



CLIENT SERVICES MANUAL

Polk St Clinic

DCHHS-PL1Q-06

(VERSION 1.0)

Revised Date: July 2026

Dallas County Health and Human Services Laboratory Division

DCHHS PHL – Polk

CLIA Certificate No. 45D2346887



Document Title:	DCHHS Client Services Manual – Polk St Clinic
Revision:	1.0
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		7/13/2026
Health & Safety Manager	Kayle Cirrincione		07/13/2026
Quality Manager:	Shaila Borna		07/13/2026
Laboratory Director:	Luke C. Short, Ph.D., HCLD(ABB)		7/13/2026

Laboratory Director Biennial Review

Initial	Date	Initial	Date	Initial	Date

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 controlled and should be checked against the server file version prior to use.



CLIENT SERVICES MANUAL
Document Code: DCHHS – PL1Q-06

Page 3 of 38

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

Revised Date: July 2026

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

**TABLE OF CONTENTS**

1. GENERAL INFORMATION.....	6
1.1 Mission Statement	6
1.2 Facility Location.....	6
1.3 Days & Hours of Operation	6
1.4 Administrative Staff Directory.....	6
1.5 Laboratory Bulletins and Memorandums	7
1.6 Interruption of Services.....	7
1.7 Reference Laboratory.....	7
2. LABORATORY SERVICES	8
2.1 Scope of Laboratory Services	8
2.2 Definitions	8
2.3 Test Menu	9
2.4 STAT.....	10
3. SPECIMEN LABELING REQUIREMENTS	20
4. TEST REQUISITIONS.....	21
4.1 Internal Submitter Requisition	21
5. PRIMARY SPECIMEN CONTAINER	22
5.1 Specimen Container	22
5.2 Polk Specimen Collection Guide.....	23
5.3 Infection Control	24
6. SPECIMEN TRANSPORTATION	25
7. SPECIMEN REJECTION	26
7.1 General Policy.....	26
7.2 Delayed Testing.....	26
7.3 Automatic Rejection.....	27
8. BLOOD SAMPLE COLLECTION	28
8.1 Accepted Blood Tubes.....	28
8.2 Venipuncture Technique and Specimen Handling.....	28
8.3 Blood Specimen Transport	30
9. STAT SAMPLE COLLECTION.....	31
9.1 STAT Urine.....	31



9.2 Direct Smear Preparation.....	31
9.3 OSOM Trichomonas Rapid Test.....	31
9.4 Endocervical Direct Smear	32
9.5 Vaginal Swab	32
9.6 Urethral Direct Smear	32
9.7 Gram Stain Specimens:	33
9.8 Rapid Plasma Reagin (RPR).....	33
9.9 Syphilis Darkfield	33
9.10 Specimen Types Not Accepted.....	34
9.11 Referral and Recollection	34
10. LABORATORY REPORTS.....	35
11. ADDITIONAL INFORMATION.....	36
11.1 Updates on Test Results.....	36
11.2 Complaints	36
12. REFERENCES.....	37

TABLE OF TABLES

Table 1: Polk Specimen Collection Guide.....	23
Table 2: Accepted Blood Tubes	28

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 is to provide a comprehensive program of diagnostic and analytical laboratory services to support the prevention, surveillance, control, and diagnosis of communicable diseases and emerging biological threats of public concern. The goal of the DCHHS Laboratories is to provide accurate, reliable, and timely test results with an emphasis on excellent community service.

1.2 Facility Location

STAT Laboratory

Dallas County Health and Human Services Polk St Clinic
7201 S. Polk St
Dallas, TX 75232
STAT Lab Phone: (945) 500-2933
Main Lab Phone: (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	(945) 500-2933
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 **Polk STAT Laboratory** is performed under CLIA certificate **45D2346887** 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 submitters. The subsequent sections of this manual contain our test menu for the Laboratory Units listed below:

1) 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 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



2.4 STAT

IMPORTANT: Only specimens collected at the DCHHS Polk Street Clinic are eligible for Polk 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

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 and interpretation.

