



Laboratory Response Network Bioterrorism Client Services Manual

VERSION 1.0

**Revised Date:
June 2026**

Dallas County Health and Human Services Laboratory Division

DCHHS PHL – Mockingbird

1410 W Mockingbird Ln, Dallas, Texas 75247

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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
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Laboratory Director Biennial Review

Initial	Date	Initial	Date	Initial	Date

Prepared by: Alexandra Portman

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

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LRN CLIENT SERVICES MANUAL
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1. General Information

1.1 Mission Statement

The Mission of the Dallas County Health and Human Services Public Health (DCHHS – PHL) Laboratory 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

LRN-B Division

Dallas County Public Health Laboratory

1410 W. Mockingbird Lane

Dallas, TX 75247

LRN 24/7 Phone: (214) 677 - 7876

1.3 Days & Hours of Operation

Daily: 8:00 AM to 4:30 PM

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 (972) 692 - 2712

Shaila Borna | Quality Manager (214) 819 - 1939

**David J. Stringer | General Laboratory Supervisor****(972) 692 - 2762****Supervisory Staff****Alexandra Portman | LRN/Bioterrorism Coordinator****(972) 692 - 2708****Eleanor Kirkscey | Lab-Epi Coordinator****(214) 212 - 2157****1.5 Laboratory Bulletins and Memorandums**

The Laboratory Response Network will issue bulletins or memorandums to health providers and staff of registered Sentinel Laboratories as needed via email distribution. These notifications will include updated information on test ordering, specimen requirements, new instrumentation, changes in reference ranges, regulatory issues, and many other topics of concern to the relevant physicians and staff. These bulletins and memorandums are an ongoing communication tool to provide submitters with current information on laboratory services.

1.6 Interruption of Services

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

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

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

In the event of sample submission during a planned or unplanned event, please contact the 24/7 phone line for instructions.

24/7 Phone: 214 - 677 - 7876

1.7 Reference Laboratory

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

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 or Center of Disease Control and Prevention
- (b) Acceptable to the DCHHS PHL Director
- (c) Acceptable to the providing hospital or clinic



Most reference testing is sent to the Texas Department of State Health Services Laboratory or Centers for Disease Control and Prevention.

1.8 Sentinel Laboratory

Sentinel laboratories play a key role in the early detection of biological agents by providing routine diagnostic services, rule-out, and referral steps in the identification process. These laboratories can evaluate whether samples should be sent to an LRN reference laboratory for further testing.

DCHHS LRN-B Clients must be considered an LRN Sentinel Laboratory and/or be authorized to submit samples by the DCHHS PHL Director and the LRN/Bioterrorism Coordinator.

The LRN works with the American Society for Microbiology and state public health laboratory directors to ensure that sentinel laboratories, such as private and commercial laboratories, are part of the Laboratory Response Network.



2. Test Menu

2.1 Definitions

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

Analyte	The target material being detected and identified during testing
APHL	Association of Public Health Laboratories
ASM	American Society for Microbiology
CHOC	Chocolate Agar
Collection Containers	Acceptable containers for collecting and transporting the specimen.
Intended Use	The objective intent or purpose of the diagnostic assay
Limitations	Circumstances or conditions known to directly impact the accuracy of test results.
LRN	Laboratory Response Network
LRN-B	Laboratory Response Network - Biological
Panel	Name of the testing system/platform
PHL	Public Health Laboratories
Reference Range	Typical result from a biological reference population (presumed healthy)
SBA	Sheep's Blood Agar
Sentinel Laboratory	A certified laboratory that meets the required responsibilities and duties as laid out by the APHL. Follows all ASM protocols for Sentinel Laboratories.
Specimen Type	Acceptable sample of biological origin intended for examination
Spp.	Species
Transportation	Required conditions for maintaining quality of the specimen during shipping and transportation, inspected upon receipt for acceptability.
Volume	Requisite amount of specimen for testing, and retesting if necessary



