



CLIENT SERVICES MANUAL

Mockingbird Laboratory

DCHHS-ML1Q-01

(VERSION 1.1)

Revised Date: July 2026

Dallas County Health and Human Services Laboratory Division

DCHHS PHL – Mockingbird

CLIA Certificate No. 45D2344320



Document Title:	DCHHS Client Services Manual
Revision:	1.1
Procedure Author(s):	Shaila Borna and Eleanor Chapman, MPH
Date of revision:	July 2026
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	<i>J Stringer</i>	7/1/26
Health & Safety Manager	Kayle Cirrincione	<i>Kayle Cirrincione</i>	7/1/2026
Quality Manager:	Shaila Borna	<i>Shaila Borna</i>	07/01/2026
Laboratory Director:	Luke C. Short, Ph.D., HCLD(ABB)	<i>[Signature]</i>	7/1/26

Laboratory Director Biennial Review

Initial	Date	Initial	Date	Initial	Date



CLIENT SERVICES MANUAL
Document Code: DCHHS-ML1Q-01

Page 3 of 57

Revised: July 2026

[illegible]

Prepared by: Shaila Borna and Eleanor Chapman, MPH

Approved by: Luke C. Short, Ph.D., HCLD (ABB)

Revised Date: July 2026

NOTE: This is a CONTROLLED document for internal use only. Any documents appearing in paper form are not control and should be checked against the server file version prior to use.

**TABLE OF CONTENTS**

1. GENERAL INFORMATION.....	7
1.1 Mission Statement.....	7
1.2 Facility Location	7
1.3 Days & Hours of Operation.....	7
1.4 Administrative Staff Directory	7
1.5 Laboratory Bulletins and Memorandums.....	8
1.6 Interruption of Services	8
1.7 Reference Laboratory	8
2. LABORATORY SERVICES	9
2.1 Scope of Laboratory Services.....	9
2.2 Definitions.....	9
2.3 Test Menu	10
2.4 Bacteriology	11
2.5 Parasitology	13
2.6 Immunology	14
2.7 Virology	29
2.8 LRN – B.....	34
2.9 Algorithm/Reflex Testing	35
2.10 Testing Outside of Algorithm.....	36
2.11 Additional Testing on Previously Collected Specimens.....	36
3. SPECIMEN LABELING REQUIREMENTS	37
4. TEST REQUISITIONS.....	38
4.1 External Submitter Requisition: CliniSys LabOnline Portal.....	38
4.2 Internal Submitter Requisition	39
5. PRIMARY SPECIMEN CONTAINER	40
5.1 Specimen Container.....	40
5.2 Infection Control.....	40
6. SPECIMEN TRANSPORTATION	42
7. SPECIMEN REJECTION	43
7.1 General Policy	43



7.2 Delayed Testing.....	43
7.3 Automatic Rejection	44
8. BLOOD SAMPLE COLLECTION	45
8.1 Venipuncture Technique and Specimen Handling	45
8.2 Blood Specimen Transport	47
9. URINE COLLECTION: GONORRHEA, CHLAMYDIA, TRICHOMONAS	48
9.1 General Information	48
9.2 Bacteriology Urine Collection	48
9.3 Urine Transport and Storage	48
10. SWAB SAMPLE COLLECTION: GONORRHEA, CHLAMYDIA, TRICHOMONAS	49
10.1 General Information	49
10.2 Vaginal Swab.....	49
10.3 Rectal	49
10.4 Throat.....	50
10.5 Anogenital Lesions.....	50
10.6 Swab Transport and Storage	51
11. LABORATORY REPORTS.....	52
11.1 Bacteriology, Immunology, and Virology	52
11.2 LRN	52
12. ADDITIONAL INFORMATION.....	53
12.1 Updates on Test Results	53
12.2 Complaints	53
13. REFERENCES.....	54
14. APPENDIX	55
14.1 DCHHS HIV, Syphilis, and HCV Interpretative Guidelines.....	55

TABLE OF TABLES

Table 1: HIV and HCV Reflex Testing.....	35
Table 2: Specimen Containers and Temperature Requirements	40
Table 3: DCHHS HIV Interpretative Guidelines	55
Table 4: DCHHS Syphilis Testing Interpretative Guidelines.....	56
Table 5: DCHHS Hepatitis C Virus Testing Interpretative Guidelines	57



Authorized by

SHAILA BORNA
Quality Manager

KAYLE CIRINCIONE
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 network 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 is to provide accurate, reliable, and timely test results with an emphasis on excellent community service.

