laboratory – MDRO Submission Form \(ok.gov\)](http://www.ok.gov)

Shipping: Room temperature in appropriate atmosphere

Common Causes for Rejection:

- Media expired
- No growth on media
- Specimen non-viable
- Specimen frozen
- Muroid CRPA isolates
- Other criteria as outlined in the *Specimen Rejection* section of this Test Directory

Turn-around Time: Within 5 working days from receipt unless referred to the ARLN Regional Laboratory or CDC for further characterization, which may delay availability of final results. Results of the Sensititre™ AST and results from the ARLN Regional Laboratory are for epidemiological purposes only and are not reported to the submitter.

Normal Value (Reference Range):

- Bacterial Isolate: Isolate could not be identified to species level, carbapenem resistance testing not performed
- mCIM: Negative
- Xpert CarbaR PCR: [KPC, NDM, VIM, IMP or OXA-48] no carbapenem resistance genes detected

Reportable Results:

- Bacterial Isolate, Identification/Serotyping/Confirmation:
- Pseudomonas aeruginosa
- Carbapenem-resistant Acinetobacter species specimen has been received, no report to follow
- Enterobacter cloacae complex
- Escherichia coli
- Klebsiella aerogenes
- Klebsiella oxytoca/Raoultella ornithinolytica
- Klebsiella pneumoniae
- Klebsiella variicola
- Morganella morganii
- Proteus mirabilis
- Providencia rettgeri
- Providencia stuartii
- Pseudomonas otitidis
- Pseudomonas spp.
- Serratia marscens
- Staphylococcus aureus
- mCIM:Carbapenemase Positive; Negative; or Indeterminate
- Xpert CarbaR PCR: [KPC, NDM, VIM, IMP or OXA-48] gene(s) Detected, ; no antimicrobial resistance genes detected; Invalid.

Isolates demonstrating a potentially new carbapenemase variant or novel mechanism of resistance or isolates that produce discordant results may be forwarded to an ARLN Regional Laboratory or the CDC for further testing.

Interpretation: Isolates demonstrating carbapenem resistance by phenotypic AST and mCIM with a positive result for one or more resistance genes are confirmed carbapenem resistant due to the presence of one or more carbapenemases. Isolates demonstrating carbapenem resistance by AST and mCIM with a negative result for resistance genes are confirmed carbapenem resistant potentially due to the presence of a new variant carbapenemase or other novel mechanism of resistance. Isolates demonstrating carbapenem sensitivity by AST but resistance by mCIM with a positive result for one or more resistance genes could potentially harbor a carbapenemase with low activity, e.g., OXA-48. Isolates demonstrating carbapenem sensitivity by AST and mCIM are confirmed carbapenem sensitive.

**Limitations/
Interferences:** Discordant results are expected between the different methods. Hydrolysis of carbapenem by carbapenemases is the most common mechanism of resistance for this class of antibacterial agents but other mechanisms of resistance occur and may not be detected by PCR. A carbapenemase may be weakly expressed producing a negative phenotypic test or the gene may be present in low copy numbers producing a negative PCR. Phenotypic antimicrobial susceptibility tests demonstrate variable sensitivities and specificities and use different combinations of antibiotics and inhibitors. Isolates that are not successfully identified to the genus/species level will not be tested. Isolates that are negative for both mCIM and AST will not have further testing performed.

CPT Codes: CPT codes will vary depending on organism identified and methods used

Notes: These tests are intended as an aid for infection control of carbapenem-non-susceptible organisms in healthcare settings. These tests are not intended to guide or monitor treatment for carbapenem-non-susceptible bacterial infections. The mCIM and Sensititre System are laboratory-developed tests; performance characteristics have been validated and determined to be suitable for diagnostic purposes by the OSDH PHL. The Bruker MALDI-ToF-MS and Xpert® Carba-R assay are approved for *in vitro* diagnostic use by the U.S. Food and Drug Administration.

Chlamydia trachomatis / Neisseria gonorrhoeae – Transcription Mediated Amplification (Chlamydia/Gonorrhea)

Use: To screen symptomatic or asymptomatic males and females for the presence of *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae* (CT/GC). This test is not to be used for monitoring therapeutic efficacy.

Methodology: Hologic Aptima Combo 2® *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Assay; Transcription Mediated Amplification (TMA). Amplification of target 23s rRNA of *C. trachomatis* and 16s rRNA of *N. gonorrhoeae*, amplicons hybridize with chemiluminescent probes that are read by the Panther testing platform.

Clinical Significance: *Chlamydia trachomatis* and *Neisseria gonorrhoeae* are the most common bacterial causes of sexually transmitted diseases in the U.S. Screening reduces the prevalence of CT/GC and potentially reduces the incidence of severe and debilitating complications associated with symptomatic infections.

Further background information, fact sheets, statistics and educational resources may be found at the OSDH Infectious Disease Services [website](#).

Specimen Type:

- Urine
- Vaginal Swab
- Throat Swab
- Rectal Swab

Minimum Volume/Size:

- To the bottom fill line for the USTT tube.
- Dry Vaginal Swab in Transport Tube
- Dry Unisex Swab in Transport Tube

Container:

- Aptima Urine Specimen Transport Tube (USTT, yellow)
- Aptima Multi-test Swab Specimen Transport Tube (MSSTT, orange)

Collection: Urine

1. Collect 20-30 mL of first-void (not mid-stream) urine in sterile collection cup; patient should not have urinated for at least 1 hour prior to collection. Excessive urine collection may dilute rRNA affecting test sensitivity.
2. Label a USTT with two patient identifiers (e.g., Patient's Name and DOB) and date collected. Place any barcodes along the length of the tube.
3. Twist the cap on the USTT to break the seal.
4. Using transfer pipette provided in kit, transfer urine from cup to USTT until level is between the two lines on the fill window (approx. 2mL). Do not over-fill or under-fill.
5. Urine should be transferred from primary collection device to USTT within 24 hours of collection at 2-30°C.
6. Immediately replace cap and tightly secure.

Multitest Swab

Vaginal

1. Label the MSSTT with two patient identifiers (e.g., Patient's Name and DOB) and date collected. Place any barcodes along the length of the tube.
2. Open the swab packaging, being careful not to contaminate the swab.
3. Hold the swab near the middle of the shaft so that your thumb and forefinger touch the score line. Do not hold it between the line and swab tip.
4. Insert the swab approximately 2 inches (5cm) past the introitus and gently rotate the swab, ensuring contact with vaginal walls, for 10 to 30 seconds.
5. Withdraw the swab, making sure to not to touch the skin. Unscrew the cap on the MSSTT.
6. Place the swab in the collection tube so that the score line is at the top of the tube. Gently flex the shaft against the tube to break at the score line, disposing of the top of the shaft.
7. Tightly secure the cap.

Throat

1. Label the MSSTT with two patient identifiers (e.g., Patient's Name and DOB) and date collected. Place any barcodes along the length of the tube.
2. Open the swab packaging, being careful not to contaminate the swab.
3. Hold the swab near the middle of the shaft so that your thumb and forefinger touch the score line. Do not hold it between the line and swab tip.
4. Insert the swab into the throat ensuring to make contact with bilateral tonsils (if present) and the posterior pharyngeal wall.
5. Withdraw the swab, making sure to not to touch the tongue or inner cheek. Unscrew the cap on the MSSTT.
6. Place the swab in the collection tube so that the score line is at the top of the tube. Gently flex the shaft against the tube to break at the score line, disposing of the top of the shaft.
7. Tightly secure the cap.

Rectal

1. Label the MSSTT with two patient identifiers (e.g., Patient's Name and DOB) and date collected. Place any barcodes along the length of the tube.
2. Open the swab packaging, being careful not to contaminate the swab.
3. Hold the swab near the middle of the shaft so that your thumb and forefinger touch the score line. Do not hold it between the line and swab tip.
4. Insert the swab approximately 1-2 inches (3-5cm) past the anal margin and gently rotate the swab for 5-10 seconds.
5. Withdraw the swab, making sure to not to touch the skin. Unscrew the cap on the MSSTT.
6. Place the swab in the collection tube so that the score line is at the top of the tube. Gently flex the shaft against the tube to break at the score line,

- disposing of the top of the shaft.
7. Tightly secure the cap.

Special Instructions: None

Shipping: Store and ship the appropriate collection tube at refrigerated or ambient temperatures (2-30°C) for delivery within 30 days of collection for urine samples and within 60 days of collection for swabs.

Common Causes for Rejection:

- Patient under 14 years of age
- Specimen transported in container other than the appropriately designated collection device
- Over-filled or under-filled specimen tube
- Raw urine
- Specimens submitted > 30 days from date of collection for urine and > 60 days for swabs
- Specimens must be individually packaged.
- Other criteria as outlined in *Specimen Rejection* section of this Test Directory

Turn-around Time: Within 7 working days from receipt

Normal Value (Reference Range):

- Presumed negative for CT rRNA
- Presumed negative for GC rRNA

Reportable Results:

- Presumed negative for CT rRNA
- Presumed negative for GC rRNA
- Positive for CT rRNA
- Positive for GC rRNA
- Indeterminate, a new specimen should be collected

Interpretation:

- A positive result indicates successful amplification of rRNA for either *C. trachomatis* or *N. gonorrhoeae* by the instrument.
- A negative result indicates that a sample should be presumed negative of rRNA for either *C. trachomatis* or *N. gonorrhoeae*.
- An equivocal result indicates that the testing platform was not able to make a determination of either analyte. A new sample should be collected.
- An invalid result indicates that the instrument encountered issues with the specimen and it was not able to be result successfully. The most likely reason is excessive physical debris in the sample inhibiting aspiration. A new sample should be collected.

Limitations/ Interferences:

- A negative result does not preclude *C. trachomatis* and/or *N. gonorrhoeae* infection since detection is dependent on adequate specimen collection, absence of inhibitors, and sufficient levels of organisms.
- A positive result does not infer viability and/or infectivity for *C. trachomatis* and/or *N. gonorrhoeae* since target DNA for these organisms may persist in the patient in the absence of viable

organisms (e.g., following anti-microbial therapy).

- This assay is not appropriate for testing of cases of sexual assault/abuse or cases with other medico-legal implications. Culture is the recommended procedure for diagnosing CT/GC infections in medico-legal cases, testing of conjunctival, rectal and nasopharyngeal specimens, and evaluating gonorrhea treatment failure; Aptima® transport tubes are inappropriate collection devices for culture. Test results may be affected by improper specimen collection, low levels of organisms in the sample, plasmid-free variants of *C. trachomatis*, technical error, specimen mix-up, or concurrent antibiotics. This test cannot be used to assess therapeutic success or failure.
- None, excessive solids present may inhibit instrument pipetting

CPT Code: 87491, 87591

Notes: This test has been cleared for in vitro diagnostic use by the U.S. Food and Drug Administration.

COVID-19 Diagnostic PCR (SARS-CoV-2)

Use: To screen symptomatic or asymptomatic people for the presence of SARS-CoV-2.

Methodology: PerkinElmer Chemagic or KingFisher Flex Extraction and Thermo TaqPath Real-Time PCR (EUA),

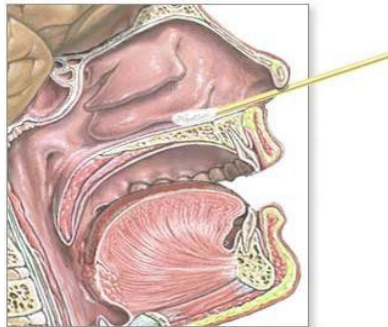
Clinical Significance: COVID-19 is a virus identified as the cause of an outbreak of respiratory illness first detected in Asia in late 2019 that has since spread globally into a pandemic. Symptoms of COVID-19 include fever, cough, and shortness of breath. While roughly 80% of cases report mild symptoms, some progress into severe pneumonia and multi-organ failure and can lead to death. On January 21, 2020, the first set of individuals in the United States tested positive for COVID-19. Further background information, fact sheets, statistics and educational resources may be found at the OSDH Infectious Disease Services COVID-19 [website](#).

Specimen Type: NP/OP Swab in Remel M4RT Vial, VTM, M4RT, UTM, AMIES, or PBS

Minimum Volume/Size 2 mL

Collection:

Nasopharyngeal and Oropharyngeal Swabs



Tip: *If the patient is seated for the procedure, have the patient sit with their head against a wall since patients have a tendency to pull away during the procedure.*

Nasopharyngeal Swab

1. Label a sterile tube Remel M4RT tube containing 2-3 mL of VTM with the patient's name and date of collection.
2. If the nasal passages have a large amount of mucus, ask the patient to blow their nose before collecting specimen.
3. With the thumb of one hand, elevate the tip of the patient's nose then gently insert the NP swab into a nostril.
4. Guide the swab straight back (not upwards), along the floor of the nasal passage until it reaches the posterior wall of the nasopharynx; the distance from the nose to the ear gives an estimate of the distance the swab should be inserted. **Note:** *Do not force the swab- if an obstruction is encountered during insertion, try the other nostril.*
5. Rotate the swab by firmly brushing against the nasopharynx several times.

6. Immediately, place swab, tip first into tube containing VTM or other suitable collection media.
7. Break-off or cut excess shaft of swab so that the tube can be capped.
8. Replace the cap of the tube and ensure it is secured.
9. Place the tube in a plastic biohazard bag and insert complete requisition form in outer pouch of the bag. The samples are stable at (2-8°C) for 4 days

Oropharyngeal Swab

1. Label a sterile Remel M4RT tube containing 2-3 mL of VTM with the patient's name and date of collection.
2. Insert saw into the posterior pharynx and tonsillar areas.
3. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.
4. Immediately, place swab, tip first, into tube containing VTM or other suitable collection media.
5. Break-off or cut excess shaft of swab so that tube cab be capped.
6. Replace the cap of the tube and ensure it is secure.
7. Place tube in plastic biohazard bag and insert completed requisition form in outer pouch of the bag. The samples are stable at (2-8°C) for 4 days.

Container: Tube with appropriate transport media (VTM, M4RT, UTM, AMIES, PBS)

Special Instructions: Synthetic dacron, nylon, or rayon swabs with aluminum or plastic shaft only. Do not use calcium alginate swabs, as they may contain substances that inhibit PCR testing.

Shipping: Store and ship the appropriate NP/OP collection tube or Spectrum saliva specimens at refrigerated (2-8°C) conditions for delivery to the PHL within 4 days of collection or deliver specimens to PHL at frozen condition <-70°C within 30 days of collection.

- Common Causes for Rejection:**
- Specimens shipped or stored at inappropriate temperatures
 - Specimens that have leaked due to the cap not properly secured
 - Specimens transported in container other than the appropriately designated collection device.
 - Over-filled or under-filled specimen tube
 - Specimens submitted >4 days from date of collection at 2-8°C
 - Specimens missing swabs
 - Other criteria as outlined in *Specimen Rejection* section of the Test Directory.

Turn-around Time: Within 2 working days from receipt

Normal Value (Reference Range): SARS-CoV-2 Not Detected

Reportable Results: SARS-CoV-2 Not Detected
SARS-CoV-2 Detected
Inconclusive
Invalid Result

- Interpretation:**
- Not Detected results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.
 - Detected results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.
 - Inconclusive results indicate amplification of only a single RNA target instead of at least 2 for positive result. Recollection is recommended for a valid result.
 - Invalid results indicate amplification failure of internal control (MS2), which may be due to presence of PCR inhibitor. Recollection is recommended for a valid result.

Limitations/ Interferences: With any diagnostic test, there is the potential for false negatives or false positives. For existing COVID-19 tests in the U.S., there have been reports of false negative tests in some patients. False negative tests can occur if a specimen was not properly obtained or if a patient was tested too early or too late in their infection. Laboratory error is also a possible cause of false negative test results. Conversely, false positive reports are less common.

CPT Code: 87635

Notes: This test is performed in compliance with a US Food and Drug Administration (FDA) Emergency Use Authorization (EUA).

COVID-19 Sequencing

Use: To determine the lineage and variants of positive COVID-19 specimens. Not for clinical diagnosis. For public health surveillance purposes only.

Methodology: Thermal cyclers and the Illumina SBS chemistry-based platform.

Clinical Significance: As COVID-19 evolves and new variants of the virus continue to emerge it is important the Oklahoma State Department of Health (OSDH) Public Health Laboratory (PHL) receive COVID-19 specimens to identify variant trends and implement mitigation measures to prevent the continued spread of COVID-19 in Oklahoma.

Specimen Type: Acceptable specimens are previously tested for COVID-19 using rt-PCR. Please refer to the [OK-HAN 345](#). The acceptable types for sequencing and potential virus characterization are upper and lower respiratory specimens, including nasopharyngeal, oropharyngeal, nasal midturbinate, and anterior nares (nasal swab) specimens. Additionally, a nasopharyngeal wash/aspirate or nasal wash/aspirate specimen collected by a healthcare professional is acceptable, as is a naturally expectorated sputum. Acceptable specimens will be limited to those collected in media that allow for viral culture (e.g., saline, PBS, and VTM). Specimens collected in Hologic Aptima buffer and Molecular Transport Media are excluded from submission.

Minimum Volume/Size: Original clinical specimens with at least 800µL volume

Container: Acceptable specimens will be limited to those collected in media that allow for viral culture (e.g., PBS, VTM). Specimens collected in Hologic Aptima buffer and Molecular Transport Media are excluded from submission.

Collection: Not applicable

Special Instructions: Sequencing and virus culture success are limited by the quality of the specimen. Ideally specimens should have an RT-PCR Ct value of ≤ 30 . If Ct values are not available, specimens that are positive for SARS-CoV-2 by another testing modality may be sent

Shipping: Once collected, specimens can be stored and shipped at 2–8°C for no more than 96 hours. After the 96-hour timeframe, samples can be stored at -20°C to -70°C for up to 7 days and frozen at $\leq -70^\circ\text{C}$ for long term storage. After the 96-hour timeframe, specimens must be shipped on dry ice.

Common Causes for Rejection:

- Specimen transported in container other than the appropriately designated collection device
- Over-filled or under-filled specimen tube
- Other criteria as outlined in the Specimen Rejection section of this Test Directory.

Turn-around Time: Within 14 working days from receipt to OSDH PHL

Normal Value (Reference Range): Due to federal regulation, the PHL is unable to provide result reports for SARS-CoV-2 variant sequencing surveillance to the submitter or patient. SARS-CoV-2 variant surveillance whole genome sequencing is intended for public health surveillance purposes.

Reportable Results: Due to federal regulation, the PHL is unable to provide result reports for SARS-CoV-2 variant sequencing surveillance to the submitter or patient. SARS-CoV-2 variant surveillance whole genome sequencing is intended for public health surveillance purposes.

Results: N/A

Interpretation: N/A

Limitations/Interferences: Sometimes the positive specimens do not amplify and a variant can't be determined.

CPT Code: N/A

Notes: The illumine COVID Seq Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Enteric Isolate Identification

Use:	Confirmation and identification of <i>Salmonella</i> spp., <i>Shigella</i> spp., <i>Escherichia coli</i> 0157, non-0157 shiga-like toxin-producing <i>E. coli</i> (STEC), <i>Campylobacter</i> spp., <i>Yersinia</i> spp., <i>Vibrio</i> spp., and <i>Listeria</i> spp. Isolates
Methodology:	Received isolates are inspected for purity before being subcultured. The resulting growth is analyzed by MALDI-ToF. PulseNet reportable organisms as defined by the CDC are then subjected to whole genome sequencing.
Clinical Significance:	The CDC estimates that each year 48 million Americans develop foodborne illnesses that result in 128,000 hospitalizations and 3000 deaths, and cost the U. S. economy an estimated 8.4 billion dollars in lost productivity. Considering the large impact on public health, it is critically important that these infections be identified and the isolates characterized as quickly as possible. Prompt identification of the causal agent can not only aid in diagnosis and implementation of individual patient management plans, but also ultimately reduce the number of infections in outbreak situations. Further background information, fact sheets, statistics and educational resources may be found at the OSDH Infectious Disease Services website.
Specimen Type:	Pure viable enteric isolate grown on species appropriate media
Minimum Volume/Size:	Minimum of 1 media plate or slate with visible growth
Container:	Petri plate or media slant
Collection:	Primary specimens should be collected according to the submitting institution's standard procedure.
Interferences:	None
Special instructions:	Per What to Report (oklahoma.gov) (OAC 310:515-1-8), specimens must be submitted within two (2) working days (Monday through Friday, State holidays excepted) of final identification or diagnosis.
Shipping:	Store and ship the acceptable media at ambient temperatures (2-30°C) for delivery within 2 days of subculture.
Common Causes for Rejection:	<ul style="list-style-type: none">• Media Expired• No Growth on Media• Specimen Not Viable• Specimen Frozen• Other criteria as outlined in <i>Specimen Rejection</i> section of this Test Directory
Turn-around Time:	<ul style="list-style-type: none">• <i>Aeromonas</i> spp. and <i>Vibrio</i> spp. within 7 working days of receipt• <i>Campylobacter</i> spp. within 8 working days of receipt• <i>E. coli</i> within 5 working days of receipt• <i>Salmonella</i> spp. within 5 working days of receipt• <i>Shigella</i> spp. within 10 working days of receipt• <i>Y. enterocolitica</i> within 5 working days of receipt

- Results of the Whole Genome Sequencing are for epidemiological purposes only and are not reported to the submitter.