2.2 LRN Test Menu

1. *Bacillus anthracis*
2. *Brucella* spp
3. *Burkholderia* spp.
4. Crimean- Congo VHF
5. Dengue
6. Ebola
7. *Francisella tularensis*
8. Influenza A (Including H5 and H7), Influenza B, and SARS-CoV-2
9. Lassa Fever
10. Marburg
11. Non-variola Orthopox
12. Orthopox
13. Yellow Fever
14. *Yersinia pestis*

BioFire Global Fever Special Pathogens Panel General Notes:

The BioFire Global Fever Special Pathogens Panel is a qualitative, multiplexed nucleic acid-based test intended for EDTA whole blood specimens collected from individuals with signs and/or symptoms of acute febrile illness or recent acute febrile illness and known or suspected exposure to target pathogens. Results must be interpreted in conjunction with clinical, epidemiologic, and other laboratory information, and according to applicable public health guidance.

For the BioFire Global Fever Special Pathogens Panel, the following organism results are presumptive and require additional testing and confirmation procedures in consultation with the appropriate public health authorities, as applicable:

Bacillus anthracis, Crimean-Congo hemorrhagic fever virus, *Ebolavirus* spp., *Francisella tularensis*, Lassa virus, Marburgvirus, Yellow fever virus, and *Yersinia pestis*.

For select agent results, negative results do not rule out infection. Positive presumptive select agent results must be reported to public health authorities in accordance with local, state, and federal requirements. Diagnostic testing for suspected select agent viral hemorrhagic fevers should be performed in consultation with public health officials, including local or state health departments and CDC in the U.S. Negative BioFire GFSP results for patients suspected of Lassa fever should be sent to CDC for additional testing.

**1. *Bacillus anthracis*****Test Name** *Bacillus anthracis* Rule-out**Target** *In vitro* qualitative detection *Bacillus anthracis***Method** Real- Time Polymerase Chain Reaction and Conventional Culture Methods**Intended Use** Qualitative detection of *Bacillus anthracis* from cell culture isolates submitted to a Laboratory Response Network (LRN) reference laboratory**Reference Range** Negative for *Bacillus anthracis***Specimen Type** Isolate**Volume/Quantity** Sufficient growth on culture to allow for reference lab testing**Collection Container** SBA, CHOC, or other growth medium in either a plate or slant format**Transportation** Send unknown clinical isolates for testing at the LRN reference laboratory at ambient temperature (15°C to 30°C) as a Category B agent.**IMPORTANT:** The PHL will perform a temperature check of the secondary transport container (*i.e.*, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.

**2. Brucella spp.****Test Name** Brucella Rule-out**Target** *In vitro* qualitative detection Brucella species**Method** Real- Time Polymerase Chain Reaction and Conventional Culture Methods**Intended Use** Qualitative detection of Brucella species from cell culture isolates submitted to a Laboratory Response Network (LRN) reference laboratory**Reference Range** Negative for Brucella spp.**Specimen Type** Isolate**Volume/Quantity** Sufficient growth on culture to allow for reference lab testing**Collection Container** SBA, CHOC, or other growth medium in either a plate or slant format

Transportation Send unknown clinical isolates for testing at the LRN reference laboratory at ambient temperature (15°C to 30°C) as a Category B agent.

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

**3. Burkholderia spp.**

Test Name	Burkholderia Rule-out
Target	<i>In vitro</i> qualitative detection of the Burkholderia species
Method	Real- Time Polymerase Chain Reaction and Conventional Culture Methods
Intended Use	Qualitative detection of Burkholderia species from cell culture isolates submitted to a Laboratory Response Network (LRN) reference laboratory
Reference Range	Negative for <i>Burkholderia mallei</i> / <i>Burkholderia pseudomallei</i>
Specimen Type	Isolate
Volume/Quantity	Sufficient growth on culture to allow for reference lab testing
Collection Container	SBA, CHOC, or other growth medium in either a plate or slant format
Transportation	Send unknown clinical isolates for testing at the LRN reference laboratory at ambient temperature (15°C to 30°C) as a Category B agent. IMPORTANT: The PHL will perform a temperature check of the secondary transport container (<i>i.e.</i>, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.