1.2 Facility Location

Dallas County BSL-3 Lab

1410 W Mockingbird Ln, Dallas, TX 75247
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

The Laboratory reserves the right to change observed holidays.

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
Shaila Borna Quality Manager	(214) 819-1939
David J. Stringer General Laboratory Supervisor	(972) 692-2762

Supervisory Staff

Victor Amadi, Ph.D. LIS Coordinator	(214) 819-2840
Eleanor Chapman, MPH Lab-Epi Coordinator	(972) 692-2711



1.5 Laboratory Bulletins and Memorandums

The DCHHS Laboratory Division will issue bulletins or memoranda 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 memoranda 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 such as observation of national holidays, facility improvement or extended in-service training typically will result in short-term halting of services. 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 coordinate confirmatory or referral testing when clinically or programmatically appropriate. Additional patient demographics, specimen information, and diagnostic history may be required before referral.

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.
- d) All reference laboratories utilized by DCHHS must maintain a current and appropriate CLIA certificate for the complexity of testing performed.

Most reference testing is sent to the Texas Department of State Health Services Laboratory. DCHHS and the ordering submitter receive the final report from the performing laboratory. The DCHHS report identifies the performing laboratory and location and does not alter the reference laboratory interpretation.



2. LABORATORY SERVICES

2.1 Scope of Laboratory Services

Testing at **Mockingbird Laboratory** is performed under CLIA certificate **45D2344320** and in accordance with approved test-specific verification, quality control, LIS validation, personnel training and competency, proficiency testing or alternative assessment, and Laboratory Director authorization requirements.

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/Parasitology)
- **Immunology**
- **Laboratory Response Network¹**
- **Virology**

¹The 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 Test Menu

1) Bacteriology Test Menu

- a) *Chlamydia trachomatis/Neisseria gonorrhoeae*, NAAT

2) Parasitology Test Menu

- a) *Trichomonas vaginalis*, NAAT

3) Immunology Test Menu

- a) Treponema pallidum Antibodies
- b) Rapid Plasma Reagin (RPR), Qualitative
- c) Rapid Plasma Reagin (RPR), Quantitative (Titer)
- d) Treponema pallidum – Particle Agglutination (TP – PA)
- e) HIV -1 and HIV – 2 Ag – Ab Diagnostic Screen
- f) HIV Differentiation and Confirmation
- g) Hepatitis C Virus Antibodies (HCV)

4) Virology Test Menu

- a) HIV – 1, NAAT—Qualitative
- b) Herpes Simplex Virus 1 & 2(HSV), NAAT
- c) HCV, NAAT – Qualitative and Quantitative (Viral Load)

5) LRN Test Menu

- a) Select Agent Testing and Other Biological Threats



2.4 Bacteriology

Chlamydia trachomatis/Neisseria gonorrhoeae, NAAT

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

Assay Name Hologic Aptima Combo 2 for CT/GC

Biological Principle Multiplex transcription – mediated amplification (TMA)

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

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

Specimen Type **Female/Male Urine**

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

Rectal, Throat, Male Urethral, Vaginal and Endocervical Swabs

Clinician–collected rectal, throat, endocervical, and male urethral swabs only (patient –collected not validated by DCHHS)

Clinician–collected and patient–collected vaginal swabs 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, RECTAL, AND VAGINAL SWAB

Aptima Multitest Swab Specimen Collection Kit for Throat, Rectal, and Vaginal Swab Specimens

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. Testing in individuals less than 14 years of age is outside the FDA-cleared intended use of this assay and will not be performed by DCHHS.
2. Excessive mucoid specimens may decrease sensitivity of assay. Remove excess mucus during endocervical sampling using Cleaning Swab¹ (White shaft in package with red printing).



