



CLIENT SERVICES MANUAL

VERSION 1.3

Revised Date:

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Dallas County Health and Human Services

Laboratory Division

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This standard operating procedure is for a:

- Specific Laboratory Procedure or Experiment
- Generic Good Laboratory Practice Procedure
- Generic Instrument Operation Procedure

Approved By	Print Name	Signature	Date
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Laboratory Director Biennial Review

Initial	Date	Initial	Date	Initial	Date

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DATE	Version	DESCRIPTION OF CHANGE	Sect, Page #
03/15/2022	1.1	-Added reference of Dr. James Malter, MD as Laboratory Director and removed reference of Dr. Edward Bannister, PhD as Laboratory Director.	
03/15/2022	1.1	-Added Juneteenth as a Dallas County observed holiday in which Laboratory will be closed.	Sect 1.3, Pg 7
03/15/2022	1.1	- Added the Multitest Swab Collection Kit as the required collection kit for rectal and throat specimens	Sect 0, Pg 11
03/15/2022	1.1	- Removed the Hologic HIV - 1 Viral Load Test from the Immunology Test Menu.	Sect 2.6, Pg 14
03/15/2022	1.1	- Removed the BioRad GS HIV Combo Ag-Ab EIA Assay (4 th Gen) from the Immunology Test Menu.	Sect 2.6, Pg 14
03/15/2022	1.1	-Added language for new blood collection procedure steps including using SSTs or removing serum from the blood cells after centrifugation for Immunological tests. Also added language for the 2-hour centrifugation requirement for whole blood and plasma specimens.	Sect 2.6, Pg 14, Sect 8.2, Pg 53, and Sect 4.1, Pg 43
03/15/2022	1.1	-Added RECOMMENDATION for submitters to submit serum within 3 days of collection	Sect 2.6, Pg 14 and Sect 8.2, Pg 53
03/15/2022	1.1	-Added the Aptima HIV – 1 Quant Dx assay to and removed reference to Aptima HIV – 1 Qual assay from the Immunology test menu.	Sect 2.6, Pg 23
03/15/2022	1.1	-Added HIV and Syphilis Result Interpretative Guidelines Tables	Sect 19., Pg 64
03/15/2022	1.1	Removed Reference to DNA probe for GISP	Pg 13.
05/10/2022	1.2	-Updated Authorization sheet with the removal of Dr. James Malter, M.D., and addition of Luke C. Short, Ph.D., HCLD (ABB) as Laboratory Director.	Page 2 and 7
08/2022	1.3	-Updated transport temperature requirements for specimens to match requirements set by test manufacturer.	Section 2.3, Pages 11-33
08/2022	1.3	-Added language requiring serum specimens be submitted within 72 hours of collection. Additionally, added language on potential impact caused by delay in shipment to include no downstream and confirmatory testing, along with potential rejection of specimen.	Section 2.6, Page 14
08/2022	1.3	-Removed language on MTB drug susceptibility testing and added language on Laboratory process for sending out MTB positives cultures to the state for DST as required.	2.7, Page 41
08/2022	1.3	Added SARS-CoV-2, SARS-CoV-2/Influenza A/B, and Non-variola Orthopoxvirus test menu items	Page 28, 29, and 39
08/2022	1.3	Added instructions on collecting Nasopharyngeal swabs and from suspected monkeypox lesions	Section 13. & 14.
08/2022	1.3	Updated TAT for all tests	Section 16.

Prepared by: Sean Berno and David A. Silva, M.S. **Approved by:** Luke C. Short, Ph.D., HCLD (ABB) **Revised Date:** AUG 2022

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1. GENERAL INFORMATION

1.1 Mission Statement

The Mission of the Dallas County Health and Human Services Public Health (DCHHS – PHL) Laboratory is to provide a comprehensive program of diagnostic and analytical laboratory services to support the prevention, surveillance, control, and diagnosis of communicable diseases and emerging biological threats of public concern. The goal of the DCHHS Laboratories is to provide accurate, reliable, and timely test results with an emphasis on excellent community service.

1.2 Facility Location

Laboratory Division

Dallas County Health and Human Services
2377 N. Stemmons Frwy. Basement, Suite 003
Dallas, TX 75207
Main Phone/Front Office: (214) 819-1950
Fax: (214) 819 - 2896

1.3 Days & Hours of Operation

Daily: 8:00AM to 4:30PM

Monday through Friday

Annually Observed Holidays

MLK Birthday	Labor Day
Memorial Day	Thanksgiving Holiday
Juneteenth	Christmas Holiday
Independence Day	New Year's Day

1.4 Administrative Staff Directory

Senior Management

Luke C. Short, Ph.D., HCLD (ABB) PHL Director	(214) 819-6375
Kayle Cirrincione Health & Safety Manager	(972) 692-2712
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1.5 Laboratory Bulletins and Memorandums

The DCHHS Laboratory Division will issue bulletins, or memorandums to health providers and staffs of submitting hospitals, clinics, and outreach clients, as needed via email and fax distribution. These notifications will include updated information on test ordering, specimen requirements, new instrumentation, changes in reference ranges, regulatory issues, and many other topics of concern to the relevant physicians and staffs. These bulletins and memorandums are an ongoing communication tool to provide submitters with current information on laboratory services.

1.6 Interruption of Services

Clients and Health providers will be notified via email, phone, or fax of any planned or unplanned events that directly affect consistent laboratory services.

Planned events typically will result in short – term halting of services such as observation of national holidays, facility improvement or extended in – service training.

Unplanned events may cause interruption, suspension, or termination of part or all the laboratory’s services. These events could result from a shortage or discontinuation of testing reagents and supplies, variable grades of damage to facility or equipment, or other catastrophic events.

1.7 Reference Laboratory

The DCHHS Laboratory may perform confirmatory testing at the request of submitter. Additional information such as patient demographics and diagnostic testing history may be required, though.

Requests for testing not performed by the DCHHS Laboratory are sent to a reference laboratory that is:

- (a) Acceptable to the DCHHS PHL Director
- (b) Acceptable to the providing hospital or clinic



Most reference testing is sent to the Texas Department of State Health Services Laboratory. The DCHHS Laboratory, along with ordering submitters will receive these test results from the performing laboratory.



2. LABORATORY SERVICES

2.1 Scope of Laboratory Services

The DCHHS PHL provides a wide range of testing to serve internal and external submitters. The subsequent sections of this manual contain our test menu for the Laboratory Units listed below:

LABORATORY UNITS

- **Microbiology** (Bacteriology/Mycobacteriology¹/Parasitology)
- **Immunology/Virology**
- **STAT¹**
- **Laboratory Response Network²**

¹The STAT and Mycobacteriology Laboratories only service internal submitters.

²The Laboratory Response Network (LRN) only services approved sentinel laboratories and special-need communities.

2.2 Definitions

The following items are defined for each of our test menu items.

- Analyte** the target material being detected and identified during testing
- Assay Name** Name of the testing system/platform
- Biological Principle** The supporting concept and technology behind the diagnostic capabilities of testing system/platform
- Intended Use** The objective intent or purpose of the diagnostic assay
- Reference Interval** Typical result from a biological reference population (presumed healthy)
- RCF** Relative Centrifugal Force
- SST** Serum Separator Tube
- Specimen Type** Acceptable sample of biological origin intended for examination
- Volume** Requisite amount of specimen for testing, and retesting if necessary
- Collection Containers** Acceptable containers for collecting and transporting the specimen.
- Transportation** Required conditions for maintaining quality of the specimen during shipping and transportation, inspected upon receipt for acceptability.
- Limitations** Circumstances or conditions known to directly impact the accuracy of test results. The Laboratory does not accept specimens from sources nor certain patient populations that have not been evaluated by the FDA nor validated by the Laboratory

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2.3 Test Menu

2.4 Bacteriology

1. *Chlamydia trachomatis/Neisseria gonorrhoeae*, NAAT
-

2.5 Parasitology

2. *Trichomonas vaginalis*, NAAT
-

2.6 Mycobacteriology

3. *Mycobacterium tuberculosis* complex and Rifampin Resistance, NAA
 4. Acid – Fast (Mycobacteria) Smear with Concentration
 5. Acid – Fast (Mycobacteria) Concentration and Culture with Reflex to Identification
-

2.7 Immunology/Virology

6. *Treponema pallidum* Antibodies
 7. Rapid Plasma Reagin (RPR), Qualitative
 8. Rapid Plasma Reagin (RPR), Quantitative (Titer)
 9. *Treponema pallidum* – Particle Agglutination (TP – PA)
 10. HIV -1 and HIV – 2 Ag – Ab Diagnostic Screen, 5th Gen.
 11. HIV Differentiation and Confirmation
 12. HIV – 1, NAAT
 13. Viral Culture, Herpes Simplex Virus (HSV)
 14. SARS-CoV-2, TMA
 15. SARS-CoV-2 & Influenza A/B, RT – PCR
-

2.8 STAT

16. Rapid Plasma Reagin (RPR), Qualitative
 17. Rapid Plasma Reagin (RPR), Quantitative (Titer)
 18. Rapid *Treponema pallidum* Antibodies, Waived
 19. Syphilis Darkfield Microscopy
 20. Rapid HIV–1 and HIV–2 Antibodies, Waived
 21. Rapid *Trichomonas vaginalis* Antigen, Waived
 22. Rapid hCG, Waived
 23. Urinalysis
 24. Gram Stain and PMN Count
-

2.9 LRN

25. Non-variola *Orthopoxvirus*, RT – PCR
 26. Select Agent Testing and Other Biological Threats
-



2.4 Bacteriology

Chlamydia trachomatis/Neisseria gonorrhoeae, NAAT

Analyte Ribosomal RNA of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

Assay Name Hologic Aptima Combo 2 for CT/GC

Biological Principle Multiplex transcription – mediated amplification (TMA)

Intended Use Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* to aid the diagnosis of chlamydial and/or gonococcal urogenital disease in symptomatic individuals.

Reference Interval **NEGATIVE** for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

Specimen Type

Female/Male Urine

Patient – Collected; 1st Catch (less than 1 hour since urination; 20 – 30mL)

Rectal, Throat, Male Urethral, Vaginal and Endocervical Swabs

Clinician-collected (patient – collected not validated by DCHHS)

Volume **Urine: 2mL in Aptima Urine Transport Tube** (between black fill lines)

Swab: N/A

Collection Containers

URINE

Primary Container: **Sterile Urine Collection Cup** (preservative-free)

Transport Container: **Aptima Urine Specimen Transport Tube**

Note: Transfer urine sample into Aptima Urine Specimen Transport Tube using disposable pipet provided within **24 hours** of collection.

MALE URETHRAL AND FEMALE ENDOCERVICAL SWAB

Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens

THROAT AND RECTAL SWAB

Aptima Multitest Swab Specimen Collection Kit for Throat and Rectal Specimens

VAGINAL SWAB

Aptima Vaginal Specimen Collection Kit

Transportation **Urine:** Transport Urine Specimen Transport Tubes at 2°C to 30°C within 30 days of collection.

Swabs: Transport Aptima Swab Transport Tubes at 4°C to 30°C within 30 days of collection.

IMPORTANT: The DCHHS PHL will perform a **temperature check** of the secondary transport container upon receipt to ensure proper storage



conditions are maintained for the specimen type and laboratory test to be performed.

Limitations

1. The performance of the Aptima Combo 2 Assay has not been evaluated by Dallas County in adolescents less than 14 years of age.
2. Excessively mucoid specimens may decrease sensitivity of assay. Remove excess mucus during endocervical sampling using Cleaning Swab¹ (White shaft in package with red printing).