**4. Crimean-Congo VHF**

Test Name	BioFire Global Fever Special Pathogens Panel
Target	<i>In vitro</i> qualitative detection of Crimean-Congo hemorrhagic fever virus RNA
Method	Real- Time Polymerase Chain Reaction
Intended Use	Qualitative detection of Crimean-Congo hemorrhagic fever virus from EDTA whole blood samples submitted to a Laboratory Response Network (LRN) reference laboratory
Reference Range	Crimean-Congo hemorrhagic fever virus RNA not detected
Specimen Type	Whole Blood
Volume/Quantity	4 mL for adult patients (1 mL for pediatric patients)
Collection Container	Two (2) EDTA vials
Transportation	1. Refrigerate (2°C to 8°C) specimens WITHIN 24 HOURS after collection 2. Send two (2) refrigerated samples (2°C to 8°C) as a Category A agent with cold packs within 7 days of collection to DCHHS IMPORTANT: The PHL will perform a temperature check of the secondary transport container (<i>i.e.</i>, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.
Sample Notes	A consult with the regional epidemiologist, local or state public health authorities, and CDC (770-488-7100), as applicable, is required prior to submission and testing. Select agent viral hemorrhagic fever results are presumptive; negative results do not rule out infection; positive presumptive results must be reported to public health authorities in accordance with local, state, and federal requirements.

**5. Dengue**

Test Name	BioFire Global Fever Special Pathogens Panel
Target	<i>In vitro</i> qualitative detection of Dengue virus RNA, serotypes 1, 2, 3, and 4
Method	Real- Time Polymerase Chain Reaction
Intended Use	Qualitative detection of Dengue virus from EDTA whole blood samples submitted to a Laboratory Response Network (LRN) reference laboratory
Reference Range	Dengue virus RNA not detected
Specimen Type	Whole Blood
Volume/Quantity	4 mL for adult patients (1 mL for pediatric patients)
Collection Container	Two (2) EDTA vials
Transportation	Refrigerate (2°C to 8°C) specimens WITHIN 24 HOURS after collection - Send two (2) refrigerated samples (2°C to 8°C) as a Category A agent with cold packs within 7 days of collection to DCHHS IMPORTANT: The PHL will perform a temperature check of the secondary transport container (<i>i.e.</i>, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.
Sample Notes	Consultation with the LRN/BT Coordinator or designee and the regional epidemiologist is required prior to submission. Results must be interpreted with clinical and epidemiologic information and according to applicable public health guidance.



6. Ebola Virus

Test Name	BioFire Global Fever Special Pathogens Panel
Target	<i>In vitro</i> qualitative detection of Ebolavirus spp. RNA
Method	Real- Time Polymerase Chain Reaction
Intended Use	Qualitative detection of Ebolavirus spp. from EDTA whole blood samples submitted to a Laboratory Response Network (LRN) reference laboratory
Reference Range	Ebolavirus spp. RNA not detected
Specimen Type	Whole Blood
Volume/Quantity	4 mL for adult patients (1 mL for pediatric patients)
Collection Container	Two (2) EDTA vials
Transportation	1. Refrigerate (2°C to 8°C) specimens WITHIN 24 HOURS after collection 2. Send two (2) refrigerated samples (2°C to 8°C) as a Category A agent with cold packs within 7 days of collection to DCHHS IMPORTANT: The PHL will perform a temperature check of the secondary transport container (<i>i.e.</i>, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.
Sample Notes	A consult with the regional epidemiologist, local or state public health authorities, and CDC (770-488-7100), as applicable, is required prior to submission and testing. Select agent viral hemorrhagic fever results are presumptive; negative results do not rule out infection; positive presumptive results must be reported to public health authorities in accordance with local, state, and federal requirements.