2.5 Parasitology

Trichomonas vaginalis, NAAT

Analyte	Ribosomal RNA of <i>Trichomonas vaginalis</i>
Assay Name	Aptima <i>Trichomonas vaginalis</i> Assay
Biological Principle	Transcription – mediated amplification (TMA)
Intended Use	Detection of <i>Trichomonas vaginalis</i> to aid in the diagnosis of trichomoniasis
Reference Interval	NEGATIVE for <i>Trichomonas vaginalis</i>
Specimen Type	<u>Female/Male Urine</u> Patient – Collected; 1 st Catch (less than 1 hour since urination; 20 – 30mL) Vaginal Swabs Clinician–collected and patient—collected vaginal swabs validated by DCHHS

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.

VAGINAL SWAB

Aptima Multitest Specimen Collection Kit for Vaginal 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. Testing in individuals less than 14 years of age is outside the FDA-cleared intended use of this assay and will not be performed by DCHHS.
2. Excessively mucoid specimens may decrease sensitivity of assay. Remove excess mucus during endocervical sampling using Cleaning Swab¹ (White shaft in package with red printing).



2.6 Immunology

Critical Information on Blood Specimen Submission

- 1) The DCHHS PHL accepts **WHOLE BLOOD** and **SERUM** 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 4.23) During Epic or CliniSys downtime, submitters must use the approved DCHHS downtime requisition. (See Section 4.1 External Submitter Requisition)
 - d) 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 collection. 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 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 specimens within **48 hours from time of collection**.

Specimens received beyond 48 hours will be evaluated against documented assay stability criteria prior to acceptance.

- a) PLEASE NOTE:



Specimen rejection will follow the established criteria outlined in Section 7: Specimen Rejection. All rejection decisions will be documented.

- 7) Approximately 7.5mL Whole Blood ($\approx$ 5mL Serum) is sufficient to perform all Immunological assays, however, we strongly recommend collecting and submitting **THREE 7.5mL blood tubes** if requesting HIV, Syphilis, and Hepatitis C Virus testing.
- 8) Refer to **Appendix 14.1, Tables 2 through 4, for HIV, Syphilis, and Hepatitis C Virus** result interpretive guidelines.
- 9) 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 <i>Treponema pallidum</i> (Syphilis)
Assay Name	Bio-Rad 2200 Syphilis Total Assay
Biological Principle	Multiplex flow immunoassay
Intended Use	Qualitative detection of <i>Treponema pallidum</i> IgG/IgM antibodies in human serum to aid in the diagnosis of syphilis infection
Reference Interval	Nonreactive
Specimen Type	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°C to 8°C within 48 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. IMPORTANT: The PHL will perform a temperature check of the secondary transport container (<i>i.e.</i>, 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	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 48 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. IMPORTANT: The PHL will perform a temperature check of the secondary transport container (<i>i.e.</i>, 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	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°C to 8°C within 48 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. IMPORTANT: The PHL will perform a temperature check of the secondary transport container (<i>i.e.</i>, 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 <i>Treponema pallidum</i>
Assay Name	Fujirebio SERODIA TP – PA
Biological Principle	Immunological particle – agglutination test for the detection of antibodies to <i>Treponema pallidum</i>
Intended Use	Serve as an aid in the diagnosis of infection by <i>Treponema pallidum</i> in serum
Reference Interval	Nonreactive
Specimen Type	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°C to 8°C within 48 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. IMPORTANT: The PHL will perform a temperature check of the secondary transport container (<i>i.e.</i>, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.
Limitations:	Samples from patients with HIV, Leprosy, Toxoplasmosis, <i>H. pylori</i> , 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**

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 *AND/OR**
Alinityi HIV Combo Assay

Biological Principle Bio-Rad BioPlex 2200 HIV Ag – Ab Assay: Multiplex Flow Immunoassay
Alinityi HIV Combo Assay: Chemiluminescent Microparticle Immunoassay (CMIA)

Intended Use Bio-Rad BioPlex 2200 HIV Ag – Ab Assay: Multiplex Flow Immunoassay for the simultaneous qualitative detection of HIV p24 antigen and antibodies to HIV – 1 and HIV – 2 in human serum.