Normal Value Pathogen Not Detected

(Reference Range):

Reportable Results: Bacterial isolate, identification/confirmation; genus/species identified; isolate could not be identified to species level

Interpretation/ Interferences: Laboratory confirmation of pathogens from fecal specimens from symptomatic individuals is evidence of fecal-oral contamination via food, water, fomites or the hands. Positive results do not rule-out co-infection with other potentially clinically-relevant, pathogens not detected by this test.

Limitations: Whole genome sequencing and the serotyping information derived from the analysis are not validated for clinical reporting.

CPT Codes: CPT codes will vary depending on organism identified and methods used.

Notes: These tests are intended as an aid for infection control of enteric organisms in healthcare settings. These tests are not intended to guide or monitor treatment for enteric infections. The Bruker MALDI-ToF assay is approved for *in vitro* diagnostic use by the U.S. Food and Drug Administration.

Enteric Pathogens, Isolation and Identification

Use:	Isolation and identification of Salmonella spp., Shigella spp., Escherichia coli 0157, non-0157 shiga-like toxin-producing E. coli (STEC), enterotoxigenic E. coli (ETEC), Campylobacter spp., Yersinia spp., Vibrio spp., Aeromonas spp., Plesiomonas shigelloides, Bacillus cereus, Staphylococcus aureus, Adenovirus, Norovirus, Rotavirus A, Cryptosporidium, and Giardia lamblia in clinical stool samples from individuals exhibiting signs and symptoms of infectious colitis or gastroenteritis.
Methodology:	Specimens are initially screened using a PCR amplification assay (xTAG® Gastrointestinal Pathogen Panel (GPP)) (see GPP section for details) that detects multiple bacterial, viral and protozoan enteric pathogens. All specimens negative by GPP are subject to limited culture to screen for potential common enteric pathogens not detected by GPP. Attempts are made to confirm GPP-positive specimens by routine microbiological procedures, including culture and biochemical as necessary; however, confirmation of certain GPP-positive results (e.g., ETEC, rotavirus, Norovirus) will be beyond the testing capabilities of the OSDH PHL and may require specimen referral by the submitter, as clinically appropriate; and the results will be reported as final.
Clinical Significance:	The CDC estimates that each year 48 million Americans develop foodborne illnesses that result in 128,000 hospitalizations and 3000 deaths, and cost the U. S. economy an estimated 8.4 billion dollars in lost productivity. Considering the large impact on public health, it is critically important that these infections be identified and the isolates characterized as quickly as possible. Prompt identification of the causal agent can not only aid in diagnosis and implementation of individual patient management plans, but also ultimately reduce the number of infections in outbreak situations. Further background information, fact sheets, statistics and educational resources may be found at the OSDH Infectious Disease Services website.
Specimen Type:	Solid or liquid feces
Minimum Volume/Size:	<ul style="list-style-type: none">• Feces: Solid, 2 grams; Liquid, 5-10 mL• GN broth: Visible growth
Container:	Preferred: Cary-Blair Transport Media (enteric kit); Alternative: GN Broth (preferred only for the use of resuspending STEC isolates).

Collection: Stool specimens should be obtained early in the course of illness, optimally 1-3 days after onset of illness, and during early morning hours when the causative agent should be present in the greatest numbers. No more than three stool specimens, collected 24 hours apart, should be submitted for initial culture. Stool specimens should be collected before antimicrobial therapy has been initiated. Test-of-cure stools should be collected 24 hours after completion of antibiotic treatment.

1. Collect the stool specimen in a wide mouth container, bedpan, clean newspaper or plastic bag placed over the toilet seat opening.
2. DO NOT pass the specimen into the toilet or directly into the collection vial. Do NOT mix urine or water with the sample.
3. If using Cary-Blair Transport Medium, open the Cary-Blair vial then using the collection spoon attached to the cap, add enough specimen (walnut-size portion, approximately 2 grams or 5-10 mL) until the liquid reaches the arrow on the label. Mix the contents of the vial with the collection spoon.

If using GN Broth, open the GN broth vial then using a sterile swab, emulsify 1g of feces or 1mL of liquid stool into the broth.

Important: Sample areas of the specimen which appear bloody, slimy, or watery. If the stool is hard, sample from each end and the middle of the specimen.

4. Replace the cap of vial tightly and shake vigorously.
5. Be sure the vial is labelled with the following information:
 - 2 unique patient identifiers (name, date of birth, accession number, etc.)
 - Date and time specimen was collected
 - Specimen number if more than one specimen was collected (e.g., No1, No2, No3)
 - Check the appropriate box for specimen consistency (formed, watery, bloody, loose or soft); orange-capped Meridian Carey-Blair containers only
6. Make sure the vial(s) is closed tightly.
7. Place each vial in a sealed biohazard specimen bag with sufficient absorbent material to absorb the contents of the vial in case of a spill in transit. Be sure to include the specimen requisition in the paperwork flap on the outside of the specimen biohazard bag.
8. Ship at ambient temperature, as soon as possible.

Special instructions:

Rectal swabs and raw stools are not acceptable

Shipping:

Store and ship the acceptable media at ambient temperatures (2-30°C) for delivery within 7 days of collection

Common Causes for Rejection:

- Specimen not in Cary-Blair Transport Media or GN broth
- Specimen received > 7 days from date of collection
- Other criteria as outlined in Specimen Rejection section of this Test Directory

Turn-around Time:	Within 10 working days; a preliminary report based on GPP is issued within 4 working days from receipt of specimen, followed by a final report within a further 6 working days upon completion of culture and other testing
Normal Value (Reference Range):	Pathogen Not Detected
Reportable Results:	Pathogen Detected (Genus or Genus/species/targeted genes/serotype, as relevant); Pathogen Not Detected
Interpretation:	Results from the GPP assay alone are considered presumptive and recommend confirmation by other laboratory methods. Laboratory confirmation of pathogens in fecal specimens from symptomatic individuals is evidence of fecal-oral contamination via food, water, fomites or the hands. Positive results do not rule-out co-infection with other, potentially clinically-relevant, pathogens not detected by this test. Detection of stx1 and/or stx2 in E. coli isolates indicates the presence of an STEC strain. Non-O157 STEC strains that produce only stx2 are more often associated with HUS than strains that produce only stx1 or both stx1 and stx2. Negative results do not exclude the diagnosis of enteric pathogens.
Limitations/Interferences:	Specimen type is not suitable for microscopic parasite examination. Stool specimens should not be collected using laxatives, mineral oil, bismuth or barium compounds for purgation. Stools should not be collected immediately following the use of anti-diarrheal or antacid compounds.
CPT Codes:	GPP: 87801; Culture: 87045, 87046 (x3), 87077; included as relevant; CPT codes will vary depending on organism identified and methods used
Notes:	These are laboratory-developed tests; performance characteristics have been validated and determined to be suitable for diagnostic purposes by the OSDH PHL. These tests have not been cleared or approved by the U.S. Food and Drug Administration.

Gastrointestinal Pathogen Panel (GPP)

Use: The xTAG® Gastrointestinal Pathogen Panel (GPP) is a multiplexed nucleic acid test intended for the simultaneous qualitative detection and identification of multiple viral, bacterial and parasitic nucleic acids in human stool specimens or human stool in Cary-Blair media from individuals exhibiting signs and symptoms of infectious colitis or gastroenteritis. The following pathogen types, subtypes, and toxin genes are identified using the xTAG GPP:

Adenovirus 40/41, Norovirus GI/GII, Rotavirus A, Campylobacter (*C. jejuni*, *C. coli*, and *C. lari* only), Clostridium difficile (*C. difficile*) toxin A/B, Escherichia coli (*E. coli*) O157, Enterotoxigenic *E. coli* (ETEC) LT/ST, Salmonella, Shiga-like Toxin producing *E. coli* (STEC) stx 1/stx 2, Shigella (*S. boydii*, *S. sonnei*, *S. flexneri*, and *S. dysenteriae*), Vibrio cholerae (*V. cholerae*) cholera toxin gene (ctx), Cryptosporidium (*C. parvum* and *C. hominis* only), Entamoeba histolytica (*E. histolytica*), Giardia (*G. lamblia* only, also known as *G. intestinalis* and *G. duodenalis*).

Methodology: The xTAG® Gastrointestinal Pathogen Panel (GPP) incorporates multiplex reverse-transcriptase polymerase chain reaction (RT-PCR) with Luminex's proprietary universal tag sorting system on the Luminex® platform. The assay also detects an internal control (Bacteriophage MS2) that is added to each sample prior to extraction.

Clinical Significance: Gastrointestinal infections in both pediatric and adult patients account for significant morbidity and mortality worldwide (Schlenker and Surawicz 2009). In the United States (US) an estimated 179 million episodes of acute gastroenteritis occur annually (Hall, Wikswo et al. 2013). Diarrheal disease can be caused by a number of pathogens including viruses, bacteria, and parasites. Prompt identification of the causal agent in symptomatic (both acute and chronic gastroenteritis) adult and pediatric patients can not only aid in diagnosis and implementation of individual patient management plans, but also ultimately reduce the number of infections in outbreak situations. Further background information, fact sheets, statistics and educational resources may be found at the OSDH Infectious Disease Services website.

Specimen Type: Preferred: Solid or liquid feces in Cary Blair
Alternative: GN Broth

Volume: Feces: Solid, 1-2 grams; Liquid, 5-10 mL

Container: Cary-Blair Transport Media (enteric kit)

Collection: Stool specimens should be collected as soon after onset of symptoms as possible. No more than three stool specimens, collected 24 hours apart, should be submitted for initial culture. Stool specimens should be collected before antimicrobial therapy has been initiated. Test-of-cure stools should be collected 24 hours after completion of antibiotic treatment. Fresh stool specimens should be placed in a container with Cary-Blair transport media or GN Broth.

If collecting stool in a Cary-Blair container:

Ensure a stool: medium ratio of 1:3 (1 part stool:3 parts medium) is obtained, so that the stool has been diluted 4x in the medium.

1. Collect the stool specimen in a wide mouth container, bedpan, clean newspaper or plastic bag placed over the toilet seat opening.
2. DO NOT pass the specimen into the toilet or directly into the collection vial. Do NOT mix urine or water with the sample.
3. Open the Carey-Blair vial then using the collection spoon attached to the cap, add enough specimen (walnut-size portion, approximately 2 grams or 5-10 mL) until the liquid reaches the arrow on the label.
Important: Sample areas of the specimen which appear bloody, slimy, or watery. If the stool is hard, sample from each end and the middle of the specimen.
4. Mix the contents of the vial with the collection spoon.
5. Replace the cap tightly and shake the tube vigorously.
6. Fill-in the information on the vial label(s):
 - Patient name
 - Date and time specimen was collected
 - Specimen number if more than one specimen was collected (e.g., No1, No2, No3)
7. Check the appropriate box for specimen consistency (formed, watery, bloody, loose or soft); orange-capped Meridian containers only
8. Make sure the vial(s) is closed tightly.
9. Place the vial(s) in the original package and seal.
10. Ship at room temperature (18°C to 25°C) or on wet ice (2°C to 8°C), as soon as possible.

If collecting stool in GN Broth:

1. Inoculate GN Broth as soon as possible after raw stool specimen is collected.
2. Emulsify 1 g of feces or 1 mL of liquid stool into each tube of GN Broth.
3. Follow manufacturer's instructions for storage and shipping.

Interferences: Stool specimens should not be collected using laxatives, mineral oil, bismuth or barium compounds for purgation. Stools should not be collected immediately following the use of anti-diarrheal or antacid compounds.

Special instructions: Rectal swabs and raw stools are not acceptable

Shipping:	<p><u>Stool in Cary Blair:</u> Store and ship the acceptable media at room temperature (18°C to 25°C) or on wet ice (2°C to 8°C)</p> <p><u>Stool in GN Broth:</u> Follow manufacturer’s instructions for storage and shipping</p>
Rejection Criteria:	<ul style="list-style-type: none"> • Specimen not in Cary-Blair Transport Media • Specimen received > 7 days from date of collection • Other criteria as outlined in Specimen Rejection section of this Test Directory
Reported:	<p>A preliminary report based on GPP is issued within 4 working days from receipt of specimen, followed by a final report within a further 6 working days upon completion of culture and other testing.</p> <p>Effective on 2/1/2024, the test results of stool in GN broth will not be reportable.</p>
CPT Codes:	GPP: 87801
Normal Results:	Pathogen Not Detected
Abnormal Results:	<p>All GPP results are issued as Preliminary Reports.</p> <p>The following results are reported for the GPP assay when specimens are submitted in Cary Blair:</p> <ul style="list-style-type: none"> • Pathogen Not Detected • Adenovirus 40/41 Detected; recommend confirmatory testing • Campylobacter Detected; will attempt confirmation by conventional microbiological methods • Cryptosporidium Detected; recommend confirmatory testing • Evidence of Entamoeba histolytica; recommend confirmatory testing • Enterotoxigenic E. coli Detected; recommend confirmatory testing • Giardia Detected; recommend confirmatory testing • Norovirus GI/GII Detected; recommend confirmatory testing • Rotavirus A Detected; recommend confirmatory testing • Salmonella Detected; will attempt confirmation by conventional microbiological methods • Shiga-like toxin-producing E. coli stx1 Detected; will attempt confirmation by conventional microbiological methods • Shiga-like toxin-producing E. coli stx1 and stx2 Detected; will attempt confirmation by conventional microbiological methods • Shiga-like toxin-producing E. coli stx2 Detected; will attempt confirmation by conventional microbiological methods • Shigella Detected; will attempt confirmation by conventional

microbiological methods

- Evidence of *Vibrio cholerae*. Note this GPP target has not been validated; will attempt confirmation by conventional microbiological methods
- Evidence of *Yersinia enterocolitica*. Note this GPP target has not been validated; will attempt confirmation by conventional microbiological methods
- Indeterminate, potential PCR inhibitors/poor sample quality; will attempt to culture For specimens that show failed MS2 amplification after sample dilutions and no targets are detected, the following language is used:
- Indeterminate, potential PCR inhibitors/poor sample quality; will attempt to culture.

The following results are reported for the GPP assay when specimens are submitted in GN Broth:

- Pathogen Not Detected
- Evidence of Adenovirus 40/41. Note this GPP target has not been validated for GN broth; recommend confirmatory testing
- Evidence of *Campylobacter*. Note this GPP target has not been validated for GN broth; will attempt confirmation by conventional microbiological methods
- Evidence of *Cryptosporidium*. Note this GPP target has not been validated for GN broth; recommend confirmatory testing
- Evidence of *Entamoeba histolytica*. Note this GPP target has not been validated for GN broth; recommend confirmatory testing
- Enterotoxigenic *E. coli* Detected; recommend confirmatory testing • Evidence of *Giardia*. Note this GPP target has not been validated for GN broth; recommend confirmatory testing
- Evidence of Norovirus GI/GII. Note this GPP target has not been validated for GN broth; recommend confirmatory testing
- Evidence of Rotavirus A. Note this GPP target has not been validated for GN broth; recommend confirmatory testing
- Evidence of *Salmonella*. Note this GPP target has not been validated for GN broth; will attempt confirmation by conventional microbiological methods
- Shiga-like toxin-producing *E. coli* stx1 Detected; will attempt confirmation by conventional microbiological methods
- Shiga-like toxin-producing *E. coli* stx1 and stx2 Detected; will attempt confirmation by conventional microbiological methods
- Shiga-like toxin-producing *E. coli* stx2 Detected; will attempt confirmation by conventional microbiological methods

- Evidence of Shigella. Note this GPP target has not been validated for GN broth; will attempt confirmation by conventional microbiological methods
- Evidence of Vibrio cholerae. Note this GPP target has not been validated for GN broth; will attempt confirmation by conventional microbiological methods
- Evidence of Yersinia enterocolitica. Note this GPP target has not been validated for GN broth; will attempt confirmation by conventional microbiological methods
- Indeterminate, potential PCR inhibitors/poor sample quality; will attempt to culture

For specimens that show failed MS2 amplification after sample dilutions and no targets are detected, the following language is used:

- Indeterminate, potential PCR inhibitors/poor sample quality; will attempt to culture

For specimens that show failed MS2 amplification after sample dilutions and a target(s) is detected, the language used in the above results list is used with the addition of “; see comment below”. The comments field indicates: “Specimen demonstrates presence of potential PCR inhibitors/poor specimen quality; therefore, will attempt comprehensive microbiological culture”. For example:

- Evidence of Shigella. Note this GPP target has not been validated for specimens submitted in GN broth; will attempt confirmation by conventional microbiological methods; see comment below.

Interpretation:

Results from the GPP assay alone are considered presumptive and recommend confirmation by other laboratory methods. Laboratory confirmation of pathogens in fecal specimens from symptomatic individuals is evidence of fecal-oral contamination via food, water, fomites or the hands. Positive results do not rule-out co-infection with other, potentially clinically-relevant, pathogens not detected by this test. Detection of stx1 and/or stx2 in E. coli isolates indicates the presence of an STEC strain. Non-O157 STEC strains that produce only stx2 are more often associated with HUS than strains that produce only stx1 or both stx1 and stx2. Negative results do not exclude the diagnosis of enteric pathogens.

Limitations:

Specimen type is not suitable for microscopic parasite examination.

Notes:

This is a laboratory-developed test; performance characteristics have been validated and determined to be suitable for diagnostic purposes by the OSDH PHL. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Human Immunodeficiency Virus (HIV) - HIV-1/2 Antigen/Antibody EIA with Reflex to HIV-1/2 Antibody Differentiation Test

Use: This test is used to screen for and confirm HIV-1/HIV-2 infection, including acute infection and to differentiate HIV-1 from HIV-2 infection.

Methodology: Sera are initially screened for HIV-1 p24 antigen and HIV-1 and HIV-2 specific antibodies using a 5th generation qualitative Enzyme Immunoassay (EIA). Specimens with an EIA-reactive screen result are repeated in duplicate using the same EIA. If either of the repeated samples is reactive, the specimen is reflexed to a supplemental HIV-1/HIV-2 antibody differentiation test.

Clinical Significance: Two HIV serotypes, designated as HIV-1 and HIV-2, have been identified based on the results of serologic and molecular studies. Both viruses have the same morphology, lymphotropism, and modes of transmission. Following infection with HIV, an individual rapidly (within 4 weeks) develops antibodies to viral proteins, a process known as seroconversion. After seroconversion, HIV-specific antibodies can be readily detected in the blood specimen. The EIA screen detects HIV-1 p24 antigen in addition to HIV-1/HIV-2 antibodies, which allows for earlier detection of HIV in individuals who have not undergone seroconversion. The supplemental differentiation test allows for differentiation between HIV-1/HIV2 antibodies, which is important in treatment management, since HIV-2 does not respond to some anti-retroviral agents. In acute infections, where patients have not yet seroconverted, the EIA screen may be positive while the differentiation test may be negative; patients with negative or indeterminate results for the supplemental differentiation test require follow-up HIV nucleic acid testing to resolve their infection status. This testing algorithm is consistent with the [2014 CDC Recommended Algorithm for Laboratory Diagnosis](#) of HIV Infection. Further background information, fact sheets, statistics and educational resources may be found at the OSDH Infectious Disease Services website.

Specimen Type: Whole blood collected in serum separator tube (SST).

Minimum Volume/Size: 2 mL serum; draw a sufficient amount of blood to yield the necessary serum volume, around 4mL whole blood. Minimal acceptable volume for testing is 1 mL serum (potential rejection if reflexive testing exhausts sample).

Container: SST or separated serum poured into sterile, plastic, screw-cap tube

Collection: Each facility should follow its guidelines for venipuncture collection of blood/serum. Following collection of blood, invert tube gently no more than 8 times then allow blood to clot in an upright position for at least 30 minutes and no more than 60 minutes then centrifuge at 3000 rpm for 10 minutes.

Special Instructions: This test is available for:

- County Health Departments in Oklahoma
- Reference sites approved through the OSDH HIV/STD Division

Follow-up nucleic acid testing, as recommended by CDC guidelines, must be approved by the HIV/STD Division. Instructions for

submitting specimens for HIV-1 RNA testing or HIV-2 DNA/RNA testing can be found on HealthHub (OSDH County Health Departments) and at the OSDH PHL website (Test Directory tab).

Shipping: Store refrigerated (2-8°C) and ship using ice packs. If transit time will be > 7 days post-collection, pour serum from SST into a sterile, plastic, screw-cap tube and store/ship frozen (-20°C or colder) and deliver to PHL within 14 days from date of collection.