**7. *Francisella tularensis***

Test Name	Francisella tularensis Rule-out
Target	<i>In vitro</i> qualitative detection of <i>Francisella tularensis</i>
Method	Real- Time Polymerase Chain Reaction and Conventional Culture Methods
Intended Use	Qualitative detection of <i>Francisella tularensis</i> from cell culture isolates submitted to a Laboratory Response Network (LRN) reference laboratory
Reference Range	Negative for <i>F. tularensis</i>
Specimen Type	Isolate
Volume/Quantity	Sufficient growth on culture to allow for reference lab testing
Collection Container	SBA, CHOC, or other growth medium in either a plate or slant format
Transportation	Send unknown clinical isolates for testing at the LRN reference laboratory at ambient temperature (15°C to 30°C) as a Category B agent. IMPORTANT: The PHL will perform a temperature check of the secondary transport container (<i>i.e.</i>, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.
Sample Notes	Not applicable

**8. Influenza A (Including H5 and H7), Influenza B, and SARS-CoV-2****Test Name** Influenza SARS-CoV-2 Multiplex Assay (CDC)**Target** Viral RNA of SARS- CoV-2, Influenza A and Influenza B**Method** Real- Time Polymerase Chain Reaction**Intended Use** Qualitative detection of Influenza and SARS-CoV-2 samples submitted to a Laboratory Response Network (LRN) reference laboratory**Reference Range** Not Detected**Specimen Type** Nasopharyngeal (NP) Swab**Volume/Quantity** Nasopharyngeal Swab in 3mL of VTM/UTM

Collection Container **Polyester -, Rayon -, or Nylon – tipped swab only,**

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

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

and

COPAN FLOQSwab 80mm (Cat. No. 525CCS01)

Transportation **2°C to 8°C**
Submit within 48 – HOURS

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

Sample Notes A consult with the CDC (770-488-7100) and regional epidemiologist is required prior to submission. Please note, the CDC must give permission prior to performing the test.

**9. Lassa Fever**

Test Name	BioFire Global Fever Special Pathogens Panel
Target	<i>In vitro</i> qualitative detection Lassa virus RNA
Method	Real- Time Polymerase Chain Reaction
Intended Use	Qualitative detection of Lassa virus from whole blood samples submitted to a Laboratory Response Network (LRN) reference laboratory
Reference Range	Lassa virus RNA not detected
Specimen Type	Whole Blood
Volume/Quantity	4 mL for adult patients (1 mL for pediatric patients)
Collection Container	Two (2) EDTA vials
Transportation	Refrigerate (2°C to 8°C) specimens WITHIN 24 HOURS after collection - Send two (2) refrigerated samples (2°C to 8°C) as a Category A agent with cold packs within 7 days of collection to DCHHS IMPORTANT: The PHL will perform a temperature check of the secondary transport container (<i>i.e.</i>, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.
Sample Notes	A consult with the regional epidemiologist, local or state public health authorities, and CDC (770-488-7100), as applicable, is required prior to submission and testing. Select agent viral hemorrhagic fever results are presumptive; negative results do not rule out infection; positive presumptive results must be reported to public health authorities in accordance with local, state, and federal requirements. Negative BioFire GFSP results for patients suspected of Lassa fever should be sent to CDC for additional testing.

**10. Marburg Virus**

Test Name	BioFire Global Fever Special Pathogens Panel
Target	<i>In vitro</i> qualitative detection of Marburgvirus RNA
Method	Real- Time Polymerase Chain Reaction
Intended Use	Qualitative detection of Marburgvirus from EDTA whole blood samples submitted to a Laboratory Response Network (LRN) reference laboratory
Reference Range	Marburgvirus RNA not detected
Specimen Type	Whole Blood
Volume/Quantity	4 mL for adult patients (1 mL for pediatric patients)
Collection Container	Two (2) EDTA vials
Transportation	1. Refrigerate (2°C to 8°C) specimens WITHIN 24 HOURS after collection 2. Send two (2) refrigerated samples (2°C to 8°C) as a Category A agent with cold packs within 7 days of collection to DCHHS IMPORTANT: The PHL will perform a temperature check of the secondary transport container (<i>i.e.</i>, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.
Sample Notes	A consult with the regional epidemiologist, local or state public health authorities, and CDC (770-488-7100), as applicable, is required prior to submission and testing. Select agent viral hemorrhagic fever results are presumptive; negative results do not rule out infection; positive presumptive results must be reported to public health authorities in accordance with local, state, and federal requirements.