Alinityi HIV Combo Assay: Chemiluminescent Microparticle Immunoassay (CMIA) 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 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°C to 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 $<-20^{\circ}\text{C}$ within 90 days of specimen 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 assay is a standalone assay result that can be used in the diagnosis of the patient. If acute HIV infection is suspected, request additional testing according to the guidelines in section **2.8 Testing Outside of Algorithm**.

***Please note:** The Alinityi HIV Combo Assay will only be performed if the initial Bio-Rad BioPlex 2200 HIV Ag – Ab Assay fails or otherwise does not produce 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	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°C to 8°C within 48 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. IMPORTANT: The PHL will perform a temperature check of the secondary transport container (<i>i.e.</i>, 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.

**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 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°C to 8°C within 48 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.

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



2.7 Virology

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 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: **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 No 367987; 7.5 mL volume; 16 x 100 mm)

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

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 48 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.

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.

**Herpes Simplex Virus 1 & 2(HSV), NAAT**

Target: An in vitro diagnostic nucleic acid amplification test (NAAT) for the qualitative detection and differentiation of herpes simplex virus type 1 (HSV-1) and type 2 (HSV-2) messenger RNA (mRNA).

Test Name: Aptima HSV 1 & 2 assay

Method: Panther system utilizes target capture, transcription mediated amplification (TMA) and real-time detection of HSV-1, HSV-2, and an internal control (IC).

Intended Use: Aid in the diagnosis of HSV 1 & 2 infection in symptomatic male and female patients.

Reference Range: The reference interval for the typical DCHHS patient population is HSV-1 and HSV-2 negative.

Specimen Type: Swab specimens from anogenital skin lesions

Volume N/A

Collection Container: Aptima Multitest Swab Specimen Collection Kit

The DCHHS Laboratory has only verified the performance of this assay using the Aptima Multitest Swab Specimen Collection kit

Transportation: **2°C to 30°C**
must be tested within 36 days of collection

-20°C to -70°C
May also be tested with the Aptima HSV 1&2 assay within 36 days of collection

- Limitations**
1. Reliable results are dependent on adequate specimen collection, transport, storage, and processing.
 2. The device is not intended for use with cerebrospinal fluid or for prenatal screening.

**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** Serum or Plasma**Volume** See important notice under **Section 2.6 , OR**
2.0mL Plasma (separated from RBCs, HCV Quant only)

Collection Container: **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 No 367987; 7.5 mL volume; 16 x 100 mm)

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

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 48 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.

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.



2.8 LRN – B

Select Agent Testing and Other Biological Threats

The DCHHS Laboratory Response Network for Biological Threats (LRN – B) serves as a Reference Laboratory for Dallas County Sentinel Laboratories. We offer several distinct tests 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 DCHHS PHL at 214 - 819 - 1950 for any inquiries regarding Select Agent testing.



2.9 Algorithm/Reflex Testing

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

Table 1: HIV and HCV Reflex Testing

Result:	Action to be performed:
HIV-1 and HIV-2 Ab/Ag, 5 th Gen. Diagnostic Screen REACTIVE	HIV Antibody Confirmation & Differentiation
HIV -1 and HIV – 2 Ab - Ag, 5 th Gen. Diagnostic Screen REACTIVE AND HIV Antibody Confirmation & Differentiation NONREACTIVE or INDETERMINATE	Aptima HIV-1 Quant Dx Assay (NAAT)
HIV -1 and HIV – 2 Ab – Ag, 5 th Gen. Diagnostic Screen NONREACTIVE	No further testing performed. Result final. HIV RNA pooling has been discontinued as of February 2026. All HIV-1 RNA testing will be performed on individual specimens.
<i>Treponema pallidum</i> Antibodies (Bio-Rad Syphilis Total) REACTIVE	RPR Qualitative AND/OR RPR Titer (if required)
<i>Treponema pallidum</i> Antibodies (Bio-Rad Syphilis Total) REACTIVE AND RPR Qualitative NONREACTIVE/INCONCLUSIVE	Treponema pallidum – Particle Agglutination (TPPA)
Alinity i Anti-Hepatitis C Virus (Anti-HCV) Assay REACTIVE	HCV, NAAT – Qualitative and Quantitative (Viral Load)