**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.

Serum and plasma are not accepted for this assay at Polk STAT

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 must be 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 or another collection device specifically authorized in the current manufacturer instructions and approved SOP.

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. Testing must be performed exactly according to the current manufacturer instructions and approved SOP.

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 or as established in the approved SOP and LIS.

Leukocytes

Negative or as established in the approved SOP and LIS.

Nitrite

Negative or as established in the approved SOP and LIS.

Glucose

Negative or as established in the approved SOP and LIS.

Specific Gravity

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

Ketone

Negative or as established in the approved SOP and LIS.

pH

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

Bilirubin

Negative or as established in the approved SOP and LIS.

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, as specified in the approved SOP.**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 Count – Moderate Complexity**

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

Assay Name Gram Stain and PMN Count

Biological Principle Conventional Gram Stain

Intended Use Microscopic evaluation of direct urethral or endocervical smears for intracellular gram-negative diplococci and polymorphonuclear leukocytes to support clinical assessment for gonococcal infection.

Reference Interval Negative

Specimen Type: Direct urethral or endocervical smears collected with an approved synthetic swab. Calcium alginate swabs and swabs with wooden shafts are not accepted.

NO calcium alginate swabs or swabs with wooden handles.

Volume N/A

Collection Container: Direct smear of urethral or endocervical specimens

Transportation Hand-deliver the labeled, air-dried slide promptly to the Polk STAT Laboratory in a protective slide holder.



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) Routine orders must be entered by an authorized person in the Epic electronic health record and transmitted to the CliniSys laboratory information system before testing.
- 2) During Epic or CliniSys downtime, submitters must use the approved DCHHS downtime requisition and notify the Polk STAT Laboratory.
 - (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.
- 3) 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.
- 4) 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 Polk Specimen Collection Guide****Table 1: Polk Specimen Collection Guide**

Specimen	Collection device	Polk 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 specimens to:

**Polk STAT Laboratory
Dallas County Health and Human Services
7201 S. Polk St, Dallas, TX 75232
Room 124
Phone: (945) 500-2933**

1) Polk 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) Promptly hand-deliver specimens to the Polk 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, 4. TEST REQUISITIONS and/or 4.11) Routine orders must be entered by an authorized person in the Epic electronic health record and transmitted to the CliniSys laboratory information system before testing.
- 2) During Epic or CliniSys downtime, submitters must use the approved DCHHS downtime requisition and notify the Polk STAT Laboratory.
 - (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.
- 3) 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.
- 4) 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.
- 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) A valid electronic order or approved downtime requisition is absent, but specimen identification is complete, and the deficiency can be corrected within the stability interval.
 - (b) The Epic order did not transmit to CliniSys, but the authorized request can be verified and reconciled.
 - (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) The submitter must contact the Polk STAT Laboratory at (945) 500-2933 and correct the deficiency before the specimen expires or within the 24-hour hold, whichever occurs first.
- (i) NOTE: If unavailable, contact the Main Laboratory Front Office at (214) 819-1950.
- 4) The specimen will be rejected and disposal documented 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 designate the following specimens as UNSATISFACTORY. Rejection, submitter notification, and specimen disposition must be documented according to approved policy.
- (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) For tests requiring plasma, K2EDTA blood not centrifuged within the laboratory-established interval in the approved SOP.
 - (e) Specimens received outside of the processing window for the test to be performed.



