CLIENT SERVICES MANUAL

VERSION 1.7

Revised Date:

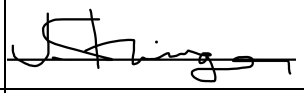
MAY 2024

Dallas County Health and Human Services
Laboratory Division
CLIA № 45D0672012

Document Title:	DCHHS Client Services Manual
Revision:	1.7
Procedure Author(s):	David A. Silva, Sean Berno, Shaila Borna, and Eleanor Kirkscey
Date of revision:	May 2024
Name of Responsible Persons:	DCHHS Laboratory Personnel and Submitters
Location to be Performed:	DCHHS Laboratory Division and Submitting Facilities

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
General Lab Supervisor:	David J. Stringer		May 17, 2024
Health & Safety Manager	Kayle Cirrincione	 Kayle Cirrincione (May 17, 2024 15:21 CDT)	May 17, 2024
Quality Manager:	David A. Silva, MS, DLM(ASCP)^{CM}	 David Silva (May 17, 2024 15:01 CDT)	May 17, 2024
Laboratory Director:	Luke C. Short, Ph.D., HCLD(ABB)		May 17, 2024

Laboratory Director Biennial Review

Initial	Date	Initial	Date	Initial	Date

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 2.5, Pg 14
03/15/2022	1.1	- Removed the Bio-Rad GS HIV Combo Ag-Ab EIA Assay (4th Gen) from the Immunology Test Menu.	Sect 2.5, 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 2.5, Pg 14, Sect 8.2, Pg 53, and Sect **Error! Reference source not found.**, Pg 43
03/15/2022	1.1	-Added RECOMMENDATION for submitters to submit serum within 3 days of collection	Sect 2.5, 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 2.5, 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.	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 2.5, 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
8/2022	1.3	Added SARS – CoV – 2, SARS-CoV-2/Influenza A/B, and Non – variola Orthopoxvirus test menu items	Page 44
8/2022	1.3	Added instructions on collecting Nasopharyngeal swabs and from suspected monkeypox lesions	Section 13. & 14.
8/2022	1.3	Updated TAT for all tests	Section 16.
03/2023	1.4	-Updated procedure for handling (*i.e*., storage and transportation) blood specimens after collection.	Section 2.6
03/23	1.4	-Updated language to require serum specimens be submitted within 72 hours to avoid rejection.	Section 2.6
03/2023	1.4	-Updated ordering and reporting section to include language on using the LabOnline Portal.	Section 4 and 16
03/2023	1.4	-Added table with criteria for testing of patient specimens on the Xpert MTB RIF Assay, along with details on how answers to these questions on the LabOnline test requisition will be handled.	Section 2.5 and 19.3
02/2024	1.5	Paper requisitions are no longer submitted. Test requests must be submitted through LabOnline or verbally.	Section 4.2. c

3/2024	1.5	Clarified the delivery of the smears for the Darkfield Microscopy ASAP, as it may impact the results.	Page 38
04/2024	1.6	Updated the collection container for vaginal swabs to include the Aptima Vaginal and Multitest Specimen Collection Kit for the Hologic Aptima Combo 2 for CT/GC.	Page 12
05/2024	1.7	Updated the Immunology/Virology Test menu to include Anti HCV and HCV, Quant tests.	Pages 36-39

TABLE OF CONTENTS

TABLE OF TABLES

TABLE OF FIGURES

Authors

SEAN BERNO
Quality Coordinator

DAVID A. SILVA, M.S., DLM(ASCP)^{CM}
Quality Manager

SHAILA BORNA
Quality Analyst

ELEANOR KIRKSCEY, MPH
Laboratory- Epidemiology Coordinator

Authorized by

DAVID A. SILVA, M.S., DLM(ASCP)^{CM}
Quality Manager

KAYLE CIRRINCIONE
Health & Safety Manager

DAVID J. STRINGER
General Laboratory Supervisor

LUKE C. SHORT, Ph.D., HCLD (ABB)
PHL Director

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	(469) 578–3048
David A. Silva, M.S., DLM(ASCP)^{CM}| Quality Manager	(972) 692-2763
David J. Stringer | General Laboratory Supervisor	(972) 692-2762
Supervisory Staff	
Reginald Watkins | Immunology Technical Supervisor	(214) 819-1959
Raquel Salmeron | STAT Team Lead	(214) 819-2182

Joy A. Wesley, M.S. | Microbiology Technical Supervisor	(214) 819-1956
Victor Amadi, Ph.D. | LIS Coordinator	(214) 819-2840
Farruk Kabir, Ph.D. | NGS Bioinformatician	(972) 692-2767
Alexandra Portman | LRN/BT Coordinator	(972) 692-2708
Eleanor Kirkscey, MPH | Lab-Epi Coordinator	(972) 692-2711

1.5 Laboratory Bulletins and Memorandums

The DCHHS Laboratory Division will issue bulletins, or memorandums to health providers and staff 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 staff. 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 the 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) Approved by the Texas Department of State Health Services

(b) Acceptable to the DCHHS PHL Director

(c) 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/Mycobacteriology[1]/Parasitology)
- **Immunology/Virology**
- **STAT[1]**
- **Laboratory Response Network[2]**