Please note: Samples ordered under the HIV PrEP/nPEP testing option will receive both HIV -1 and HIV – 2 Ab – Ag, 5th Gen. Diagnostic Screen and Aptima HIV-1 Quant Dx ASSAY (NAAT) testing regardless of the 5th Gen. result per standard PrEP and nPEP testing guidelines. Both assays are performed in tandem and neither assay is considered a reflex test when this option is selected. Additionally, HIV-1 RNA testing is not performed as a standalone assay outside of the defined PrEP/nPEP pathway or documented public health or legal exceptions.



2.10 Testing Outside of Algorithm

- 1) On a limited basis, DCHHS PHL Clients can provide a written request via encrypted email, to the DCHHS PHL Director to perform clinical laboratory testing outside of the algorithms described in Section 2.9 Algorithm/Reflex Testing. Algorithm exception requests will be reviewed, and a final decision made by the PHL Laboratory Director according to overarching regulatory requirements and documented PHL policy.
- 2) IMPORTANT: The PHL will not provide final interpretative guidelines for specimens tested outside of the prescribed PHL testing algorithm. Instead, only the individual result for each assays performed will be provided.
- 3) EXCEPTIONS:

Requesting additional testing for HIV PrEP and nPEP patient specimens does not require prior approval. To request the HIV PrEP algorithm (both HIV -1 and HIV – 2 Ab – Ag, 5th Gen. Diagnostic Screen AND Aptima HIV-1 Quant Dx ASSAY (NAT) is performed, per standard testing requirements, please select the “PrEP or nPEP HIV screen” test option when ordering via Clinisys LabOnline or EPIC.

2.11 Additional Testing on Previously Collected Specimens

- 1) DCHHS PHL can accept requests for additional testing to be performed on specimens already in the custody of the PHL. These specimens must meet the following requirements for consideration.
 - a) The specimen must meet all requirements for the requested testing/assay. This includes, but is not limited to, being within the allowable stability window of the requested testing/assay. Additional testing on previously collected specimens will be performed only if specimen storage conditions and stability remain within manufacturer instructions or documented DCHHS validation parameters. Provider authorization and rationale will be documented in the LIS.
 - b) The testing/assay requested must align with the original testing intent. Requests for testing outside the original intent will require new orders and authorization. (*i.e.*, a request for syphilis testing on a specimen that has undergone HIV testing only, and was not designated as a shared tube, will require a new order.)

To request additional testing, contact the Lab-Epi Coordinator to determine if the specimen(s) meet the eligibility requirements and they will coordinate submitting a request to the Laboratory Director.



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 in a manner that does not impede specimen processing. This includes ensuring all labels are vertical, flush with the sample, and do not cover volume indicator windows (*i.e.* no label “flags” and the Aptima Urine Tube window is visible).