2.5 Parasitology

***Trichomonas vaginalis*, NAAT**

Analyte Ribosomal RNA of *Trichomonas vaginalis*

Assay Name Aptima *Trichomonas vaginalis* Assay

Biological Principle Transcription – mediated amplification (TMA)

Intended Use Detection of *Trichomonas vaginalis* to aid in the diagnosis of trichomoniasis

Reference Interval **NEGATIVE** for *Trichomonas vaginalis*

Specimen Type

Endocervical Swab

Clinician-collected (patient – collected not validated by DCHHS)

Female/Male Urine

Patient – Collected; 1st Catch (less than 1 hour since urination; 20 – 30mL)

Volume **Urine: 2mL** in Aptima Urine Transport Tube (between black fill lines)

Swab: N/A

Collection Container:

URINE

Primary Container: **Sterile Urine Collection Cup** (preservative-free)

Transport Container: **Aptima Urine Specimen Transport Tube**

Note: Transfer urine sample into Aptima Urine Specimen Transport tube using disposable pipet provided within 24 hours of collection.

ENDOCERVICAL SWAB:

Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens

Transportation **Urine:** Transport Aptima Urine Specimen Tubes at 2°C to 30°C within 30 days of collection

Swabs: Transport Aptima Swab Transport Tubes at 4°C to 30°C within 30 days of collection.

IMPORTANT: The DCHHS PHL will perform a **temperature check** of the secondary transport container upon receipt to ensure proper storage and transport conditions were maintained during transport

Limitations

1. The performance of the Aptima *Trichomonas vaginalis* Assay has not been evaluated by Dallas County in adolescents less than 14 years of age.
2. Excessively mucoid specimens may decrease sensitivity of assay. Remove excess mucus during endocervical sampling using Cleaning Swab¹ (White shaft in package with red printing).



2.6 Mycobacteriology

IMPORTANT: DCHHS only accepts specimens for Mycobacteriology Laboratory from the DCHHS TB Elimination Clinic. All other specimens are ineligible for Mycobacteriology testing.

Mycobacterium tuberculosis complex and Rifampin Resistance, NAA

Analyte *Mycobacterium tuberculosis* complex DNA and Rifampin – resistance associated mutations of the *rpoB* gene

Assay Name Cepheid Xpert MTB/RIF Assay

Biological Principle Real – Time Polymerase Chain Reaction

Intended Use Detect and identify *Mycobacterium tuberculosis* complex DNA and *rpoB* mutation that is associated with rifampin resistance

Reference Interval MTB Complex Not Detected
Rifampin Resistance Not Detected

Specimen Type: Induced or Expecterated Sputum

Volume: 3mL to 5mL

Collection Container 50mL Conical Falcon Tube

Transportation

2°C to 8°C

Submit within SEVEN DAYS

IMPORTANT: The DCHHS PHL may perform a **temperature check** of the secondary transport container upon receipt to ensure proper storage conditions are maintained for the specimen type and laboratory test to be performed.

- Limitations:**
1. The Xpert MTB/RIF Assay is not indicated for use with sputum samples from patients being treated with antituberculosis greater that three days.
 2. The assay should be used in conjunction with mycobacterial culture to address the risk of false negative results.
 3. Reports of rifampin resistance must be confirmed by phenotype drug susceptibility testing.



Acid - Fast (Mycobacteria) Smear with Concentration

Analyte Microscopic detection of Mycobacteria

Assay Name Auramine - Rhodamine Fluorescent Microscopy

Biological Principle Concentrated smears are stained with auramine/rhodamine and read by fluorescence microscopy

Intended Use Identify the presence or absence of acid - fast bacilli

Reference Interval Acid - Fast Bacilli Not Observed

Specimen Type: Induced or Expectored Sputum

Volume: 3mL to 5mL

Collection Container: 50mL Conical Falcon Tube

Transportation

2°C to 8°C

Submit within SEVEN DAYS

IMPORTANT: The DCHHS PHL may perform a **temperature check** of the secondary transport container upon receipt to ensure proper storage conditions are maintained for the specimen type and laboratory test to be performed.



Acid – Fast (Mycobacteria) Concentration and Culture with Reflex to Identification

Analyte Detection, recovery and identification of Mycobacteria

Assay Name BD BACTEC MGIT Mycobacterial Growth Indicator Tubes

Lowenstein Jensen Medium

Hologic AccuProbe Culture Identification test

- *Mycobacterium tuberculosis* complex
- *Mycobacterium avium* complex
- *Mycobacterium kansasii*
- *Mycobacterium goodnae*

Biological Principle Continuous Monitoring Broth Culture System

Conventional Culture

DNA Probe Hybridization of ribosomal RNA to DNA probe; detected by chemiluminescence.

Intended Use Detect and identify Mycobacterium in patient

Reference Interval Mycobacterium Negative

Specimen Type: Induced or Expectorated Sputum

Volume: 3mL to 5mL

Collection Container: 50mL Conical Falcon Tube

Transportation

2°C to 8°C

Submit within SEVEN DAYS

IMPORTANT: The DCHHS PHL may perform a **temperature check** of the secondary transport container upon receipt to ensure proper storage conditions are maintained for the specimen type and laboratory test to be performed.



2.7 Immunology/Virology

Critical Information on Blood Specimen Submission

- 1) The DCHHS PHL accepts **WHOLE BLOOD, SERUM** and **PLASMA** specimens. Reference the test information tables for required collection containers and matrix acceptability.
- 2) Refer to the following sections to ensure acceptability of the specimen and test requisition
 - (a) Section 3. SPECIMEN LABELING REQUIREMENTS,
 - (b) Section 4. TEST REQUISITIONS
 - (c) Section 5. PRIMARY SPECIMEN CONTAINER
- 3) Reference to Section 8. BLOOD SAMPLE COLLECTION for information on sample collection, handling and storage/transportation. Ensure the sample is allowed sufficient time to clot and is centrifuged separated from RBCs within two hours of centrifugation.
- 4) Deliver SERUM/PLASMA physically separated from red blood cells (RBCs), either by the gel in blood collection tube or in a separate secured tube. We **STRONGLY RECOMMEND** the use of Serum Separator Tubes (SST) for collection of whole blood specimens and submission to avoid pouring over serum into another container.
 - (a) NOTE – If unable to centrifuge within the allotted time, ensure whole blood specimens are transported and delivered cold (2°C to 8°C) to the Laboratory within **TWO (2) HOURS** of collection to perform the centrifugation.
- 5) Ensure specimen(s) are maintained at 2°C to 8°C during transport. The PHL will perform a temperature check of the secondary transport container (*i.e.*, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature. Refer to the assay information and/or contact the laboratory for further instructions on submission on frozen samples.
- 6) The DCHHS **STRONGLY RECOMMENDS** the delivery of SERUM or PLASMA specimens within **72 – hours** from time of collection. Specimens received at or outside of the 72 – hour submission window may be rejected and/or discarded due to specimens exceeding the stability window of downstream and confirmatory HIV/Syphilis tests.
- 7) Approximately 7.5mL Whole Blood (\approx 4mL Serum) is sufficient to perform all Immunological assays, however, we strongly recommend collecting and submit **TWO 7.5mL blood tubes**.
- 8) Specimens for qualitative and quantitative HIV – 1 NAAT purposes may be requested individually if the submitter provides additional patient information. See HIV – 1, NAAT – Qualitative Table for more information.
- 9) Refer to **Appendix 17.1 for HIV Result Interpretive Guidelines** and **Appendix 17.2 for Syphilis Result Interpretive Guidelines**.
- 10) New whole blood samples should be drawn after two to four weeks in the event of Equivocal or Invalid final interpretations of HIV or Syphilis test results.



***Treponema pallidum* Antibodies**

Analyte Total (IgG/IgM) antibodies to *Treponema pallidum* (Syphilis)

Assay Name Bio-Rad 2200 Syphilis Total Assay

Biological Principle Multiplex flow immunoassay

Intended Use Qualitative detection of *Treponema pallidum* IgG/IgM antibodies in human serum to aid in the diagnosis of syphilis infection

Reference Interval Nonreactive

Specimen Type Whole Blood or Serum

Volume See important notice under **Section 2.6**

Collection Container: **SST** - Blood collection tube with a polymer present at the tube bottom that forms a barrier during centrifugation separating serum from fibrin and cells. Tube also contain a silicone - coated interior tube wall.

Preferred - BD Vacutainer SST Blood Collection Tubes (Reference № 367987; 7.5 mL volume; 16 x 100 mm)

Storage/Preservation: Store specimens at 2°C to 8°C
 DO NOT FREEZE whole blood specimens, or serum specimens in SSTs.

Transportation: Transport specimens in an enclosed container with ice packs to ensure the Laboratory receives specimens at 2-8°C.

WHOLE BLOOD: Deliver within **TWO HOURS** of collection.

SERUM: Delivery to DCHHS PHL suggested within **72 hours** of collection time. Failure to submit within this window may impact the DCHHS PHL's ability to perform downstream and confirmatory tests.

IMPORTANT: The PHL will perform a temperature check of the secondary transport container (*i.e.*, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.

- Limitations:**
1. The Syphilis Total (IgG/IgM) results should be considered with other laboratory results as well as the clinical presentation of the patient.
 2. Detection of treponemal antibodies may indicate recent, past or successfully treated syphilis infections and therefore cannot be used to differentiate between active and cured cases.
 3. Contaminated, icteric, lipemic, hemolyzed or heat inactivated serum may cause erroneous results
 4. Results obtained from immunocompromised individuals should be interpreted with caution



Rapid Plasma Reagin (RPR), Qualitative

Analyte Reagin antibodies (Nontreponemal tests for syphilis)

Assay Name Arlington Scientific RPR Card Test for Syphilis

Biological Principle Macroscopic nontreponemal flocculation test

Intended Use Qualitative detection of reagin antibodies in human serum as a screening test for Immunological evidence of syphilis

Reference Interval Nonreactive

Specimen Type Whole Blood or Serum

Volume See important notice under **Section 2.6**

Collection Container: **SST:** Blood collection tube with a polymer present at the tube bottom that forms a barrier during centrifugation separating serum from fibrin and cells. Tube also contains a silicone – coated interior tube wall.

Preferred – BD Vacutainer SST Blood Collection Tubes (Reference № 367987; 7.5 mL volume; 16 x 100 mm)

Storage/Preservation: Store specimens at 2°C to 8°C
 DO NOT FREEZE whole blood specimens, or serum specimens in SSTs.

Transportation: Transport specimens in an enclosed container with ice packs to ensure the Laboratory receives specimens at 2-8°C.

WHOLE BLOOD: Deliver within **TWO HOURS** of collection.

SERUM: Delivery to DCHHS PHL suggested within **72 hours** of collection time. Failure to submit within this window may impact the DCHHS PHL's ability to perform downstream and confirmatory tests.

IMPORTANT: The PHL will perform a temperature check of the secondary transport container (*i.e.*, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.

- Limitations:**
1. Biological false positive reactions occur occasionally with the CARBON ANTIGEN. Such reactions sometimes occur in samples from individuals with a history of drug abuse, pregnancy or with diseases such as lupus erythematosus, malaria, vaccinia, mononucleosis, leprosy, viral pneumonia, and after smallpox vaccinations.
 2. Pinta, yaws, bejel and other treponemal diseases produce positive reactions in this test. Contaminated, lipemic, icteric or grossly hemolyzed sera should not be used because of the possibility of nonspecific reactions. A specimen is too hemolyzed for testing when printed matter cannot be read through it



Rapid Plasma Reagin (RPR), Quantitative (TITER)

Analyte Reagin antibodies (Nontreponemal tests for syphilis)

Assay Name Arlington Scientific RPR Card Test for Syphilis

Biological Principle Macroscopic nontreponemal flocculation test

Intended Use Semi-quantitative detection of reagen antibodies in human serum as a screening test for Immunological evidence of syphilis and to monitor effectiveness of treatment.