[1]The STAT and Mycobacteriology Laboratories only service internal submitters.
[2]The Laboratory Response Network (LRN) only services approved sentinel laboratories and special-need communities. Contact the LRN/BT Coordinator for more information

2.2 Definitions

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

ABX	Antibiotic Treatment
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
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

2.3 Bacteriology Test Menu

1. *Chlamydia trachomatis/Neisseria gonorrhoeae*, NAAT

2.4 Parasitology Test Menu

2. *Trichomonas vaginalis*, NAAT

2.5 Mycobacteriology Test Menu

3. *Mycobacterium tuberculosis* complex and Rifampin Resistance, NAA
4.
5. **Acid – Fast (Mycobacteria) Smear with Concentration**
6.
7. Acid – Fast (Mycobacteria) Concentration and Culture with Reflex to Identification

2.6 Immunology/Virology Test Menu

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

2.7 STAT Test Menu

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

2.8 LRN Test Menu

28. Non-variola *Orthopoxvirus*, RT – PCR

29. Select Agent Testing and Other Biological Threats

2.3 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 and Multitest 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. Excessive mucoid specimens may decrease sensitivity of assay. Remove excess mucus during endocervical sampling using Cleaning Swab[1] (White shaft in package with red printing).

2.4 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 male urine validated by DCHHS)* 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 Swab[1] (White shaft in package with red printing).

2.5 Mycobacteriology

IMPORTANT: The DCHHS Mycobacteriology Laboratory only accepts specimens from the DCHHS TB Elimination Clinic. All other specimens are currently not accepted 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 the *rpoB* mutation associated with rifampin resistance
Reference Interval	MTB Complex Not Detected and Rifampin Resistance Not Detected
Specimen Type:	Induced or Expectorated Sputum
Volume:	3mL to 5mL
Collection Container	50mL Conical Falcon Tube
Patient Criteria for Testing	New patient (≥18 years) who has been on antibiotic treatment for three (3) days or less at time of specimen collection. See **Appendix 19.3** for further details on patient criteria for testing along with how to document this information on the LabOnline test request.
Transportation	**2°C to 8°C** Submit within SEVEN DAYS
Limitations:	1. Specimens from patient who have been on anti-tuberculosis therapy for more than **three (3) days** will not be tested. 2. The performance of the Cepheid Xpert MTB/RIF Assay has not been evaluated by DCHHS Laboratory in adolescents less than **18 years of age**. 3. The assay should be used in conjunction with mycobacterial culture to address the risk of false negative results. Additionally, 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 Expectorated Sputum
Volume:	3mL to 5mL
Collection Container:	50mL Conical Falcon Tube
Transportation	**2°C to 8°C** Submit within SEVEN DAYS

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 Culture ID with the GeneXpert MTB/RIF Assay
Biological Principle	Continuous Monitoring Broth Culture System Conventional Culture Qualitative, nested real-time polymerase chain reaction (PCR) *in vitro* diagnostic test
Intended Use	Detect and identify Mycobacterium in patient specimens
Reference Interval	***Mycobacterium spp.*** 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

2.6 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 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 (*i.e.*, separated from RBCs) within two hours of centrifugation. Samples spun down sooner than 30 minutes from time of collection will be reviewed to ensure proper separation. Samples determined to have adequate separation will be checked in and tested. If separation is determined to be insufficient, the sample will be rejected.

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, or <-20°C with dry ice (if appropriate) 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 range. Refer to the assay information and/or contact the laboratory for further instructions on submission of frozen samples.

6) The DCHHS LABORATORY **RECOMMENDS** the delivery of SERUM or PLASMA specimens within **48 hours from time of collection**. Specimens received outside of the **48 – hour submission** window may have disruptions to needed downstream and confirmatory HIV/Syphilis tests.

   (a) PLEASE NOTE: The rejection of specimens will be at the discretion of the Unit Team Leader or Laboratory Director.

7) Approximately 7.5mL Whole Blood (≈5mL Serum) is sufficient to perform all Immunological assays, however, we strongly recommend collecting and submitting **THREE 7.5mL blood tube**s if requesting HIV, Syphilis, and Hepatitis C Virus testing.

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 19.1** for **HIV Result Interpretive Guidelines**, **Appendix 19.2** for **Syphilis Result Interpretative Guidelines**, and **Appendix 19.4** for **Hepatitis C Virus Result Interpretative Guidelines.**

