



CLIENT SERVICES MANUAL

Stemmons Laboratory

DCHHS-L1Q-06

(VERSION 3.2)

Revised Date: July 2026

Dallas County Health and Human Services Laboratory Division

DCHHS PHL – Stemmons

CLIA Certificate No. 45D0672012



Document Title:	DCHHS Client Services Manual – Stemmons Laboratory
Revision:	3.2
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 Cirrin</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>LS</i>	7/1/26

Laboratory Director Biennial Review

Initial	Date	Initial	Date	Initial	Date



DATE	Version	DESCRIPTION OF CHANGE	Sect, Page #
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
08/2024	1.8	Corrected to the HIV-2 Positive with HIV-1 Cross-Reactivity.	Section 19.1
01/2025	1.9	Added Specimen Type Guide appendix	Section 19.5
11/2025	2.0	Updated accepted specimen types for CT/GC and Trich	Section 2.3
11/2025	2.0	Updating HSV Section with new assay	Page 34
11/2025	2.0	Moved SARS-COV2 & Influenza testing from Immunology to LRN section	Sections 2.3, 2.6, and 2.8
11/2025	2.0	Updated LIS names from "LabOnline" to "Clinisys LabOnline" and "HORIZON" to "Clinisys"	Throughout
11/2025	2.0	Updated Specimen Type Guide appendix	Pages 88-89
11/2025	2.0	Removed Authors Section	Page 7
11/2025	2.0	Added information to holiday closure section	Page 8
11/2025	2.0	Added specimen labeling requirements	Page 57
11/2025	2.0	Clarified accepted matrices for Immunology/Virology Department assays	Section 2.7
11/2025	2.0	Updated external submitter testing menu	Page 59
11/2025	2.0	Clarified test ordering and reporting information	Pages 66 and 90
02/2026	2.1	Updated HIV algorithm to reflect ending HIV RNA pooling	Section 2.6, 2.9 and 2.10
02/2026	2.1	Added additional information regarding requesting performing additional testing on existing specimens and algorithm breaks	Section 2.6, 2.10, and 2.11
02/2026	2.1	Updated rejection and acceptance language for blood specimens and additional testing requests	Section 2.6 and 2.10
02/2026	2.1	Updated age limit language for Bacteriology Unit assays	Section 2.3, 2.4, and 2.5
02/2026	2.1	Added CLIA certification requirement	Section 1.7
06/2026	3.0	Removed testing departments and assays that have been moved to the Mockingbird facility	Overall
06/2026	3.0	Cleaned up STAT, TB, and Virology sections	Overall
07/2026	3.1	Removed HIV-1 NAAT, HCV NAAT, and HSV-1/2 NAAT sections following transfer of those tests to the DCHHS PHL – Mockingbird facility.	Overall
07/2026	3.2	Synched formatting across all CSMs	Overall
07/2026	3.2	Aligned STAT information with Polk STAT CSM	Overall

**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 Mycobacteriology	11
2.4 STAT	15
3. SPECIMEN LABELING REQUIREMENTS	24
4. TEST REQUISITIONS.....	25
4.1 Internal Submitter Requisition	25
5. PRIMARY SPECIMEN CONTAINER	26
5.1 Specimen Container.....	26
5.2 Stemmons STAT Specimen Collection Guide.....	27
5.3 Infection Control.....	27
6. SPECIMEN TRANSPORTATION	29
7. SPECIMEN REJECTION	30
7.1 General Policy	30
7.2 Delayed Testing.....	31
7.3 Automatic Rejection	31
8. BLOOD SAMPLE COLLECTION	33
8.1 Accepted Blood Tubes	33
8.2 Venipuncture Technique and Specimen Handling	33
8.3 Blood Specimen Transport	35
9. STAT SAMPLE COLLECTION.....	36