Reference Interval Nonreactive

Specimen Type Whole Blood or Serum

Volume See important notice under **Section**

Collection Container: **SST:** Blood collection tube with a polymer present at the tube bottom that forms a barrier during centrifugation separating serum from fibrin and cells. Tube also contains a silicone – coated interior tube wall.

Preferred – BD Vacutainer SST Blood Collection Tubes (Reference № 367987; 7.5 mL volume; 16 x 100 mm)

Storage/Preservation: Store specimens at 2°C to 8°C
 DO NOT FREEZE whole blood specimens, or serum specimens in SSTs.

Transportation: Transport specimens in an enclosed container with ice packs to ensure the Laboratory receives specimens at 2-8°C.

WHOLE BLOOD: Deliver within **TWO HOURS** of collection.

SERUM: Delivery to DCHHS PHL suggested within **72 hours** of collection time. Failure to submit within this window may impact the DCHHS PHL's ability to perform downstream and confirmatory tests.

IMPORTANT: The PHL will perform a temperature check of the secondary transport container (*i.e.*, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.

Limitations:

1. Biological false positive reactions occur occasionally with the CARBON ANTIGEN. Such reactions sometimes occur in samples from individuals with a history of drug abuse, pregnancy or with diseases such as lupus erythematosus, malaria, vaccinia, mononucleosis, leprosy, viral pneumonia, and after smallpox vaccinations.
2. Pinta, yaws, bejel and other treponemal diseases produce positive reactions in this test. Contaminated, lipemic, icteric or grossly hemolyzed sera should not be used because of the possibility of nonspecific reactions. A specimen is too hemolyzed for testing when printed matter cannot be read through it

**Treponema pallidum – Particle Agglutination (TP – PA)****Analyte** Antibodies to *Treponema pallidum***Assay Name** Fujirebio SERODIA TP – PA**Biological Principle** Immunological particle – agglutination test for the detection of antibodies to *Treponema pallidum***Intended Use** Serve as an aid in the diagnosis of infection by *Treponema pallidum* in serum**Reference Interval** Nonreactive**Specimen Type** Whole Blood or Serum**Volume** See important notice under **Section 2.6****Collection Container:** **SST:** Blood collection tube with a polymer present at the tube bottom that forms a barrier during centrifugation separating serum from fibrin and cells. Tube also contains a silicone – coated interior tube wall.**Preferred** – BD Vacutainer SST Blood Collection Tubes (Reference № 367987; 7.5 mL volume; 16 x 100 mm)**Storage/Preservation:** Store specimens at 2°C to 8°C
DO NOT FREEZE whole blood specimens, or serum specimens in SSTs**Transportation:** Transport specimens in an enclosed container with ice packs to ensure the Laboratory receives specimens at 2-8°C.**WHOLE BLOOD:** Deliver within **TWO HOURS** of collection.**SERUM:** Delivery to DCHHS PHL suggested within **72 hours** of collection time. Failure to submit within this window may impact the DCHHS PHL's ability to perform downstream and confirmatory tests.**IMPORTANT:** The PHL will perform a temperature check of the secondary transport container (*i.e.*, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.**Limitations:** Samples from patients with HIV, Leprosy, Toxoplasmosis, H. pylori, and drug addiction may react, on occasion, with either the sensitized or the unsensitized particles, causing false – positive or inconclusive results.



HIV -1 and HIV - 2 Ag - Ab Diagnostic Screen, 5th Gen.

Analyte Human Immunodeficiency Virus (HIV) p24 antigen and HIV Type 1 (groups O and M) and HIV Type 2 Antibodies.

Assay Name Bio-Rad BioPlex 2200 HIV Ag - Ab Assay

Biological Principle Multiplex Flow Immunoassay

Intended Use Multiplex Flow Immunoassay for the simultaneous qualitative detection of HIV p24 antigen and antibodies to HIV - 1 and HIV - 2 in human serum.

Reference Interval Nonreactive

Specimen Type Whole Blood or Serum

Volume See important notice under **Section 2.6**

Collection Container: **SST:** Blood collection tube with a polymer present at the tube bottom that forms a barrier during centrifugation separating serum from fibrin and cells. Tube also contains a silicone - coated interior tube wall.

Preferred - BD Vacutainer SST Blood Collection Tubes (Reference № 367987; 7.5 mL volume; 16 x 100 mm)

Storage/Preservation: Store specimens at 2°C to 8°C
 DO NOT FREEZE whole blood specimens, or serum specimens in SSTs

Transportation: Transport specimens in an enclosed container with ice packs to ensure the Laboratory receives specimens at 2-8°C.

WHOLE BLOOD: Deliver within **TWO HOURS** of collection.

SERUM: Delivery to DCHHS PHL suggested within **72 hours** of collection time. Failure to submit within this window may impact the DCHHS PHL's ability to perform downstream and confirmatory tests.

IMPORTANT: The PHL will perform a temperature check of the secondary transport container (*i.e.*, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.

- Limitations**
1. A nonreactive test result at any point in the investigation of individual subjects does not preclude the possibility of exposure to or infection with HIV-1 and/or HIV-2.
 2. The performance of the BioPlex 2200 HIV Ag-Ab Assay has not been established for neonates and is not used in individuals younger than two years of age.
 3. Bacterially contaminated, icteric, lipemic hemolyzed or heat inactivated samples may cause erroneous results and should be avoided.

**HIV Differentiation and Confirmation**

Analyte Multiple differential antibodies to HIV Type 1 and Type 2

Assay Name Bio-Rad Geenius HIV ½ Supplemental Assay

Biological Principle Immunochromatographic assay for the confirmation and differentiation of individual antibodies to HIV-1 and HIV-2 in serum

Intended Use A specific test to confirm the presence of antibodies to HIV-1 and HIV-2 for specimens found to be repeatedly reactive to diagnostic screening procedures.

Reference Interval Nonreactive

Specimen Type Whole Blood or Serum

Volume See important notice under **Section 2.6**

Collection Container: **SST:** Blood collection tube with a polymer present at the tube bottom that forms a barrier during centrifugation separating serum from fibrin and cells. Tube also contains a silicone – coated interior tube wall.

Preferred – BD Vacutainer SST Blood Collection Tubes (Reference № 367987; 7.5 mL volume; 16 x 100 mm)

Storage/Preservation: Store specimens at 2°C to 8°C
DO NOT FREEZE whole blood specimens, or serum specimens in SSTs

Transportation: Transport specimens in an enclosed container with ice packs to ensure the Laboratory receives specimens at 2-8°C.

WHOLE BLOOD: Deliver within **TWO HOURS** of collection.

SERUM: Delivery to DCHHS PHL suggested within **72 hours** of collection time. Failure to submit within this window may impact the DCHHS PHL's ability to perform downstream and confirmatory tests.

IMPORTANT: The PHL will perform a temperature check of the secondary transport container (*i.e.*, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.

- Limitations**
1. A negative or indeterminate Final Assay Interpretation does not preclude the possibility of exposure to HIV or infection with HIV.
 2. A HIV-1 NAT is performed when the HIV-1 and HIV-2 Ag-Ab Diagnostic Screen is reactive, and the HIV Confirmation is nonreactive or indeterminate.



HIV - 1, NAAT - Qualitative

Analyte Viral RNA of Human Immunodeficiency Virus (HIV) Type 1

Assay Name Hologic Aptima HIV-1 Quant Dx Assay

Biological Principle *In vitro* nucleic acid assay system for the detection of HIV-1 RNA

Intended Use Aid in the diagnosis of HIV-1 infection, including acute or primary infection

Reference Interval Nonreactive

Specimen Type Whole Blood, Serum or Plasma

Volume See important notice under **Section 2.6**

OR

2.0mL Serum or Plasma (separated from RBCs, HIV-1, NAAT only)

Collection Container: **Whole Blood/Serum:** Blood collection tube with a polymer present at the tube bottom that forms a barrier during centrifugation separating serum from fibrin and cells. Tube also contains a silicone - coated interior tube wall.

Preferred - BD Vacutainer SST Blood Collection Tubes (Reference № 367987; 7.5 mL volume; 16 x 100 mm)

Plasma: Specimens collected in K₂EDTA, K₃EDTA, ACD, sodium citrate, Becton-Dickinson EDTA Plasma Preparation Tubes (BD PPT)

Storage/Preservation: Whole blood, serum, and plasma specimens can be stored at 2°C to 8°C.

Serum and plasma specimens can be frozen at -20°C for up to 90 days. **DO NOT** freeze specimens in the primary SST or PPT.

DO NOT FREEZE whole blood specimens

No more than three freeze/thaw cycles for other specimens, or serum specimens in SSTs

Transportation: Transport specimens in an enclosed container with ice packs to ensure the Laboratory receives specimens at 2° to 8°C.

WHOLE BLOOD: Deliver within **TWO HOURS** of collection.

SERUM:

If specimens are refrigerated, delivery to DCHHS PHL highly recommended within **72 hours** of collection time. Failure to submit within this window may impact the DCHHS PHL's ability to perform downstream and confirmatory tests.

If specimens are frozen:



HIV-1, NAAT Only – Submit at LEAST 2.0 mL of frozen (-20°C) plasma or serum with dry ice to ensure the Laboratory receives the specimens frozen.

IMPORTANT: The PHL will perform a temperature check of the secondary transport container (*i.e.*, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.

**Viral Culture, Herpes Simplex Virus (HSV)**

Target: Culture and qualitative detection of Herpes Simplex Virus

Test Name: ELVIS HSV ID Test System

Method: Cell culture by Enzyme - linked virus - inducible system (ELVIS)

Intended Use: Aid in the diagnosis of HSV infection

Reference Range: Negative

Specimen Type: Lesions in the acute or vesicular stage; ulcerated lesions have a decreased yield of viable virus

Volume: N/A

Collection Container: The swab and the transport medium should not be inhibitory to HSV or BHK cells. Use cotton, rayon or Dacron swabs.

DO NOT USE calcium alginate swabs.

Preferred: UTM/VTM with COPAN FLOQSwab 80mm (Cat. No. 525CCS01)

Transportation:

2°C to 8°C

Submit within 48 HOURS

Frozen at -70°C or colder

if the specimen will not be processed within 48 hours

IMPORTANT: The PHL will perform a temperature check of the secondary transport container (*i.e.*, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.

- Limitations**
1. Bloody specimens may contain antibodies that may inhibit viral replication in cell cultures
 2. The ELVIS HSV ID Test System cannot differentiate between the HSV Type 1 and HSV Type 2

**SARS-CoV-2, TMA****Target:** Viral RNA of SARS-CoV-2**Test Name:** Aptima SARS-CoV-2 Assay (Panther System)**Method:** Transcription – mediated amplification (TMA)**Intended Use:** Qualitative detection of RNA from SARS-CoV-2 isolated and purified from individuals meeting COVID-19 clinical and/or epidemiological criteria**Reference Range:** Negative**Specimen Type:** Nasopharyngeal (NP) Swab**Volume** Swab in 3mL of VTM/UTM**Collection Container:** Polyester -, Rayon -, or Nylon – tipped swab only in 3mL of Viral or Universal Transport Medium (VTM/UTM)

DO NOT USE VTM/UTM material that may contain Guanidinium thiocyanate or any guanidine – containing materials on the instrument. Highly reactive and/or toxic compounds may form if combined with sodium hypochlorite.