10) New whole blood samples should be drawn after two to four weeks in the event of Equivocal or Invalid final interpretations for HIV, Syphilis, and Hepatitis C Virus 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 contains a silicone – coated interior tube wall. **Preferred** – BD Vacutainer SST Blood Collection Tubes (Reference № 367987; 7.5 mL volume; 16 x 100 mm) **Plastic Transfer Tube** (if specimen is to be frozen)
Storage/Preservation:	The specimen must be stored at one of the following conditions: • Store specimens at 2°C to 8°C, or • Freeze serum specimens in a plastic transfer tube at <-20°C. PLEASE NOTE: DO NOT FREEZE whole blood specimens, or serum specimens in SSTs.
Transportation:	**SERUM (IF REFRIGERATED)**: Transport specimens in an enclosed container with cold packs to ensure the Laboratory receives specimens at 2-8°C within 72 hours of collection. **SERUM (IF FROZEN)**: Transport specimens in an enclosed container with dry ice to ensure the Laboratory receives specimens at the required <-20°C within 90 days of specimen collection. **WHOLE BLOOD:** Deliver at 2-8°C within **TWO HOURS** of collection. **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) **Plastic Transfer Tube** (if specimen is to be frozen)
Storage/Preservation:	The specimen must be stored at one of the following conditions: • Store specimens at 2°C to 8°C, or • Freeze serum specimens in a plastic transfer tube at <-20°C. **PLEASE NOTE**: DO NOT FREEZE whole blood specimens, or serum specimens in SSTs.
Transportation:	**SERUM (IF REFRIGERATED)**: Transport specimens in an enclosed container with cold packs to ensure the Laboratory receives specimens at 2-8°C within 72 hours of collection. **SERUM (IF FROZEN)**: Transport specimens in an enclosed container with dry ice to ensure the Laboratory receives specimens at the required <-20°C within 90 days of specimen collection. **WHOLE BLOOD:** Deliver at 2-8°C within **TWO HOURS** of collection. **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 reagin 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 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) **Plastic Transfer Tube** (if specimen is to be frozen)
Storage/Preservation:	The specimen must be stored at one of the following conditions. • Store specimens at 2°C to 8°C, or • Freeze serum specimens in a plastic transfer tube at <-20°C. **PLEASE NOTE**: DO NOT FREEZE whole blood specimens, or serum specimens in SSTs.
Transportation:	**SERUM (IF REFRIGERATED)**: Transport specimens in an enclosed container with cold packs to ensure the Laboratory receives specimens at 2-8°C within 72 hours of collection. **SERUM (IF FROZEN)**: Transport specimens in an enclosed container with dry ice to ensure the Laboratory receives specimens at the required <-20°C within 90 days of specimen collection. **WHOLE BLOOD:** Deliver at 2-8°C within **TWO HOURS** of collection. **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 2.5**
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) **Plastic Transfer Tube** (if specimen is to be frozen)
Storage/Preservation:	The specimen must be stored at one of the following conditions. • Store specimens at 2°C to 8°C, or • Freeze serum specimens in a plastic transfer tube at <-20°C. **PLEASE NOTE**: DO NOT FREEZE whole blood specimens, or serum specimens in SSTs.
Transportation:	**SERUM (IF REFRIGERATED)**: Transport specimens in an enclosed container with cold packs to ensure the Laboratory receives specimens at 2-8°C within 72 hours of collection. **SERUM (IF FROZEN)**: Transport specimens in an enclosed container with dry ice to ensure the Laboratory receives specimens at the required <-20°C within 90 days of specimen collection. **WHOLE BLOOD:** Deliver at 2-8°C within **TWO HOURS** of collection. **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 2.5**
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) **Plastic Transfer Tube** (if specimen is to be frozen)
Storage/Preservation:	The specimen must be stored at one of the following conditions. • Store specimens at 2°C to 8°C, or • Freeze serum specimens in a plastic transfer tube at <-20°C. **PLEASE NOTE**: DO NOT FREEZE whole blood specimens, or serum specimens in SSTs.
Transportation:	**SERUM (IF REFRIGERATED)**: Transport specimens in an enclosed container with cold packs to ensure the Laboratory receives specimens at 2-8°C within 72 hours of collection. **SERUM (IF FROZEN)**: Transport specimens in an enclosed container with dry ice to ensure the Laboratory receives specimens at the required <-20°C within 90 days of specimen collection. **WHOLE BLOOD:** Deliver at 2-8°C within **TWO HOURS** of collection. **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.
Interpretation	Please note, a nonreactive result on the HIV - 1 and HIV – 2 Ag – Ab Diagnostic Screen, 5th Gen. assay is a standalone assay result that can be used in the diagnosis of the patient. If acute HIV infection is suspected, review HIV -1 RNA, NAAT – Qualitative results.

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) **Plastic Transfer Tube** (if specimen is to be frozen)
Storage/Preservation:	Within the first 24 hours after collection, the specimen must be stored at one of the following conditions. • Store specimens at 2°C to 8°C, or • Freeze serum specimens in a plastic transfer tube at <-20°C. **PLEASE NOTE**: DO NOT FREEZE whole blood specimens, or serum specimens in SSTs. **IMPORTANT**: Once a specific storage route is chosen, the specimen must be maintained at these conditions through specimen receipt by the laboratory.
Transportation:	**SERUM (IF REFRIGERATED)**: Transport specimens in an enclosed container with cold packs to ensure the Laboratory receives specimens at 2-8°C within 72 hours of collection. **SERUM (IF FROZEN)**: Transport specimens in an enclosed container with dry ice to ensure the Laboratory receives specimens at the required <-20°C within 90 days of specimen collection. **WHOLE BLOOD:** Deliver at 2-8°C within **TWO HOURS** of collection. **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 K_2EDTA, K_3EDTA, ACD, sodium citrate, Becton-Dickinson EDTA Plasma Preparation Tubes (BD PPT) **Plastic Transfer Tube** (if specimen is to be frozen)
Storage/Preservation:	Within the first 24 hours after collection, the specimen must be stored at one of the following conditions. • Store specimens at 2°C to 8°C, or • Freeze serum specimens in a plastic transfer tube at <-20°C. **DO NOT FREEZE** whole blood specimens, or serum specimens in SSTs. **IMPORTANT**: Once a specific storage route is chosen, the specimen must be maintained at these conditions through specimen receipt by the laboratory.
Transportation:	**SERUM OR PLASMA (IF REFRIGERATED)**: Transport specimens in an enclosed container with cold packs to ensure the Laboratory receives specimens at 2-8°C within 72 hours of collection. **SERUM (IF FROZEN)**: Transport specimens in an enclosed container with dry ice to ensure the Laboratory receives specimens at the required <-20°C within 90 days of specimen collection. **WHOLE BLOOD:** Deliver at 2-8°C within **TWO HOURS** of collection. If specimens are frozen – within 90 days, 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 with Regular FLOQSwab Set (Cat. No. 502CS01)
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
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.
Limitations	1. Negative results do not preclude SARS-CoV-2 infections and should be used as the sole basis for treatment or tother management decisions. 2. 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
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. № 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.