Common Causes for Rejection:

- Facility not approved for testing
- Patient younger than 2 years of age
- Blood collected in tube other than SST
- SST received unspun at 2-8°C, and > 24 hours from DOC
- Specimen received at ambient temperature and > 48 hours from collection
- Specimen received at 2-8°C and > 7 days from DOC
- SST frozen
- Serum specimen received frozen and >14 days from DOC
- QNS
- Bacterial contamination
- Extensive hemolysis
- Extensive lipemia
- Other criteria as outlined in *Specimen Rejection* section of this Test Directory

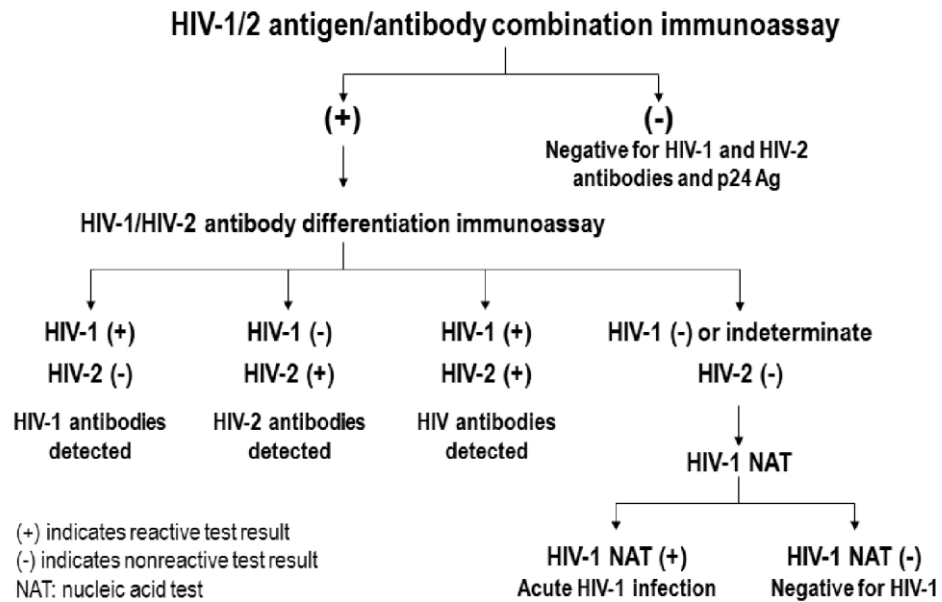
Turn-around Time: Within 10 working days from receipt

Normal Value (Reference Range): HIV-1 Ab: Non-reactive; HIV-1 Ag: Non-reactive; HIV-2 Ab: Non-reactive; Bioplex MBIA 2200 Ag-AB: Non-reactive for HIV

Reportable Results:

- HIV-1 Ab: Non-reactive
- HIV-1 Ag: Non-reactive
- HIV-2 Ab: Non-reactive
- Bioplex MBIA 2200 Ag-AB: Non-reactive for HIV Inconclusive. Initial reactive HIV-1/HIV-2 screening test result could not be confirmed by the differentiation test. This result could be due to either an acute or early infection or false positive reaction. Recommend repeat HIV antigen/antibody testing and HIV-1 RNA testing.
- HIV-1 Reactive. Positive for HIV-1 antibodies. Results are consistent with an established HIV-1 infection.
- HIV-2 Reactive. Positive for HIV-2 antibodies. Results are consistent with established HIV-2 infection.
- HIV Reactive (Undifferentiated). Evidence of HIV infection is present but unable to differentiate antibodies as HIV-1 or HIV-2. Consider referral testing for HIV-1 RNA and HIV-2 RNA or DNA to verify or rule-out dual infection.

The OSDH PHL follows the [CDC-recommended laboratory HIV testing algorithm](#) for serum specimens, which is indicated below:



- Interpretation:**
- Non-Reactive, HIV-1 antigen and HIV-1/HIV-2 antibodies not detected: A non-reactive test result does not exclude the possibility of infection with HIV. Levels of HIV-1 p24 antigen and antibodies to HIV-1 and HIV-2 may be undetectable in early infection. If a recent HIV exposure is suspected, consider re-testing.
 - HIV-1 Reactive: Specimens that are HIV-1 reactive with differentiation test (following a reactive HIV-1/HIV-2 screening results are considered HIV-1 positive, and no further testing is necessary.
 - HIV-2 Reactive: Specimens that are HIV-2 reactive with differentiation test (following a reactive HIV-1/HIV-2 screening result) are considered HIV-2 positive, and no further testing is necessary.
 - HIV Reactive, Undifferentiated: Specimens that are HIV-1 and HIV-2 reactive with differentiation test (following a reactive HIV-1/HIV-2 screening result) have evidence of HIV infection but the test is unable to differentiate antibodies as HIV-1 or HIV-2, i.e., undifferentiated HIV-1 RNA testing and HIV-2 RNA or DNA testing is recommended to verify or rule-out dual infection.
 - Inconclusive: Specimens that are HIV, HIV-1 or HIV-2 indeterminate (i.e., incomplete pattern of antibodies) or are non-reactive with the differentiation test (following a reactive HIV-1/HIV-2 screening result) could either indicate either an acute or early infection or false positive reaction. Recommend submission of additional specimens for repeat HIV antigen/antibody testing and HIV-1 RNA testing or HIV-2 RNA or DNA testing, as indicated.

- Limitations:**
- A person who has antibodies to HIV-1 is presumed to be infected with the virus, except that a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV. Clinical correlation is indicated with appropriate counseling, medical evaluation and possibly additional testing to decide whether a diagnosis of an HIV infection is accurate.
 - Detection of HIV antibodies in infants born to seropositive mothers is not adequate to diagnose HIV infection in the infant, since maternal IgG frequently persists in the infant's blood for as long as 18 months after birth. Supplemental assays designed specifically for neonatal specimens may be helpful in resolving such cases.
 - Non-reactive, inconclusive and undifferentiated HIV-1/HIV-2 Differentiation Test results should be referred for HIV-1 and/or HIV-2 nucleic acid testing as per CDC guidelines. See Guidance for HIV Nucleic Acid Testing on HealthHub (OSDH County Health Departments) and at the OSDH PHL website (Test Directory tab).
 - Bacterial contamination
 - Extensive hemolysis
 - Extensive lipemia

CPT Codes: 87389 / 86689

Notes: These tests are approved for in vitro diagnostic use by the U.S. Food and Drug Administration.

Human Papillomavirus, High-risk - Transcription-Mediated Amplification (HPV)

Use: To screen women 25 years and older with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results to determine the need for referral to colposcopy.

Note: High-risk human papillomavirus (hrHPV) testing of standard-risk women aged 21-24 years with ASC-US cervical cytology results is no longer recommended. However, it is acceptable if done. See the updated [American Society for Colposcopy and Cervical Pathology \(ASCCP\) Consensus Screening Guidelines](#).

To screen women 30-65 years old adjunctively with cervical cytology to assess for the presence/absence of hrHPVs.

Other uses of this test may include those indicated by consensus guidelines for cervical cancer screening and the management of women with abnormal cervical cytology and/or hrHPV results, such as those from the [ASCCP](#); clinical indications must be explicitly documented on the requisition form.

Methodology: Transcription-mediated amplification of E6/E7 viral mRNA from 14 hrHPVs: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68.

Clinical Significance: hrHPVs detected by the assay are associated with cervical pre-cancerous and cancerous lesions.

Specimen Type: ThinPrep Pap specimens

Minimum 1.0 mL

Volume/Size:

Container: ThinPrep Pap Test vials containing PreservCyt Solution

Collection: Collect cervical specimens in ThinPrep Pap Test vials containing PreservCyt Solution with broom-type or cytobrush/spatula collection devices according to the manufacturer's instructions

Special Instructions:

	<21 years old	21 to <25 years old		25 to <30 years old		> 30 years old	
Cytology Results	-	Negative	ASC-US	Negative	ASC-US	Negative	ASC-US
HPV Per Provider Order	Reject	Accept	Accept	Accept	Accept	Accept	Accept
HPV Reflex	Reject	Reject	Accept	Reject	Accept	Reject	Accept
Co-Testing	Reject	Reject	Accept	Reject	Accept	Accept	Accept
HPV Reflex Not Indicated	Reject	Reject	Reject	Reject	Reject	Reject	Reject

Shipping: Store and ship ThinPrep liquid cytology specimens at 2°C to 30°C for delivery within 30 days from collection. Store and ship specimens at -20 to -70 °C within 24 months from date of collection.

- Common Causes for Rejection:**
- Specimen collection > 30 days prior to receipt at 2°C to 30°C
 - Specimen collection > 24 months prior to receipt at -20 to -70 °C.
 - Patient under 21 years of age
 - The specimen is deemed unsatisfactory for evaluation due to insufficient cellularity.
 - QNS: < 1 mL ThinPrep liquid cytology specimen
- Other criteria as outlined in Specimen Rejection section of this Test Directory

Turn-around Time: Within 7 working days of receipt

CPT Codes: 87624

Normal Value (Reference Range): High-risk HPV Not Detected

- Reportable Results:**
- High-risk HPV Not Detected
 - High-risk HPV Detected

Interpretation: A positive result may be due to the presence of one or more hrHPV types. Infection with HPV is not an indicator of cytologic HSIL or underlying high-grade CIN, nor does it imply that CIN2/3 or cancer will develop; most women infected with hrHPV do not develop CIN2/3 or cancer. False positive results may occur; some cross-reactivity is exhibited with low-risk HPV types 26, 67, 70, and 82. A negative result does not exclude the possibility of, underlying or future cytologic abnormalities, CIN2, CIN3, or cancer, infection with low levels of hrHPV, or other HPV types not detected by this assay. Detection of HPV is dependent on adequate specimen collection and handling, absence of inhibitors, and sufficient levels of virus. Results should be interpreted in conjunction with other laboratory and clinical data. Consensus guidelines for cervical cancer screening and the management of women with abnormal cervical cytology and/or hrHPV results should be followed, such as those from the [ASCCP](#).

- Limitations/Interferences:**
- This test is not intended for use in cases of suspected sexual abuse or for screening for anal and penile cancers; currently, availability of this test is restricted to County Health Departments in Oklahoma.
 - Personal lubricants containing Polyquaternium 15 at concentrations > 0.025% of test sample
 - Anti-fungals containing tioconazole at concentrations > 0.075% of test sample
 - Effects of other potential variables such as vaginal discharge, use of tampons, douching, etc. and specimen collection variables have not been evaluated.

CPT Codes: 87624

Notes: This test is approved for *in vitro* diagnostic use by the U.S. Food and Drug Administration.

Influenza Virus A and B – PCR

Use: Detection and characterization of influenza virus types A (subtypes H1, pdm09, H3, H5, H7), or B (Victoria and Yamagata lineages) in patients with influenza-like symptoms.

Methodology: Specimens are tested using the Human Influenza Virus Real-time Reverse Transcriptase-PCR Diagnostic Panel, which was developed by the CDC to diagnose human infections with seasonal influenza viruses and novel influenza A viruses. Specimens may be initially screened using the Respiratory Pathogen Panel (see this Test Directory), which is able to detect a spectrum of viruses and bacteria associated with respiratory infections, including influenza viruses A and B.

Clinical Significance: Influenza virus types A, B, and C are RNA viruses that cause acute respiratory disease with associated fever, shivering, chills, headache, malaise, dry cough, loss of appetite, body aches and nausea. Severe cases are associated with prostration, hemorrhagic bronchitis, pneumonia and occasionally death, especially in the young and elderly. Most influenza-like infections are not caused by influenza but by other viruses (e.g., rhinoviruses and respiratory syncytial virus, adenoviruses, and parainfluenza viruses).

Further background information, fact sheets, statistics and educational resources may be found at the [OSDH Infectious Disease Services website](#).

Specimen Type: Nasopharyngeal swab (recommended); Nasal swab; Throat swab

Minimum 1 or 2 swabs

Volume/Size:

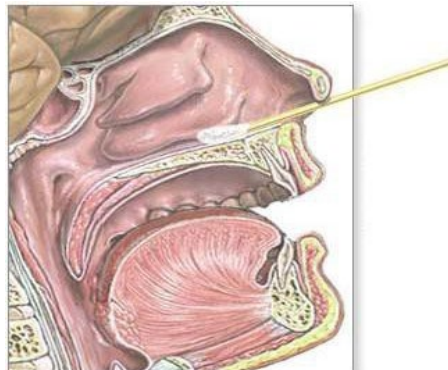
Container: Tube containing viral transport medium (VTM; provided by OSDH PHL) or another appropriate commercial medium (UTM, M4, and M4RT). VTM contains antibiotics and must be stored in the refrigerator prior to and subsequent to specimen collection. Do not use media if cloudy or when past expiration date.

Collection: Respiratory virus diagnosis depends on the collection of high-quality specimens, their rapid transport to the testing laboratory and appropriate storage before testing. Training in specimen collection is highly recommended due to the importance of specimen quality. Specimens should be collected preferably within 3 days of onset of clinical symptoms.

Tip: Have the patient sit with their head against a wall since patients have a tendency to pull away during the procedure.

Nasopharyngeal Swab

1. Label a sterile tube containing 2-3 mL of VTM or other suitable collection media with patient's name and date of collection.



2. If the nasal passages have a large amount of mucus, ask patient to blow their nose before specimen collection.
3. With the thumb of one hand, elevate the tip of the patient's nose then gently insert the NP swab into a nostril.
4. Guide the swab straight back (not upwards), along the floor of the nasal passage until it reaches the posterior wall of the nasopharynx; the distance from the nose to the ear gives an estimate of the distance the swab should be inserted.
Note: *Do not force the swab – if an obstruction is encountered during insertion, try the other nostril.*
5. Rotate the swab by firmly brushing against the nasopharynx several times.
6. Immediately, place swab into tube containing VTM or other suitable collection media.
7. Break-off or cut excess shaft of swab so that tube can be capped.
8. Replace the cap of the tube; tighten and wrap with Parafilm to prevent leakage of contents of tube during transport.
9. Place tube in plastic biohazard bag and insert completed requisition form in outer pouch of the bag.
10. Refrigerate (2-8°C) immediately.

Nasal Swab

1. Label a sterile tube containing 2-3 mL of VTM or other suitable collection media with patient's name and date of collection.
2. If the nasal passages have a large amount of mucus, ask the patient to blow their nose before collecting specimen.
3. With the thumb of one hand, elevate the tip of the patient's nose then gently insert a dry polyester swab into one nostril, keeping swab shaft parallel to the palate.
4. Hold it there for a few seconds then with a rotating motion gently remove it.
5. Using the same swab, repeat the process, inserting the swab in the other nostril.
6. Place swab immediately into VTM or other suitable collection media.
7. Break-off or cut excess shaft of swab so that tube can be capped.
8. Place tube in plastic biohazard bag and insert completed requisition form in outer pouch of the bag.
9. Refrigerate (2-8°C) immediately.

Special Instructions: Only synthetic (nylon, rayon or Dacron)-tipped swabs with plastic or aluminum shafts are acceptable.

Note: Submission of specimens from patients with suspected influenza A/H5 or Eurasian H7 requires OSDH Infectious Disease Service pre-approval to verify the patient meets clinical case criteria, including travel history to an area of novel influenza circulation.

Shipping: Store and ship specimens refrigerated (2-8°C) for delivery within 3 days (72 hours) of collection. If delivery will be delayed for more than 72 hours,

specimens should be frozen at -70°C or colder and shipped with dry ice.

1. Place specimen in round cardboard container and place this in Styrofoam mailer box (both containers are supplied by OSDH PHL for influenza surveillance).
2. Remove frozen cold pack from freezer and place in the mailer with specimen then fill the mailer with packing material.
3. Mailers are returned to submitting sites with fresh tubes of VTM corresponding to the number of specimens submitted. If additional VTM is required, fill-out the order form and return with the specimens in the mailer.
4. Send via OSDH PHL courier service.

Common Causes for Rejection:

- Incorrect collection device (cotton, wooden, or calcium alginate swab) or media
- Received > 72 hours from time of collection and not frozen at -70°C or colder
- Swab without transport medium
- Specimens missing swabs
- Specimens that have leaked due to the cap not properly secured
- Specimen at ambient temperature

Other criteria as outlined in *Specimen Rejection* section of this Test Directory

Turn-around Time: Within 5 working days of receipt.

Within 7 working days of receipt if specimens have reflex testing.

Specimens initially screened using the Respiratory Pathogens Panel, and in which influenza virus A and/or B is detected, will be issued a preliminary report pending testing by the Human Influenza Virus RT-PCR Diagnostic Panel. Specimens in which variant or potential novel influenza viruses are detected by the Human Influenza Virus RT-PCR Diagnostic Panel will be issued a preliminary report, pending further characterization by the CDC.

Normal Value (Reference Range):

- Influenza Not Detected

Reportable Results:

- Influenza Not Detected
- Influenza Virus A Detected, Subtype: H1 2009 pandemic strain
- Influenza Virus A Detected, Subtype: H3 strain
- Influenza Virus A Detected, Subtype: H1 2009 pandemic strain; possible coinfection or recent live attenuated influenza virus vaccination
- Influenza Virus A Detected, Subtype: H3 strain; possible co-infection or recent live attenuated influenza virus vaccination
- Influenza Virus A Detected, Subtype: Eurasian H7 strain
- Influenza Virus A Detected, Subtype: Undetermined
- Influenza Virus A Detected, Subtype: Undetermined, referred to CDC for subtyping
- Presumptive Positive for Influenza A/H3N2 variant; referred to CDC for confirmation
- Presumptive Positive for Influenza A/H5; referred to CDC for confirmation
- Influenza Virus B Detected
- Influenza Virus B Detected, Lineage: Victoria

- Influenza Virus B Detected, Lineage: Yamagata
- Influenza Virus B Detected, Lineage: Victoria; possible co-infection or recent live attenuated influenza virus vaccination
- Influenza Virus B Detected, Lineage: Yamagata; possible co-infection or recent live attenuated influenza virus vaccination
- Indeterminate, potential PCR inhibitor/poor sample quality

Interpretation: When a clinical sample fails to amplify, the sample is reported as “Indeterminate, potential PCR inhibitor/poor sample quality”. It is recommended that a new sample is submitted for testing.

Limitations: Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. Positive results do not rule-out other viral or bacterial co-infections. Individuals immunized with live attenuated influenza nasal spray vaccine may be positive for one or more influenza virus targets for several days post-vaccination; vaccination history should be considered when interpreting positive test results, especially early in the flu season. Lineage typing of influenza B is used for epidemiological purposes, and has no bearing on patient treatment. Performance characteristics of this assay may vary in the detection of novel or emerging influenza viruses.

Cotton swab; calcium alginate swab (shown to inhibit PCR); wooden shaft swab

CPT Codes: 87502, 87503 (x3)

Notes: This test is approved for *in vitro* diagnostic use by the U.S. Food and Drug Administration.

Newborn Screening (NBS) Panel

Abnormal results from the presumptive screens in the Public Health Lab (PHL) indicate that there may be a metabolic issue in the newborn. These will result in a re-test, which will be the end of the testing process if the test is normal. If the result from the newborn is confirmed to be abnormal, then the newborn is referred for further diagnostic testing by NBS Follow-Up. See "Limitations" below.

Use: Screening of newborns for certain metabolic, endocrine, and genetic disorders that can adversely affect a child's long-term health or survival

Methodology: Tandem mass spectrometry; fluorimetric analysis; isoelectric focusing; polymerase chain reaction amplification

Clinical Significance: The Newborn Screening Panel includes measurement of a number of analytes of newborns that are associated with the following conditions:

- Biotinidase deficiency
- Congenital adrenal hyperplasia
- Congenital hypothyroidism
- Cystic fibrosis
- Galactosemia
- Hemoglobinopathy
- Fatty acid oxidation disorders
- Organic acid disorders
- Amino acid disorders
- X-Linked adrenoleukodystrophy
- Lysosomal storage disorders
- Severe combined immunodeficiency
- Spinal muscular atrophy

Specimen Type: Dried blood spots prepared by applying fresh whole blood on Whatman 903, Ahlstrom PerkinElmer 226, or equivalent filter paper from infant less than 6 months of age, in accordance with the current CLSI Section NBS01-A6 standards. Specimen must not be applied to filter paper from EDTA, heparin, or citrate collected blood.

Minimum Volume/Size: 5 filled circles

Container: ODH #450 Newborn Screening Form and Collection Kit.

The submitter must ensure that the newborn screening form kit is not expired, and must complete all information requested by printing legibly.

Oklahoma Newborn Screening (NBS) Form
To order forms, call the OSDH NBS Program (405) 271-5070

DO NOT WRITE HERE

SN 1710050

First Screen Repeat Screen Previous NBS Lab # _____
 Not Screened Due To _____ Refused Expired ____/____/____ Tests Requested All Tests NICU/SCN Lactose-Free Formula (Soy)
 Transferred ____/____/____ to _____ HGB Only GALT TPN/SNAP Meconium Ileus
 Phe Monitor CFTR Lipids/Carnitine/MCT Family History of CF

BABY'S INFORMATION

Last Name _____ First Name _____

Birth Date ____/____/____ Time ____:____ (24 Hr Clock) Sex Male Female Race (check all as apply)
 White Black Hispanic Asian American Indian Pacific Islander
 Unknown

Collection Date ____/____/____ Time ____:____ (24 Hr Clock) Multiple Birth Order A- _____

Medical Record # _____ Gest. Age _____ Birth Wt. (gm) _____

MOTHER'S/GUARDIAN'S INFORMATION

DHS Custody Last Name _____ First Name _____
 Adoption

Address _____ Apt. # _____

City _____ State _____ Zip _____

Telephone # (____) _____ Alternate Telephone # (____) _____

Mother's Date of Birth ____/____/____ Mother's Medicaid ID # _____ Mother's Last 4 of SSN _____

PROVIDER'S INFORMATION

Physician Ordering NBS (Last, First) _____ Provider ID # _____

Primary Care/Follow-up Physician (Last, First) _____ Provider ID # _____

MEDICAL/FEEDING HISTORY (check all that apply)

Transfusion Date ____/____/____ Time ____:____ (24 Hr Clock)
 NICU/SCN Lactose-Free Formula (Soy)
 TPN/SNAP Meconium Ileus
 Lipids/Carnitine/MCT Family History of CF

PULSE OXIMETRY/CCHD SCREEN

Pass Fail Not Performed Refused Echo

HEARING SCREEN

Do not write in this box

Date of Final Screen ____/____/____

Right Ear: Pass Refer Left Ear: Pass Refer

Screen Method ABR OAE

If not screened, reason
 Delayed Family History
 Discharged In Utero Infection
 No Supplies Craniofacial Anomalies
 Refused ECMO
 Technical Problem Both Hyperbilirubinemia AND Exchange Transfusion
 NICU

SUBMITTER'S INFORMATION

Submitting Facility's/Provider's ID # _____

Submitter's Name/Address _____

Use black or blue ink ball point pen only. See full instructions for completion of form on back page.