**11. Non-variola Orthopox****Test Name** Non-variola Orthopox**Target** *In vitro* qualitative detection Non-variola *Orthopoxvirus* DNA**Method** Real- Time Polymerase Chain Reaction (RT-PCR)**Intended Use** Qualitative detection of Non-variola *Orthopoxvirus* from human pustular or vesicular rash specimens and viral cell culture lysates submitted to a Laboratory Response Network (LRN) reference laboratory**Reference Range** Non-variola *Orthopoxvirus* DNA not detected by real-time PCR**Specimen Type** Multiple Dry Swab(s) from lesions collected from different locations on the body and/or from lesions with differing appearances**Volume/Quantity** Two (2) dry Swabs collected from the same lesion**Collection Container** Sterile, Dry Synthetic Swab (*i.e.*, polyester, nylon, or Dacron) with a plastic, wood, or thin aluminum shaft. (Any type of shaft is acceptable as long as it can be broken or cut.)**DO NOT USE** cotton swabs**DO NOT ADD or STORE** in viral or universal transport media**Transportation**

1. **Refrigerate** (2°C to 8°C) or **freeze** (-20°C or lower) specimens **WITHIN AN HOUR** after collection
2. Send refrigerated samples (2°C to 8°C) as a Category B agent with cold packs
3. Send frozen samples (-20°C or lower) as a Category B agent using dry ice

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

**12. Orthopox**

Test Name	Other Select Agent Rule-out
Target	<i>In vitro</i> qualitative detection <i>Orthopoxvirus</i> DNA
Method	Real- Time Polymerase Chain Reaction
Intended Use	Qualitative detection of <i>Orthopoxvirus</i> from human pustular or vesicular rash specimens and viral cell culture lysates submitted to a Laboratory Response Network (LRN) reference laboratory
Reference Range	<i>Orthopoxvirus</i> DNA not detected by real-time PCR
Specimen Type	Multiple Dry Swab(s) from lesions collected from different locations on the body and/or from lesions with differing appearances
Volume/Quantity	Two (2) dry Swabs collected from the same lesion
Collection Container	Sterile, Dry Synthetic Swab (<i>i.e.</i> , polyester, nylon, or Dacron) with a plastic, wood, or thin aluminum shaft. (Any type of shaft is acceptable as long as it can be broken or cut.) DO NOT USE cotton swabs DO NOT ADD or STORE in viral or universal transport media
Transportation	1. Refrigerate (2°C to 8°C) or freeze (-20°C or lower) specimens WITHIN AN HOUR after collection 2. Send refrigerated samples (2°C to 8°C) as a Category B agent with cold packs 3. Send frozen samples (-20°C or lower) as a Category B agent using dry ice IMPORTANT: The PHL will perform a temperature check of the secondary transport container (<i>i.e.</i> , insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.
Sample Notes	A consult with the CDC (770-488-7100) and regional epidemiologist is required prior to submission, and CDC has given permission to test.

**13. Yellow Fever**

Test Name	BioFire Global Fever Special Pathogens Panel
Target	<i>In vitro</i> qualitative detection of Yellow fever virus RNA
Method	Real- Time Polymerase Chain Reaction
Intended Use	Qualitative detection of Yellow fever virus from EDTA whole blood samples submitted to a Laboratory Response Network (LRN) reference laboratory
Reference Range	Yellow fever virus RNA not detected
Specimen Type	Whole Blood
Volume/Quantity	4 mL for adult patients (1 mL for pediatric patients)
Collection Container	Two (2) EDTA vials
Transportation	Refrigerate (2°C to 8°C) specimens WITHIN 24 HOURS after collection - Send two (2) refrigerated samples (2°C to 8°C) as a Category A agent with cold packs within 7 days of collection to DCHHS IMPORTANT: The PHL will perform a temperature check of the secondary transport container (<i>i.e.</i>, insulated transport bag) to ensure compliance and will reject samples outside of the required temperature.
Sample Notes	Consultation with the LRN/BT Coordinator or designee, regional epidemiologist, and appropriate public health authorities is required prior to submission. Yellow fever virus results are presumptive and require confirmatory testing. Results must be interpreted with clinical and epidemiologic information and according to applicable public health guidance.