Anti-Hepatitis C Virus (Anti-HCV)	
Analyte	Hepatitis C Virus (HCV) HCr43 protein (NS3 region of HCV) and c100-3 antigen (NS3 and NS4 regions of HCV) and HCV Antibodies
Assay Name	Alinity i Anti-HCV Assay
Biological Principle	Multiplex Flow Immunoassay
Intended Use	Multiplex Flow Immunoassay for the simultaneous qualitative detection of HCV HCr43 protein, c100-3 antigen, and HCV antibodies in human serum.
Reference Interval	Nonreactive
Specimen Type	Whole Blood, Serum or Plasma
Volume	See important notice under **Section 2.5**
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) **Plastic Transfer Tube** (if specimen is to be frozen)
Storage/Preservation:	The specimen must be stored at one of the following conditions. • Store specimens at 2°C to 8°C, or • Freeze serum specimens in a plastic transfer tube at <-20°C. **PLEASE NOTE**: DO NOT FREEZE whole blood specimens, or serum specimens in SSTs.
Transportation:	**SERUM (IF REFRIGERATED)**: Transport specimens in an enclosed container with cold packs to ensure the Laboratory receives specimens at 2-8°C within 72 hours of collection. **SERUM (IF FROZEN)**: Transport specimens in an enclosed container with dry ice to ensure the Laboratory receives specimens at the required <-20°C within 90 days of specimen collection. **WHOLE BLOOD:** Deliver at 2-8°C within **TWO HOURS** of collection. **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 reactive anti-HCV result does not exclude co-infection by another hepatitis virus. 2. The performance of the Alinity i Anti-HCV Assay has not been established for neonates and is not used in individuals younger than 17 years of age.

3. 3. Bacterially contaminated, icteric, lipemic hemolyzed or heat inactivated samples may cause erroneous results and should be avoided.

HCV, NAAT – Qualitative and Quantitative (Viral Load)	
Analyte	Viral RNA of Hepatitis C (HCV)
Assay Name	Hologic Aptima HCV Quant Dx Assay
Biological Principle	*In vitro* nucleic acid assay system for the detection of HCV RNA
Intended Use	Aid in the diagnosis of HCV active infection
Reference Interval	Nonreactive
Specimen Type	Whole Blood, Serum or Plasma
Volume	See important notice under **Section 2.6 , OR** **2.0mL Plasma** (separated from RBCs, HCV Quant 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 K_2EDTA, K_3EDTA, ACD, sodium citrate, Becton-Dickinson EDTA Plasma Preparation Tubes (BD PPT) **Plastic Transfer Tube** (if specimen is to be frozen)
Storage/Preservation:	Within the first 24 hours after collection, the specimen must be stored at one of the following conditions. • Store specimens at 2°C to 8°C, or • Freeze serum specimens in a plastic transfer tube at <-20°C. **DO NOT FREEZE** whole blood specimens, or serum specimens in SSTs. **IMPORTANT**: Once a specific storage route is chosen, the specimen must be maintained at these conditions through specimen receipt by the laboratory.
Transportation:	**SERUM OR PLASMA (IF REFRIGERATED)**: Transport specimens in an enclosed container with cold packs to ensure the Laboratory receives specimens at 2-8°C within 72 hours of collection. **SERUM (IF FROZEN)**: Transport specimens in an enclosed container with dry ice to ensure the Laboratory receives specimens at the required <-20°C within 90 days of specimen collection. **WHOLE BLOOD:** Deliver at 2-8°C within **TWO HOURS** of collection. If specimens are frozen – within 90 days, 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.

2.7 STAT

IMPORTANT: Only specimens submitted from the DCHHS Sexual Health Clinic (SHC) are eligible for STAT Laboratory Testing. All other specimens are not accepted 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:	K_2EDTA 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	1:1 to 1:2048 Titer
Specimen Type:	Whole Blood or Plasma
Volume	5mL Whole Blood in EDTA
Collection Container:	K_2EDTA 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:	K_2EDTA 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 *Treponema 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 within ten (10) minutes 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. 4. Direct Smears must be read within 20 minutes of collection. Providers must transport the direct smear to the STAT Laboratory ASAP (see *Transportation* guidelines listed above). Any appreciable delay in transporting the specimen may result in reduced diagnostic value.