9.1 Urine	36
9.2 Endocervical.....	36
9.3 Rectal	36
9.4 Urethral.....	37
9.5 Gram Stain Specimens	37
9.6 Direct Smear Preparation	37
9.7 OSOM Trichomonas Rapid Test.....	37
9.8 Rapid Plasma Reagin (RPR)	38
9.9 Syphilis Darkfield.....	38
9.10 Accepted Swab Types	39
10. SPUTUM SPECIMEN COLLECTION	40
10.1 General Information	40
11. LABORATORY REPORTS.....	41
11.1 Mycobacteriology	41
11.2 STAT	41
12. ADDITIONAL INFORMATION.....	42
12.1 Updates on Test Results	42
12.2 Complaints	42
13. REFERENCES.....	43

TABLE OF TABLES

Table 1: Xpert MTB RIF Assay Decision Matrix.....	14
Table 2: Tuberculosis Reflex Testing Algorithm	14
Table 3: Stemmons STAT Specimen Collection Guide.....	27
Table 4: Accepted Blood Tubes	33
Table 5: Accepted Swab Types	39

TABLE OF FIGURES

Figure 1: Sputum Type and Quality Requirements	40
--	----



Authorized by

SHAILA BORNA
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 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

Stemmons 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

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**

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
Eleanor Kirkscey, 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 **Stemmons Laboratory** is performed under CLIA certificate **45D0672012** 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:

1) Mycobacteriology

2) STAT

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 Mycobacteriology Test Menu

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

2.4 STAT Test Menu

1. Rapid Plasma Reagin (RPR), Qualitative - Moderate Complexity
2. Rapid Plasma Reagin (RPR), Quantitative (Titer) - Moderate Complexity
3. Rapid Treponema pallidum Antibodies - Moderate Complexity
4. Syphilis Darkfield Microscopy - Moderate Complexity
5. Rapid HIV-1 and HIV-2 Antibodies - Waived
6. Rapid Trichomonas vaginalis Antigen - Waived
7. Rapid hCG - Waived
8. Urinalysis - Waived
9. Gram Stain and PMN Count - Moderate Complexity



2.3 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 Expectored Sputum

Volume: 3mL to 5mL

Collection Container 50mL Conical Falcon Tube

Patient Criteria for Testing New patient (≥ 12 years) who has been on antibiotic treatment for three (3) days or less at time of specimen collection.

See **Table 1: Xpert MTB/RIF Assay Decision Matrix** 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. Testing in individuals less than 18 years of age represents a modification of the FDA-cleared intended use. DCHHS has validated pediatric (≥ 12 years) use in accordance with CLIA 42 CFR 493.1253 requirements for modified testing. Validation documentation is maintained by the Laboratory.
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 Expecterated 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



1) Patient Criteria for Xpert MTB RIF Assay Testing

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

(i) 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)

Table 1: Xpert MTB RIF Assay Decision Matrix

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

(b) *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.

Table 2: Tuberculosis Reflex Testing Algorithm

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 <i>Mycobacterium tuberculosis</i> 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



2.4 STAT

IMPORTANT: Only specimens submitted from the DCHHS Sexual Health Clinic (SHC) are eligible for STAT Laboratory Testing. Specimens from other locations are not accepted unless specifically authorized under an approved referral process.

Rapid Plasma Reagin (RPR), Qualitative – Moderate Complexity

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 or plasma as a screening test for serologic evidence of syphilis. Reactive results require interpretation with treponemal testing and clinical findings.

Reference Interval Nonreactive

Specimen Type Plasma

Volume Sufficient K₂EDTA whole blood to prepare plasma and permit repeat testing, as specified in the approved SOP.