2020-02-28

SN 1710050
ODH #450 Rev. 10.18

- Mark if First Screen or Repeat Screen. If repeat screen, enter Previous Lab Number, if known. If unknown, enter Previous Filter Paper Number.
- Mark Reason Not Screened if appropriate. If parent(s)/guardian refused screening, then the *NBS Refusal Form* must be faxed to Screening and Special Services at 405-900-7556.
- Mark Tests Requested, only if a special test is needed. If this is an initial newborn screen, do not mark any category in this section; if nothing is marked, all tests will be performed.

Infant's Information:

- Print infant's Last Name. If baby is being adopted, fill-in BUFA for last name and mark adoption box. Print infant's First Name or fill-in with Male/Female.
- Mark appropriate Gender.
- Print Date of Birth.
- Print Time of Birth using military time.
- Mark appropriate race.
- Print Date of Collection.
- Print Time of Collection using military time.
- Print Medical Record Number.
- Print Gestational Age.
- Print Birth Weight in grams.
- If multiple births, indicate birth order (i.e., A, B, C). If not a multiple birth, leave blank.

Mother's Information:

If infant is not in mother's care, put information for person responsible for getting infant to doctor's appointments (e.g., other family member, case worker, social worker) in the Mother's/Guardian's Information section.

- Mark whether infant is in DHS Custody or Up for Adoption if applicable, otherwise leave field blank.
- Print Last and First Names for mother/guardian.
- Print Address and Apartment Number, as applicable; if not applicable, leave field blank.
- Print name of City where mother/guardian resides.
- Print name of State where mother/guardian resides.
- Print Zip Code of city where mother/guardian resides.
- Print Telephone Number for mother/guardian.
- Print Alternate Telephone Number for mother/guardian if available.
- Print mother's Date of Birth.
- Print mother's Medicaid Number.
- Print last 4 Digits of Mother's SSN.

Provider's Information:

- Print Ordering Physician's Last and First Names and Provider's ID Number.
- Print Primary Care/Follow-Up Physician's Last and First Names and Provider's ID Number.

Medical/Feeding History:

- Print Transfusion Date and Time, if infant was transfused. If infant was not transfused, leave blank.
- Mark appropriate fields to indicate treatments/health history of infant (i.e., NICU/SCN, TPN/SNAP, Lipids/Carnitine/MCT, Lactose-Free Formula, Meconium Ileus, Family History of CF).

Pulse Oximetry/CCHD Screen:

- Mark appropriate box for CCHD Screen, if the parent(s)/guardian refused screening then *NBS Refusal Form* must be faxed to Screening and Special Services at 405-900-7556.

Hearing Screening Results:

- Print Date of Final Hearing Screen
- Mark Pass/Refer for right/left ear.
- Mark Screening Method used to perform hearing test.
- If infant was not screened, mark the Reason Screen not Performed.
- Mark all hearing risk categories that apply to the infant.

Submitter's Information:

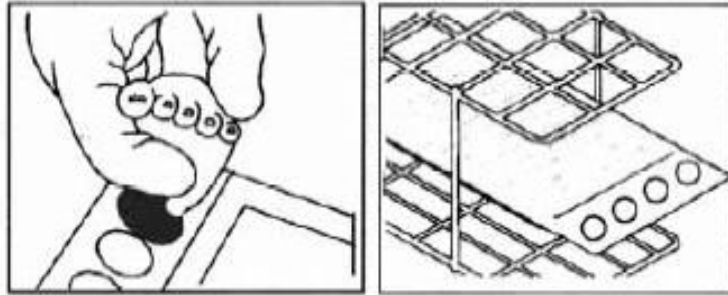
- Print Facility ID Number. Print Facility Name and Address. A pre-printed sticker or stamp may be used for this section.

Collection: Special attention must be paid to the storage and transportation conditions of the dried blood spot samples. Storage of samples in an environment with elevated temperatures and humidity increases the risk of false positive screening results.

1. To prevent specimen contamination do not touch any of the filter paper circles before or after collection.
2. Warm infant's foot site with a soft cloth, moistened with warm water up to

41°C (105°F) for 3 to 5 minutes.

3. Select puncture site and cleanse with 70% isopropanol and allow heel to air-dry. Black areas shown on image of foot indicate safe areas for puncture site.
4. Keep the heel in a horizontal position (heel-down) at or below the heart level.
5. Use a sterile, disposable lancet or heel incision device to perform a swift clean puncture to the infant's heel.
6. Use sterile gauze to wipe away first blood drop.
7. Allow a second LARGE blood drop to form.
8. Gently, touch the filter paper against the large drop of blood, following a sufficient quantity of the blood to completely fill the pre-printed circle on the filter paper and soak through to the other side. Do not touch the heel to the filter paper. Do not apply multiple drops of blood to the same circle. Apply blood only to one side of the filter paper.



9. Continue filling the other circles with successive single large drops of blood.
10. Allow both sides of blood spots to air-dry at room temperature for at least 3 hours in a horizontal position. Fold the cardboard cover to hold the blood spots off of any surface or place on a rack to dry. Be sure the attached coverslip does not come into contact with the blood until completely dry. NOTE: Do not use artificial heat (lamps, incubators, etc.) to dry the samples. Keep away from direct sunlight. Do not stack wet specimens. Insufficient drying will adversely affect the test results.
11. Replace the coverslip over the blood spots when completely dry.
12. Check the quality of the specimens (see Simple Spot Check below). All specimens are judged for acceptability at the OSDH PHL, and those not acceptable are reported as "Unsatisfactory".

Special Instructions: Screening requirements for all newborns:

- Collect specimen as early as possible after 24 hours of age or immediately prior to discharge or prior to blood transfusion, whichever comes first.
- If infant is screened at ≤ 24 hours of age, repeat screen at 3-5 days of age (if premature or sick infant, repeat screen at 7-14 days of age).
- All premature and sick infants should have a repeat screen at 14 days of age.
- The Newborn Screening follow-up may reach out requesting additional tests or consults based on initial result.

- Shipping:**
- Ideally, specimens **should be transported within 24 hours after collection** but send specimens as soon as possible after drying.
 - Transport specimens at ambient temperature of 2–30°C (35–86°F) in a sealed paper envelope or container that will provide protection from moisture, light, heat, and contact with other materials.
 - **Never place filter paper specimens in plastic bags.**
 - **Do not batch specimens from multiple days** except for days when there is no courier service.
 - Send specimens via OSDH PHL courier service.
 - Courier pick-up occurs daily at most sites.
 - For sites without weekend courier service, specimens collected on the weekend will be picked-up on the next workday.
 - Specimens older than 14 days from collection are unsatisfactory for testing and repeat collection will be required.

- Common Causes for Rejection:**
- Circles not completely filled or not thoroughly saturated
 - Specimens not collected by a healthcare provider
 - Uneven saturation of circles or multiple sample applications
 - Specimen appears diluted, discolored, or contaminated
 - Clotted or caked blood on filter paper
 - Peripheral serum rings present on filter paper
 - Specimen appears scratched or abraded or filter paper damaged
 - No blood applied to filter paper
 - Specimen received on incorrect or expired form
 - Specimen received more than 14 days from date of collection
 - Serial number on form and (detached) filter paper do not match
 - Other criteria as outlined in Specimen Rejection section of this Test Directory

- Turn-around Time:** Within 5 working days of receipt (7 working days if reflex testing is required)
- Initial normal/abnormal results:
 - Written report sent to baby’s physician and sample collection site
 - Repeat of initial abnormal results:
 - Written report to physician and collection site

Normal Value (Reference Range): See specific Newborn Screening Test sections for details.

Reportable Results: See specific Newborn Screening Test sections for details.

Interpretation: See specific Newborn Screening Test sections for details.

Limitations/Interferences: Newborn screening is performed as a means to assess risk in clinically asymptomatic newborns for a host of disorders; it is not intended to establish diagnosis. Abnormal biomarker levels, identified through screening and evaluated using cutoffs, only indicate that a newborn may be at increased risk for a screened disorder. The healthcare provider may request additional

diagnostic testing to determine if the newborn has the disorder in question. Healthcare providers should understand that in instances where a newborn has a family history of a disease or is symptomatic, additional diagnostic testing is necessary regardless of the NBS result. Even though algorithms are used to determine infants at highest risk, NBS may not detect all affected newborns. A positive (i.e., abnormal) screening result is not a confirmed diagnosis of a disorder, and a negative (i.e., normal) screening result is not a confirmed exclusion of a disorder.

CPT Codes: 82261, 83498, 84443, 83516, 82760, 83020-52, 82017, 82139, 82017, 82657, 81479

Notes: See each individual test for additional notes.

Neonatal Screening

Blood Specimen Collection and Handling Procedure



1 Equipment: sterile lancet with tip approximately 2.0 mm, sterile alcohol prep, sterile gauze pads, soft cloth, blood collection form, gloves.



2 Complete ALL information. Do not contaminate filter paper circles by allowing the circles to come in contact with spillage or by touching before or after blood collection. Keep "SUBMITTER COPY" if applicable.



3 Hatched area (■■■■■■■■■■) indicates safe areas for puncture site.

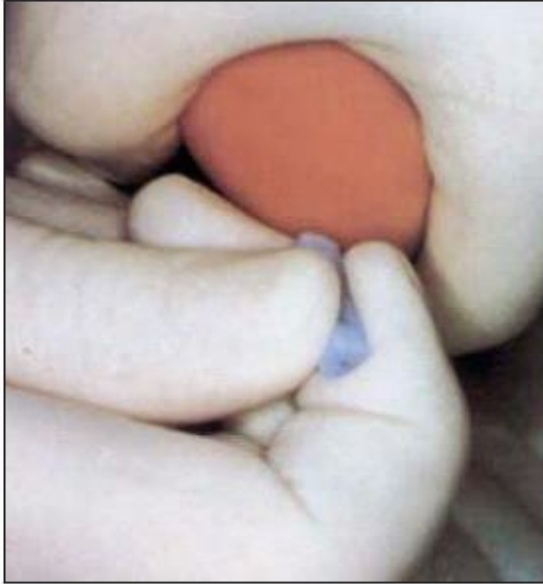


4 Warm site with soft cloth, moistened with warm water up to 41°C, for three to five minutes.



5 Cleanse site with alcohol prep. Wipe DRY with sterile gauze pad.





6 Puncture heel. Wipe away first blood drop with sterile gauze pad. Allow another LARGE blood drop to form.



8 Fill remaining circles in the same manner as step 7, with successive blood drops. If blood flow is diminished, repeat steps 5 through 7. Care of skin puncture site should be consistent with your institution's procedures.



7 Lightly touch filter paper to LARGE blood drop. Allow blood to soak through and completely fill circle with SINGLE application to LARGE blood drop. (To enhance blood flow, VERY GENTLE intermittent pressure may be applied to area surrounding puncture site). Apply blood to one side of filter paper only.



9 Dry blood spots on a dry, clean, flat non-absorbent surface for a minimum of four hours.



10 Mail completed form to testing laboratory within 24 hours of collection.

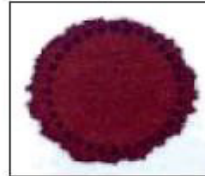
Information provided by The New York State Department of Health.

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 Schleicher & Schuell BioScience GmbH • P.O. Box 1160, D-37582 Dassel • Germany • Tel. 49-5561-791-676 • Fax 49-5561-791-583 • www.s-und-s.de • salediagcomp@s-und-s.com

3/04/02 LIT #719E

Simple Spot Check

Valid Specimen



Allow a sufficient quantity of blood to soak through to completely fill the pre-printed circle on the filter paper. Fill all required circles with blood. Do not layer successive drops of blood or apply blood more than once in the same collection circle. Avoid touching or smearing spots.

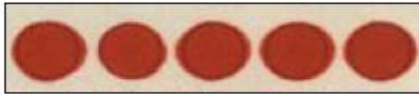
Invalid Specimens:



1. Specimen quantity insufficient for testing



2. Specimen appears scratched or abraded.



3. Specimen not dry before mailing.



4. Specimen appears supersaturated.



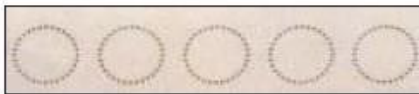
5. Specimen appears diluted, discolored or contaminated.



6. Specimen exhibits serum rings.



7. Specimen appears clotted or layered.



8. No blood.

Possible Causes:

- Removing filter paper before blood has completely filled circle or before blood has soaked through to second side.
- Applying blood to filter paper with a capillary tube.
- Touching filter paper before or after blood specimen collection with gloved or ungloved hands, hand lotion, etc.
- Allowing filter paper to come in contact with gloved or ungloved hands or substances such as hand lotion or powder, either before or after blood specimen collection.
- Applying blood with a capillary tube or other device.
- Mailing specimen before drying for a minimum of four hours.
- Applying excess blood to filter paper, usually with a device.
- Applying blood to both sides of filter paper.
- Squeezing or "milking" of area surrounding the puncture site.
- Allowing filter paper to come in contact with gloved or ungloved hands or substances such as alcohol, formula, antiseptic solutions, water, hand lotion or powder, etc., either before or after blood specimen collection.
- Exposing blood spots to direct heat.
- Not wiping alcohol from puncture site before making skin puncture.
- Allowing filter paper to come in contact with alcohol, hand lotion, etc.
- Squeezing area surrounding puncture site excessively.
- Drying specimen improperly.
- Applying blood to filter paper with a capillary tube.
- Touching the same circle on filter paper to blood drop several times.
- Filling circle on both sides of filter paper.
- Failure to obtain blood specimen.

Information provided by The New York State Department of Health.

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3/04/02 Lit. #718E

Specific information regarding each newborn screening test follows:

Biotinidase Deficiency (NBS)

Use: Determination of biotinidase enzyme activity in blood specimens dried on filter paper as an aid in screening newborns for biotinidase deficiency.

Methodology: The GSP Neonatal Biotinidase assay combines a solution-based enzyme reaction, involving cleavage of the amide bond in europium-labeled biotin by biotinidase (eluted from the dried blood spot [DBS]), followed by a solid phase, time-resolved immunofluorescence reaction. The initial enzyme reaction is stopped by the addition of streptavidin, which binds to both Eu-labeled and free biotin. The streptavidin-biotin complexes are then captured by monoclonal antibodies directed against streptavidin that are immobilized on the walls of 96-well plates. The wells are washed, and then DELFIA® Inducer is used to dissociate the captured complexes into solution where the Eu fluorescence is measured. The measured fluorescence is inversely proportional to the biotinidase activity in the original DBS.

Clinical Significance: Biotinidase-deficient newborns have an inborn error of metabolism characterized by the inability to utilize dietary protein-bound vitamin or to recycle endogenous biotin derived from the turnover of carboxylases. Biotin deficiency develops progressively, resulting in deficiency of the biotindependent carboxylases: propionyl-CoA carboxylase, 3-methyl-crotonyl-CoA carboxylase, and pyruvate carboxylase. The disorder is autosomal recessive. Individuals lacking biotinidase activity exhibit a variety of symptoms, which are frequently not present at birth, thus making it difficult to diagnose the disease by clinical observation. Symptoms and the time of onset vary greatly. *Profound biotinidase deficiency*, the more severe form of the condition, occurs when the activity of biotinidase is reduced to < 10% of normal and usually manifests itself in infants between two and six months of age. By contrast, *partial biotinidase deficiency*, the milder form of the condition, occurs when biotinidase activity is reduced to between 10 and 30% of normal, and presents later in life. Affected infants between two and six months of age usually develop hypotonia, ataxia, seizures, breathing difficulties, and display developmental delay. Cutaneous abnormalities (skin rash, alopecia) also may be manifested. Treatment with biotin is effective; however, if the therapy is delayed, neurological damage may not be completely reversed.

Specimen Type: See [Newborn Screening Specimen Type](#).

Minimum Volume/Size:	See Newborn Screening Minimum Volume/Size .
Container:	See Newborn Screening Container and Instructions .
Collection:	See Newborn Screening Collection Instructions .
Special Instructions:	See Newborn Screening Special Instructions .
Shipping:	See Newborn Screening Shipping Instructions .
Common Causes for Rejection:	See Newborn Screening Common Causes for Rejection .
Turn-around Time:	Within 5 working days after receipt
Normal Value (Reference Range):	BIO ≥ 57 U/dL
Reportable Results:	<ul style="list-style-type: none"> • Within Normal Limits • *Outside Normal Limits; See Comments (BIO)
Interpretation:	<ul style="list-style-type: none"> • Not consistent with biotinidase deficiency. • *Decreased biotinidase enzyme observed; submit repeat specimen as soon as possible • *Possible biotinidase deficiency; recommend immediate confirmatory testing • *Consistent with biotinidase deficiency; recommend immediate confirmatory testing
Limitations/Interferences:	<p>This is a screening test only. It should not be used to distinguish partial from profound biotinidase deficiency. A diagnostic procedure should be used to confirm a diagnosis of biotinidase deficiency.</p> <p>Abnormal neonatal conjugated bilirubin levels (> 2.5 mg/dL) or triglycerides (≥ 250 mg/dL) may decrease biotinidase activity measured using this assay (i.e., produce a false positive reaction), while elevated glutathione (> 30.0 mg/dL), unconjugated bilirubin (10 mg/dL), sulfisoxazole (≥ 7.5 mg/dL) and ampicillin (≥ 1.4 mg/dL) can increase biotinidase activity measured using this assay (i.e., produce false negative reaction). High heat and humidity can cause rapid loss of biotinidase activity in DBS. The following conditions may also cause anomalous assay results: poorly collected specimen, spot not uniformly saturated with blood, improperly dried specimen, contamination of filter paper.</p>
CPT Code:	82261
Notes:	This test is approved for <i>in vitro</i> diagnostic use by the U.S. Food and Drug Administration.

Congenital Adrenal Hyperplasia (CAH, NBS)

Use: Quantitative determination of human 17 β -OH-progesterone (17-OHP) in blood specimens dried on filter paper as an aid in screening newborns for congenital adrenal hyperplasia (CAH). If the 17-OHP value is elevated, the specimen is referred for 2nd tier MS/MS steroid profiling.

Methodology: The GSP Neonatal 17 α -OH-progesterone (17-OHP) is a solid phase, time resolved fluoroimmunoassay based on the competitive reaction between europium-labeled 17-OHP and sample 17-OHP for a limited number of binding sites on 17-OHP specific polyclonal antibodies (derived from rabbit). Danazol facilitates the release of 17-OHP from the binding proteins. A second antibody, directed against rabbit IgG, is coated to the solid phase, giving convenient separation of the antibody-bound and free antigen. DELFIA Inducer dissociates europium ions from the labeled antigen into solution where they form highly fluorescent chelates with components of the Enhancement Solution. The fluorescence in each well is then measured. The fluorescence of each sample is inversely proportional to the concentration of 17-OHP in the sample.

Clinical Significance: There are various congenital enzyme defects of the steroid biosynthesis, which cause CAH. They are genetically different, but are all transmitted in an autosomal recessive manner. The most frequent types are 21 β -hydroxylase deficiency (about 80% of all cases) and 11 β -hydroxylase deficiency (about 15% of all cases). CAH due to 21 β -hydroxylase deficiency is characterized by a deficiency in the hormones, cortisol and aldosterone, and an over-production of androgen. Serious loss of body salt and water can result in death. In girls, the genitalia may appear like that of a male, and can result in incorrect sex assignment. Symptoms of adrenal insufficiency include: emesis, excessive weight loss relative to birth weight, diaphoresis, hyperventilation, pallor, dry mucosa, and lethargy. 17-OHP, a precursor of cortisol, is increased in both 21 and 11 β -hydroxylase deficiency. Its determination is thus useful as a screening method for the two most frequent types of CAH or about 95% of all cases.

Specimen Type: See [Newborn Screening Specimen Type](#).

Minimum Volume/Size: See [Newborn Screening Minimum Volume/Size](#).

Container: See [Newborn Screening Container and Instructions](#).

Collection: See [Newborn Screening Collection Instructions](#).

Special Instructions: See [Newborn Screening Special Instructions](#).