Preferred Container Combination:**Remel MicroTest M4RT Transport Media (Cat. № R12505)**

and

COPAN FLOQSwab 80mm (Cat. No. 525CCS01)**Transportation:****2°C to 8°C**

Submit within 72 HOURS

IMPORTANT: The PHL will perform a temperature check of the secondary transport container (*i.e.*, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.

Delays can impact the ability of the PHL to perform testing due to additional sample processing, ultimately resulting in rejection and the PHL discarding the specimen.

- Limitations**
1. This assay is for *in vitro* diagnostic use under FDA Emergency Use Authorization only.
 2. Negative results do not preclude SARS-CoV-2 infections and should be used as the sole basis for treatment or tother management decisions.
 3. All SARS-CoV-2 testing must be ordered through the DCHHS LabOnline Portal, a self-service online platform that provides authorized users the ability to order tests, track sample progression and view/print/download



results securely. Contact the DCHHS PHL to gain access to the LabOnline Portal

**SARS-CoV-2 & Influenza A/B, RT – PCR****Target:** Viral RNA of SARS-CoV-2, influenza A virus, and/or influenza B virus**Test Name:** Influenza SARS-CoV-2 Multiplex Assay (CDC)**Method:** Real-time RT-PCR**Intended Use:** Simultaneous qualitative detection and differentiation of SARS-COV-2, influenza A virus, and/or influenza B virus.**Reference Range:** Not Detected or**Specimen Type:** Nasopharyngeal (NP) Swab**Volume** Swab in 3mL of VTM/UTM**Collection Container:** Polyester -, Rayon -, or Nylon - tipped swab only,

DO NOT USE VTM/UTM material that may contain Guanidinium thiocyanate or any guanidine - containing materials on the instrument. Highly reactive and/or toxic compounds may form if combined with sodium hypochlorite.

Preferred Container Combination:**Remel MicroTest M4RT Transport Media (Cat. No R12505)**

and

COPAN FLOQSwab 80mm (Cat. No. 525CCS01)**Transportation:****2°C to 8°C**

Submit within 72 – HOURS

IMPORTANT: The PHL will perform a temperature check of the secondary transport container (*i.e.*, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.

- Limitations**
1. This assay is for *in vitro* diagnostic use under FDA Emergency Use Authorization only.
 2. Negative results do not preclude influenza or SARS-CoV-2 infection and should be used as the sole basis for treatment or other patient management decision.

**2.8 STAT**

IMPORTANT: Only specimens submitted via the DCHHS Sexual Health Clinic are eligible for STAT Laboratory Testing. All other specimens are ineligible for STAT testing.

Rapid Plasma Reagin (RPR), Qualitative

Analyte Reagin antibodies (Nontreponemal tests for syphilis)

Assay Name Arlington Scientific RPR Card Test for Syphilis

Biological Principle Macroscopic nontreponemal flocculation test

Intended Use Qualitative detection of reagin antibodies in human serum as a screening test for Immunological evidence of syphilis

Reference Interval Nonreactive

Specimen Type Whole Blood or Plasma

Volume 5mL Whole Blood in EDTA

Collection Container: K₂EDTA BD Vacutainer Blood Collection tube with Lavender Top

Transportation Deliver immediately to STAT Laboratory after collection

Limitations: Contaminated, lipemic, icteric or grossly hemolyzed sera should not be used because of the possibility of nonspecific reactions. A specimen is too hemolyzed for testing when printed matter cannot be read through it

**Rapid Plasma Reagin (RPR), Quantitative (Titer)****Analyte** Reagin antibodies (Nontreponemal tests for syphilis)**Assay Name** Arlington Scientific RPR Card Test for Syphilis**Biological Principle** Macroscopic nontreponemal flocculation test**Intended Use** Semiquantitative detection of reagin antibodies in human serum as a screening test for Immunological evidence of syphilis and to monitor effectiveness of treatment**Reference Interval** Nonreactive**Reportable Range** Up to 1:2048 Titer**Specimen Type:** Whole Blood or Plasma**Volume** 5mL Whole Blood in EDTA**Collection Container:** K₂EDTA BD Vacutainer Blood Collection tube with Lavender Top**Transportation** Deliver immediately to STAT Laboratory after collection**Limitations:** Contaminated, lipemic, icteric or grossly hemolyzed sera should not be used because of the possibility of nonspecific reactions. A specimen is too hemolyzed for testing when printed matter cannot be read through it.

**Rapid *Treponema pallidum* Antibodies, Waived****Analyte** Antibodies of *Treponema pallidum***Assay Name** Trinity Biotech Syphilis Health Check**Biological Principle** Qualitative rapid membrane immunochromatographic assay**Intended Use** Point-of-care test to aid in diagnosis of syphilis infection**Reference Interval** Nonreactive**Specimen Type:** Plasma**Volume** 5mL Whole Blood in EDTA**Collection Container:** K₂EDTA BD Vacutainer Blood Collection tube with Lavender Top**Transportation** Deliver immediately to STAT Laboratory after collection

- Limitations:**
1. All treponemal tests tend to remain reactive following treatment and cannot be quantified; therefore, they should not be used to evaluate responses to therapy. Because of the persistence of reactivity, probably for the life of the patient the treponemal tests are of no value to the clinician in determining relapse or re-infection in a patient who has had a treated infection.
 2. The assay should not be ordered for patients that are immunocompromised or immunosuppressed.
 3. The assay is not recommended in neonates to diagnose congenital syphilis as passive transfer of maternal antibodies can cause false positive results.

**Syphilis Darkfield Microscopy****Analyte** Direct observation of *Treponema pallidum***Assay Name** Syphilis Darkfield**Biological Principle** Microscopic detection of organisms with motility and morphology characteristic of *Treponema pallidum***Intended Use** Determined the presence of *Treponomena pallidum* from suspected lesions**Reference Interval**

1. No organisms observed or,
2. Organisms observed WITHOUT the characteristic morphology and motility of *T. pallidum*

Specimen Type: SEROUS FLUID from a genital lesion
NO ORAL LESIONS**Collection Container:** Direct smears of suspected syphilitic lesions**Transportation** Deliver immediately to STAT Laboratory after collection**Limitations**

1. Oral lesions at or near the gingival margin are unsatisfactory for darkfield examination, as the indigenous flora in this area frequently contains *T. denticola*, a spiral organism that is indistinguishable from *T. pallidum*.
2. The examination of lesion material from patients who have received anti-treponemal drugs topically or systemically may produce negative results.
3. Fading lesions of the skin are less likely to yield a positive darkfield because fewer treponemes are present.

**Rapid HIV-1 and HIV-2 Antibodies, Waived****Analyte** Antibodies to Human Immunodeficiency Virus (HIV) Type 1 and Type 2**Assay Name** Chembio HIV ½ STAT – Pak Assay**Biological Principle** Qualitative rapid membrane immunochromatographic assay**Intended Use** Point-of-care test to aid in the diagnosis of infection with HIV Type 1 and Type 2**Reference Interval** Nonreactive**Specimen Type:** Venous Whole Blood**Volume** 5mL Whole Blood in EDTA**Collection Container:** K₂EDTA BD Vacutainer Blood Collection tube with Lavender Top**Transportation** Deliver immediately to STAT Laboratory after collection**Limitations:** The performance of the Chembio HIV ½ STAT – Pak Assay has not been evaluated by Dallas County in adolescents less than 13 years of age.

**Rapid *Trichomonas vaginalis* Antigen, Waived****Analyte** *Trichomonas vaginalis* antigens**Assay Name** OSOM Trichomonas Rapid Test**Biological Principle** Qualitative rapid membrane immunochromatographic assay**Intended Use** Point - of - care test for use in patients with symptoms of vaginosis/vaginitis or suspected exposure to the *Trichomonas* pathogen**Reference Interval** Negative**Specimen Type:** Vaginal Swab**Volume** N/A**Collection Container:** BD BBL CultureSwab with container**Transportation** Deliver immediately to STAT Laboratory after collection

- Limitations:**
1. This assay is only for the exclusive qualitative detection of *T. vaginalis* antigens in vaginal swabs.
 2. This assay does not differentiate between viable and non - viable organisms, nor carriers or individuals that have an acute infection.
 3. Samples contaminated with preparations containing iodine or by the immediate prior use of vaginal lubricants are not recommended.

**Rapid hCG, Waived****Analyte** Human Chorionic Gonadotropin (hCG)**Assay Name** Alere hCG (25 mIU/mL)**Biological Principle** Rapid chromatographic immunoassay**Intended Use** Qualitative detection of hCG in female urine to aid in the early detection of pregnancy**Reference Interval** Negative**Specimen Type:** Female Urine**Volume** 20mL to 30ml First Catch Urine
Minimum: 100µL**Collection Container:** Sterile Urine Collection Cup (Free of Preservatives)**Transportation** Deliver immediately to STAT Laboratory after collection



Urinalysis

Analyte Urine Chemistry

Assay Name Siemens Multistix 10 SG

Biological Principle Urine Chemistry

Intended Use Point - of - care In vitro diagnostic for use in assessment of:

Kidney function

Urinary tract infection

Carbohydrate metabolism

Liver function

Reference Interval

Protein < 15 mg/dL

Blood <0.010 mg/dL

Leukocytes Negative

Nitrite Negative

Glucose Negative, or <30 mg/dL

Specific Gravity 1.001 - 1.035

Ketone Negative, or <2 mg/dL acetoacetic acid

pH 2.6 - 8.0

Bilirubin Negative, or <0.02 mg/dL

Urobilinogen <1.0 mg/dL

Specimen Type: First Catch Urine

Volume Recommended 20mL to 30ml First Catch Urine

Collection Container: Sterile Urine Collection Cup (Free of Preservatives)

Transportation Deliver immediately to STAT Laboratory after collection

**Gram Stain and PMN Count**

Analyte Intracellular, gram-negative diplococci and polymorphonuclear leukocytes cell count

Assay Name Gram Stain and PMN Count

Biological Principle Conventional Gram Stain

Intended Use Detection of *Neisseria gonorrhoeae* in genitourinary or extra- genitourinary sites

Reference Interval Negative

Specimen Type: Genitourinary or extra- genitourinary specimens collected with nylon flocked swabs.

NO calcium alginate swabs or swabs with wooden handles.

Volume N/A

Collection Container: Direct smear of Genitourinary or extra- genitourinary specimens

Transportation Deliver immediately to STAT Laboratory after collection



2.9 LRN – B

Non-variola *Orthopoxvirus*, RT – PCR

Target: *In vitro* qualitative detection Non-variola *Orthopoxvirus* DNA

Test Name: Non-variola *Orthopoxvirus* Generic Real – Time PCR Test (CDC)

Method: Real – Time Polymerase Chain Reaction (RT – PCR)

Intended Use: Qualitative detection of non – variola *Orthopoxvirus* from human pustular or vesicular rash specimens and viral cell culture lysates submitted to a Laboratory Response Network (LRN) reference laboratory

Reference Range: Non- variola *Orthopoxvirus* DNA not detected by real-time PCR.

Specimen Type: Multiple Dry Swab(s) from lesions collected from different locations on the body and/or from lesions with differing appearances.

Volume/Quantity Two (2) dry Swabs collected from the same lesion

Collection Container: Sterile, Dry Synthetic Swab (*i.e.* polyester, nylon or Dacron) 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 swab

DO NOT ADD or **STORE** in viral or universal transport media

Transportation: 1. **Refrigerate** (2°C to 8°C) or **freeze** (-20°C or lower) specimens **WITHIN AN HOUR** after collection

2. Send refrigerated samples (2°C to 8°C) as a Category B agent with cold packs

3. Send frozen samples (-20°C or lower) as a Category B agent using dry ice

IMPORTANT: The PHL will perform a temperature check of the secondary transport container (*i.e.*, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.