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

Transportation Deliver immediately to STAT Laboratory after collection

**Rapid Plasma Reagin (RPR), Quantitative (Titer) – Moderate Complexity****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 or plasma to support diagnosis and monitoring of treatment response when interpreted with treponemal testing and clinical findings.**Reference Interval** Nonreactive**Reportable Range** 1:1 to 1:2048 Titer**Specimen Type:** Plasma**Volume** Sufficient K2EDTA whole blood to prepare plasma and permit endpoint titration and repeat testing, as specified in the approved SOP.**Collection Container:** K₂EDTA BD Vacutainer Blood Collection tube with Lavender Top**Transportation** Deliver immediately to STAT Laboratory after collection**Limitations:** Grossly hemolyzed, excessively lipemic, icteric, or contaminated specimens may produce unreliable or nonspecific reactions. Follow the current manufacturer instructions and approved SOP for acceptability, endpoint titration, and interpretation.

**Rapid *Treponema pallidum* Antibodies, Waived – Moderate Complexity****Analyte** Antibodies of *Treponema pallidum***Assay Name** Trinity Biotech Syphilis Health Check**Biological Principle** Qualitative rapid membrane immunochromatographic assay**Intended Use** Qualitative detection of *Treponema pallidum* antibodies in plasma as an initial screening test or in conjunction with a nontreponemal test and clinical findings. Plasma testing is moderate complexity.**Reference Interval** Nonreactive**Specimen Type:** Plasma**Volume** Sufficient K2EDTA whole blood to prepare plasma and permit repeat testing, as specified in the approved SOP.**Collection Container:** K₂EDTA BD Vacutainer Blood Collection tube with Lavender Top**Transportation** Deliver immediately to STAT Laboratory after collection

- Limitations:**
1. Treponemal antibodies commonly remain reactive after treatment; this assay must not be used alone to assess treatment response or distinguish active infection from previously treated infection. Interpret results with nontreponemal testing, clinical history, and the current manufacturer instructions.
 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 – Moderate Complexity****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** Direct microscopic evaluation of serous fluid from a suspected primary or secondary syphilitic genital lesion for organisms with morphology and motility characteristic of *Treponema pallidum*.**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. Oral lesions are not accepted because oral treponemes may be morphologically indistinguishable from *T. pallidum*.**NO ORAL LESIONS****Collection Container:** Direct smears of suspected syphilitic lesions**Transportation** Hand-deliver the freshly prepared slide immediately, preferably within 5 minutes and no later than 10 minutes after preparation. Testing must begin so the slide is read within 20 minutes of smear creation.**Limitations**

1. Negative darkfield microscopy does not exclude syphilis. Prior topical or systemic antimicrobial therapy, fading lesions, blood contamination, drying, excessive fluid, delayed transport, and oral specimens may reduce diagnostic value. Interpret results with clinical and serologic findings.
2. Examination of lesion material from patients who have received anti-treponemal drugs topically / 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 1/2 STAT-PAK Assay

Biological Principle Qualitative rapid membrane immunochromatographic assay

Intended Use Qualitative point-of-care test to aid in the diagnosis of HIV-1 or HIV-2 infection using fingerstick capillary whole blood or venipuncture whole blood. Both whole-blood specimen types are CLIA-waived when assay is performed without modification exactly as described in the current manufacturer instructions and approved SOP.

Reference Interval Nonreactive

Specimen Type: Fingerstick capillary whole blood or venipuncture whole blood collected in a K2EDTA tube.

Volume 5mL Whole Blood in EDTA

Collection Container: Fingerstick: sterile safety lancet and the manufacturer-supplied disposable 5 µL sample loop; no collection tube is used. Venipuncture: K2EDTA blood collection tube. Mix the tube adequately and sample 5 µL of well-mixed whole blood with the manufacturer-supplied loop before centrifugation.

Transportation Fingerstick specimens must be tested immediately. Venipuncture whole blood may be kept at room temperature when tested the same day or refrigerated at 2 to 8°C for up to 3 days. Do not freeze whole blood. If transported, maintain refrigerated conditions with cold packs or wet ice.