Shipping: See [Newborn Screening Shipping Instructions](#).

Common Causes for Rejection: See [Newborn Screening Common Causes for Rejection](#).

Turn-around Time:

- Within 5 working days after receipt

- Within 7 working days after receipt if 2nd tier steroid profile is required*

Normal Value
(Reference Range):

- Within Normal Limits; Not Consistent with CAH
- 17-OHP < 28.0 ng/mL if birth weight is ≥ 2500 grams
 - 17-OHP < 75.0 ng/mL if birth weight is < 2500 grams

Reportable Results:

- Within Normal Limits
- *17-OHP Outside Normal Limits, See Comments (CAH)

Interpretation:

- Not Consistent with CAH
- *Submit repeat specimen as soon as possible. Steroid profile performed at Mayo Medical Labs, 200 First Street SW, Rochester, MN 55905. This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration
- *CAH screening inconclusive. Confirmatory testing recommended. Steroid profile performed at Mayo Medical Labs, 200 First Street SW, Rochester, MN 55905. This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration
- *CAH follow-up recommended if clinically indicated, or if family history indicators are present. Steroid profile performed at Mayo Medical Labs, 200 First Street SW, Rochester, MN 55905. This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration
- *Consistent with CAH. Immediate confirmatory testing recommended. Steroid profile performed at Mayo Medical Labs, 200 First Street SW, Rochester, MN 55905. This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration

**Limitations/
Interferences:**

- This is a screening test only. A diagnostic procedure should be used to confirm a diagnosis of CAH
- Late onset, non-classic CAH is not accurately detected by newborn screening
- Newborn screening for CAH is not intended to detect mild cases, although some are detected
- Despite adjusting 17-OHP cut-off concentrations for birth weight, preterm or low birth weight and samples taken at ≤ 24 hours of age are major factors for false-positive results
- Do not use EDTA or citrate tubes or capillaries to collect blood, as these anticoagulation reagents will affect the assay by chelating the europium label. Treatment of the mother or the child with dexamethasone, hydrocortisone or prednisone may result in false-negative results. The following conditions may cause anomalous assay results: poorly collected

specimen, spot not uniformly saturated with blood, improperly dried specimen, exposure of specimen to high heat and humidity, contamination of filter paper with feces.

CPT Codes: 83498

Notes: This test is approved for *in vitro* diagnostic use by the U.S. Food and Drug Administration.

Second-Tier steroid profile performed at Mayo Clinic Labs, 200 First St. SW, Rochester, MN 55905. This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Congenital Hypothyroidism (TSH, NBS)

Use: Quantitative determination of human thyroid stimulating hormone (hTSH) in blood specimens dried on filter paper as an aid in screening newborns for congenital (neonatal) hypothyroidism.

Methodology: The GSP Neonatal hTSH assay is a solid phase, two-site fluoroimmuno-metric assay based on the direct sandwich technique in which two monoclonal antibodies are directed against two separate antigenic determinants on the hTSH molecule. Standards, controls and test specimens containing hTSH are reacted simultaneously with immobilized monoclonal antibodies directed against a specific antigenic site on the β hTSH subunit and europium-labeled monoclonal antibodies (directed against a different antigenic site located partly on the β subunit and partly on the subunit) in assay buffer. The assay buffer elutes hTSH from the dried blood spots. DELFIA Inducer dissociates europium ions from the labeled antibody into solution where they form highly fluorescent chelates with components of the DELFIA Inducer. The fluorescence in each well is then measured. The fluorescence of each sample is proportional to the concentration of hTSH in the sample.

Clinical Significance: Congenital hypothyroidism is usually caused by abnormal development or absence of the thyroid gland. An elevated hTSH concentration in infant blood is the earliest available laboratory manifestation of primary hypothyroidism. Due to its high specificity and sensitivity, hTSH testing is the screening method of choice for the detection of neonatal hypothyroidism. Since a clinical diagnosis is difficult to establish and since the condition needs early medical attention, large scale laboratory screening programs have been implemented in many countries to detect neonatal hypothyroidism.

Specimen Type: See [Newborn Screening Specimen Type](#).

Minimum Volume/Size: See [Newborn Screening Minimum Volume/Size](#).

Container: See [Newborn Screening Container and Instructions](#).

Collection: See [Newborn Screening Collection Instructions](#).

Special Instructions: See [Newborn Screening Special Instructions](#).

Shipping: See [Newborn Screening Shipping Instructions](#).

Common Causes for Rejection: See [Newborn Screening Common Causes for Rejection](#).

Turn-around Time: Within 5 working days after receipt

Normal Value (Reference Range): TSH < 27.0 μ IU/mL serum

Reportable Results:

- Within Normal Limits
- *Outside Normal Limits, See Comments (CH)

Interpretation:

- Not consistent with CH
- *Submit repeat specimen within 48 hours or perform serum TSH and free-T4 tests at 12 to 15 days of life
- *Possible congenital hypothyroidism; recommend immediate serum TSH and free-T4 confirmatory testing
- *Consistent with hypothyroidism; recommend immediate serum TSH and free-T4 confirmatory testing

Limitations/

This is a screening test only. A diagnostic procedure performed on a serum

Interferences:

sample should be used to confirm diagnosis of congenital hypothyroidism.

Do not use EDTA or citrate tubes or capillaries to collect blood, as these anticoagulation reagents will affect the assay by chelating the europium label. Heterophilic antibodies in the sample may interfere with the assay. The following conditions may cause anomalous assay results: poorly collected specimen, spot not uniformly saturated with blood, improperly dried specimen, exposure of specimen to high heat and humidity, contamination of filter paper with feces.

CPT Codes: 84443

Notes: This test is approved for in vitro diagnostic use by the U.S. Food and Drug Administration.

Cystic Fibrosis (CF, NBS)

Use: Quantitative determination of human immunoreactive trypsinogen (IRT) in blood specimens dried on filter paper is used as an aid in the screening of newborns for Cystic Fibrosis (CF). Specimens with elevated IRT values are reflexed to 2nd tier *CFTR* gene mutation analysis. Newborns identified with meconium ileus or family history of CF also undergo *CFTR* mutation analysis.

Methodology: **IRT Assay:**

The GSP Neonatal IRT kit is a solid phase, two-site fluoroimmuno-metric assay based on the direct sandwich technique in which two monoclonal antibodies (mAbs) are directed against two separate antigenic determinants on the IRT molecule. Standards, controls and patient dried blood spot specimens containing IRT are reacted simultaneously with anti-IRT mAbs immobilized on the walls of reaction wells in a 96-well plate and to europium-labeled anti-IRT mAbs in assay buffer. The assay buffer elutes IRT from the dried blood on the filter paper disks, which is then captured onto the walls of the reaction wells by the unlabeled mAbs and reacts with the europium-labeled mAbs in the assay buffer. Delfia Inducer then dissociates europium from the captured IRT-mAb complexes to form highly fluorescent chelates with components of the solution. The fluorescence of each sample is proportional to the concentration of IRT in the sample.

CFTR Mutation Analysis:

The xTag Cystic Fibrosis 60 kit v2 is a PCR-bead array based genotyping assay that identifies a panel of 60 mutations and 6 variants in the *CFTR* gene, including those currently recommended by the American College of Medical Genetics and American College of Obstetricians and Gynecologists (ACMG/ACOG), plus some of the world's most common and North American-prevalent mutations (see table below).

Luminex xTAG Cystic Fibrosis 60 Kit v2 Mutation Targets			
F508del	1717-1G>A	W1282X	2307insA
I507del	R560T	1078delT	Y1092X
G542X	R553X	394delTT	M1101K
G85E	G551D	Y122X	S1255X
R117H	1898+1G>A	R347H	3876delA
621+1G>T	2184delA	V520F	3905insT
711+1G>T	2789+5G>A	A559T	5T/7T/9T
N1303K	3120+1G>A	S549N	F508C
R334W	R1162X	S549R	I507V
R347P	3659delC	1898+5G>T	I506V
A455E	3849+10kbC>T	2183AA>G	CFTR dele2, 3
L206W	1677delTA	3199del6	E60X
935delA	2055del9>A	R1066C	R75X
G330X	2143delT	W1089X	406-1G>A
Q493X	K710X	D1152H	G178R
Q890X	R1158X	3791delC	S1196X

Clinical Significance: CF is the most common recessive genetic disorder found in Caucasians with an incidence of 1 in 2,500 live births. The main clinical symptoms are characterized by functional abnormalities in the airway epithelium, the exocrine pancreas, the gastrointestinal tract, and the secretory duct of the sweat gland, leading to pancreatic and pulmonary insufficiency. Early detection of CF can decrease the risk of malnutrition, failure to thrive, zinc deficiency, fat-soluble vitamin (A, D, E and K) deficiency-related disorders of the eye, bone, heart, and immune and nervous systems, and chest infections. Trypsinogen, one of the principal enzyme precursors produced by the pancreas, is abnormally increased in the blood of CF infants at birth due to obstructive pancreatic damage, making it a suitable marker for neonatal screening for CF. Heterozygous carriers of CF can also have elevated blood IRT values; therefore, it is not diagnostic in isolation.

Generally, CF is characterized as “pancreatic insufficient” (PI) or “pancreatic sufficient” (PS), based on whether the individual has enough pancreatic function to grow and maintain health without supplemental pancreatic enzyme therapy (PERT). PI is the result of obstructive destruction of exocrine pancreatic tissue. About 85% of CF patients are PI before the age of 1 year. PI correlates closely with the specific *CFTR* mutations found in the individual. Individuals with 2 severe *CFTR* mutations (classes I, II, III, and VI) tend to have early PI, often beginning at birth, while those with 2 mild *CFTR* mutations (classes IV and V) or with one severe and one mild mutation tend to be PS at birth. However, there is considerable variation in genotype/phenotype correlates, indicating the critical role for environmental factors and modulatory genetic elements in clinical outcomes. CF individuals born PS may become PI at any age, and without symptoms initially, emphasizing the importance of constant monitoring.

- Specimen Type:** See [Newborn Screening Specimen Type](#).
- Minimum Volume/Size:** See [Newborn Screening Minimum Volume/Size](#).
- Container:** See [Newborn Screening Container and Instructions](#).
- Collection:** See [Newborn Screening Collection Instructions](#).
- Special Instructions:** See [Newborn Screening Special Instructions](#).
- Shipping:** See [Newborn Screening Shipping Instructions](#).
- Common Causes for Rejection:** See [Newborn Screening Common Causes for Rejection](#).
- Turn-around Time:** IRT within 5 working days after receipt
IRT and *CFTR* mutation analysis within 7 working days after receipt*
- Normal Value (Reference Range):** IRT < 57 ng/mL (Neonatal IRT); No mutations detected (*CFTR* mutation analysis)
- Reportable Results:**
- Within Normal Limits
 - *Outside Normal Limits, *CFTR* < > Mutations; See Comments (CF)

- Interpretation:**
- Not consistent with Cystic Fibrosis.
 - *Not consistent with Cystic Fibrosis, unless symptomatic, or if there is a family history of cystic fibrosis. Requires further testing; refer for sweat testing and genetic counseling. CFTR mutation analysis may be based on prior or current specimen. Mutation(s) detected - <<list mutation(s)/variant(s)>>
 - *Consistent with Cystic Fibrosis; however, considerable clinical heterogeneity exists for individual CFTR genotypes; Refer for sweat testing and genetic counseling. Mutation(s) detected - <<list mutation(s)/variant(s)>>

Limitations/ Interferences: Do not use EDTA, citrate, or heparin tubes or capillaries to collect blood. EDTA and citrate will affect the assay by chelating the europium label. Heparin is also an inhibitor of the PCR used to detect *CFTR* mutations. The following conditions may cause anomalous assay results: poorly collected specimen, spot not uniformly saturated with blood, improperly dried specimen, exposure of specimen to high heat and humidity, contamination of filter paper with feces.

The GSP Neonatal IRT assay is a screening test only. Other diseases may mimic PI CF, including other causes of PI, intestinal malabsorption, and some behavioral problems. Therefore, a diagnostic procedure should be used to confirm a diagnosis of CF. The Cystic Fibrosis 60 kit v2 assay can be used to confirm abnormal IRT values when two mutations are present in either homozygous or compound heterozygous states. However, because this kit only detects a subset of *CFTR* mutations, albeit common mutations for the US population, individuals with *CFTR* mutations may be missed. Testing of individuals with an expanded *CFTR* mutation panel that includes other less common mutations may be indicated if the initial panel of mutations demonstrates a single mutation, or is suspected of having CF. A sweat chloride test should be an early step in the differential diagnosis of PI or malabsorption in newborns, and remains the “gold standard” for diagnosis of CF.

CPT Codes: 83516

Notes: False negative IRT values are known to occur in some CF newborns that present with meconium ileus. If an infant has meconium ileus or there is a family history of CF, it is important to mark the appropriate area of the NBS collection form, so that *CFTR* mutation analysis will be performed even if the IRT level is <57 ng/mL. Both the Neonatal IRT assay and the xTag® Cystic Fibrosis 60 kit v2 assay are approved for *in vitro* diagnostic use by the U.S. Food and Drug Administration.

Galactosemia (GALT, NBS)

Use: Quantitative determination of total galactose (galactose and galactose-1-phosphate) in blood specimens dried on filter paper as an aid in screening newborns for classic galactosemia (GALT), galactokinase deficiency (GALK), and galactose epimerase deficiency (GALE). Specimens with elevated total galactose are reflexed to analysis of galactose-1-phosphate uridyl transferase (GALT) enzyme activity. Newborns identified as receiving lactose-free formula also undergo GALT enzyme testing.

Methodology: The GSP Neonatal Total Galactose kit quantitatively measures total galactose, i.e., both galactose and galactose-1-phosphate, in dried blood spot specimens based on a fluorescent galactose oxidase method.

Clinical Significance: Galactosemia is an autosomal recessive disorder that is characterized by elevated concentrations of galactose in the blood resulting from the absence or dysfunction of any of the three enzymes responsible for the transformation of galactose to glucose, i.e., D-galactose-1-phosphotransferase, -D-galactose-1-phosphate-uridyltransferase, or UDP-glucose-4-epimerase. If not diagnosed and treated within the newborn period, galactosemia can lead to diarrhea, dehydration, jaundice, hepatic failure, hypoglycemia, cataracts, developmental retardation and death within a few weeks. Sepsis due to *Escherichia coli* seems to be particularly frequent among galactosemic neonates and is usually the cause of death. Treatment of the disease consists of withdrawal of all foods containing lactose and galactose from the diet.

Specimen Type: See [Newborn Screening Specimen Type](#).

Minimum See [Newborn Screening Minimum Volume/Size](#).

Volume/Size:**Container:** See [Newborn Screening Container and Instructions](#).**Collection:** See [Newborn Screening Collection Instructions](#).**Special Instructions:** See [Newborn Screening Special Instructions](#).**Shipping:** See [Newborn Screening Shipping Instructions](#).**Common Causes for Rejection:** See [Newborn Screening Common Causes for Rejection](#).**Turn-around Time:** Within 5 working days after receipt**Normal Value (Reference Range):** TG < 12 mg/dL;**Reportable Result:**

- Within Normal Limits
- *Outside Normal Limits; See Comments (GAL)

Interpretation:

- Not consistent with classic galactosemia
- *Not consistent with classic galactosemia; repeat testing at provider's discretion
- *Repeat screen unless on lactose free formula, family history, or symptomatic then consult
- *Possible Galactosemia; Immediate confirmatory testing, start baby on lactose free formula

Limitations/Interferences: Infants that have not ingested breast milk or formula containing lactose prior to the sample collection may have lower total galactose values. Conjugated bilirubin concentrations greater than 16.6 mg/dL and acetaminophen concentrations greater than 2.75 mg/dL in the blood of infants may decrease measured TG concentrations, which may cause false negative results. Exchange transfusions may also lead to a false negative screening test. The following conditions may cause anomalous assay results: poorly collected specimen, spot not uniformly saturated with blood, improperly dried specimen, exposure of specimen to high heat and humidity, contamination of filter paper with feces.

This is a screening test only. This test is not designed to screen for GALT heterozygosity. A diagnostic procedure should be used to confirm a diagnosis of galactosemia.

CPT Codes: 82760**Notes:** Samples subjected to heat, light, or moisture may have decreased total galactose levels. Samples stored in warm and/or humid conditions lose GALT activity. Therefore, improper handling and storage of specimens may cause both false positive and false negative galactosemia screening results.

This test is approved for in vitro diagnostic use by the U.S. Food and Drug Administration.

Hemoglobinopathy - Isoelectric Focusing (HGB, NBS)

Use: Qualitative detection of normal and variant hemoglobins in blood specimens dried on filter paper used as an aid in the detection of sickle cell anemia, sickle C disease, S/beta-thalassemia, homozygous C disease, and variant hemoglobinopathies in newborns and children, and in adults.

Methodology: Hemoglobin variants are separated by isoelectric focusing in pH gradient agarose gels. Hemoglobin bands are visualized by staining with *o*-dianisidine, which is readily oxidized by the heme portion of the hemoglobin molecule in the presence of hydrogen peroxide. The reaction forms an insoluble precipitate that intensifies each band.

Clinical Significance: Detection of hemoglobin variants is important as a diagnostic tool and for genetic counseling. Detecting hemoglobins S, C and E (Hb S, Hb C, and Hb E) is particularly important because each of these variants in their homozygous state produces clinically significant effects. Additionally, these variants are found as double heterozygotes (Hb SC, Hb SE) that also produce disease states.

Screening of blood for hemoglobin variants has become important mainly for detection of Hb S. Early treatment of sickle cell anemia (Hb SS) with antibiotics has lessened the infections associated with the disease.

Specimen Type: Dried blood spot collected from infant in accordance with the current CLSI Section NBS01-A6 standards; or dried blood spot collected from adult of childbearing age (females < 46 years of age, maternity or family planning patients of any age, males of any age). Newborn screening specimen must not be applied to filter paper from EDTA, heparin, or citrate collected blood.

Minimum • 5 filled circles (Newborn)

Volume/Size: • 3 filled circles (Adult/Child)

Container: The submitter must ensure that the expiration date of the screening form has not passed. Legibly print and complete all information requested. See [Sample Collection section](#) for detailed instructions on completion of screening form.

- ODH #450 Newborn Screening Form (Newborn)
- ODH #485 Child/Adult Sickle Cell Screening Form (Child/Adult)

Collection: For Child/Adult Sickle Cell Screening Form:

Special attention must be paid to the storage and transportation conditions of the dried blood spot samples. Storage of samples in an environment with elevated temperatures and humidity increases the risk of false positive screening results.

1. To prevent specimen contamination do not touch any of the filter paper circles before or after collection.
2. Use a sterile, disposable lancet or incision device to perform a swift clean puncture to the fingertip.
3. Use sterile gauze to wipe away first blood drop.

4. Allow a second LARGE blood drop to form.
5. Gently, touch the filter paper against the large drop of blood, following a sufficient quantity of the blood to completely fill the pre-printed circle on the filter paper and soak through to the other side. Do not apply multiple drops of blood to the same circle. Apply blood only to one side of the filter paper.
6. Continue filling the other circles with successive single large drops of blood.
7. Allow both sides of blood spots to air-dry at room temperature for at least 3 hours in a horizontal position. Fold the cardboard cover to hold the blood spots off of any surface or place on a rack to dry. Be sure the attached coverslip does not come into contact with the blood until completely dry. NOTE: Do not use artificial heat (lamps, incubators, etc.) to dry the samples. Keep away from direct sunlight. Do not stack wet specimens. Insufficient drying will adversely affect the test results.
8. Replace the coverslip over the blood spots when completely dry.
9. Check the quality of the specimens (see Simple Spot Check below). All specimens are judged for acceptability at the OSDH PHL, and those not acceptable are reported as “Unsatisfactory”.

For Newborn Screening specimens, follow [NBS Collection Instructions](#).

Special Instructions: For Newborn Screening specimens, see [Newborn Screening Special Instructions](#).

Shipping: See [Newborn Screening Shipping instructions](#).

Common Causes for Rejection: See [Newborn Screening Common Causes for Rejection](#).