- Limitations**
1. Submitters must be approved by DCHHS LRN before submitting specimens to DCHHS PHL for non – variola *Orthopoxvirus* testing
 2. All non – variola *Orthopoxvirus* testing must be ordered through the DCHHS LabOnline Portal, a self-service online platform that provides authorized users the ability to order tests, track sample progression and view/print/download results securely. Contact the DCHHS PHL to gain access to the LabOnline Portal



Select Agent Testing and Other Biological Threats

The DCHHS Laboratory Response Network for Biological Threats (LRN - B) serves as a Reference Laboratory for Dallas County Sentinel Laboratories. We offer several distinct tests for identifying biological threats, emerging diseases and other high consequence pathogens.

DCHHS LRN - B Clients must be considered a LRN Sentinel Laboratories and/or be authorized to submit samples by the DCHHS PHL Director and LRN/BT Coordinator. Contact the DCHHS PHL at 214 - 819 - 1950 for any inquiries regarding Select Agent testing.

**2.10 Reflex Testing**

DCHHS Laboratory administration has approved the following testing to be performed reflexively.

Table 1 Immunology Reflex Testing

Result:	Action to be performed:
HIV-1 and HIV-2 Ab/Ag, 5 th Gen. Diagnostic Screen REACTIVE	HIV Antibody Confirmation & Differentiation
HIV -1 and HIV - 2 Ab - Ag, 5 th Gen. Diagnostic Screen REACTIVE AND HIV Antibody Confirmation & Differentiation NONREACTIVE or INDETERMINATE	Aptima HIV-1 Quant Dx ASSAY (NAT)
HIV -1 and HIV - 2 Ab - Ag, 5 th Gen. Diagnostic Screen NONREACTIVE:	
<i>Treponema pallidum</i> Antibodies (Bio-Rad Syphilis Total) REACTIVE	RPR Qualitative AND/OR RPR Titer (if required)
<i>Treponema pallidum</i> Antibodies (Bio-Rad Syphilis Total) REACTIVE AND RPR Qualitative NONREACTIVE/INCONCLUSIVE	Treponema pallidum - Particle Agglutination
<i>Treponema pallidum</i> Antibodies (Bio-Rad Syphilis Total) EQUIVOCAL	Recollect a new sample within two to four weeks.



Table 2 Tuberculosis Reflex Testing

Result:	Action to be performed:
<p>Mycobacterial Culture</p> <p>AFB DETECTED:</p>	<p>Hologic Accuprobe Culture Identification for <i>Mycobacterium tuberculosis</i> complex</p>
<p>Hologic Accuprobe Culture Identification for <i>Mycobacterium tuberculosis</i> complex</p> <p>MTB POSITIVE</p> <p>AND</p> <p>The patient's first POSITIVE MTB laboratory diagnosis</p> <p>OR</p> <p>At least THREE MONTHS since first POSITIVE MTB result</p>	<p>Send out to DSHS Laboratory for Anti-mycobacterial Susceptibility Testing of <i>Mycobacterium tuberculosis</i> complex (S.I.R.E)</p> <p>AND</p> <p>Shipment to Texas DSHS Laboratory for sequencing</p>
<p>Hologic Accuprobe Culture Identification for <i>Mycobacterium tuberculosis</i> complex</p> <p>MTB NEGATIVE</p>	<p>Hologic Accuprobe Culture Identification for</p> <ul style="list-style-type: none"> • <i>Mycobacterium avium</i> complex • <i>Mycobacterium kansasii</i> • <i>Mycobacterium gordonae</i>

2.11 Testing Outside of Algorithm

- 1) On a limited basis, DCHHS PHL Clients must provide a written request to the DCHHS PHL Director to perform clinical laboratory testing outside of the algorithm described in Section **Error! Reference source not found. Error! Reference source not found.** .
- 2) **IMPORTANT:** The DCHHS PHL will not provide final interpretative guidelines for specimens tested outside of the prescribed DCHHS testing algorithm.

2.12 Additional Testing on Previously Collected Specimens

DCHHS Laboratory Division accept requests from submitters for additional testing to be performed on specimens already in the custody of the Laboratory. These specimens must meet the following requirements for consideration.

- (a) Meet all the specimen requirements for the requested testing/assay
- (b) Specimen must be within the allowable stability window of requested testing/assay



- (c) To request additional testing, contact the Laboratory Director to determine if add-on testing can be performed.

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3. SPECIMEN LABELING REQUIREMENTS

All specimens and their containers received at DCHHS Laboratory Division MUST BE:

1) **Identified with an unobstructed electronically generated or hand – printed label soliciting the following information.**

(a) Patient FULL FIRST and LAST NAME

(I) IMPORTANT – Ensure the test requisition and specimen label of patients with multiple names or hyphenated names match and are in the same order. Specimens with errors or discrepancies may be rejected and discarded.

(II) NOTE – Middle names may be abbreviated with a single letter. Discrepancies in abbreviated middle names will delay reporting, pending supervisory review

(b) AT LEAST one additional unique identifier from the following list:

(I) Date of Birth (recommended)

(II) Medical Record Number such as an EMR number

(III) Social Security Number

(c) Location of Lesion (Non – variola Orthopoxvirus ONLY)

2) Not conflicting with information provided by the Test Requisition

3) Additional Considerations

(a) The Label must be affixed to the outside of the container by the submitter.

(b) If the provider produces labels with information on specimen type, the provider must ensure the correct label is placed onto the correct specimen, especially in instances where multiple specimens may be collected, and multiple labels produced. Inconsistencies may cause delays.

(c) **Mycobacteriology DCHHS PHL ONLY** – If multiple specimens are collected during a single visit, indicate the order of collection by labeling 1st, 2nd or 3rd on the specimen container and test requisition.

(d) **STAT Laboratory ONLY** – Glass slides must be labeled with the

(I) FIRST and LAST NAME Initials

(II) Medical Record Number

(III) Provider code of the collecting provider.



4. TEST REQUISITIONS

4.1 Requisitions

Health Providers **MUST SUBMIT** an Official DCHHS Laboratory Test Requisitions with **EACH** submitted patient specimen. All Test Requisitions **MUST SOLICIT** the following patient information:

1) **Patient's FULL FIRST and LAST name, or another unique identifier**

(a) **NOTE:** The unique identifier on the tube must match the unique identifier on the requisition.

2) **Date of Birth**

3) **Biological Sex**

4) **Clinic or hospital address and phone number**

5) **Collecting Health Provider**

6) **Specimen source of collection (e.g. whole blood, serum, rectal or urethral swab, etc.)**

7) **Date of Collection**

8) **Time of Collection is REQUIRED for the following specimens**

(a) Blood: Whole, Plasma, or Serum

(b) Nasopharyngeal (SARS-CoV-2)

(c) Live-cell Microscopy

(I) Syphilis Darkfield – STAT Laboratory

9) **Time of Centrifugation for the following specimens**

(a) Blood: Serum or Plasma Specimens

(b) **IMPORTANT:** Centrifugation time **MUST** be within **TWO (2) hours** of specimen collection. If specimen is **NOT** centrifuged within **TWO (2) hours** of collection, the specimen will be rejected and given an **UNSATISFACTORY** result.

10) Additional information involving specimen preparation may be required and will be indicated when appropriate (e.g. incubation time, etc.).

4.2 Outside Submitter Requisition Form

1) Submitters outside of the DCHHS Building must complete and submit an Official DCHHS Requisition Form for the following Tests:

(a) Bacteriology – See Laboratory Services **Section 2.4 Bacteriology**



- (b) Immunology – See Laboratory Services **Section 2.7 Immunology/Virology**
- (c) DCHHS Laboratory will provide additional copies of paper requisitions upon request.
- (d) **NOTE:** *Ensure the latest version of the requisition is being used or specimens may be rejected*

4.3 Internal Submitter Requisition

- 1) Submitters/Clinics within the Dallas County Organization **MUST** submit electronic test requisitions through the Greenway Prime Suite Electronic Medical Record (EMR) System.
- 2) A Requisition Template is available for the following group of Laboratory tests:
 - (a) Bacteriology – See Laboratory Services **Section 2.4 Bacteriology**
 - (b) Immunology – See Laboratory Services **Section 2.7 Immunology/Virology**
 - (c) STAT – See Laboratory Services **Section 2.8 STAT**
- 3) The Greenway Prime Suite EMR solicits the requisite patient information, except for the Date and Time of Collection. Health providers must use the empty flask icon with each row of ordered tests on the requisition page to add specimen collection information.
- 4) In the event the EMR is inoperable, Internal Submitters must
 - (a) Immediately notify the Laboratory Director of EMR issues. If unreachable, contact other administrative staff. See *section 1.4 Administrative Staff Directory* for contact information.
 - (b) Complete and submit Official DCHHS Requisition Forms for each collected specimen until EMR service is reestablished. Refer to **Section 7. SPECIMEN REJECTION** for requirements.
 - (1) **WARNING** – Any specimens submitted to the STAT or Main Laboratory without electronic or paper requisitions will not be tested and may be discarded if not rectified within 24 hours. It is the responsibility of the Submitter to ensure all specimens are submitted with an accompanying test requisition.
 - (c) The STAT Laboratory will maintain a reserve of paper requisitions for STAT and Main Laboratory tests that are available upon request.
 - (d) **IMPORTANT** – Only samples and requisitions from the DCHHS SHC Clinic are accepted by the STAT Laboratory.

4.4 Mycobacteriology Submitter

- 1) An updated DCHHS Tuberculosis requisition form soliciting the requisite patient information must be included with each submitted patient sample.
- 2) Ensure the required patient information is included on each order requisition form (see **Section 3.1 Requisitions** for further details).



- 3) Ensure the DCHHS Tuberculosis requisition form indicates the patient as a **New Patient** or as a **Returning Patient**.

IMPORTANT: A **New Patient** is defined as a patient who has not been previously diagnosed with an infection with *Mycobacterium tuberculosis* (MTB) by DCHHS, or has just been recently diagnosed with a MTB infection AND has been on an antibiotic drug treatment plan for less than 3 days at time of sputum sample collection

- 4) If multiple specimens are collected during a single visit, indicate the order of collection by labeling first, second or 3rd on the specimen container and test requisition.

4.5 LabOnline Portal

- 1) Only the following DCHHS assays are available and exclusively use LabOnline Portal to place electronic orders.
 - (a) SARS-CoV-2, TMA
 - (b) SARS-CoV-2 & Influenza A/B, RT – PCR
 - (c) Non-variola *Orthopoxvirus*, RT – PCR,
 - (d) Select Agent Testing and Other Biological Threats
- 2) Instructions for navigating DCHHS LabOnline Portal is described in the DCHHS – L3I-02 LabOnline Help Guide
- 3) A completed LabOnline Client Request Form will be required to configure submitter access on the LabOnline Portal.
- 4) Electronic test requests for the remainder of the DCHHS Test Menu is pending.