- Limitations:**
1. The waived workflow includes fingerstick capillary whole blood and venipuncture whole blood only.
 2. Serum and plasma are not authorized for this waived procedure.
 3. A reactive result is preliminary and requires supplemental testing according to the approved HIV diagnostic algorithm. A nonreactive result does not exclude recent infection, and false-negative results may occur in individuals receiving highly active antiretroviral therapy.
 4. The assay has not been evaluated for newborn screening, cord blood, or individuals younger than 13 years and must not be used for donor screening.
 5. Testing must follow the current manufacturer instructions, including the 15- to 20-minute result-reading window, quality control, temperature requirements, and result interpretation.

**Rapid *Trichomonas vaginalis* Antigen – Waived****Analyte** *Trichomonas vaginalis* antigens**Assay Name** OSOM Trichomonas Rapid Test**Biological Principle** Qualitative rapid membrane immunochromatographic assay**Intended Use** Qualitative detection of *Trichomonas vaginalis* antigen from vaginal swabs in patients with symptoms of vaginosis or vaginitis or suspected exposure. The waived procedure is performed exactly as described in the current manufacturer instructions.**Reference Interval** Negative**Specimen Type:** Vaginal Swab for OSOM Trichomonas**Volume** N/A**Collection Container:** BD BBL CultureSwab**Transportation** Deliver immediately to STAT Laboratory after collection**Limitations:**

1. This assay is limited to vaginal swabs or other specimen preparations explicitly authorized by the current manufacturer instructions. It does not distinguish viable from nonviable organisms. Results must be interpreted with clinical findings and other testing as appropriate.
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 Cassette (25 mIU/mL)**Biological Principle** Rapid chromatographic immunoassay**Intended Use** Qualitative detection of hCG in female urine to aid in the early detection of pregnancy**Reference Interval** Negative**Specimen Type:** Urine**Volume** Sufficient urine to apply the manufacturer-specified aliquot and permit repeat testing, if necessary.
Minimum: 100µL**Collection Container:** Clean, dry, preservative-free urine collection container.**Transportation** Deliver promptly. First-morning urine may be preferred when testing very early pregnancy, but collection and testing must follow the current manufacturer instructions and approved SOP.

**Urinalysis – Waived****Analyte** Urine Chemistry**Assay Name** Siemens Multistix 10 SG**Biological Principle** Urine Chemistry**Intended Use** Waived semiquantitative urine chemistry screening using Siemens Multistix 10 SG.

Kidney function;

Urinary tract infection;

Carbohydrate metabolism;

Liver function

Reference Interval**Protein**

Laboratory-established reference interval maintained in the approved SOP and LIS.

Blood

Negative

Leukocytes

Negative

Nitrite

Negative

Glucose

Negative

Specific Gravity

Laboratory-established reference interval maintained in the approved SOP and LIS.

Ketone

Negative

pH

Laboratory-established reference interval maintained in the approved SOP and LIS.

Bilirubin

Negative

Urobilinogen

Laboratory-established reference interval maintained in the approved SOP and LIS.

Specimen Type: Fresh, well-mixed urine**Volume** Sufficient volume to immerse all reagent pads completely and permit repeat testing**Collection Container:** Clean, dry, preservative-free urine collection container.**Transportation** Deliver promptly and test within the manufacturer-specified stability interval. Do not add preservatives unless explicitly authorized by the current manufacturer instructions.

**Gram Stain and PMN Qualitative**

Analyte	Intracellular gram-negative diplococci and qualitative assessment of polymorphonuclear leukocytes.
----------------	--

Assay Name	Gram Stain and PMN Qualitative
-------------------	--------------------------------

Biological Principle	Conventional Gram Stain
-----------------------------	-------------------------

Intended Use	Detection of <i>Neisseria gonorrhoeae</i> 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
-----------------------	---



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) CliniSys LIS chain number or order identifier, when available

2) Does not have information that conflicts with information provided by the Test Requisition

3) Additional Considerations

(a) Affix the label to the outside of the primary container so it does not impede specimen processing, obscure the specimen, cover fill or volume indicators, or interfere with instrument loading. Labels must be secure, legible, and flush with the container without creating a label flag.