Turn-around Time: Within 5 working days after receipt (Newborn)
Within 10 working days after receipt (Child/Adult)

Normal Value (Reference Range): Hb FA (Newborn)
Hb AA (Child Adult)

Reportable Results:

- Within Normal Limits
- *Outside Normal Limits; See Comments (HGB)
- *Inconclusive

Interpretation:

- No Abnormal Bands Detected
- *F Only: Submit new filter paper specimen at 2 months of age.
- *Consistent with transfusion: Submit new filter paper specimen at 4 months of age
- *FA, Bart’s: Recommend CBC with indices at 1 year of age; or at 3 months if of Asian descent

- *FAS: Consistent with S trait. Submit new filter paper specimen at 4 months of age
- *FAC: Consistent with C trait. Submit new filter paper specimen at 4 months of age
- *FA, Other: Consistent with a trait. Submit new filter paper specimen at 4 months of age
- *FS: Consistent with SS disease. Refer to pediatric hematologist for confirmatory testing
- *FC: Consistent with CC disease. Refer to pediatric hematologist for confirmatory testing
- *FSC: Consistent with SC disease. Refer to pediatric hematologist for confirmatory testing
- *FSA: Consistent with S-thalassemia. Refer to pediatric hematologist for confirmatory testing
- *FEO: Consistent with Disease. Refer To Pediatric Hematologist to Confirm.
- *FDG: Consistent with Disease. Refer To Pediatric Hematologist to Confirm.
- *F, Other: Consistent with disease. Refer to pediatric hematologist to confirm
- *FAS, Barts: Consistent with S trait. Submit New Filter Paper Specimen At 4 Months of Age. Recommend CBC with Indices at 3 or 12 Months of Age as Indicated.
- *FAC, Barts: Consistent with C trait. Submit New Filter Paper Specimen At 4 Months of Age. Recommend CBC with Indices at 3 or 12 Months of Age as Indicated.
- *FA, Other, Barts: Consistent with a trait. Submit New Filter Paper Specimen At 4 Months of Age. Recommend CBC with Indices at 3 or 12 Months of Age as Indicated.
- *A, Other: Family Counseling Recommended
- *AS: Consistent With S-trait. Family Counseling Recommended
- *AC: Consistent With C-trait. Family Counseling Recommended
- *SAF: HGB - Consistent With S-beta Thalassemia. Refer To Pediatric Hematologist for Confirmatory Testing.
- *Specimen results inconclusive. Submit new specimen as soon as possible.
-
- Note: Any variant reported as “F, Other” or “FA, Other” will include an additional comment to convey location of the unidentified variant, e.g., “Other Band in D/G Region” or “Other Band in E/O Region”, etc.

Limitations/ Interferences: Older samples may yield “aging bands” due to decomposition and/or oxidation of hemoglobin. The following conditions may cause anomalous assay results: poorly collected specimen, spot not uniformly saturated with blood, improperly dried specimen, exposure of specimen to high heat and humidity, contamination of filter paper with feces.

Isoelectric focusing is able to separate hemoglobin variants with isoelectric points (pI) that differ by 0.01 pH units or greater. Variants with the same pI migrate together.

This is a screening testing only. A diagnostic procedure should be used to confirm the identity of variant hemoglobins.

CPT Codes: 83020-52

Notes: This test is approved for in vitro diagnostic use by the U.S. Food and Drug Administration.

Fatty Acid Oxidation Disorders (FAO, NBS)

Use: Quantitative measurement of acylcarnitines C0, C4, C6, C8, C10, C10:1, C14, C16, C16OH, C16:1OH, C18, C18OH, C18:1, C18:1OH, and C18:2 in blood specimens dried on filter paper as an aid in screening newborns for mediumchain acyl-CoA dehydrogenase deficiency and other fatty acid oxidation (FAO) and organic acid disorders, including carnitine uptake defect, short-chain acylCoA dehydrogenase deficiency, glutaric acidemia type II, very long-chain acylCoA dehydrogenase deficiency, carnitine acylcarnitine translocase deficiency, carnitine palmitoyltransferase I deficiency, carnitine palmitoyltransferase II deficiency, long-chain L-3-hydroxyacyl-CoA dehydrogenase deficiency, and trifunctional protein deficiency.

Methodology: The measurement of free carnitine and acylcarnitines uses an Amino Acids, Acylcarnitines, Lysophospholipids, and Succinylacetone tandem mass spectrometry (MS/MS) kit to extract dried blood spots with a solution containing stable-isotope labeled internal standards with subsequent analysis by MS/MS. The response of each analyte relative to its corresponding stable isotope labeled internal standard is proportional to analyte concentration.

Clinical Significance: Elevated or decreased free carnitine and elevated acylcarnitine levels in newborn blood can be indicative of one or more of several metabolic disorders. Free carnitine and acylcarnitines are markers for disorders that are generally classified as FAO disorders and organic aciduria (OA) disorders. These disorders are inborn errors of metabolism (or genetic metabolic deficiencies).

In FAO disorders, enzymes necessary for fatty acid breakdown are unavailable or have reduced activity. Breakdown, or oxidation, of fatty acids is necessary for energy production when glucose levels are low. Without this energy supply, some individuals may have recurring incidences of low blood sugar levels. In cases of fasting, often caused by illnesses such as ear infections or flu, there may be metabolic crisis. Affected individuals may show vomiting, diarrhea, lethargy, seizures or coma. Failure to diagnose FAO disorders may result in excessive fat build-up in the liver, heart and kidneys. This build-up can cause a variety of symptoms, ranging from hepatic failure, encephalopathy, heart and eye complications to general problems with muscle development. Many of these clinical symptoms can lead to death. Many deaths due to FAO disorders have been misdiagnosed as Sudden Infant Death Syndrome (SIDS) or Reye's Syndrome.

Specimen Type: See [Newborn Screening Specimen Type](#).

Minimum Volume/Size: See [Newborn Screening Minimum Volume/Size](#).

Container: See [Newborn Screening Container and Instructions](#).

Collection: See [Newborn Screening Collection Instructions](#).

Special Instructions: See [Newborn Screening Special Instructions](#).

Shipping: See [Newborn Screening Shipping Instructions](#).

Common Causes for Rejection: See [Newborn Screening Common Causes for Rejection](#).

Turn-around Time: Within 5 working days after receipt

Normal Value C0 5.51 – 82.99 µmol/L
(Reference Range): C4 < 1.27 µmol/L
C6 < 0.25 µmol/L
C8 < 0.40 µmol/L
C10 < 0.40 µmol/L
C10:1 < 0.30 µmol/L
C14 < 0.71 µmol/L
C14:1 < 0.70 µmol/L
C16 < 7.46 µmol/L
C16OH < 0.16 µmol/L
C16:1OH < 0.47 µmol/L
C18 < 2.15 µmol/L
C18OH < 0.12 µmol/L
C18:1 < 3.41 µmol/L
C18:1OH < 0.15 µmol/L
C18:2 < 2.40 µmol/L
C0/(C16 + C18) ratio < 90
C4/C2 ratio < 0.06
C8/C10 ratio < 3.0

Reportable Results:

- Within Normal Limits
- *Outside Normal Limits, See Comments (FAO)

Interpretation:

- Not consistent with <FAO disorder>.
- *Submit repeat specimen as soon as possible.
- *FAO - Consistent with <FAO disorder>; Immediate confirmatory testing recommended.
- *FAO – Pattern of Multiple Elevations, Consistent with TPN. Submit new filter paper specimen at 14 days of age.

Limitations/ Interferences: This is a screening test only. A diagnostic procedure should be used for confirmation of presumptive abnormal acylcarnitine profiles.

High nutritional intake of carnitine or medium-chain triglyceride (MCT) oil may interfere with the measurement of acylcarnitines. Variables such as hematocrit, prematurity, and age of infant may affect the interpretation of values produced by the assay. The following conditions may cause anomalous assay results: poorly collected specimen, spot not uniformly saturated with blood, improperly dried specimen, exposure of specimen to high heat and humidity, contamination of filter paper with feces.

CPT Codes: 82017 (includes organic acid disorders)

Notes: This test is approved for *in vitro* diagnostic use by the U.S. Food and Drug Administration.

Organic Acid Disorders (NBS)

Use: Quantitative measurement of acylcarnitines C3, C3DC, C4, C5, C5:1, C5DC, C5OH_C4DC, C6DC in blood specimens dried on filter paper as an aid in screening newborns for organic acid disorders, including propionic acidemia (PROP), methylmalonic acidemia (MUT; CBL-C,D; CBL-A,B), malonic acidemia (MAL), isobutyrylglycinuria (IBG), isovaleric acidemia (IVA), 2methylbutyrylglycinuria (2MBG), 3-methylcrotonyl-CoA carboxylase deficiency (3MCC), 3-methylglutaconic aciduria (3MGA), 3-hydroxy-3-methylglutaric aciduria (HMG), holocarboxylase synthetase deficiency (MCD), 2-methyl-3-hydroxybutyric aciduria (2M3HBA), beta-ketothiolase deficiency (BKT), and glutaric acidemia type 1 (GA1).

Methodology: The measurement of free carnitine and acylcarnitines uses an Amino Acids, Acylcarnitines, Lysophospholipids, and Succinylacetone tandem mass spectrometry (MS/MS) kit to extract dried blood spots with a solution containing stable-isotope labeled internal standards with subsequent analysis by MS/MS. The response of each analyte relative to its corresponding stable-isotope labeled internal standard is proportional to analyte concentration.

Clinical Significance: Elevated acylcarnitine levels in newborn blood can be indicative of one or more of several metabolic disorders. Acylcarnitines are markers for disorders that are generally classified as fatty acid oxidation (FAO) disorders and organic aciduria (OA) disorders. These disorders are inborn errors of metabolism (or genetic metabolic deficiencies).

The metabolic pathways of organic acids are disrupted in OA disorders and thus accumulation of the acids in blood and urine alters the acid-base balance of the body. Resulting modifications or adaptations to intermediary metabolic pathways may cause numerous clinical symptoms, including metabolic acidosis, ketosis, hyperammonemia, failure to thrive, sepsis or coma.

Specimen Type: See [Newborn Screening Specimen Type](#).

Minimum Volume/Size: See [Newborn Screening Minimum Volume/Size](#).

Container: See [Newborn Screening Container and Instructions](#).

Collection: See [Newborn Screening Collection Instructions](#).

Special Instructions: See [Newborn Screening Special Instructions](#).

Shipping: See [Newborn Screening Shipping Instructions](#).

Common Causes for Rejection: See [Newborn Screening Common Causes for Rejection](#).

Turn-around Time: Within 5 working days after receipt

Normal Value (Reference Range):
C3 < 8.20 μmol/L
C3DC < 0.44 μmol/L
C4 < 1.27 μmol/L
C5 < 0.87 μmol/L
C5:1 < 0.10 μmol/L
C5DC < 0.46 μmol/L
C5OH_C4DC < 0.80 μmol/L
C6DC < 0.27 μmol/L
C3/C2 ratio < 0.30
C5/C2 ratio < 0.05
C5DC/C8 ratio < 7.64
C5DC/C16 ratio < 0.66

Reportable Results:

- Within Normal Limits
- *Outside Normal Limits, See Comments (OA)

Interpretation:

- Not consistent with <OA disorder>.
- *Submit repeat specimen as soon as possible.
- *OA - Consistent with <OA disorder>; Immediate confirmatory testing recommended.
- *OA – Pattern of Multiple Elevations, Consistent with TPN. Submit new filter paper specimen at 14 days of age.

Limitations/ Interferences:

This is a screening test only. A diagnostic procedure should be used for confirmation of presumptive abnormal acylcarnitines profiles.

Pivalic acid (an antibiotic that may be administered during pregnancy or to the infant) may result in false positive cases for IVA. High nutritional intake of carnitine or medium-chain triglyceride (MCT) oil may interfere with the validity of acylcarnitines concentrations. Variables such as hematocrit, prematurity, and age of infant may affect the interpretation of the values produced. The following conditions may cause anomalous assay results: poorly collected specimen, spot not uniformly saturated with blood, improperly dried specimen, exposure of specimen to high heat and humidity, contamination of filter paper with feces.

CPT Codes: 82017 (includes MCAD and other fatty acid oxidation disorders)

Notes: This test is approved for in vitro diagnostic use by the U.S. Food and Drug Administration.

Amino Acid Disorders (NBS)

Use: Quantitative measurement of phenylalanine, arginine, citrulline, leucine, methionine, tyrosine, and valine in blood specimens dried on filter paper as an aid in screening newborns for phenylketonuria (PKU) and other amino acid disorders including argininemia, argininosuccinic aciduria, citrullinemia type I, citrullinemia type II, homocystinuria, hypermethioninemia, maple syrup urine disease, benign hyperphenylalanemia, bipterin defect in cofactor biosynthesis, bipterin defect in cofactor regeneration, tyrosinemia type I, tyrosinemia type II, tyrosinemia type III.

Methodology: The measurement of amino acids uses an Amino Acids, Acylcarnitines, Lysophospholipids, and Succinylacetone tandem mass spectrometry (MS/MS) kit to extract dried blood spots with a solution containing stable-isotope labeled internal standards with subsequent analysis by MS/MS. The response of each analyte relative to its corresponding stable-isotope labeled internal standard is proportional to analyte concentration.

Clinical Significance: Elevated amino acids in newborn blood can be indicative of one or more of several metabolic disorders, collectively known as amino acidopathies. In amino acidopathies, enzymes necessary for the metabolism of certain amino acids are unavailable or have reduced activity. As a result, the concentration of the affected amino acids and alternative metabolites increases in the infant's body. These excesses can have severe deleterious effects on the infant's health, including death. Some commonly studied amino acidopathies are:

- *PKU* is a disorder of aromatic amino acid metabolism in which phenylalanine cannot be converted to tyrosine. If untreated, PKU leads to various degrees of mental retardation.
- *Hyperphenylalaninemia* leads to mental retardation and muscular rigidity.
- *Homocystinuria* leads to vascular occlusive disease, osteoporosis, accumulation of homocysteine and methionine, and variable developmental delays.
- *Maple Syrup Urine Disease (MSUD)* is caused by a disorder of branched-chain amino acid metabolism resulting in elevated levels of leucine, isoleucine and valine in the blood. If untreated, lethargy progressive to coma, developmental delay, and convulsions will develop.
- *Tyrosinemia type 1* (hereditary tyrosinemia) leads to acute hepatic failure or chronic cirrhosis and hepatocellular carcinoma.
- *Citrullinemia* leads to convulsions, anorexia, vomiting and lethargy, followed rapidly by potentially lethal coma.

Turn-around Time: Within 5 working days after receipt

Normal Value Phenylalanine < 150 µmol/L
(Reference Range): Arginine < 100 µmol/L
Citrulline < 55 µmol/L
Leucine < 330 µmol/L
Methionine < 75 µmol/L
Succinylacetone < 1.30 µmol/L
Tyrosine < 370 µmol/L

Valine < 330 µmol/L
Phe/Tyr ratio < 2.0
Cit/Arg ratio < 6.5
Leu/Phe ratio < 4.8
Met/Phe ratio < 1.2

Reportable Results:

- Within Normal Limits
- *Outside Normal Limits, See Comments (AA)

Interpretation:

- Not consistent with <AA disorder>.
- *Submit repeat specimen as soon as possible.
- *AA - Consistent with <AA disorder>; Immediate referral to metabolic specialist.
- *AA – Pattern of Multiple Elevations, Consistent with TPN. Submit new filter paper specimen at 14 days of age.

**Limitations/
Interferences:**

This is a screening test only. A diagnostic procedure should be used for confirmation of presumptive abnormal amino acid profiles.

False negative results for some amino acid disorders can be obtained from blood samples that have been collected too soon after birth, i.e., ≤ 24 hours post- partum; or that have been collected from infants who have not received an adequate protein-containing diet within the 24-hour period prior to sample collection. High nutritional intake of amino acids may interfere with the validity of amino acid concentrations. Variables such as hematocrit, prematurity, and age of infant may affect the interpretation of the values produced. The following conditions may cause anomalous assay results: poorly collected specimen, spot not uniformly saturated with blood, improperly dried specimen, exposure of specimen to high heat and humidity, contamination of filter paper with feces.

CPT Codes: 82139

Notes: This is a test approved for *in vitro* diagnostic use by the U.S. Food and Drug Administration

X-Linked Adrenoleukodystrophy (X-ALD, NBS)

Use: Quantitative measurement of lysophospholipid C26:0 lysophosphatidylcholine (C26:0-LPC) concentration in blood specimens dried on filter paper as an aid in screening for X-linked adrenoleukodystrophy (X-ALD).

Methodology: The measurement of this lysophospholipid uses an Amino Acids, Acylcarnitines, Lysophospholipids, and Succinylacetone tandem mass spectrometry (MS/MS) kit to extract dried blood spots with a solution containing stable-isotope labeled internal standards with subsequent analysis by MS/MS. The response of each analyte relative to its corresponding stable-isotope labeled internal standard is proportional to analyte concentration.

Clinical Significance: Elevated C26:0-LPC in newborn blood can be indicative of an inborn error of metabolism (or genetic metabolic deficiency). C26:0-LPC is a primary marker for X-ALD, a progressive metabolic condition which affects the adrenal glands and nervous system. When very long chain fatty acids (VLCFAs) cannot be broken down in the body, they accumulate in the plasma and tissues and may disrupt the myelin of nerve cells. The accumulation of VLCFAs has shown to result in an accumulation of C26:0-LPC as well. X-ALD affects males more severely and is more common in males. 20-40% of women who are carriers have symptoms in adulthood.

There are three different typical presentations of X-ALD:

- *Childhood cerebral ALD (cALD)* can present as early as age 2 but more commonly between ages 4-10. Symptoms start with attention deficit disorder/hyperactivity and can progress with worsening nervous system deterioration, seizures, paralysis, and coma. Left untreated, death occurs within a few years of symptoms appearing.
- *Adrenomyeloneuropathy (AMN)* presents in men around 20 years of age or older. Most, but not all, have adrenocortical insufficiency. About 10-20% will have severe brain and nervous system damage causing an early death. Women who are carriers may develop similar symptoms.
- *Adrenal insufficiency or Addison's disease* occurs in 90% of males with X-ALD and can present as early as 6 months of age. Addison's can be managed with corticosteroids but can result in adrenal crisis or coma if left untreated.

Specimen Type: See [Newborn Screening Specimen Type](#).

Minimum Volume/Size: See [Newborn Screening Minimum Volume/Size](#).

Container: See [Newborn Screening Container and Instructions](#).

Collection: See [Newborn Screening Collection Instructions](#).

Special Instructions: See [Newborn Screening Special Instructions](#).

Shipping: See [Newborn Screening Shipping Instructions](#).

Common Causes for See [Newborn Screening Common Causes for Rejection](#).

Rejection:

Reported: Within 5 working days after receipt
Within 7 working days after receipt if 2nd tier Reflex C26:0-LPC performed

Normal Value (Reference Range): C26:0-LPC < 0.58 µmol/L

Reportable Results:

- Within Normal Limits
- *Outside Normal Limits, See Comments (XALD)

Interpretation:

- Not consistent with X-ALD
- *XALD - Possible X-linked adrenoleukodystrophy (X-ALD); immediate confirmatory testing recommended. Reflex C26:0-LPC test performed at PerkinElmer Genomics, Inc., 250 Industry Drive, Pittsburg PA15275. This test was developed and its performance characteristics determined by PerkinElmer. This test has not been cleared by the US Food and Drug Administration.

Limitations/ Limitations: This is a screening test only. A diagnostic procedure should be used for confirmation of presumptive abnormal C26:0-LPC and C24:0-LPC profiles.

Elevated C26:0-LPC concentrations have been measured in newborn blood spots taken from children diagnosed with Aicardi Goutières Syndrome (AGS) leading to false positive results in screening. Chlorhexidine digluconate (an antimicrobial agent that can be found in some disinfectant wipes used to wipe the heel prior to specimen) was found to increase the measured C26:0-LPC concentration. Amounts >0.03% could theoretically cause false positives. Variables such as hematocrit, prematurity, and age of infant may affect the interpretation of the values produced. The following conditions may cause anomalous assay results: poorly collected specimen, spot not uniformly saturated with blood, improperly dried specimen, exposure of specimen to high heat and humidity, contamination of filter paper with feces.

CPT Codes: 82017

Notes: This test is approved for in vitro diagnostic use by the U.S. Food and Drug Administration.

Second-Tier test (Reflex C26:0-LPC) performed at PerkinElmer Genomics, Inc., 250 Industry Drive, Pittsburg PA 15275. This test was developed and its performance characteristics determined by PerkinElmer in a manner consistent with CLIA requirements. This test has not been cleared by the U.S. Food and Drug Administration.

Lysosomal Storage Disorders (LSD, NBS)

Use: Quantitative measurement of the activity of the enzymes, acid- α -glucosidase (GAA) and α -L-iduronidase (IDUA), in blood specimens dried on filter paper as an aid in screening newborns for the lysosomal storage disorders Pompe Disease and Mucopolysaccharidosis Type 1 (MPS 1) Disease.

Methodology: The quantitative measurement of the activities of the lysosomal enzymes deficient in Pompe disease and MPs 1 (GAA and IDUA, respectively) uses a tandem mass spectrometry kit (MS/MS) to measure the product generated when an enzyme reacts with a synthesized substrate to create a specific product. Enzymatic activities are expressed as micromoles (μmol) per hour (h) per Liter (L) calculated from the peak ratio of each measured product and its associated, stable-isotope mass labeled, internal standard using the calculation:

$$\text{enzyme activity} = \frac{\text{product intensity}}{\text{IS intensity}} \times \frac{(\text{IS concentration} \times \text{IS volume})}{(\text{Blood volume} \times \text{incubation time})} \times \text{RRF}$$

Clinical Significance: Lysosomal storage disorders result from the dysfunction, deficiency, or absence of a lysosomal enzyme. Affected individuals are unable to metabolize the disease specific substrate of the deficient enzyme, leading to accumulation in the lysosomes of tissues.

Pompe is a disease in which complex sugars cannot be broken down in the lysosomes. There are three forms of Pompe which determines the severity of disease and age of onset.