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:	K_2EDTA 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 mlU/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

2.8 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 O*rthopoxvirus* 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℃ to 8℃) or **freeze** (-20℃ or lower) specimens **WITHIN AN HOUR** after collection. 2. Send refrigerated samples (2℃ to 8℃) as a Category B agent with cold packs within 7 days. 3. Send frozen samples (-20℃ or lower) with dry ice as a Category B agent. **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 Treats (LRN – B) serves as a Reference Laboratory for Dallas County Sentinel Laboratories. We offer several distinct tests offered for identifying biological threats, emerging diseases, and other high consequence pathogens.

DCHHS LRN – B Clients must be registered as 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.

2.9 Algorithm/Reflex Testing

1) 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, 5th Gen. Diagnostic Screen **REACTIVE**	**HIV Antibody Confirmation & Differentiation**
HIV -1 and HIV – 2 Ab - Ag, 5th 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, 5th Gen. Diagnostic Screen **NONREACTIVE:**	
Treponema pallidum Antibodies (Bio-Rad Syphilis Total) **REACTIVE**	**RPR Qualitative** AND/OR **RPR Titer (if required)**
Treponema pallidum Antibodies (Bio-Rad Syphilis Total) **REACTIVE** AND RPR Qualitative **NONREACTIVE/INCONCLUSIVE**	**Treponema pallidum – Particle Agglutination (TPPA)**
Alinity i Anti-Hepatitis C Virus (Anti-HCV) Assay **REACTIVE**	**HCV, NAAT – Qualitative and Quantitative (Viral Load)**

Table 2 Tuberculosis Reflex Testing

Result:	Action to be performed:
Mycobacterial Culture **AFB DETECTED**	**Culture ID by GeneXpert MTB/RIF Assay**
Culture ID by GeneXpert MTB/RIF Assay **MTB POSITIVE** **AND** The patient's first **POSITIVE MTB** laboratory diagnosis **OR** At least **THREE MONTHS** since first **POSITIVE MTB** result	**Send out to DSHS Laboratory for Anti-mycobacterial Susceptibility Testing of *Mycobacterium tuberculosis* complex** AND **Shipment to Texas DSHS Laboratory for sequencing**
Culture ID by GeneXpert MTB/RIF Assay **MTB NEGATIVE**	**Shipment to Texas DSHS Laboratory for secondary identification testing**

2.10 Testing Outside of Algorithm

1) On a limited basis, DCHHS PHL Clients can provide a written request to the DCHHS PHL Director to perform clinical laboratory testing outside of the algorithm described in Section 2.9 Algorithm/Reflex Testing. These special requests will be reviewed, and a final decision made at the discretion of the PHL Laboratory Director. The Client will be notified of the final decision in regard to these special test requests.

2) IMPORTANT: The DCHHS PHL will not provide final interpretative guidelines for specimens tested outside of the prescribed DCHHS testing algorithm. Instead, ONLY the individual result for the assays performed will be provided.

2.11 Additional Testing on Previously Collected Specimens

DCHHS Laboratory Division accepts 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.

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

(iv) LabOnline Chain ID

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

(d) **Swab collections for Aptima GC/CT and Trich Testing Only**: Location of Collection (*i.e.*, rectal, throat, urethral specimens).

2) Does not have information that conflicts 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 place onto the correct specimen, especially in instances where multiple specimens may be collected, and multiple labels produced. Inconsistences may cause delays.

(c) **Mycobacteriology Lab 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 Electronic Test Request: LabOnline Portal

1) Please note: The following tests and/or test systems are currently active on the LabOnline Portal:

   (a) HIV Screen with Reflex

   (b) HIV-1 RNA, NAAT

   (c) Syphilis Screen with Reflex

   (d) Chlamydia and Gonorrhoeae, NAAT

2) The LabOnline Portal will generate an appropriate Test Requisition that must be included with EACH submitted patient specimen. The LabOnline portal will solicit the requisite patient and specimen information from the client when a test order is placed.

3) Instructions for navigating DCHHS LabOnline Portal are described in the ***DCHHS – L3I-02 LabOnline Help Guide.***

4) Please note: In the event of LabOnline being inoperable, Submitters must:

   (a) Immediately notify the Laboratory Director of LabOnline issues. If unreachable, contact other administrative staff. See section 1.4 Administrative Staff Directory for contact information.

   (b) Either of the following methods can be used to place an order in the event of LabOnline being non-functional:

      (i) Complete and submit Official DCHHS Requisition Forms for each collected specimen until LabOnline service is reestablished. All Test Requisitions MUST SOLICIT the following patient information:

i. Patient's FULL FIRST and LAST name, or another unique identifier

ii. **NOTE:** The unique identifier on the tube must match the unique identifier on the requisition.

iii. Date of Birth

iv. Biological Sex

v. Clinic or hospital address and phone number

vi. Collecting Health Provider

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

viii. Date of Collection

ix. Time of Collection is REQUIRED for the following specimens: a) **Blood**: Whole, Plasma, or Serum, b) **Nasopharyngeal** (SARS – CoV – 2 and Influenza SARS – CoV - 2), and c) Syphilis Darkfield – STAT Laboratory

x. Time of Centrifugation for the following specimens: Serum or Plasma Specimens

xi. **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.

xii. **Mycobacteriology Lab 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.

xiii. **Mycobacteriology Lab ONLY**: Indicate on the order requisition whether the specimen was collected from a new patient who has been on antibiotic treatment for three (3) days or less.