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

(c) **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 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) 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.
- 4) During Epic or CliniSys downtime, submitters must use the approved DCHHS downtime requisition and notify the STAT Laboratory.
 - (a) 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.**



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.



5.2 Stemmons STAT Specimen Collection Guide

Table 3: Stemmons STAT Specimen Collection Guide

Specimen	Collection device	STAT test(s) and key handling directions
Vaginal swab	BD BBL CultureSwab, or another device authorized by the current OSOM IFU and approved SOP	OSOM Trichomonas Rapid Test. Deliver promptly.
Urethral or endocervical specimen	Approved synthetic swab and labeled glass slide	Gram stain and PMN count. Roll gently onto the slide, air-dry, and transport in a protective slide holder.
Genital-lesion serous fluid	Labeled glass slide	Syphilis darkfield. Oral lesions are not accepted. Hand-deliver immediately; the slide must be read within 20 minutes of smear creation.
Fingerstick whole blood	Sterile safety lancet and manufacturer-supplied 5 µL sample loop	Chembio HIV 1/2 STAT-PAK. Provide the Subject Information Notice, collect the second drop, and test immediately.
Venipuncture whole blood	K2EDTA lavender-top tube	Chembio HIV 1/2 STAT-PAK: test 5 µL of well-mixed whole blood before centrifugation. RPR and Syphilis Health Check: prepare plasma according to the approved SOP.
Urine	Clean, dry, preservative-free urine container	hCG and Multistix 10 SG. Deliver promptly and test within the approved stability interval.

5.3 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 non-STAT specimens to:

**Stemmons Accessioning Unit
Room 017
Dallas County Health and Human Services
2377 N Stemmons Freeway
Dallas, TX 75207
Phone: (214) 819-5128**

2) Deliver all STAT specimens to:

**Stemmons STAT Laboratory
Room 108
Dallas County Health and Human Services
2377 N Stemmons Freeway
Dallas, TX 75207
Phone: (214) 819-2182**

1) The laboratory 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.

2) 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.

3) STAT Laboratory Only - Promptly hand-deliver deliver specimens to the STAT reception window. and confirm that laboratory personnel receive them. Darkfield slides require immediate hand delivery as specified in Section 2.4.



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, All specimens and their containers received at DCHHS Laboratory Division MUST BE:
 - 2) **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) **CliniSys LIS chain number or order identifier, when available**
 - 3) Does not have information that conflicts with information provided by the Test Requisition
 - 4) Additional Considerations
 - (a) Affix the label to the outside of the primary container so it does not impede specimen processing, obscure the specimen, cover fill or volume indicators, or interfere with instrument loading. Labels must be secure, legible, and flush with the container without creating a label flag.
 - (b) If the provider produces labels with information on specimen type, the provider must ensure the correct label is placed onto the correct specimen, especially in instances where multiple specimens may be collected, and multiple labels produced. Inconsistencies may cause delays.
 - (c) **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.

5) TEST REQUISITIONS and/or 5. PRIMARY SPECIMEN CONTAINER.

6) 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.

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) Discrepancy between patient information on test requisition or LIS and specimen label.
- (g) Inappropriate specimen container for the diagnostic assay requested.
- (h) Underfilled or overfilled containers.
- (i) Unsecured/Leaking container.
- (j) Expired collection container
 - (i) Note – Collection devices expiring the day after collection are typically acceptable. Consult with the Laboratory if this occurs.
- (k) Improperly shipped, stored, or prepared specimens at requisite temperatures or conditions.
- (l) Test sample degradation resulting in the inhibition of its testing.