5. PRIMARY SPECIMEN CONTAINER

5.1 Specimen Container

- 1) The Submitter must select the correct collection container as dictated by the diagnostic assay requested. (See **Section 2. LABORATORY SERVICES** for specific collection container needed)
- 2) All containers or items used in the collection of specimens must be inspected for **expiration date**. Do not use supplies to collect patient specimens if they are expired. Remove all expired materials from your stock and reorder supplies or request fresh supplies from the Laboratory.
 - (a) NOTE: If a specimen is submitted in an expired primary container, it will be rejected and given an **UNSATISFACTORY** result
 - (b) NOTE: Specimens collected in unexpired specimen containers that expire in transit will be allowed to be tested on a case – by – case basis. The submitter will then be advised to inspect their supply of collection containers for upcoming expiration dates.
- 3) **IMPORTANT** – Several required collection containers require different storage environments when NOT in-use versus after specimen collection. It is the responsibility of the submitter to monitor and maintain records of temperature requirements for storage environments:

Specimen Container	Storage Requirements
K₂EDTA BD Vacutainer Blood Collection Tube 4.0mL with Lavender Top (Reference № 367862)	4°C to 25°C
BD Vacutainer SST Blood Collection Tubes (7.5 mL volume; 16 x 100 mm) (Reference № 367987)	4°C to 25°C
Aptima Urine Specimen Collection Kits for Male and Female Urine Specimens (Reference № 301040)	15°C to 30°C
Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens (Reference № 301041)	15°C to 30°C
Aptima Multitest Swab Specimen Collection Kit for Throat and Rectal Swab Specimens (Reference № PDR-03546)	15°C to 30°C
Remel MicroTest M4RT Transport Media (Cat. № R12505)	2°C to 30°C

5.2 Infection Control

- 1) Standard precautions **MUST** be used when handling any clinical specimen.
- 2) Specimens submitted to the Laboratory **MUST** be:



- (a) Tightly sealed to ensure the integrity of the specimen and avoid contamination and spillage.
 - (b) Submitted in a sealed biohazard bag with accompanying paperwork in outer pocket of the biohazard bag and separated from the specimen.
- 3) It is acceptable for multiple specimens to be submitted in a test tube rack as long as each specimen is properly sealed and labeled, and the order requisition paperwork is included.
- (a) **RECOMMENDED:** *It is highly recommended that loose individual specimens packaged together in a large biohazard bag be also packaged in secondary leak – proof containers, i.e. small biohazard bags, so as to prevent cross – contamination and loss of multiple specimens in case of breakage or leakage.*



6. SPECIMEN TRANSPORTATION

1) Deliver all specimens to:

Accessioning Section

Room 017

Elevator Lobby, DCHHS Building Basement

Phone: 214 - 819 - 1955

- 2) The Accessioning Section performs an initial inspection of the submitted specimens ensuring the following:
- (a) Temperature of the specimen lot was maintained during shipping
 - (b) No expired, leaking, or broken collection containers are present
 - (c) Accompanying test requisitions are present
- 3) The Main Laboratories perform additional screening specific to the requested test.
- (a) **IMPORTANT:** If the sample fails this initial inspection or the additional screening, the sample will be discarded, and a sample resubmittal will be requested.
- 4) **STAT Laboratory Only** - Promptly deliver specimens to the STAT reception window. Ensure STAT Laboratory Personnel is present to receive the specimen.



7. SPECIMEN REJECTION

7.1 General Policy

- 1) The Laboratory will designate specimens and test requests as **UNSATISFACTORY** if the specimen, the collection container and/or test requisition do not meet the requirements in Section 3. SPECIMEN LABELING REQUIREMENTS, 4. TEST REQUISITIONS and/or 5. PRIMARY SPECIMEN CONTAINER.
- 2) The Laboratory will not process, test, or report results if the specimen is unsatisfactory.

7.2 Delayed Testing

- 1) The submitter may rectify specimens designated as Unsatisfactory in the following situations:
 - (a) DCHHS Test Requisition is Absent
 - (b) Test Requisition is missing **REQUIRED** patient and submitter information. (See **Section 4. TEST REQUISITIONS**)
- 2) The Laboratory will notify the Submitter with one telephone call to a designated point of contact and hold specimens for 24 hours if deemed Unsatisfactory.
 - (a) If the point of contact is absent, the laboratory will leave a generic voicemail that does not specify patient information.
- 3) It is the responsibility of the Submitter to call the Laboratory Accessioning Section at 214-819-1955 to correct the deficiency within the 24 - hour holding period
 - (I) NOTE: If unavailable, contact the Laboratory Front Office 214 - 819 - 1950.
- 4) The Sample will be discarded if:
 - (a) The submitter fails to correct the deficiency in the required time, or
 - (b) The specimen expires during the 24-hour holding period
 - (c) The specimen falls out of the stability window for the test being requested during the 24-hour hold.
- 5) In these situations, the submitter must recollect and resubmit another specimen.

7.3 Automatic Rejection

- 1) The Laboratory will automatically designate specimens as **UNSATISFACTORY** and discard them for the following reasons.
 - (a) Unlabeled specimen collection container or microscope slide
 - (b) **INCORRECT, ILLEGIBLE, and INCOMPLETE** patient information on the container or microscope slide label (See **Section 3. SPECIMEN LABELING REQUIREMENTS**).



- (c) Incorrect specimen type
- (d) Blood Specimens that are not centrifuged within **TWO HOURS** of specimen collection.
- (e) Specimens received outside of the time of stability for the ordered test.
- (f) Test Requisition is missing **REQUIRED date of collection and time of centrifugation**.
- (g) Inappropriate specimen container for the diagnostic assay requested.
- (h) Underfilled or overfilled containers.
- (i) Unsecured/Leaking container.
- (j) Expired collection container
 - (I) Note – Collection devices expiring the day after collection are typically acceptable. Consult with the Laboratory if this occurs.
- (k) Improperly shipped, stored, or prepared specimens at requisite temperatures or conditions.
- (l) Test sample degradation resulting in the inhibition of its testing.



8. BLOOD SAMPLE COLLECTION

8.1 Venipuncture Technique and Specimen Handling

WARNING: Wear gloves during venipuncture and when handling blood collection tubes to minimize exposure hazard

IMPORTANT: The venipuncture technique listed below was adapted from the BD manufacturer instructions (modified 06/2019) of the Vacutainer tube, and is **RECOMMENDED** should this tube be used, but if non-BD- blood tubes are used for collection, it is recommended that the manufacturer's instructions for that tube be followed. Following the manufacturer's verified collection procedures ensures the generation of the most accurate and reliable results.

- 1) Confirm the patient information on test requisition
- 2) Acquire blood collection tube for testing ordered. Inspect the expiration date.
- 3) Label the blood collection tube with patient information. Ask the patient to verify the information.
- 4) Assemble needle in holder. Be sure needle is firmly seated to ensure needle does not unthread during use.
- 5) Gently tap tubes containing additives to dislodge any material that may be adhering to the stopper.
- 6) Place tube into holder.
- 7) Select site for venipuncture.
- 8) Apply tourniquet. Prepare venipuncture site with an appropriate antiseptic. **DO NOT PALPATE VENIPUNCTURE AREA AFTER CLEANSING.**
- 9) Place patients arm in a downward position.
- 10) Remove needle shield. Perform venipuncture **WITH ARM DOWNWARD AND TUBE STOPPER UPPER - MOST.**
- 11) Center tubes in holder when penetrating the stopper to prevent sidewall penetration and resultant premature vacuum loss. Push tube onto needle, puncturing stopper diaphragm.
- 12) Remove tourniquet as soon as blood appears in tube. **DO NOT** allow contents of tube to contact the stopper or end of the needle during procedure.
- 13) **NOTE:** Blood may occasionally leak from the needle sleeve. Practice Universal Precautions to minimize exposure hazard. If no blood flows into tube or if blood ceases to flow before an adequate specimen is collected, the following steps are suggested to complete satisfactory collection:
 - (a) Push tube forward until tube stopper has been penetrated. If necessary, hold in place to ensure complete vacuum draw.
 - (b) Confirm correct position of needle cannula in vein.



- (c) REMOVE TUBE AND PLACE NEW TUBE INTO THE HOLDER.
- (d) If second tube does not draw, remove needle and discard. Repeat procedure.
- (e) When first tube has filled to its stated volume and blood flow ceases, remove it from holder.
- (f) Place succeeding tubes in holder, puncturing diaphragm to begin flow.
- (g) Recommended Order of Draw
 - (I) Tubes for sterile samples
 - (II) Tubes for coagulation studies (*e.g.*, citrate)
 - (III) BD SST, BD SST II Advance and Serum Tubes
 - (IV) Tubes with other additives (*e.g.*, heparin, K₂EDTA, EDTA, fluoride)
- 14) While each successive tube is filling, turn the filled tube upside – down and return it to the upright position. This is one complete inversion.
 - (a) **NOTE:** Invert BD Vacutainer K-2EDTA blood collection tube 8 – 10 times. Do not shake. Vigorous mixing may cause foaming or hemolysis. Insufficient mixing or delayed mixing in tubes with anticoagulants may result in platelet clumping, clotting and/or incorrect test results.
- 15) As soon as blood stops flowing in the last tube, remove tube from holder, remove needle from vein, applying pressure to puncture site with dry sterile swab until bleeding stops.
- 16) Once clotting has occurred, apply bandage.
- 17) After venipuncture, the top of the stopper may contain residual blood. Take proper precautions when handling tubes to avoid contact with this blood.
- 18) Dispose of needle and holder.
- 19) Allow blood to clot thoroughly before centrifugation. Sixty (60) minutes must transpire for a non-SST and thirty (30) minutes for an SST.
- 20) Centrifuge **Whole Blood** specimens at **1000-1300 RCF for 10 minutes** within **TWO (2) HOURS** of specimen collection. Ensure the centrifugation time is documented on the test requisition.
 - (a) If using a non – SST, make sure to pour – over serum into a separate container and deliver to the PHL

8.2 Blood Specimen Transport

- 1) Blood specimens must be transported in an insulated container with sufficient ice packs to maintain the specimen in a 2°C to 8°C environment during transportation.



- (a) If a whole blood specimen is not centrifuged, the specimen **MUST** be transported to the DCHHS Laboratory cold (2-8°C) within **TWO HOURS** of collection so that DCHHS PHL can perform centrifugation.
- 2) Submit the specimen to the PHL within **THREE DAYS** of collection to avoid potential interference with stability windows of several downstream and confirmatory tests that may be affected by delays in shipment.
- 3) Failure to submit specimens within this submission window may result in an inability for the Laboratory to perform downstream and confirmatory HIV and Syphilis testing, which may result in an incomplete laboratory result record, or an overall specimen rejection.



9. URINE COLLECTION (STAT)

9.1 STAT Urine: Testing Procedure

- 1) Acquire urine collection cup. Inspect the expiration date.
- 2) Label the urine collection cup with patient information. Ask the patient to verify the information.
- 3) Direct patient to provide a FIRST-CATCH urine (approximately 20 to 30 mL of the INITIAL urine stream) into a sterile urine collection cup free of any preservatives.
 - (a) NOTE - The patients should not have urinated for at least 1 hour prior to specimen collection.
 - (b) NOTE - Female patients should not cleanse the labial area prior to providing the specimen.
- 4) Promptly deliver the labeled urine collection cup to the STAT Laboratory.
 - (a) NOTE: Ensure urine within collection cup is below 30°C prior to submitting to the STAT Laboratory.



10. URINE COLLECTION (GONORRHEA, CHLAMYDIA, TRICHOMONAS)

10.1 General Information

- 1) The DCHHS Bacteriology Laboratory accept Urine specimens. See **Section 2. LABORATORY SERVICES** for requisite specimen collection container needed and affected assays
- 2) Refer to Section 3. SPECIMEN LABELING REQUIREMENTS, Section 4. TEST REQUISITIONS, and Section 5. PRIMARY SPECIMEN CONTAINER for requirements to ensure acceptability of specimen and test requisition.
- 3) DCHHS Laboratory requires the use of the Aptima Urine Specimen Collection Kits for Male and Female Urine Specimens (Reference №. 301040) for urine collection.
 - (a) Each Kit contains one disposable transfer pipette and one specimen transport tube containing 2.0mL Aptima urine transport medium. **This transfer pipette is used to transfer the urine sample from the urine collection cup to the Aptima transport tube.**
 - (b) The Kit and its contents must be maintained at 15°C – 30°C through the storage, collection, and transport process.
 - (c) Do not apply the transport medium directly to skin or mucous membranes or take internally.