- *Classic infantile-onset Pompe* begins before or shortly after birth with symptoms that include hypotonia (poor muscle tone), failure to thrive, difficulty breathing, trouble feeding, and respiratory infections.
- *Non-classic infantile-onset Pompe* usually presents by age one and affected babies show signs of delayed motor skills, progressive muscle weakness (myopathy), and difficulty breathing.
- *Late-onset Pompe* may develop in childhood, adolescence, or even adulthood. It is also associated with progressive muscle weakness and difficulty breathing. Symptoms are usually milder and progress more slowly. Infantile forms of Pompe may be fatal within the first year of life if untreated.

Even with treatment, children with both forms of infantile-onset Pompe usually pass away in early childhood.

Mucopolysaccharidosis Type 1 (MPS 1) is an inherited condition in which complex sugars cannot be broken down in the lysosomes. MPS 1 comprises a wide spectrum and severity and individuals may be categorized anywhere from severe to attenuated. Age of onset, symptoms, and long-term outcome within this spectrum vary widely. Babies with severe MPS 1 usually develop signs and symptoms within the first year of life and have a rapid disease progression. In the attenuated form, symptoms are generally milder and do not appear until later in childhood. Early signs include umbilical or inguinal hernia, macrocephaly, varying degrees of developmental delay and learning disabilities,

and hearing loss. Life expectancy is varied, with affected individuals having a reasonably normal life span while severely affected individuals may die before becoming teenagers. The most common cause of death, even with treatment, is heart or respiratory failure.

- Specimen Type:** See [Newborn Screening Specimen Type](#).
- Minimum Volume/Size:** See [Newborn Screening Minimum Volume/Size](#).
- Container:** See [Newborn Screening Container and Instructions](#).
- Collection:** See [Newborn Screening Collection Instructions](#).
- Special Instructions:** See [Newborn Screening Special Instructions](#).
- Shipping:** See [Newborn Screening Shipping Instructions](#).
- Common Causes for Rejection:** See [Newborn Screening Common Causes for Rejection](#).
- Turn-around Time:** Within 5 working days after receipt
Within 7 working days after receipt, if 2nd tier GAGS or PD2T performed.
- Normal Value (Reference Range):** GAA > 2.5 µmol/L/h
IDUA >1.3 µmol/L/h
- Reportable Results:**
- Within Normal Limits
 - *See Comments (LSD)
 - *Invalid
- Interpretation:**
- Not consistent with POMPE or MPS1.
 - *LSD - Possible Pompe disease; Immediate referral to clinical genetics recommended. PD2T test performed at Mayo Clinic Labs, 200 First St SW, Rochester, MN55905. This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared by the US Food and Drug Administration.
 - *LSD - Possible mucopolysaccharidosis type 1 (MPS1); Immediate referral to clinical genetics recommended. GAGS test performed at Mayo Clinic Labs, 200 First St SW, Rochester, MN 55905. This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared by the US Food and Drug Administration.
 - *LSD – All enzymes decreased, specimen results inconclusive. Submit a new specimen as soon as possible.
- Limitations/ Interferences:** Certain late onset forms of Pompe disorder may have GAA enzymatic activity in the normal range and result in a false negative newborn screening result. False positives for Pompe and MPS 1 can result by identifying pseudo deficiencies and carriers.

This is a screening test only. A diagnostic procedure should be used for confirmation of presumptive Pompe and MPS 1 diseases.

Elevated hemoglobin level at 18.0 g/dL increases IDUA activity which may result in false negative results for MPS 1. Hemoglobin does not interfere at normal (≤ 15 g/dL) levels.

Glucose levels above 0.25 g/dL can interfere by causing decreased measured GAA activity resulting in false positive results for Pompe disease. Preterm infants typically with very low birthweights have a high risk of hyperglycemia due to glucose infusion.

Triglyceride (Intralipid®) can interfere by increasing the measured GAA and IDUA activity. Intralipid® ≤ 0.15 g/dL does not interfere with GAA and ≤ 0.30 g/dL does not interfere with IDUA activity. High triglyceride concentrations in newborns due to medication effects or pathological conditions may cause a false negative newborn screening result for a specimen with measured GAA or IDUA activity close to the cut-off values.

Variables such as hematocrit, prematurity, and age of infant may affect the interpretation of the values produced. The following conditions may cause anomalous assay results: poorly collected specimen, spot not uniformly saturated with blood, improperly dried specimen, exposure of specimen to high heat and humidity, contamination of filter paper with feces.

CPT Codes: 82657

Notes: This is a test approved for *in vitro* diagnostic use by the U.S. Food and Drug Administration.

Second-Tier tests PD2T and GAGS performed at Mayo Clinic Labs, 200 First St. SW, Rochester, MN 55905. This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Severe Combined Immunodeficiency (SCID, NBS)

Use: Semi-quantitative determination of T-Cell Receptor Excision Circles (TRECs) in dried blood spots (DBSs) as an aid in screening newborns for severe combined immunodeficiency (SCID).

Methodology: Real-time, polymerase chain reaction (rt PCR) amplification is used to detect levels of TREC DNA in DBSs collected from newborn infants using a multiplex rt PCR reagent kit that uses target sequence-specific primers and TaqMan™ probes to amplify and detect targets: TREC, SMN1 exon 7, and RPP30 in a single PCR reaction. DNA is extracted from the dried blood spot using a DNA extraction kit. Each TaqMan™ probe has a unique dye linked to their terminal 5'-end allowing the simultaneous detection of each target if present. The amount of each target present in the DNA is determined by the intensity of fluorescence emitted by each dye released by the degraded probe during amplification and detected by a rt PCR thermocycler. The fluorescence signals are measured and converted into comparative quantitative readouts which are expressed as a function of crossing threshold (Ct) values.

Clinical Significance: The initial protective effects afforded by maternal antibodies transferred during pregnancy and nursing can initially mask the inherent immunodeficiency of the SCID infant during the first weeks of life. Subsequently, SCID infants experience recurrent infections, including pneumonia, bronchitis, meningitis, ear infections, thrush, chronic diarrhea, fail to thrive, and often develop a scaly erythematous rash over the entire body. Left undiagnosed, SCID infants usually die from severe infections within the first year of life. Identification of the asymptomatic infant with a primary immunodeficiency during the first few weeks of life is essential for successful treatment, which generally involves immune reconstitution by hematopoietic cell transplantation (HCT), gene therapy or enzyme replacement (for ADA deficiency); thereafter, morbidity from infections makes treatment much less effective.

Specimen Type: See [Newborn Screening Specimen Type](#).

Minimum Volume/Size: See [Newborn Screening Minimum Volume/Size](#).

Container: See [Newborn Screening Container and Instructions](#).

Collection: See [Newborn Screening Collection Instructions](#).

Special Instructions: See [Newborn Screening Special Instructions](#).

Shipping: See [Newborn Screening Shipping Instructions](#).

Common Causes for Rejection: See [Newborn Screening Common Causes for Rejection](#).

Normal Value Term (*gestational age ≥ 37 weeks*)

- (Reference Range):**
- TREC threshold cycle (Ct) < 33.5 (i.e., > 1290 TREC copies per 10,000 cells)
Preterm (*gestational age < 37 weeks*)
 - TREC Ct < 33.8 (i.e., > 1048 TREC copies per 10,000 cells)

Reportable Results: Term

- Within Normal Limits
- *TREC Outside Normal Limits; See Comments (SCID)
- *TRECs Decreased; See Comments (SCID)
- *TRECs Low; See Comments (SCID)
- *Unsatisfactory; See Comments (SCID)

Interpretation:

- Not Consistent with SCID
- *Mildly decreased screen result for primary immunodeficiency; submit repeat specimen as soon as possible.
- *Not consistent with primary immunodeficiency; previous result for this infant was within normal limits. No follow-up needed, unless clinically indicated.
- *Consistent with primary immunodeficiency; recommend immediate confirmatory testing.
- *Unsatisfactory; Poor DNA amplification; submit repeat specimen as soon as possible

Preterm

- Not consistent with SCID
- *Submit new filter paper specimen at 37 weeks gestational age.
- *Not consistent with primary immunodeficiency; previous result for this infant was within normal limits. No follow-up needed, unless clinically indicated.
- *Consistent with primary immunodeficiency; recommend immediate confirmatory testing.
- *Unsatisfactory; Poor DNA amplification; submit repeat specimen as soon as possible

Limitations/ Interferences: This is a screening test only. A diagnostic procedure should be used to confirm a diagnosis of SCID.

Do not use heparinized tubes or capillaries to collect blood; heparin is a known inhibitor of PCR. The following conditions may cause anomalous assay results: poorly collected specimen, spot not uniformly saturated with blood, improperly dried specimen, exposure of specimen to high heat and humidity, contamination of filter paper with feces.

CPT Codes: 81479

Notes: This is a laboratory-developed test; performance characteristics have been validated and determined to be suitable for diagnostic purposes by the OSDH PHL. These tests have not been cleared or approved by the U.S. Food and Drug Administration.

Spinal Muscular Atrophy (SMA, NBS)

Use: Qualitative determination of the exon 7 SMN1 gene in dried blood spots (DBSs) as an aid in screening newborns for spinal muscular atrophy (SMA).

Methodology: Real-time, polymerase chain reaction (rt PCR) amplification is used to detect levels of the exon 7 SMN1 gene in DBSs collected from newborn infants using a multiplex rt PCR reagent kit that uses target sequence-specific primers and TaqMan™ probes to amplify and detect targets: TREC, SMN1 exon 7, and RPP30 in a single PCR reaction. DNA is extracted from the dried blood spot using a DNA extraction kit. Each TaqMan™ probe has a unique dye linked to their terminal 5'-end allowing the simultaneous detection of each target if present. The amount of each target present in the DNA is determined by the intensity of fluorescence emitted by each dye released by the degraded probe during amplification and detected by a rt PCR thermocycler. The fluorescence signals are measured and converted into comparative quantitative readouts which are expressed as a function of crossing threshold (Ct) values.

Clinical Significance: The SMN1 gene provides the instructions for making the survival motor neuron (SMN) protein. These proteins are important for the maintenance and continued health of motor neurons, specialized nerve cells that control the muscles used for activities such as breathing, crawling, and walking. SMA is a group of inherited (autosomal recessive) conditions that affect these motor proteins due to changes in the SMN1 gene. The loss of motor neurons leads to progressive muscle weakness and atrophy. The four primary forms are classified based on the severity of the condition and the age at which symptoms begin. In general, forms of SMA with an earlier age of onset are more severe and have a greater impact on motor function.

- *SMA type I* is the most common and severe form. Signs and symptoms often begin within the first six months of life. Severe muscle weakness and poor muscle tone leads to significant development delay. Most are unable to support their heads or sit unassisted. Other signs include breathing problems, difficulty swallowing, poor growth, and joint abnormalities.
- *SMA type II* is generally characterized by muscle weakness that develops between six months and two years of age. Affected individuals can typically maintain a seated position but are unable to walk.
- *SMA type III* is often diagnosed between 18 months and three years of age, with some not developing muscle weakness until adolescence. Affected individuals are able to stand and walk independently, but have increasingly limited mobility with age.
- *SMA type IV* is characterized by mild to moderate symptoms that usually don't develop until adulthood. Mild motor impairment such as gradual muscle weakness, tremor, twitching, and mild breathing problems are

common symptoms.

Specimen Type: See [Newborn Screening Specimen Type](#).

Minimum Volume/Size: See [Newborn Screening Minimum Volume/Size](#).

Container: See [Newborn Screening Container and Instructions](#).

Collection: See [Newborn Screening Collection Instructions](#).

Special Instructions: See [Newborn Screening Special Instructions](#).

Shipping: See [Newborn Screening Shipping Instructions](#).

Common Causes for Rejection: See [Newborn Screening Common Causes for Rejection](#).

Normal Value (Reference Range): Gene Present

Reportable Results:

- Within Normal Limits
- *Outside Normal Limits; See Comments (SMA)
- *Unsatisfactory; See Comments (SCID)

Interpretation:

- Not consistent with SMA
- *Consistent with SMA. Immediate confirmatory testing recommended.
- *Poor DNA amplification; submit repeat specimen as soon as possible.

Limitations/ Interferences: This is a screening test only. A diagnostic procedure should be used to confirm a diagnosis of SMA.

Do not use heparinized tubes or capillaries to collect blood; heparin is a known inhibitor of PCR. The following conditions may cause anomalous assay results: poorly collected specimen, spot not uniformly saturated with blood, improperly dried specimen, exposure of specimen to high heat and humidity, contamination of filter paper with feces.

CPT Codes: 81479

Notes: This is a laboratory-developed test; performance characteristics have been validated and determined to be suitable for diagnostic purposes by the OSDH PHL. These tests have not been cleared or approved by the U.S. Food and Drug Administration.

Non-Variola Orthopoxvirus (Monkeypox Rule-Out)

Use: Detection of non-variola Orthopoxvirus. These tests are intended as an aid for infection control of non-variola Orthopoxvirus and are reported to the submitter, as well as the Oklahoma State Department of Health for epidemiological purposes.

Per the [Oklahoma Administrative Code, Title 310 Chapter 515-1-8](#), samples should be sent to the OSDH Public Health Laboratory for detection (or reported to Oklahoma State Department of Health personnel) immediately upon diagnosis and referral by state epidemiologists.

Methodology: Real-Time PCR Primers and Probes sets developed by LRN

Clinical Significance: The prevalence of Non-variola Orthopoxvirus is being monitored by state and national public health services in order to update preventative measures and limit infections.

Further background information, fact sheets, statistics and educational resources may be found at the OSDH Infectious Disease Services and the Center for Disease Control websites.

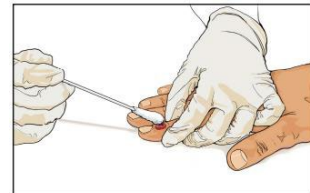
Specimen Type: Dry synthetic Swabs (including, but not limited to polyester, nylon, or Dacron) collected from lesions. Swabs should be separated individually into sterile containers (15 mL conical tubes). DO NOT add or store swabs in viral or universal transport media.

Suspected case of Non-variola Orthopoxvirus that meets epidemiological criteria and/or have a new, clinically compatible rash lesion.

Minimum Volume/ Size: Two swabs collected from 2 separate lesions. Preferably selected lesions should reside on two different bodily sources. (i.e., 2 swabs from one lesion on torso & 2 swabs from one lesion on external appendage)

Container: Lesion swab placed in conical tube. Freeze (-20°C or lower) specimens within an hour after collection. Store frozen samples for up to 60 days. Freezing is strongly recommended.

- Collection:**
- Personnel who collect specimens should use personal protective equipment (PPE) in accordance with recommendations for healthcare settings.
 - When possible, use a plastic, sterile, leak-proof container rather than glass materials for specimen collection.
 - Collect two swabs from each lesion (in general, 2-3 lesions should be sufficient), preferably from different locations on the body or from lesions which differ in appearance.
 - Use sterile, dry synthetic swabs with a plastic, wood, or thin aluminum shaft. (Any type of shaft is acceptable as long as it can be broken or cut).
 - Do not use cotton swabs.



- Generally, with vigorous swabbing, sufficient monkeypox virus DNA is present on the surface of a lesion, and you don't need to de-roof the lesion before swabbing (Figure 1). Put each swab into a separate container

Special Instructions: Per What to Report (oklahoma.gov) (OAC 310:515-1-3), specimen test results must be reported immediately to Public Health personnel (refer to variola orthopox/Smallpox).

- The Standard Laboratory Requisition Form (LRN#419) must be completed for each collection source and submitted with specimen.
- Before submission of non-variola Orthopoxvirus samples for testing, state epidemiologist must first be consulted. Specimens submitted for non-variola Orthopoxvirus testing without epidemiological approval could be subject to cancellation. Once epidemiological approval has been achieved, please notify the Public Health Lab before shipment of specimen.
- Label each primary container with:
 - Client first and last name
 - Date of birth
 - Lesion collection site (i.e., face, neck, left hand, etc.)
 - Date of collection
 - Initials of collector

Shipping: Specimens should be received at the Public Health Lab on the same day as collection. If shipment of specimen on the same day of collection is not possible, specimens must remain frozen (-20°C or lower). Store frozen samples for up to 60 days.

Samples should be shipped in dry ice packaging. If dry ice is unavailable, frozen ice packs may be used. Specimen should remain frozen from time of collection until received at the Public Health Lab. Refer to DOT and IATA shipment standards for proper protocols, packaging, and procedures of biological hazards.

Common Causes for Rejection:

- Submission of specimen for non-variola Orthopoxvirus testing without epidemiological approval.
- Specimens arriving at ambient temperature, without dry ice or cold packs
- Incorrect transport medium (transport media should not be added to specimens).
- Incorrect collection device, e.g., cotton or calcium alginate swab
- Swabs not refrigerated within an hour after collection.
- Incomplete labeling or documentation of samples
- Other criteria as outlined in *Specimen Rejection* section of this Test Directory

Turn-around Time: Within 2 working days from receipt unless referred to the CDC for further characterization, which may delay availability of final results.

Normal Value (Reference Range):

- Non-variola Orthopoxvirus DNA NOT detected

Reportable Results:

- Non-variola Orthopoxvirus DNA NOT detected

- Non-variola Orthopoxvirus DNA detected
- Inconclusive for presence of non-variola orthopoxvirus DNA
- Equivocal for the presence of non-variola orthopoxvirus

Interpretation:

- VAC1 Ct < 37: non-variola Orthopoxvirus detected
- VAC1 $37 \leq Ct \leq 40$: equivocal
- VAC1 Ct > 40, RP ≤ 40 , non-variola Orthopoxvirus NOT detected
- VAC1 Ct ≥ 40 , RP > 40, inconclusive

**Limitations/
Interferences:**

- This assay is designed ONLY for use with the clinical specimens of dry or wet swab of lesion.
- Non-variola Orthopoxvirus Real-time PCR Primer and Probe Set assay results are considered presumptive and should be interpreted in conjunction with other laboratory testing.
- Although this assay does not differentiate Vaccinia or Monkeypox virus from Cowpox, Camelpox, Ectromelia or Gerbilpox virus, a positive result with this assay in the United States is most likely due to Vaccinia virus; however, potential exposure to other Orthopoxvirus should be considered.
- This assay does not detect the novel Orthopoxvirus detected in 2015 in Alaska. This assay does not detect some typical non-human pathogenic Orthopoxvirus species including Raccoonpox virus, Skunkpoxvirus, and Volepox virus.
- Cotton swabs and swabs in media designed for bacterial preservation and/or transport may cause PCR inhibition and should not be used. Specimens with insufficient human DNA will be resulted as inconclusive.

CPT Codes: 87593

Notes: Before submission of non-variola Orthopoxvirus samples for testing, state epidemiologist must first be consulted. Once epidemiological approval has been achieved, please notify the Public Health Lab before shipment of specimen.

This is a laboratory-developed test; performance characteristics have been validated and determined to be suitable for diagnostic purposes by the OSDH PHL. These tests have not been cleared or approved by the U.S. Food and Drug Administration.

Respiratory Pathogen Panel (RPP)

Use: Detection and identification of nucleic acids from multiple respiratory viral and bacterial pathogens extracted from nasopharyngeal swabs collected from individuals with clinical signs and symptoms of respiratory tract infection.

Methodology: Specimens are tested using the NxTAG® Respiratory Pathogen Panel (RPP), a qualitative PCR amplification assay.

Clinical Significance: Respiratory pathogens are responsible for an estimated 80% of respiratory tract infections annually. A respiratory tract infection can be the result of one of dozens of viral or bacterial pathogens. The symptoms caused by these different pathogens are nearly indistinguishable, but how a healthcare provider chooses to treat a respiratory infection may depend greatly on a rapid and accurate diagnosis of the responsible pathogen. These infections can range from a mild, self-limiting illness to severe disease that can cause death. More severe disease is seen in the young, the immunocompromised, and the elderly. The frequency of respiratory viral infections is highest in children under 4 years of age. School children become infected, on average, with 5 to 8 respiratory viruses per year, and adults average 2 to 4 respiratory viruses annually. Bacteria that cause respiratory infections represent approximately 10% of all upper respiratory tract infections. In children, respiratory syncytial virus (RSV) is the most common cause of severe lower respiratory tract infection worldwide. Timely detection of these viruses can lead to initiation of proper antiviral treatment, decreased use of unnecessary antibiotics, reduced transmission of disease from person to person and better clinical outcomes.

Further background information, fact sheets, statistics and educational resources may be found at the [OSDH Infectious Disease Services website](#).

Specimen Type: Nasopharyngeal swab

**Minimum Volume/
Size:** 1 or 2 swabs

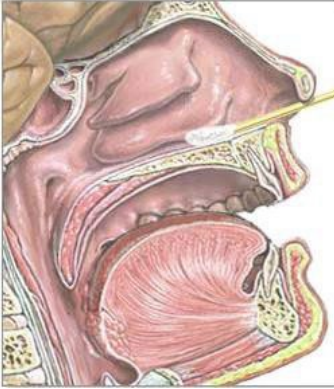
Container: Tube containing viral transport medium (M4RT; provided by OSDH PHL)). VTM must be stored in the refrigerator prior to and subsequent to specimen collection. Do not use media if cloudy or when past expiration date.

Collection: Respiratory virus diagnosis depends on the collection of high-quality specimens, their rapid transport to the testing laboratory and appropriate storage before testing. Training in specimen collection is highly recommended due to the importance of specimen quality. Specimens should be collected preferably within 3 days of onset of clinical symptoms.