8. BLOOD SAMPLE COLLECTION

8.1 Accepted Blood Tubes

Table 4: Accepted Blood Tubes

Specimen Container	Storage Requirements
K ₂ EDTA BD Vacutainer Blood Collection Tube 4.0mL with Lavender Top	4°C to 25°C
BD Vacutainer SST Blood Collection Tubes (7.5 mL volume; 16 x 100 mm)	4°C to 25°C

8.2 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) K2EDTA specimens do not require a clotting period. For venipuncture whole-blood HIV 1/2 STAT-PAK testing, obtain the 5 µL whole-blood aliquot before centrifugation. After centrifugation for plasma-based syphilis testing, inspect the specimen for adequate plasma separation and integrity.
- 20) For RPR and Syphilis Health Check plasma testing, centrifuge K2EDTA whole blood at 1000-1300 RCF for 10 minutes within 2 hours of collection, or according to the approved SOP. Document centrifugation in CliniSys or the approved downtime record.
 - (a) If plasma must be transferred, use a properly labeled, approved secondary tube and maintain specimen traceability.

8.3 Blood Specimen Transport

- 1) Deliver K2EDTA specimens promptly to the STAT Laboratory. For venipuncture whole-blood HIV 1/2 STAT-PAK testing, keep the specimen uncentrifuged until the HIV aliquot is obtained; whole blood may remain at room temperature when tested the same day. STAT specimens must not be routed to the Stemmons Accessioning Unit.
- 2) If venipuncture whole-blood HIV testing is delayed beyond the day of collection, refrigerate the specimen at 2 to 8°C and test within 3 days. Do not freeze whole blood. If the specimen is transported, maintain refrigerated conditions with cold packs or wet ice. Follow the approved SOP for plasma-based syphilis specimen stability.
- 3) **Serum, plasma, and frozen whole blood are not accepted for HIV 1/2 STAT-PAK testing.**



9. STAT SAMPLE COLLECTION

9.1 Urine

- 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 the patient to collect fresh urine in a clean, dry, preservative-free container. Mix the specimen before Multistix testing. First-morning urine may be preferred for very early hCG testing when clinically appropriate.
 - (a) Follow clinic collection instructions that minimize contamination without introducing cleansers or preservatives into the specimen.
- 4) Promptly deliver the labeled urine collection cup to the STAT Laboratory.
 - (a) Do not add preservatives or transfer urine to an unapproved container. Deliver promptly within the assay stability interval.

9.2 Endocervical

- 1) Remove excess mucus from the cervical os and surrounding mucosa using a cleaning swab. 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 sample collection swab 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.

9.3 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 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.



9.4 Urethral

- 1) The patient should not have urinated for at least 1 hour prior to sample collection.
- 2) 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 swab package.
- 3) Insert the specimen collection swab 2 to 4 cm into the urethra.
- 4) Gently rotate the swab clockwise for 2 to 3 seconds in the urethra to ensure adequate sampling.
- 5) Withdraw the swab carefully.

9.5 Gram Stain Specimens

- 1) The DCHHS STAT Laboratory accepts direct smears from urethral, cervical, or rectal swab specimens collected from patients suspected of *Neisseria gonorrhoeae* infection based on patient history and clinical symptoms.
- 2) Consult Section 9.3 Direct Smear Preparation and Section 9.7 Accepted Swab Types for information regarding preparation and acceptable collection devices for genitourinary and extra-genitourinary direct smears.

9.6 Direct Smear Preparation

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

9.7 OSOM Trichomonas Rapid Test

- 1) Collect only a vaginal swab using the device authorized in the current OSOM Trichomonas manufacturer instructions and approved SOP.
- 2) Collection Protocol:



- (a) Obtain a sterile BD BBL™ CultureSwab™ tube.
 - (b) Label the CultureSwab™ tube with:
 - (i) EPIC 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.

9.8 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.