10.2 Bacteriology Urine Collection

- 1) Acquire urine collection cup. Inspect the expiration date.
- 2) Label the urine collection tube with patient information. Ask the patient to verify the information.
- 3) The patient should not have urinated for at least 1 hour prior to specimen collection.
- 4) Direct patient to provide a FIRST-CATCH urine (approximately 20 to 30 mL of the INITIAL urine stream) into a urine collection cup free of any preservatives. Collection of larger volumes of urine may result in rRNA target dilution that may reduce test sensitivity. Female patients should not cleanse the labial area prior to providing the specimen.
- 5) Remove the cap and transfer 2 mL of urine into the urine specimen transport tube using the disposable pipette provided. The correct volume of urine has been added when the fluid level is between the black fill lines on the urine specimen transport tube label.
- 6) Re-cap the urine specimen transport tube tightly. This is now known as the processed urine specimen.

10.3 Urine Transport and Storage

- 1) After collection, transport the processed urine specimens in the Aptima Urine Specimen Transport Tube at 2°C to 30°C and store at 2°C to 30°C until tested.
- 2) Refer to **Section 6. SPECIMEN TRANSPORTATION**.



11. SWAB SAMPLE (GONORRHEA, CHLAMYDIA, TRICHOMONAS)

11.1 General Information

- 1) **IMPORTANT:** Refer to the specific test information in **Section 2. LABORATORY SERVICES** result to determine acceptable specimens
- 2) The Laboratory has validated the use of the Aptima Unisex Swab for collection of pharyngeal and rectal specimens in January 2014.

11.2 Endocervical

- 1) Remove excess mucus from the cervical os and surrounding mucosa using the cleaning swab (white shaft swab in the package with red printing). Discard this swab.
 - (a) NOTE: To remove excess mucus from the cervical os, a large-tipped swab (not provided) may be used.
- 2) Insert the specimen collection Unisex swab (blue shaft swab in the package with the green printing) into the endocervical canal.
- 3) Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling.
- 4) Withdraw the swab carefully; avoid any contact with the vaginal mucosa.
- 5) Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
- 6) Carefully break the swab shaft against the side of the tube at the score line and discard the top portion of the swab shaft; use care to avoid splashing of contents.
- 7) Re-cap the swab specimen transport tube tightly.

11.3 Vaginal Swab

- 1) Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft top is touched, the swab is laid down, or the swab is dropped, open a new swab package
- 2) Hold the swab, placing your thumb and forefinger in the middle of swab shaft covering the score line. Do not hold the swab shaft below the score line.
- 3) Carefully insert the swab into the vagina about 2 inches (5cm) past the introitus and gently rotate the swab for 10 – 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab and then withdraw the swab without touching the skin.
- 4) While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, open a new swab package.
- 5) Immediately place the swab into the transport tube so that the score line is at the top of the tube.



11.4 Rectal

- 1) Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft top is touched, the swab is laid down, or the swab is dropped, open a new Aptima Multitest swab package.
- 2) Hold the swab, placing your thumb and forefinger in the middle of swab shaft covering the score line. Do not hold the swab shaft below the score line.
- 3) Carefully insert the swab into the rectum about 1 – 2 inches (3 – 5 cm_ past the anal margin and gently rotate the swab for 5 – 10 seconds. Withdraw the swab without touching the skin.
- 4) While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, open a new swab package.
- 5) Immediately place the swab into the transport tube so that the score line is at the top of the tube.
- 6) Carefully break the swab shaft at the score line against the side of tube.
- 7) Immediately discard the top portion of the swab shaft.
- 8) Tightly screw the cap onto the tube.

11.5 Throat

- 1) Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft top is touched, the swab is laid down, or the swab is dropped, open a new Aptima Multitest swab package.
- 2) Hold the swab, placing your thumb and forefinger in the middle of swab shaft covering the score line. Do not hold the swab shaft below the score line.
- 3) Carefully insert the swab into the throat ensuring contact with bilateral tonsils (if present) and the posterior pharyngeal wall, then withdraw the swab without touching the inside of the cheeks or tongue.
- 4) While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, open a new swab package.
- 5) Immediately place the swab into the transport tube so that the score line is at the top of the tube.
- 6) Carefully break the swab shaft at the score line against the side of tube.
- 7) Immediately discard the top portion of the swab shaft.
- 8) Tightly screw the cap onto the tube.

11.6 Urethral

- 1) The patient should not have urinated for at least 1 hour prior to sample collection.



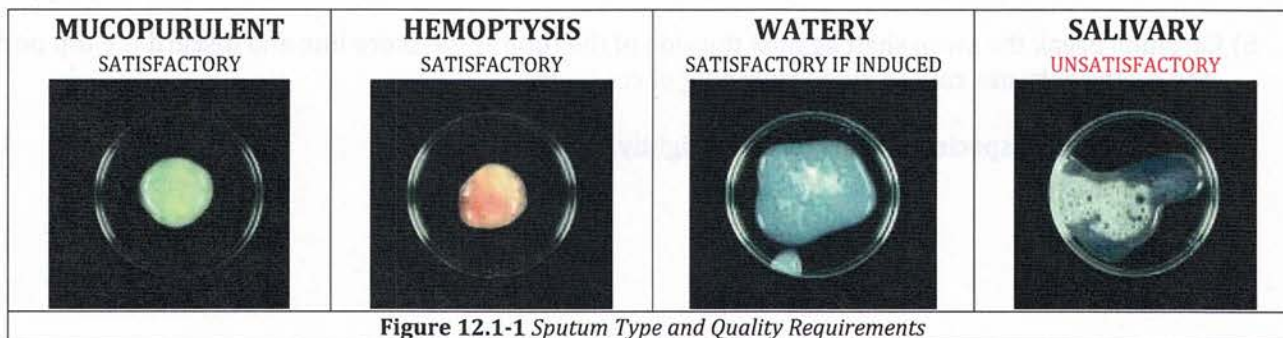
- 2) Insert the specimen collection Unisex swab (blue shaft swab in the package with the green printing) 2 to 4 cm into the urethra.
- 3) Gently rotate the swab clockwise for 2 to 3 seconds in the urethra to ensure adequate sampling.
- 4) Withdraw the swab carefully.
- 5) Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
- 6) Carefully break the swab shaft against the side of the tube at the score line and discard the top portion of the swab shaft; use care to avoid splashing of contents.
- 7) Re-cap the swab specimen transport tube tightly.



12. SPUTUM SPECIMEN COLLECTION

12.1 General Information

- 1) The DCHHS Tuberculosis only accepts Natural/Expectorated and Induced Sputum from the DCHHS TB Elimination Clinic.
- 2) A satisfactory specimen should be mucopurulent or hemoptysis and should not just be salivary in nature



- 3) The Optimal Specimen Volume is 3 – 5 mL per 50 mL conical tube. Smaller quantities are considered if the quality is satisfactory.
- 4) Specimen must be stored at 2 – 8°C after collection.
- 5) Specimens must be delivered cold (2 – 8°C) to the DCHHS PHL.
- 6) The submitter must provide the following information
 - (a) Whether the patient is new to DCHHS or if it is a returning patient.
 - (1) If the patient is new, indicate whether the patient is undergoing anti-mycobiotic treatment, and the date treatment was started.
- 7) Refer to **Section 6. SPECIMEN TRANSPORTATION** for other instructions on delivery.



13. NASOPHARYNGEAL SWAB

13.1 Provider – Collected Swab

- 1) Label the container with the required patient information outlined in section 3. **SPECIMEN LABELING REQUIREMENTS.**
- 2) Tilt patient's head back to a 70° angle.
- 3) Check for nasal obstructions. If there is an obstruction, try the other nostril.
- 4) Gently insert the swab straight back into a nostril aiming posteriorly along the floor of the nasal cavity until reaching the posterior wall of the nasopharynx. Leave swab in place for up to 10 seconds to absorb secretions. **DO NOT** force the swab.
- 5) Slowly remove swab while rotating it.
- 6) While holding the swab in hand, unscrew the tube cap. **DO NOT** spill the tube contents. Place the swab specimen into 3mL of VTM/UTM.
- 7) Immediately place the swab into the transport tube and seal. If score line is present, break swab at the score line at the top of the tube. The swab will drop to the bottom of the vial. Discard the top portion of the shaft. Tightly screw the cap onto the tube.



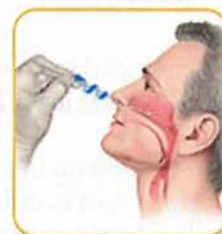
Step 1)



Step 2)



Step 4)



Step 5)



Step 7)

13.2 Storage and Transport

- 1) Store the sample at 2°C to 8°C.
- 2) Submit the sample with sufficient ice packs in an insulated container to maintain a 2°C to 8°C environment the transportation.
- 3) Transport to the laboratory within 72 hours of collection.
 - (a) **IMPORTANT:** Delays can impact the ability of the PHL to perform testing due to additional sample processing, ultimately resulting in rejection and the PHL discarding the specimen.



14. LESION COLLECTION (MONKEYPOX)

14.1 Lesion Collection

- 1) Wear appropriate personal protective equipment (PPE).
- 2) Select two sterile, dry synthetic swabs (including, but not limited to polyester, nylon, or Dacron 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.
 - (a) NOTE – Avoid using NP swabs, which have a higher rate of inconclusive results, likely due to inhibition
- 3) Do not clean the lesion with ethanol or any other disinfectant.
- 4) Hold the swab with a firm grasp. Avoid touching the swab shaft at least an inch before the tip if collecting a dry swab.
- 5) Apply firm pressure (generally firm enough so that the swab shaft, if plastic may bend slightly). This may result in discomfort or slight pain, but it is necessary to obtain adequate DNA.
 - (a) If lesion ruptures while swabbing, ensure the swab collects lesion fluid. It is not necessary to de-roof the lesion before swabbing.
 - (b) If possible, avoid using swabs that bend too easily which may make applying firm pressure difficult.
- 6) Swipe the swab back and forth on the lesion surface at least 2 – 3 times then rotate and repeat on the other side of the swab at least 2 – 3 times.
 - (a) If material is visible on the swab surface (such as skim material or from lesion fluid that is leaking from the lesion), this is indicative of an adequate collection. Although please note that material may not always be visible on swabs.
- 7) Put each swab into separate 15mL or 50mL screw – capped conical container by breaking off or cutting the end of each swab's applicator.
 - (a) Alternatively, the collector may use the Puritan Dry Transport System instead of the 15mL/50mL conical container.
- 8) Collect and submit two swabs from each sampled lesion.
 - (a) If collecting from multiple sites, make sure to collect from different locations on the body and/or from lesions which differ in appearance.

14.2 Storage and Transport

- 1) **Refrigerate** (2°C to 8°C) or **freeze** (-20°C or lower) specimens **WITHIN AN HOUR** after collection
- 2) Submit to the PHL LRN – B as UN 3373 Biological Substance, Category B with sufficient ice packs or dry ice to ensure the specimen is received by the PHL cold (2°C to 8°C) or frozen (-20°C or lower), respectively.