**14. *Yersinia pestis*****Test Name** *Yersinia pestis* Rule-out**Target** *In vitro* qualitative detection *Yersinia pestis***Method** Real- Time Polymerase Chain Reaction and Conventional Culture Methods**Intended Use** Qualitative detection of *Yersinia pestis* from cell culture isolates submitted to a Laboratory Response Network (LRN) reference laboratory**Reference Range** Negative for *Y. pestis***Specimen Type** Isolate**Volume/Quantity** Sufficient growth on culture to allow for reference lab testing**Collection Container** SBA, CHOC, or other growth medium in either a plate or slant format

Transportation Send unknown clinical isolates for testing at the LRN reference laboratory at ambient temperature (15°C to 30°C) as a Category B agent.

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



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**

(c) **Location of Lesion (Non - variola Orthopoxvirus or Orthopoxvirus ONLY)**

2) Not conflicting with information provided by the Test Requisition

3) Additional Considerations

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

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



4. Test Requisitions

4.1 Submission Approval

- 1) All samples must have a consultation with the LRN/BT Coordinator or designee prior to sample requisition on LabOnline.

Senior Management

Kayle Cirrincione | Health & Safety Manager (972) 692–2712

David J. Stringer | General Laboratory Supervisor (972) 692-2762

Supervisory Staff

Alexandra Portman | LRN/BT Coordinator (972) 692-2708

24/7 Phone (214) 677-7876

- 2) Consultation information includes Sentinel Laboratory test results, patient demographic, and requested test to be performed.
- 3) Samples not found congruent with Select Agent characteristics may be declined to be tested by the Reference LRN.
 - (a) Refer to ASM guidelines for Select Agent Rule/Out testing by the Sentinel Laboratories

4.2 Information required for test requisition

Sentinel Laboratories will submit approved test orders using LabOnline. Reference the ***DCHHS LabOnline Help Guide*** for instructions on using the LabOnline Portal.

In the event of LabOnline being inoperable or a test system not being available on the LabOnline Portal for ordering, Sentinel Laboratories MUST SUBMIT an Official DCHHS Laboratory Test Requisition(s) with EACH submitted patient specimen.

All Test Requisitions MUST SOLICIT the following patient information:

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

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

- 2) **Date of Birth**

- 3) **Biological Sex**

**4) Patient's Address**

5) Ordering provider or submitting laboratory name and contact information, including a phone number for urgent result notification.

6) Collecting Health Provider

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

8) Date of Collection

9) Time of Collection is REQUIRED for the following specimens

(a) Whole Blood

(b) Nasopharyngeal

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

4.3 Placing Test Orders to the DCHHS Laboratory

All LRN Reference Laboratory assays are available and exclusively use LabOnline Portal to place electronic orders. A completed LabOnline Client Request Form will be required to configure submitter access on the LabOnline Portal. New submitters should contact the following email to obtain a Client Request Form and an account:

DCHHS-PHL.Services@dallascounty.org

Instructions for navigating DCHHS LabOnline Portal is described in the ***LabOnline Help Guide***

NOTE: To comply with all laws and regulations concerning protected health information, it is advisable to notify the DCHHS Laboratory of any staffing changes within the Sentinel Laboratories and verify the up-to-date contact information for releasing preliminary and final reports.

4.4 Chain of Custody

A chain of custody form can be found after a sample is submitted in the LabOnline Portal via the provided link. All samples submitted to the LRN Reference Laboratory must have a chain of custody form included with the submission that has been signed by the individual responsible for packaging the sample for transport.



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.

NOTE: If a specimen is submitted in an expired primary container, it will be rejected and given an **UNSATISFACTORY** result.