9.9 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) **Hand-deliver the slide immediately, preferably within 5 minutes and no later than 10 minutes after smear preparation. Testing must begin so the slide is read within 20 minutes of smear creation.**



9.10 Accepted Swab Types

Table 5: Accepted Swab Types

Swab Location	Swab Type	Assay	
		Gram Stain	Syphilis Darkfield
Clinician-Collected Rectal Swab	COPAN FLOQSwabs® Flocked Swabs (or equivalent)	✓	
Clinician-Collected Male Urethral Swab	COPAN FLOQSwabs® Flocked Swabs (or equivalent)	✓	
Clinician-Collected Female Urethral Swab	COPAN FLOQSwabs® Flocked Swabs (or equivalent)	✓	
Genital lesion direct smear / serous fluid	Direct smear slide		✓
Clinician-Collected Endocervical Swab	COPAN FLOQSwabs® Flocked Swabs or equivalent	✓	

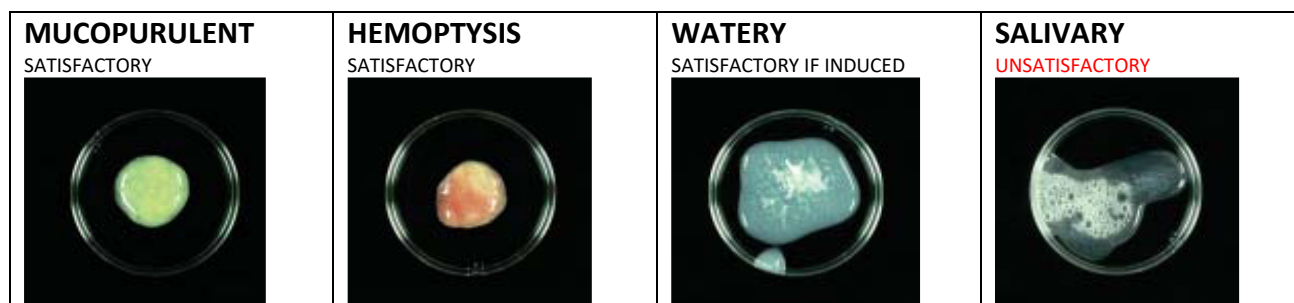


10. SPUTUM SPECIMEN COLLECTION

10.1 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 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°C to 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 Table 1: Xpert MTB/RIF Assay Decision Matrix 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 Table 1: Xpert MTB/RIF Assay Decision Matrix.
- 6) Refer to **Section 6. SPECIMEN TRANSPORTATION** for other instructions on delivery.



11. LABORATORY REPORTS

11.1 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.

11.2 STAT

- 1) The target turnaround time for routine STAT testing is 30 minutes after receipt of an acceptable specimen and valid order. Actual turnaround time may vary by assay, specimen condition, repeat or confirmatory testing, instrument status, and workload. Results are released through Epic and CliniSys only to authorized persons.
- 2) When an established turnaround time cannot be met, the laboratory assesses clinical urgency and notifies the appropriate authorized person. Results meeting the laboratory's approved critical or alert criteria are communicated immediately using closed-loop communication and documented read-back.
- 3) 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. ADDITIONAL INFORMATION

12.1 Updates on Test Results

- 1) Authorized submitters seeking information beyond the established turnaround time may contact the STAT Laboratory or the Lab-Epi Coordinator. Laboratory personnel verify caller authorization before disclosing patient information.
- 2) For all tests performed by a reference laboratory, DCHHS reports identify the performing laboratory and its location in accordance with CLIA reporting requirements.

12.2 Complaints

- 1) Comments, inquiries, or complaints may be submitted verbally or in writing to the Lab-Epi Coordinator or Quality Team, 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 for the Arlington Scientific RPR Card Test, Syphilis Health Check, Chembio HIV 1/2 STAT-PAK Assay Product Insert 10-6072-1 Rev. 2 (August 2016), OSOM Trichomonas Rapid Test, Alere hCG cassette, and Siemens Multistix 10 SG