Tip: If the patient is seated for the procedure, have the patient sit with their head against a wall since patients have a tendency to pull away during the procedure.

Nasopharyngeal Swab

1. Label a sterile tube containing 2-3 mL of VTM with the patient's name and date of collection.
2. If the nasal passages have a large amount of mucus, ask the patient to



- blow their nose before collecting specimen.
3. With the thumb of one hand, elevate the tip of the patient's nose then gently insert the NP swab into a nostril.
 4. Guide the swab straight back (not upwards), along the floor of the nasal passage until it reaches the posterior wall of the nasopharynx; the distance from the nose to the ear gives an estimate of the distance the swab should be inserted.

Note: *Do not force the swab – if an obstruction is encountered during insertion, try the other nostril.*

6. Rotate the swab by firmly brushing against the nasopharynx several
7. times.
8. Immediately, place swab into tube containing VTM or other suitable collection media.
9. Break-off or cut excess shaft of swab so that tube can be capped.
10. Replace the cap of the tube; tighten and wrap with Parafilm to prevent
11. leakage of contents of tube during transport.
12. Place tube in plastic biohazard bag and insert completed requisition form
13. in outer pouch of the bag.
14. Refrigerate (2-8°C) immediately.

Special Instructions: Only synthetic (nylon, rayon or Dacron)-tipped swabs with plastic or aluminum shafts are acceptable.

Submission of specimens from patients with suspected influenza A/H5 or Eurasian H7 requires OSDH Infectious Disease Service pre-approval to verify the patient meets clinical case criteria, including travel history to an area of novel influenza circulation.

Shipping: Store and ship specimens refrigerated (2-8 °C) for delivery within 7 days of collection. If delivery will be delayed for more than 7 days, specimens should be frozen at -70°C or colder and shipped with dry ice.

1. Place specimen in round cardboard container and place this in Styrofoam mailer box (both containers are supplied by OSDH PHL for respiratory pathogen surveillance).
2. Remove frozen cold pack from freezer and place in the mailer with specimen then fill the mailer with packing material.
3. Mailers are returned to submitting sites with fresh tubes of VTM corresponding to the number of specimens submitted. If additional VTM is required, fill-out the order form and return with the specimens in the mailer.
4. Send via OSDH PHL Courier service.

- Common Causes for Rejection:**
- Incorrect collection device (cotton, wooden, or calcium alginate swab)
 - Nasal swab
 - Throat swab
 - Swab without transport medium
 - Specimens missing swabs
 - Specimens that have leaked due to caps not being properly secured
 - Received > 7 days from time of collection and not frozen at -70°C or colder
 - Specimen at ambient temperature
 - Other criteria as outlined in *Specimen Rejection* section of this Test Directory

Turn-around Time: Within 3 working days of receipt
Within 7 working days of receipt if specimens have reflex testing.

Normal Value (Reference Range):

- Pathogens Not Detected

- Reportable Results:**
- Pathogens Not Detected
 - Adenovirus Detected
 - *Chlamydomphila pneumoniae* Detected
 - Coronavirus OC43 Detected
 - Coronavirus 229E Detected
 - Coronavirus HKU1 Detected
 - Coronavirus NL63 Detected
 - Human Bocavirus Detected
 - Human Metapneumovirus Detected
 - Influenza Detected; presumptive positive pending additional testing
 - For specimens in which influenza virus is detected by RPP, a preliminary report will be issued, pending testing by the OSDH PHL using the CDC Human Influenza Virus RT-PCR Diagnostic Panel.
 - For specimens in which variant or potential novel influenza viruses are detected by the Human Influenza Virus RT-PCR Diagnostic Panel, a preliminary report will be issued, pending further characterization by the CDC.
 - *Mycoplasma pneumoniae* Detected
 - Parainfluenza Virus 1 Detected
 - Parainfluenza Virus 2 Detected
 - Parainfluenza Virus 3 Detected
 - Parainfluenza Virus 4 Detected
 - Respiratory Syncytial Virus A Detected
 - Respiratory Syncytial Virus B Detected
 - Rhinovirus/Enterovirus Detected
 - Indeterminate, potential PCR inhibitors/poor sample quality; suggest additional sample submission

Interpretation: The RPP test is indicated to aid in the detection and identification of viral and bacterial agents causing respiratory tract infections in symptomatic adult and pediatric patients, who are either hospitalized, admitted to emergency departments or who are outpatients with suspected respiratory tract infection. The results of this test should not be used as the sole basis for diagnosis,

treatment, or other patient management decisions. The use of additional laboratory testing and clinical findings must be taken into consideration in order to obtain the final diagnosis of respiratory tract infection.

Limitations/ Interferences: Negative results in the setting of a respiratory illness may be due to infection with pathogens not detected by this test or lower respiratory tract infection that is not detected by a nasopharyngeal swab specimen. Positive results do not rule out co-infection with other pathogens. The agent(s) detected may not be the definite cause of disease.

Cotton swab; Calcium alginate swab (shown to inhibit PCR); Wooden shaft swab

CPT Codes: 87633, 87581, 87486

Notes: This test is approved for *in vitro* diagnostic use by the U.S. Food and Drug Administration.

Syphilis – Treponemal Screen with Reflex to RPR, with Titer and TP-PA Confirmation, as Indicated

Use: This test comprises a set of serologic treponemal and non-treponemal assays that are used in a “reverse sequence algorithm” as an aid in the diagnosis of syphilis. The BioPlex 2200’s Syphilis Total & RPR Assay qualitatively detects antibodies (IgG and IgM) to *Treponema pallidum* in human serum.

Methodology: The reverse sequence algorithm for syphilis testing initially uses a qualitative treponemal screening assay to detect antibodies (IgG and IgM) to *T. pallidum* in human serum. Screen-reactive specimens are reflexed to a qualitative Rapid Plasma Reagin (RPR) flocculation test for the detection of reagin antibodies and a subsequent semi-quantitative endpoint titer determination if RPR reactive. RPR-negative specimens are reflexed to the qualitative *T. pallidum* Particle Agglutination (TP-PA) treponemal test to verify the initial screen-reactive result.

Clinical Significance: *T. pallidum*, the etiological agent of syphilis, induces the production of at least two types of antibodies in human infection: anti-treponemal antibodies that can be detected by treponemal antigen, and anti-non-treponemal antibodies (reagin) produced as the result of reaction to cellular breakdown due to infection that can be detected by RPR antigen. Diagnosis of syphilis relies on the use of two types of serologic tests: non-treponemal and treponemal. The use of only one type of serologic test is generally insufficient for diagnosis because each test has limitations: false-positive RPR results may occur in persons without syphilis and treponemal tests are unable to distinguish between recent and past infections.

Non-treponemal test titers usually correlate with current disease activity, and the results are reported quantitatively. Sequential non-treponemal test endpoint titers can be used to monitor effectiveness of treatment. A 4-fold change in titers (e.g., from 1:16 to 1:4 or from 1:8 to 1:32) is considered necessary to demonstrate a clinically significant difference. Non-treponemal tests usually become non-reactive with time after treatment. In some patients, however, non-treponemal antibodies can persist at a low titer for a long period of time (i.e., “serofast reaction”), sometimes for the life of the patient. By contrast, reactive treponemal tests usually remain reactive for the life of the patient. While rare, non-treponemal tests can also produce false negative results, particularly during tertiary syphilis, due to the “prozone effect” whereby the reaction is overwhelmed by excess antibody.

Traditional serologic screening for syphilis initially uses non-treponemal testing with confirmation of reactive results using a treponemal test; however, reverse sequence algorithms, which initially use treponemal testing, with confirmation of reactive results using a non-treponemal test, are gaining popularity, and offer certain advantages analytically and clinically.

Detects early primary and treatment infection that might be missed with traditional algorithm

Automated and lower cost in high-volume settings

No false negatives as a result of prozone reaction

Because of the treponemal screen cannot differentiate active versus previously treated infections, all screen-reactive specimens are reflexed to a nontreponemal test with titer to define those with active infections. False-positive screen results (i.e., initial reactive treponemal screen with negative reflexed non-treponemal test) are resolved by further testing using a second treponemal test.

Further background information, fact sheets, statistics and educational resources may be found at the OSDH Infectious Disease Services [website](#).

Specimen Type: Whole blood collected in serum separator tube (SST)

Minimum Volume/ Size: 2 mL serum; draw a sufficient amount of blood to yield the necessary serum volume, around 4mL whole blood. Minimal acceptable volume for testing is 1 mL serum (potential rejection if reflexive testing exhausts sample).

Container: SST or separated serum poured into sterile, plastic, screw-cap tube

Collection: Each facility should follow its guidelines for venipuncture collection of blood/serum. Following collection of blood, invert tube gently no more than 8 times then allow blood to clot in an upright position for at least 30 minutes and no more than 60 minutes then centrifuge at 3000 rpm for 10 minutes.

Interferences: Bacterial contamination, hemolysis, lipemia

Special Instructions: The RPR has utility in monitoring the effectiveness of treatment by comparing sequential RPR titer results from the same lab. Because treponemal antibodies are generally detectable for the lifetime of the patient after syphilis infection, sera from previously-treated patients will remain reactive by the treponemal screen, and will be automatically reflexed to RPR with titer. Therefore, when monitoring the effectiveness of treatment, specific requests for an RPR titer should not be needed. RPR titer requests on screen-negative specimens require advance notice of the OSDH Public Health Laboratory. Also, such requests must be clearly indicated on the Laboratory Test Requisition Form.

Shipping:

- Separated serum (in spun SSTs or poured-off serum) to be received within 5 days of date of collection (DOC) when stored/transported at 2-8°C
- If specimen will be > 5 days from DOC when received at the testing laboratory, pour serum into sterile, plastic, screw-cap tube and freeze at -20°C or colder, then ship on dry ice; specimens may be stored at -20°C or colder for a maximum of 14 days from DOC

Rejection Criteria:

- Blood collected in tube other than SST
- SST received unspun at 2-8°C, and > 24 hours from DOC
- Specimen received at ambient temperature and > 72 hours from collection
- Specimen received at 2-8°C and > 7 days from DOC
*TP-PA testing, if reflexed to, can only be performed within 5 days of collection if received at 2-8°C, see **Syphilis Reverse Algorithm Pathway***
- Specimen received frozen and >14 days from DOC

- SST received frozen
- QNS (1 mL allows for treponemal screen testing only)
- Specimen too old for TP-PA; a TP-PA test cannot be performed after 5 days from DOC unless serum is poured off and shipped frozen
- Specimen subjected to > 1 freeze/thaw cycle (TP-PA test only)
- Bacterial contamination
- Extensive hemolysis
- Extensive lipemia
- Other criteria as outlined in *Specimen Rejection* section of this Test Directory

Turn-around Time: Within 7 working days from receipt

Normal Value (Reference Range): Syphilis Interpretation: No laboratory evidence of syphilis infection. If recent exposure is suspected, re-draw and submit specimen in 2-4 weeks.

Total Syphilis MBIA Treponemal Screen: Non-reactive

Reportable Results: **Treponemal screen:**

- Non-reactive
- Reactive
- Equivocal

RPR:

- Non-reactive
- Reactive

RPR Titer:

- 1:1 to \geq 1:2048 (at sequential two-fold dilutions)

TP-PA:

- Non-reactive
- Reactive/Inconclusive

Interpretation: **Treponemal screen:**

- Non-Reactive: A non-reactive treponemal screen result alone suggests the absence of a current syphilis infection; however, it does not exclude the possibility of syphilis infection. *T. pallidum* antibodies may be undetectable in some stages of infection and in some clinical conditions. If recent exposure is suspected, re-draw sample in 2-4 weeks.
- Reactive: Specimens with reactive treponemal screen results are tested by RPR to determine potential current or past infection.
- Equivocal: Result was in a range above the cut-off for non-reactive specimens, but below that of reactive specimens. Equivocal specimens are screened once more before reporting as equivocal.

RPR:

- Reactive: Specimens with reactive RPR results are tested by semiquantitative RPR to determine the endpoint titer.
- Non-Reactive: Specimens with non-reactive RPR results are tested by TP-PA to confirm the initial treponemal (TP-N) result.

RPR Titer:

- Specimens with endpoint titers \geq 1.1 are consistent with

syphilis infection, either current or past. Patients should be evaluated clinically to identify signs, symptoms, or past history of infection.

- RPR titers can be used to monitor a patient's response to treatment. RPR titers usually become non-reactive with time, following successful treatment. Because RPR titers are semi-quantitative and methodology can differ, tracking the progression of titers as part of treatment should only be done for submissions to the same testing facility.
 - A ≥ 4 -fold decline in titers at 12 months signifies successful treatment.
 - A < 4 -fold decline in titers at 12 months indicates treatment failure or reinfection, or "serofast" condition

TP-PA:

- Reactive: A reactive TP-PA test result, together with a reactive treponemal screen and nonreactive RPR, is consistent with past or potential early syphilis infection.
- Non-Reactive: A non-reactive TP-PA result, together with a reactive treponemal screen and non-reactive RPR, is considered inconclusive for syphilis infection, likely signifying a false positive treponemal screening or potentially an early infection.
- Inconclusive: Patients with reactive treponemal screens, non-reactive RPR, and inconclusive TP-PA results should have blood drawn in 2-4 weeks for re-test

Limitations/ Interferences: Bacterial contamination, hemolysis, lipemia

Treponemal screen:

- All treponemal tests tend to remain reactive for the life of a treponeme-infected individual, even after treatment. Treponemal antibody titers correlate poorly with disease activity; therefore, they should not be used to evaluate response to therapy. Because of the persistence of reactivity, treponemal tests are of no value in determining relapse or re-infection in a patient who has had a reactive TP-PA result.
- False positives, especially in low prevalence populations, and false negatives may occur.
- Interference may be encountered with certain sera containing non-specific and/or unidentified reactive substances.
- Test results from specimens obtained from immunosuppressed patients should be interpreted with caution.
- Assay interference due to possible circulating antibodies against pinta, yaws, and bejel has not been evaluated.

RPR:

- False negative reactions may occur, particularly in tertiary syphilis but also in early primary and late latent stages.
- Rarely, false negative results arise from a phenomenon called "prozone effect", whereby the reaction is overwhelmed by excess antibody.

- False positive reactions occur occasionally in samples from individuals with a history of drug abuse, with febrile illness, women who are pregnant or with diseases such as lupus erythematosus, malaria, vaccinia, mononucleosis, leprosy, viral pneumonia, and after smallpox vaccinations.
- Pinta, yaws, bejel and other treponemal diseases produce positive reactions in this test

TP-PA:

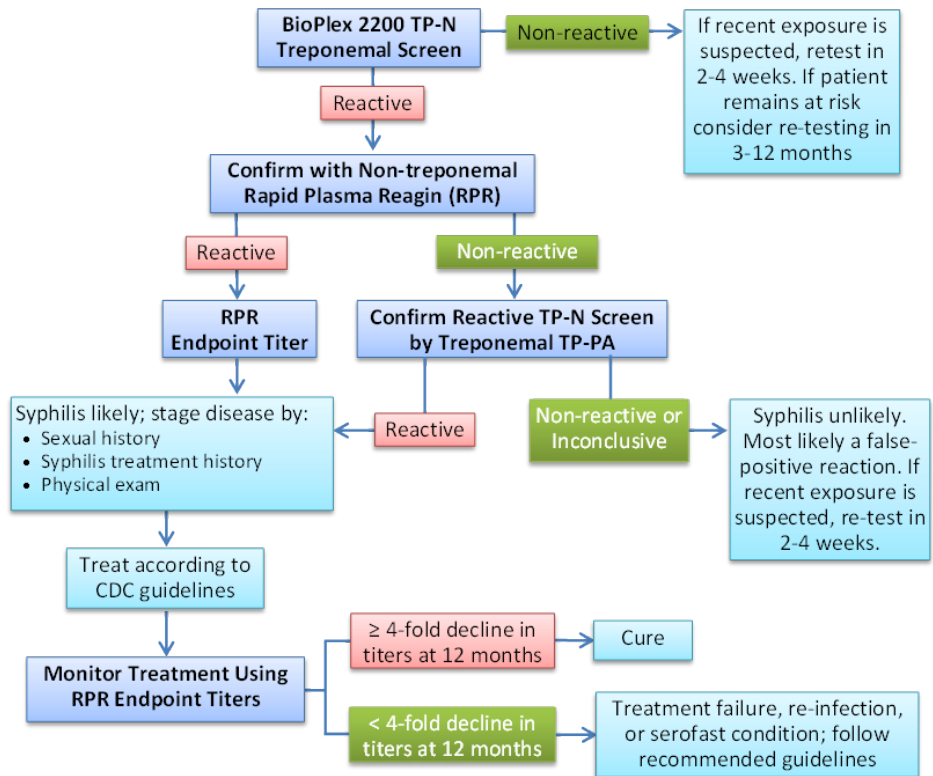
- TP-PA may be reactive in a small percentage (< 1%) of normal or healthy persons; these false positive results are often transient, and their cause is unknown.
- TP-PA may be reactive in persons from areas where yaws or pinta, bejel, and other treponemal diseases were, or are, endemic.
- Samples from patients with HIV, leprosy, toxoplasmosis, *H. pylori*, cardiovascular disease, and drug addiction may react, on occasion, causing false positive or indeterminate results.
- TP-PA is less sensitive than the fluorescent treponemal antibody absorption (FTA-ABS) test in untreated primary syphilis but compares favorably in all other stages of syphilis.

In accord with all diagnostic methods, a final diagnosis should not be made on the result of a single test, but should be based on a correlation of all laboratory test results with other clinical findings.

CPT Codes: 86592, 86593, 86780

Notes: These tests are approved for in vitro diagnostics use by the U.S. Food and Drug Administration.

Syphilis Reverse Algorithm Pathway



Outsourced Test List

These individual tests are currently being referred to other laboratories from the Public Health Lab. In some cases, the specimens are collected and sent to the PHL, where they are subsequently sent to the reference lab. In other cases, the submitter will work directly with the reference lab for all phases, including the materials, courier services, analysis and reporting. Reporting times are provided as an approximation only, as the samples require more time for transit between the laboratories. Reference laboratories that are currently performing these tests may have different specimen collection, storage and transport requirements than provided here. For specific testing requirements please email the PHL at PublicHealthLab@health.ok.gov.

Laboratory / Test Directory	Tests Performed	Turn-around Time (Working Days)
Clinical Pathology Laboratories; CPL, Test Directory Clinical Pathology Laboratories (cpllabs.com)	Cervical Cancer Screening	Submitters send directory to CPL
	Blood Parasite/Malaria	Four (4)
Minnesota Public Health Laboratory (List of Tests - MN Dept. of Health (state.mn.us))	<i>Haemophilus influenzae</i> (HAI)	Five (5)
	<i>Neisseria meningitidis</i> (HAI)	Five (5)
Nebraska Public Health Laboratory (Welcome to the Nebraska Public Health Laboratory (nphl.org))	Organism Archival and Whole Genome Sequencing for PulseNet	Ten (10)
	Bioterrorism Agent Identification from bacterial isolate or viral clinical specimen	Three (3)
	Unknown isolate identification	Twenty-Three (23)
	Fungal ID	Forty-Five (45)
Kansas Health and Environmental Laboratory (Laboratory Quick Reference Guide KDHE, KS)	Tuberculous Testing	<i>(See Below)</i>
	AFB Smear	Three (3)
	AFB PCR	Four (4)
	AFB Culture/CFI	Forty-Five (45)
	MCTB Susceptibilities	Thirty (30)
Centers for Disease Control and Prevention (Test Directory Submitting Specimens to CDC Infectious Diseases Laboratories CDC)	Arboviral Infections	Fifteen (15) Days
	Tickborne Diseases	Fifteen (15) Days
	Hantavirus	Fifteen (15) Days

Newborn Screening Reference Laboratories

Newborn Screening sends out-of-range results for second tier testing at our reference laboratories for the following disorders: Congenital Adrenal Hyperplasia (17-OHP), Lysosomal Storage Disorders (Pompe (GAA) & Mucopolysaccharidosis Type 1 (IDUA)) and X-Linked Adrenoleukodystrophy (X-ALD).

Laboratory / Test Directory	Tests Performed	Turn-around Time (Working Days)
Mayo Clinic Laboratories (Download Test Catalog - Mayo Clinic Laboratories mayocliniclabs.com) Perkin Elmer Genomics (Test Catalog (Clinicians) perkinelmer.com)	Congenital Adrenal Hyperplasia (17-OHP)	Seven (7)
	Lysosomal Storage Disorders: Pompe (GAA) & Mucopolysaccharidosis Type 1 (IDUA)	Seven (7)
	X-Linked Adrenoleukodystrophy (X-ALD)	Seven (7)



Test Directory
Oklahoma State Department of Health
Public Health Laboratory
4615 W. Lakeview Rd
Stillwater, Oklahoma 74075
Telephone: (405) 564-7750
Fax: (405) 900-7611
Email: PublicHealthLab@health.ok.gov
Website: <https://oklahoma.gov/health/locations/public-health-laboratory>
Federal Tax ID: 736017987
CLIA Number: 37D0656594

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