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

(ii) Submit a verbal test request for each collected specimen until EHR service is reestablished.

i. NOTE: Verbal test requests can be verbally communicated to the Laboratory Director. Additionally, these requests can also be made through an email to the Laboratory Director.

4.2 Internal Submitter Requisition

1) Submitters/Clinics within the Dallas County Organization can submit electronic test requisitions through the EPIC Electronic Health Record (EHR) System. The test orders will be automatically transferred from the EPIC EHR System to the Laboratory's HORIZON LIS.

2) The EPIC EHR solicits the requisite patient and sample information required for a specific laboratory test order.

3) In the event the EPIC EHR is inoperable, Internal Submitters must:

   (a) Immediately notify the Laboratory Director of EHR issues. If unreachable, contact other administrative staff. See *section 1.4 Administrative Staff Directory* for contact information.

4) Submit a paper requisition as outlined above in section 4.1.4(b), or

5) Submit a verbal test request for each collected specimen until EHR service is reestablished.

   (i) NOTE: Verbal test requests can be verbally communicated to the Laboratory Director. Additionally, these requests can also be made through an email to the Laboratory Director.

   (ii) **WARNING** – Any specimens submitted to the STAT or Main Laboratory without electronic or verbal requests will not be tested and may be discarded if not rectified within the allotted time. It is the responsibility of the Submitter to ensure all specimens are submitted with an accompanying test requisition.

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 mandate 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
K_2EDTA BD Vacutainer Blood Collection Tube 4.0mL with Lavender Top (Reference № 367862)	4°C to 25°C
UTM with Regular FLOQSwab Set (Reference № 502CS01)	2°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 or 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 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, 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) LabOnline Test Requisition is Absent, and Chain ID is not documented on specimen tube.

   (b) Orders not placed through LabOnline Portal if appropriate for a given test system.

   (c) In the event of LabOnline being inoperable, DCHHS Laboratory Test Requisition is missing **REQUIRED** patient and/or 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 processing window for the test to be performed.

(f) In the event of LabOnline being inoperable and DCHHS Test Requisition being back in use, test requisition is missing.

(i) Date of collection and Time of Centrifugation

(g) Discrepancy between patient information on test requisition or LIS and specimen label.

(h) Inappropriate specimen container for the diagnostic assay requested.

(i) Underfilled or overfilled containers.

(j) Unsecured/Leaking container.

(k) Expired collection container

(i) Note – Collection devices expiring the day after collection are typically acceptable. Consult with the Laboratory if this occurs.

(l) Improperly shipped, stored, or prepared specimens at requisite temperatures or conditions.

(m) 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) 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 test 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, K_2EDTA, 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) Samples spun down sooner than 30 minutes from time of collection will be reviewed to ensure proper separation. Samples determined to have adequate separation will be checked in and tested. If separation is determined to be insufficient, the sample will be rejected.

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) 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) **REFRIGERATED SERUM OR PLASMA SPECIMENS:** The specimen MUST be transported to the DCHHS Laboratory cold (2-8°C) within **72 HOURS** of collection to avoid potential rejection.

3) **FROZEN SERUM OR PLASMA SPECIMENS:** The specimen MUST be transported to the DCHHS Laboratory frozen (<-20°C) with dry ice within **90 DAYS** of collection to avoid potential 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) Within **24 hours** of collection, 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.

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.

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.

11.7 Swab Transport and Storage

1) After collection, transport the swab specimens in the appropriate Aptima Tube at 4°C to 30°C.

2) Refer to **Section 6. SPECIMEN TRANSPORTATION.**

12. SPUTUM SPECIMEN COLLECTION

12.1 General Information

1) The DCHHS Tuberculosis Laboratory 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.

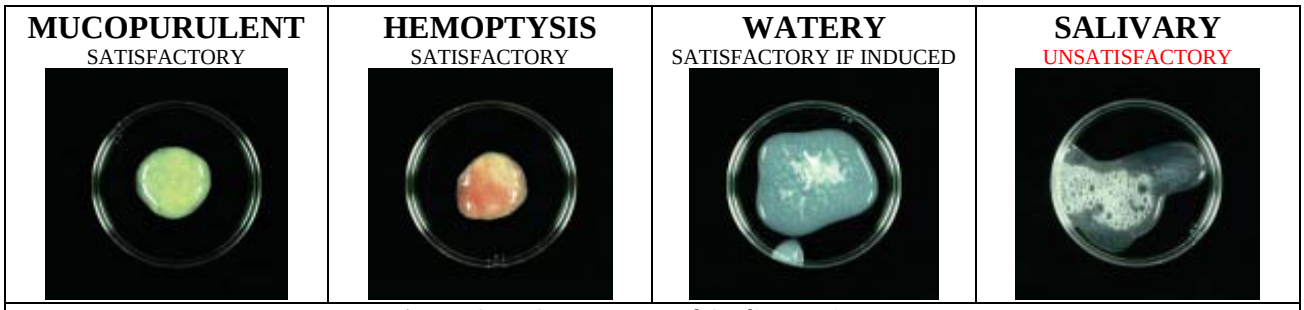


Figure 12.1-1 *Sputum Type and Quality Requirements*

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) The submitter must provide the following information.