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



4. TEST REQUISITIONS

4.1 External Submitter Requisition: CliniSys LabOnline Portal

- 1) Please note: The following tests and/or test systems are currently active on the CliniSys LabOnline Portal:
 - a) HIV Screen with Reflex
 - b) HIV PrEP/nPEP
 - c) Syphilis Screen with Reflex
 - d) Chlamydia and Gonorrhoeae, NAAT
 - e) *Trichomonas vaginalis*, NAAT (*requires prior approval from Laboratory Director*)
- 2) The CliniSys LabOnline Portal will generate a Test Requisition that must be included with EACH submitted patient specimen. The CliniSys LabOnline portal will solicit the requisite patient and specimen information from the client when a test order is placed.
- 3) Instructions for navigating DCHHS CliniSys LabOnline Portal are described in the ***DCHHS-ML3I-02 LabOnline Help Guide***.
- 4) During Epic or CliniSys downtime, submitters must use the approved DCHHS downtime requisition.
 - a) The electronic order or approved downtime requisition must include the ordering provider or clinic and contact information, patient name or unique identifier, sex and age or date of birth, test(s) requested, specimen source when applicable, collection date and time, and test-specific clinical information needed for accurate testing and interpretation.
 - b) The laboratory may accept an oral test request only when necessary to avoid delay in patient care. The request must be received from an authorized person and documented contemporaneously by authorized laboratory staff.
- 5) For each oral request, the laboratory will solicit written or electronic authorization within 30 days and retain the authorization or documentation of efforts to obtain it.
- 6) When the electronic systems are restored, downtime and oral orders must be reconciled to the patient record and CliniSys LIS according to the approved downtime procedure.
 - (i) Specimens without a valid order will be held only within the established test-specific stability window and handled under Section 7. Email alone is not a substitute for the approved order or documented oral-request process.
 - (ii) **Specimens will not be tested until a valid request is available. The submitter is responsible for ensuring that every specimen is linked to a complete electronic order or approved downtime requisition.**



4.2 Internal Submitter Requisition

- 1) Submitters/Clinics within the Dallas County Organization must 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 CliniSys LIS.
- 2) The EPIC EHR solicits the requisite patient and sample information required for a specific laboratory test order.
- 3) During Epic or CliniSys downtime, submitters must use the approved DCHHS downtime requisition. (See Section 4.1 External Submitter 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.
- 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.

Table 2: Specimen Containers and Temperature Requirements

Specimen Container	Storage Requirements
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 Multitest Swab Specimen Collection Kit for Throat, Rectal, and Vaginal Swab Specimens (Reference № PDR-03546)	15°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:

**Mockingbird Accessioning Unit
Dallas County Health and Human Services
1410 W Mockingbird Ln, Dallas, TX 75247
Room 140
Phone: (945) 500-2206**

2) Accessioning Unit personnel document the date and time of receipt and perform an initial assessment of the following:

- a) Patient identification and order information agree and meet Section 3 and Section 4 requirements.
- b) Specimen type, collection container, integrity, volume, collection time, temperature when applicable, and test-specific stability meet the current manufacturer instructions and approved SOP.
- c) The specimen is linked to a valid electronic order or approved downtime requisition.

3) Testing personnel perform any additional test-specific acceptability assessment before testing.

- a) **IMPORTANT:** Specimens that fail acceptance criteria are not tested unless a documented exception is authorized under laboratory policy. Rejection, notification, and final disposition are documented.



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 4.23) During Epic or CliniSys downtime, submitters must use the approved DCHHS downtime requisition. (See Section 4.1 External Submitter Requisition)
- 2) PRIMARY SPECIMEN CONTAINER.
- 3) The laboratory will not test or report an unsatisfactory specimen unless a documented exception is authorized by the Laboratory Director or qualified designee under approved policy. Any exception must include the reason, patient-risk assessment, and appropriate report comment.

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 or EPIC EHR if appropriate for a given test system.
 - c) During Epic or CliniSys downtime, the approved DCHHS downtime requisition is missing required patient, submitter, collection, or test information. See 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, K₂EDTA, EDTA, fluoride)
- 14) While each successive tube is filling, turn the filled tube upside – down and return it to the upright position. This is one complete inversion.
- a) **NOTE:** Invert BD Vacutainer K₂EDTA 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°C to 8°C) within **TWO HOURS** of collection so that DCHHS PHL can perform centrifugation.
- 2) **REFRIGERATED SERUM SPECIMENS:** The specimen **MUST** be transported to the DCHHS Laboratory cold (2-8°C) within **48 HOURS** of collection to avoid potential rejection.
- 3) **FROZEN SERUM 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: GONORRHEA, CHLAMYDIA, TRICHOMONAS

9.1 General Information

DCHHS Laboratory requires the use of the Aptima Urine Specimen Collection Kits for Male and Female Urine Specimens for urine collection.