- (f) During Epic or CliniSys downtime, the approved downtime requisition is absent.
 - (i) Required collection date and time, and centrifugation time when applicable, are absent.
- (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 Accepted Blood Tubes

Table 2: 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

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) Order of Draw
 - (i) When multiple tubes are collected for clinic services, follow the approved clinic phlebotomy order-of-draw procedure. The Polk laboratory accepts only K2EDTA tubes for the blood tests described in this manual.
- 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) After hemostasis is achieved, apply a bandage according to clinic procedure.
- 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 Polk 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. Polk testing specimens must not be routed to the Stemmons or Mockingbird 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) **Frozen whole blood is not acceptable for HIV 1/2 STAT-PAK testing. Other frozen specimens are accepted only when explicitly authorized by the current manufacturer instructions, approved SOP, and laboratory supervisor.**



9. STAT SAMPLE COLLECTION

9.1 STAT 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) No precollection voiding restriction is required unless specified by the current manufacturer instructions or approved SOP.
 - (b) 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 Direct Smear Preparation

- 1) Label the microscope slide with:
 - (a) Epic medical record number or other approved unique identifier
 - (b) Patient first and last name, or approved abbreviated identifier when slide size is limited
 - (c) Specimen source and collection date/time
 - (d) Provider initials
- 2) Roll the swab gently over an area less than 1 cm² to preserve cellular morphology. Do not scrub the slide.
- 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.

9.3 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.
 - (i) Epic medical record number or other approved unique identifier
 - (ii) Patient first and last name
 - (iii) Collection date/time and collector identification
 - (b) Collect the vaginal specimen according to the current manufacturer instructions. Avoid lubricants, iodine preparations, and other substances identified as interfering in the instructions.
 - (c) Reinsert the swab into the CultureSwab Container.
 - (d) Hand-deliver the labeled specimen with a valid order to the Polk STAT reception window.
- 3) If testing is delayed, store the swab only under the time and temperature conditions specified in the current manufacturer instructions and approved SOP.

9.4 Endocervical Direct Smear

- 1) Remove excess mucus from the cervical os with a separate swab and discard it. Collect from the endocervical canal using an approved synthetic swab.
 - (a) Roll the collection swab gently onto a labeled glass slide, air-dry, and place the slide in a protective holder.
- 2) Follow the approved Gram stain SOP for specimen adequacy, slide preparation, transport, and rejection criteria.

9.5 Vaginal Swab

- 1) Use aseptic technique and the collection device authorized in the current OSOM Trichomonas manufacturer instructions. Do not use a swab if the tip is touched, dropped, or otherwise contaminated.
- 2) Collect vaginal fluid from the vaginal walls according to the current manufacturer instructions, then return the swab to the approved transport container.
- 3) Label the transport container with two patient identifiers and collection date/time, link it to a valid order, and deliver it within the approved stability interval.

9.6 Urethral Direct Smear

- 1) When clinically appropriate, the patient should not urinate for at least 1 hour before urethral specimen collection, consistent with the approved Gram stain SOP.



- 2) Using aseptic technique, remove an approved synthetic swab without touching or contaminating the tip.
- 3) Collect the urethral specimen according to the approved Gram stain SOP, then roll the swab gently onto a labeled glass slide.
- 4) Air-dry the slide, place it in a protective holder, and deliver it promptly to the Polk STAT Laboratory.

9.7 Gram Stain Specimens:

- 1) The DCHHS STAT Laboratory accepts direct smears of a swab specimen collected from the urethra or cervix of patients suspected of *Neisseria gonorrhoeae* infection based on patient history and clinical symptoms.

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.
- 2) Perform the initial serial dilution through 1:16 following the approved RPR SOP.

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 Specimen Types Not Accepted

- 1) Rectal and throat swabs are not accepted for any test on the Polk CMS-116 test menu. Aptima GC/CT/Trich, HSV, mpox, and other non-Polk specimens must not be collected under this manual.

9.11 Referral and Recollection

- 1) For testing outside the Polk menu, contact the appropriate DCHHS laboratory site before collection. Recollect using the receiving laboratory's approved container, specimen type, labeling, and transport instructions.



10. LABORATORY REPORTS

- 1) The target turnaround time for routine Polk 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.



11. ADDITIONAL INFORMATION

11.1 Updates on Test Results

- 1) Authorized submitters seeking information beyond the established Polk turnaround time may contact the Polk 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.

11.2 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.



12. REFERENCES

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) 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