(a) Whether the patient is a new to DCHHS or if it is a returning patient.

(i) If the patient is new, indicate whether the patient is undergoing anti-mycobacterial treatment for three (3) days or less, or greater than 3 days.

(ii) NOTE: The Xpert MTB/RIF Assay will only be performed on specimens collected on new patients who have been on antibiotic treatment for 3 days or less. See Appendix 19.2 for further details on testing criteria.

(iii) IMPORTANT: Patients not meeting these criteria will not be tested on the Xpert MTB/RIF Assay unless a documented special request is made via email, via comment on the test requisition, or another method. Each special request will be assessed by the Laboratory Director and/or Unit Technical Supervisor prior to testing, and the final decision will be provided back to the submitter. See Appendix 19.3.

6) 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.

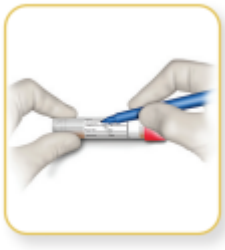
3) Check for nasal obstructions. If there is an obstruction, try the other nostril.

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.

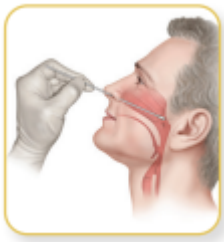
6) While holding the swab in hand, unscrew the tube cap. DO NOT spill the tube contents. Place the swab specimen into 3mL of VTM/UTM.

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.

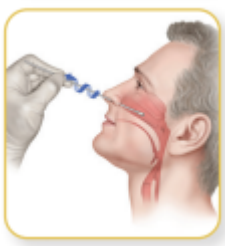


Step 1)

Step 2)



Step 4)



Step 5)

Step 7)

13.2 Storage and Transport

1) Store the sample at 2℃ to 8℃.

2) Submit the sample with sufficient ice packs in an insulated container to maintain a 2℃ to 8℃ 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.

4) If unable to submit within this timeframe, freeze the specimens at <-70℃ and submit with dry ice to the laboratory within 90 days of collection.

14. LESION COLLECTION (M POX)

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. <u>It is not necessary to de-roof the lesion before swabbing.</u>

   (b) If possible, avoid using swabs that bend to 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 not 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 within 7 days 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℃ to 8℃) or frozen (-20℃ 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 $1cm^2$

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 (*i.e*., within 5 minutes) to ensure viability of organism. **Note: The slide must be read by a DCHHS STAT Laboratory Technician within 20 minutes of smear creation.**

16. LABORATORY REPORTS

16.1 Immunology/Virology

1) Immunology and Virology electronic test reports will be available within **FIVE (5) BUSINESS DAYS** of specimen receipt for both external and internal submitters.

   (a) **Internal Submitters** will receive electronic test results through the EPIC EHR system.

   (b) **Outside Submitters** will receive electronic test reports through the LabOnline Portal.

   (c) PLEASE NOTE: 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.

16.2 Bacteriology

1) Bacteriology electronic test reports should be available within **FIVE (5) BUSINESS DAYS** of specimen receipt for both external and internal submitters.

   (a) Internal Submitters will receive test results through the EPIC EHR system.

   (b) **Outside Submitters** will receive electronic test reports through the LabOnline Portal.

   (c) PLEASE NOTE: 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.

16.3 Mycobacteriology

1) Preliminary electronic test results will be received through the EPIC EHR within **ONE (1) BUSINESS DAY** of test completion for the following tests:

   (a) AFB Smear Test

   (b) GeneXpert MTB/RIF Assay (if performed)

   (c) GeneXpert Culture DNA ID Test Results

2) Final electronic culture test results will be available through the EPIC EHR Portal within **SIXTY (60) DAYS** of specimen receipt.

   (a) Submitters will be notified of a delay in the availability of test results.

16.4 STAT

1) STAT Laboratory results will be available within 20 minutes of specimen receipt. The test results will be available via EPIC HER within 20 minutes of sample receipt.

2) Submitters will be notified of a delay in the availability of test results.

16.5 LRN and SARS-CoV-2: Electronic Reports

1) Final electronic test reports will be available through the LabOnline Portal within **FIVE (5) BUSINESS DAYS** for the following tests.

   (a) SARS-CoV-2, TMA

   (b) SARS-CoV-2 & Influenza A/B, RT – PCR

   (c) Non-variola *Orthopoxvirus*, RT – PCR

2) Please note, confirmatory testing results for Select agent specimens, or isolates will be available within **TWO (2) WEEKS** of sample receipt.

17. ADDITIONAL INFORMATION

17.1 Updates on Test Results

1) Submitters seeking information or updates on specific laboratory test results beyond Laboratory's turn-around-times can reach the Laboratory using the following methods:

   (a) Use the ***Contact Laboratory*** feature on LabOnline as described in ***Section 10 of the DCHHS – L3I – 02 LabOnline Help Guide***. These inquiries will be reviewed and directed to the proper team for handling and follow-up.

   (b) Call the Laboratory Office Phone (214) 819 – 1950. Front Office Staff will direct your call to the appropriate party or relay the information.