- 1) 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.**
- 2) The Kit and its contents must be maintained at 15°C to 30°C through the storage, collection, and transport process.
- 3) Do not apply the transport medium directly to skin or mucous membranes or take internally.

9.2 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 mL 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.

9.3 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.**



10. SWAB SAMPLE COLLECTION: GONORRHEA, CHLAMYDIA, TRICHOMONAS

10.1 General Information

DCHHS Laboratory requires the use of the Aptima Multitest Swab Specimen Collection Kits for vaginal, rectal, throat, and anogenital lesions swab specimen collection.

- 1) Each Kit contains one swab and one specimen transport tube containing 2.9mL Aptima specimen transport medium.
- 2) The Kit and its contents must be maintained at 15°C to 30°C through the storage, collection, and transport process.
- 3) Do not apply the transport medium directly to skin or mucous membranes or take internally.

10.2 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.

10.3 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 inch to 2 inches (3 cm to 5 cm) past the anal margin and gently rotate the swab for 5 seconds to 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.

10.4 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 tip 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.

10.5 Anogenital Lesions

Note: Do not use disinfectants or cleaners on the lesion before the specimen is collected.

- 1) Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Aptima Multitest Swab Specimen Collection kit.
- 2) Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
- 3) If needed, expose the base of the lesion to access fluid.
- 4) Vigorously swab the base of the lesion to absorb fluid, being careful not to draw blood. Withdraw the swab without touching any other site outside the lesion.



- 5) 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, use a new Aptima Multitest Swab Specimen Collection kit.
- 6) Immediately place the swab into the transport tube so that the score line is at the top of the tube.
- 7) Carefully break the swab shaft at the score line against the side of the tube.
- 8) Discard the top portion of the swab shaft.
- 9) Tightly screw the cap onto the tube.

10.6 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.**



11. LABORATORY REPORTS

11.1 Bacteriology, Immunology, and Virology

- 1) Immunology 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 CliniSys LabOnline Portal.
 - c) PLEASE NOTE: The Laboratory will notify Submitters if test results will be delayed outside of the normal turnaround time. In addition, submitters can contact the Laboratory should they have any questions on the availability of a particular patient test report.

11.2 LRN

- 1) Final electronic test reports will be available through the CliniSys LabOnline Portal within **FIVE (5) BUSINESS DAYS**
- 2) Please note, confirmatory testing results for Select agent specimens, or isolates will be available within **TWO (2) WEEKS** of sample receipt.



12. ADDITIONAL INFORMATION

12.1 Updates on Test Results

- 1) Submitters seeking information or updates on specific laboratory test results beyond Laboratory's turnaround times may contact the Lab-Epi Coordinator. Laboratory personnel verify caller authorization before disclosing patient information.
- 2) LabOnline Electronic Test Reports – Refer to the ***DCHHS-ML3I-02 LabOnline Help Guide*** for information on navigating LabOnline Portal and retrieving electronic orders or reports.
- 3) For all tests performed by a reference laboratory, DCHHS reports identify the performing laboratory and its location in accordance with CLIA reporting requirements.
- 4) When a released report is corrected or amended, the laboratory retains the original report, clearly identifies the correction, records the date and time of the change, and promptly notifies the appropriate authorized person when the revision may affect patient care.

12.2 Complaints

- 1) Comments, inquiries, or complaints may be submitted verbally or in writing to the Lab-Epi Coordinator, including anonymously. Complaints are logged, assessed, investigated, resolved, and trended according to Policy and Procedure for Complaints and Inquiries. Records of the complaint, investigation, corrective action, and response are retained according to laboratory policy.



13. 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.
- 3) Current manufacturer instructions for use of all listed assays.



14. APPENDIX

14.1 DCHHS HIV, Syphilis, and HCV Interpretative Guidelines

Table 3: 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-2 Positive with HIV-1 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.

**Table 4: DCHHS Syphilis Testing Interpretative Guidelines**

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

**Table 5: 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.