15. OTHER STAT REQUIREMENTS

15.1 Gram Stain Specimens:

- 1) The DCHHS STAT Laboratory accepts direct smears of a swab specimen collected from the urethra, cervix, or rectum of patients suspected of *Neisseria gonorrhoeae* infection based on patient history and clinical symptoms.
- 2) Consult Section 11. SWAB SAMPLE (GONORRHEA, CHLAMYDIA, TRICHOMONAS) for information regarding swabbing genitourinary and extra – genitourinary specimens.

15.2 Direct Smear Preparation

- 1) Label the microscope slide with the patient
 - (a) Primesuite EMR №
 - (b) Patient FIRST and LAST name initials
 - (c) DCHHS Provider Identification Code
- 2) The swab must be rolled GENTLY onto the slide to preserve cellular morphology and over an area less than 1cm²
- 3) There should be enough specimen extracted so the nurse can roll the swab across the middle of the glass slide in 2-3 uniform, horizontal lines.

15.3 OSOM Trichomonas Rapid Test

- 1) The BD BBL™ CultureSwab™ is required to collect a Vaginal Swab only.
- 2) Collection Protocol
 - (a) Obtain a sterile BD BBL™ CultureSwab™ tube
 - (b) Label the CultureSwab™ tube with:
 - (I) Primesuite EMR №
 - (II) Patient FIRST and LAST name initials
 - (III) DCHHS Provider Identification Code
 - (c) Collect specimens from the vaginal cavity with BD BBL™ CultureSwab™.
 - (d) Reinsert the swab into the CultureSwab Container.
 - (e) Bring sample and test request to STAT Sample Reception Window.



- 3) Swabs may be held at room temperature for NO LONGER THAN 24 HOURS.

15.4 Rapid Plasma Reagin (RPR)

- 1) The STAT RPR Titer is performed up to 1:16 for both new patients and patients being monitored during treatment. If needed, STAT technicians will prepare higher dilutions on a separate card.

15.5 Syphilis Darkfield

- 1) The ideal specimen for darkfield examination is a SEROUS FLUID that is rich in *Treponema pallidum* but that contains few blood cells (treponemes may be obscured if many cells are present).
- 2) Consider every genital lesion in sexually active patients as syphilis until subjected to a darkfield examination and proven otherwise. Other lesions on the skin or mucous membranes should also be examined when syphilis is suspected.
- 3) Darkfield examination of oral lesions is NOT RECOMMENDED. The indigenous floras of the oral cavity frequently contain a spiral organism, *Treponema denticola*, which is indistinguishable from *Treponema pallidum*.
- 4) The slide preparations should not contain a large volume of fluid (large volumes cause a rapid liquid flow across the field), nor should the preparation be so thin that it begins to dry before an adequate examination can be made.
- 5) Collected specimen slides should be walked to the STAT laboratory immediately to ensure viability of organism.



16. LABORATORY REPORTS

16.1 Immunology/Virology and Bacteriology

- 1) Immunology and Bacteriology test results should be available within **FIVE (5) BUSINESS DAYS** of specimen receipt for both outside and inside submitters.
 - (a) **Internal Submitters** will receive test results through the Prime Suite EMR system
 - (b) **Outside Submitters** will receive test results on a copy of the original paper test requisition. The Laboratory can Fax and/or Mail Laboratory Reports. Contact DCHHS Laboratory Division personnel (**Section 1.4 Administrative Staff Directory**) for more information on reporting options.
 - (c) The Laboratory will notify Submitters if test results will be delayed outside of the normal turn – around – time. In addition, submitters can contact the Laboratory should they have any questions on the availability of a particular patient test report.
- 2) SARS – CoV – 2 Test Results should be available within **FIVE (5) BUSINESS DAYS** of specimen receipt

16.2 Mycobacteriology

- 1) Final Test results will be available within **SIXTY (60) DAYS** of specimen receipt.
- 2) Paper reports of completed Tuberculosis Laboratory tests will be hand – delivered to the DCHHS TB Clinic within 24 hours of completion.
- 3) For any questions regarding how specific laboratory reports will be released and delivered, please contact the DCHHS Tuberculosis Laboratory at 214-819-1956.
 - (a) Submitters will be notified of a delay in the availability of test results. In addition, submitters can contact the Tuberculosis Laboratory at 214-819-1956 should they have any questions on the availability of a particular patient test report

16.3 STAT

- 1) STAT Laboratory results will be available immediately upon completion of the test. The reports will be available via Prime Suite EMR within **ONE (1) HOUR** of sample submittal and receipt.
- 2) Submitters will be notified of a delay in the availability of test results. In addition, submitters can contact the STAT Laboratory at 214-819-2182 should they have any questions on the availability of a particular patient test report.

16.4 LRN and SARS-CoV-2: Electronic Reports

- 1) Select Agent Testing
 - (a) Preliminary Test Results will be available within **THREE (3) BUSINESS DAYS** of sample receipt.



- (b) Confirmatory Testing will be available within **TWO (2) WEEKS** of sample receipt.
- 2) Non - variola Orthopoxvirus results should be available within **THREE (3) BUSINESS DAYS**.
- 3) Only the following DCHHS assays are available and exclusively use LabOnline Portal to receive electronic test reports within **TWO (2) to FIVE (5) BUSINESS DAYS**.
 - (a) SARS-CoV-2, TMA
 - (b) SARS-CoV-2 & Influenza A/B, RT - PCR
 - (c) Non-variola *Orthopoxvirus*, RT - PCR
 - (d) Select Agent Testing and Other Biological Threats
- 4) **Electronic test requests and reports for the remainder of the DCHHS Test Menu is pending.**



17. ADDITIONAL INFORMATION

17.1 Updates on Test Results

- 1) Paper Test Requests: Submitters seeking information or updates on specific laboratory test results beyond Laboratory's turn-around-times should call the Laboratory Office Phone (214) 819 – 1950. The Front Office staff will direct your call to the appropriate party or relay the information.
- 2) LabOnline Electronic Test Reports – Refer to the LabOnline Help Guide for information on navigating LabOnline Portal and retrieving

17.2 Complaints

Comments, questions or complaints should be directed to the Front Office at the Laboratory Office Phone (214) 819 – 1950. The Front Office Staff will notify the appropriate parties of the incident and action taken, if needed.



18. REFERENCES

- 1) GP44-A4: Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline – Fourth Edition *Clinical and Laboratory Standards Institute (CLSI)*, 2010.. Vol. 30(10), pp.6-7.
- 2) "Collection, Storage and Shipment of Specimens for Laboratory Diagnosis And Interpretation Of Results". 2010, p. Annex 3.



19. APPENDIX

19.1 DCHHS HIV Interpretative Guidelines

Results			Final Laboratory Interpretation	Recommended Actions
HIV Antigen-Antibody	HIV ½ Antibody Differentiation	HIV-1 RNA Qualitative Assay		
No Result	Not Performed	Not Performed	Inconclusive	Inconclusive. Recommendation for a new specimen to be submitted for additional testing.
Nonreactive	Not Performed	Not Performed	Nonreactive	If recent HIV exposure is suspected or reported, submit a new specimen for additional testing.
		HIV-1 RNA Not Detected	HIV Negative	If recent HIV exposure is suspected or reported, submit a new specimen for additional testing.
		HIV-1 RNA Detected	Acute HIV-1 Positive	Positive for HIV-1 RNA. Laboratory evidence of HIV-1 infection consistent with an acute HIV-1 infection.
Not Performed	Not Performed	HIV-1 RNA Not Detected	HIV-1 Negative	If recent HIV exposure is suspected or reported, submit a new specimen for additional testing.
Reactive	HIV-1 Positive	Not Performed	HIV-1 Positive	Positive for HIV-1 antibodies. Laboratory evidence of HIV-1 infection is present.
	HIV-2 Positive	Not Performed	HIV-2 Positive	Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection present. Recommended that specimen be referred to the CDC for additional testing.
	HIV-1 Positive with HIV-2 Cross-reactivity	Not Performed	HIV-2 Positive (distinct from HIV Positive Untypable/Undifferentiated)	Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection present. Recommended that specimen be referred to the CDC for additional testing.
	HIV Positive Untypable (undifferentiated)	Not Performed	HIV Positive	Positive for HIV-1 and HIV-2 antibodies. Laboratory evidence of HIV-1 and/or HIV-2 infection is present. Recommended that specimen be referred to the CDC for additional testing.
	HIV-1 Indeterminate	HIV-1 RNA Detected	Acute HIV-1 Positive	Positive for HIV-1. Laboratory evidence of HIV-1 infection consistent with an acute HIV-1 infection.
		HIV-1 RNA Not Detected	HIV Negative	HIV-1 antibodies were not confirmed and HIV-1 RNA was not detected. If recent HIV exposure is suspected or reported, submit a new specimen for additional testing.
	HIV-2 Indeterminate	HIV-1 RNA Detected	Acute HIV-1 Positive	Positive for HIV-1. Laboratory evidence of HIV-1 infection consistent with an acute HIV-1 infection.
		HIV-1 RNA Not Detected	HIV-1 Negative HIV-2 Inconclusive	HIV-1 antibodies were not confirmed and HIV-1 RNA was not detected. HIV-2 inconclusive. If recent HIV exposure is suspected or reported, submit a new specimen for additional testing.
	HIV Indeterminate	HIV-1 RNA Detected	Acute HIV-1 Positive	Positive for HIV-1. Laboratory evidence of HIV-1 infection consistent with an acute HIV-1 infection.
		HIV-1 RNA Not Detected	HIV-1 Negative HIV-2 Inconclusive	HIV-1 antibodies were not confirmed and HIV-1 RNA was not detected. HIV-2 inconclusive. If recent HIV exposure is suspected or reported, submit a new specimen for additional testing.
HIV Antibody Negative	HIV-1 RNA Detected	Acute HIV-1 Positive	Positive for HIV-1. Laboratory evidence of HIV-1 infection consistent with an acute HIV-1 infection.	
	HIV-1 RNA Not Detected	HIV Negative	HIV antibodies were not confirmed and HIV-1 RNA was not detected. If recent HIV exposure is suspected or reported, submit a new specimen for additional testing.	
HIV Antibody Negative or Indeterminate	Invalid	Inconclusive	Inconclusive. Recommendation for a new specimen to be submitted for additional testing.	



19.2 DCHHS Syphilis Testing Interpretative Guidelines

Results				Final Lab Interpretation	Recommended Actions
Syphilis IgG	RPR	RPR Titer (if performed)	TP-PA		
No Result or Equivocal	Not Performed	Not Performed	Not Performed	No Result or Equivocal	Recommended patient samples to be redrawn in three (3) to four (4) weeks for additional testing.
Non-Reactive	Not Performed	Not Performed	Not Performed	Syphilis Negative <i>Infection Unlikely</i>	No Immunological evidence of infection with T. pallidum. Cannot exclude incubating or early syphilis. Submit second sample in 3-4 weeks if clinically indicated.
Reactive	Reactive	Reference Titer on Result Sheet	Not Performed	Syphilis Positive <i>Infection Likely</i>	Based on IgG, RPR and TP-PA results, Immunological evidence of infection with T. pallidum present.
Reactive	Non-Reactive	N/A	Reactive	Syphilis Positive <i>Infection Likely</i>	Based on IgG, RPR and TP-PA results, Immunological evidence of infection with T. pallidum present.
Reactive	Non-Reactive	N/A	Non-Reactive	Syphilis Negative <i>Infection Unlikely</i>	No Immunological evidence of infection with T. pallidum. Cannot exclude incubating or early syphilis. Recommend for patient sample to be redrawn in two to four (2-4) weeks for additional testing.
Reactive	Non-Reactive	N/A	Inconclusive	Inconclusive	Based on IgG, RPR and TP-PA results, a second sample should be submitted. Repeat testing in three to four (3-4) weeks if high risk of acquiring syphilis infection.