2) LabOnline Electronic Test Reports – Refer to the ***DCHHS – L3I – 02 LabOnline Help Guide*** for information on navigating LabOnline Portal and retrieving electronic orders or reports.

17.2 Complaints

1) 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 Quant Dx 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 *Infection Unlikely*	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 *Infection Likely*	Based on IgG, RPR and TP-PA results, Immunological evidence of infection with T. pallidum present.
Reactive	Non-Reactive	N/A	Reactive	Syphilis Positive *Infection Likely*	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 *Infection Unlikely*	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.

19.3 Patient Criteria for Xpert MTB RIF Assay Testing

1) To help DCHHS Laboratory Technicians determine a specimen's suitability for testing on the Gene Xpert MTB RIF assay, the EPIC HER will request the following information from the submitter when placing an AFB Culture and Smear test order.

   (a) Patient Antibiotic Status, </=3 days Antibiotics (ABX), Yes, No, or Unknown (*i.e.*, Patient on antibiotic therapy for three (3) days or less at time of collection)

2) Please review the table below for further information on how the DCHHS Laboratory will interpret the various answer combinations on the test request in regard to determining whether Xpert testing will be performed on a specific patient specimen.

	Antibiotic Status (*i.e.*, <= 3 days ABX)	**Perform GeneXpert (Yes or No)**
1	Yes (*i.e.*, 3 days or less on ABX)	**Yes, Xpert MTB RIF assay will be performed on 1st patient specimen**
2	No (*i.e.*, more than 3 days on ABX) *	**No, Xpert MTB/RIF assay will not be performed.**
3	Unknown*	

3) *NOTE: In these scenarios, a written request will be required from submitter to request the Xpert MTB/RIF assay. The Unit Technical Supervisor and/or Laboratory Director will review the request and make a final decision on specimen suitability for test performance.

19.4 DCHHS Hepatitis C Virus Testing Interpretative Guidelines

Results		Final Laboratory Interpretation	Recommended Actions
HCV Antibody	**HCV RNA**		
Non-Reactive	Not Performed	HCV Negative	Antibodies to HCV not detected; does not exclude the possibility of exposure to HCV.
Reactive	Reactive	HCV Positive	Both HCV antibodies and RNA detected. Laboratory evidence of HCV infection is present.
Reactive	Non-Reactive	HCV Negative	Positive for HCV antibodies but RNA was not detected. Laboratory evidence of past HCV infection is present. If appropriate, submit another specimen for testing.
Equivocal	Not Performed	Equivocal	Antibodies to HCV may or may not be present, another specimen should be obtained from the patient for further testing.

DCHHS Client Services Manual. (v1.7)

Final Audit Report 2024-05-18

Created:	2024-05-17
By:	Shaila Borna (Shaila.Borna@dallascounty.org)
Status:	Signed
Transaction ID:	CBJCHBCAABAAoDIiJX1SAcgt0KAVbjD8cVYWTTJq7l9h

"DCHHS Client Services Manual. (v1.7)" History

Document created by Shaila Borna (Shaila.Borna@dallascounty.org)
2024-05-17 - 7:51:35 PM GMT- IP address: 76.164.228.5

Document emailed to David Silva (David.Silva@dallascounty.org) for signature
2024-05-17 - 7:53:15 PM GMT

Email viewed by David Silva (David.Silva@dallascounty.org)
2024-05-17 - 8:00:47 PM GMT- IP address: 76.164.228.5

Document e-signed by David Silva (David.Silva@dallascounty.org)
Signature Date: 2024-05-17 - 8:01:02 PM GMT - Time Source: server- IP address: 76.164.228.5

Document emailed to Kayle Cirrincione (Kayle.Cirrincione@dallascounty.org) for signature
2024-05-17 - 8:01:03 PM GMT

Email viewed by Kayle Cirrincione (Kayle.Cirrincione@dallascounty.org)
2024-05-17 - 8:21:40 PM GMT- IP address: 104.47.64.254

Document e-signed by Kayle Cirrincione (Kayle.Cirrincione@dallascounty.org)
Signature Date: 2024-05-17 - 8:21:59 PM GMT - Time Source: server- IP address: 76.164.228.5

Document emailed to Joey Stringer (Joey.Stringer@dallascounty.org) for signature
2024-05-17 - 8:22:01 PM GMT

Email viewed by Joey Stringer (Joey.Stringer@dallascounty.org)
2024-05-17 - 10:52:35 PM GMT- IP address: 104.47.64.254

Document e-signed by Joey Stringer (Joey.Stringer@dallascounty.org)
Signature Date: 2024-05-17 - 10:52:59 PM GMT - Time Source: server- IP address: 76.164.228.5

Document emailed to Luke Short (Luke.Short@dallascounty.org) for signature
2024-05-17 - 10:53:01 PM GMT

Email viewed by Luke Short (Luke.Short@dallascounty.org)

2024-05-18 - 0:09:22 AM GMT- IP address: 104.47.64.254

Document e-signed by Luke Short (Luke.Short@dallascounty.org)

Signature Date: 2024-05-18 - 0:11:15 AM GMT - Time Source: server- IP address: 47.188.209.57

Agreement completed.

2024-05-18 - 0:11:15 AM GMT