- 3) **IMPORTANT** – Several required collection containers require different storage environments when NOT in-use versus after specimen collection. It is the responsibility of the submitter to monitor and maintain records of temperature requirements for storage environments:

5.2 Infection Control

- 1) Standard precautions **MUST** be used when handling any clinical specimen.
- 2) Specimens submitted to the Laboratory **MUST** be:
 - (a) **Tightly sealed with Parafilm (or equivalent) to ensure the integrity of the specimen and avoid contamination and spillage.**
 - (b) **Submitted in a sealed biohazard bag with accompanying paperwork in outer pocket of the biohazard bag and separated from the specimen.**



6. Specimen Transportation

- 1) **IMPORTANT:** Prior to specimen transport, the Sentinel Laboratory is **REQUIRED** to notify the LRN Reference Laboratory. If notification is made via email, a confirmation email from DCHHS LRN staff is required prior to specimen transport.

Senior Management

Kayle Cirrincione | Health & Safety Manager (972) 692–2712

David J. Stringer | General Laboratory Supervisor (972) 692-2762

Supervisory Staff

Alexandra Portman | LRN/BT Coordinator (972) 692-2708

24/7 Phone (214) 677-7876

DCHHS LRN Email DCHHS.LRNB@dallascounty.org

- 2) When notifying the LRN Reference Laboratory, the following information is required:

- (a) Suspected organism for rule-out testing
- (b) Estimated time of arrival for the sample at DCHHS

- 3) Deliver all specimens to:

Laboratory Division - LRN

Dallas County Health and Human Services

1410 W Mockingbird Lane

Dallas, TX 75247

NOTE: All samples must be delivered between 8AM-4:30PM, unless special arrangements have been made for after-hours delivery.

- 4) The LRN staff performs an initial inspection of the submitted specimens ensuring the following:

- (a) Temperature of the specimen was maintained during shipping
- (b) No expired, leaking, or broken collection containers are present
- (c) Accompanying test requisitions and chain of custody are present

- 5) It is recommended that **all** patient- related samples are sent along with the specimen for rule-out testing unless an autoclave is available at the Sentinel Laboratory facility.



7. Specimen Rejection

7.1 General Policy

- 1) The LRN Reference 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 2 (Test Menu) and/or Section 3 (Specimen Labeling Requirements).
- 2) The Laboratory will not process, test, or report results if the specimen is unsatisfactory.

7.2 Delayed Testing

- 1) The submitter may rectify specimens designated as Unsatisfactory in the following situations:
 - (a) Contact has not been made with the LRN Laboratory prior to sample arrival
 - (b) DCHHS Test Requisition or Chain of Custody is absent
 - (c) Test Requisition is missing **REQUIRED** patient and submitter 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 LRN at 214-677-7876 to correct the deficiency within the 24 – hour holding period.
- 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.
- (c) Incorrect specimen type
- (d) Specimens received outside of the time of stability for the ordered test.
- (e) Inappropriate specimen container for the diagnostic assay requested.
- (f) Underfilled or overfilled containers.
- (g) Unsecured/Leaking container.
- (h) Expired collection container

Note: Collection devices expiring the day after collection are typically acceptable. Consult with the Laboratory if this occurs.

- (i) Improperly shipped, stored, or prepared specimens at requisite temperatures or conditions.
- (j) Test sample degradation resulting in the inhibition of its testing.



8. Laboratory Reports

1) Select Agent Testing

- (a) Preliminary Test Results will be available within **ONE (1) to THREE (3) BUSINESS DAYS** of sample receipt.
- (b) Confirmatory Testing will be available within **TWO (2) WEEKS** of sample receipt.
 - (I) In the event that a sample must be referred to the Texas Department of State Health Services or the Centers for Disease Control for either confirmatory testing or a positive result from testing at the LRN Reference Laboratory, test results may take longer than the designated two-week window.

2) Reports will be issued via the LabOnline portal and by email if requested.

3) For testing referred to another laboratory, DCHHS will retain or be able to produce an exact duplicate of the testing laboratory's report and will ensure the authorized requester is notified of the name and address of the laboratory location where testing was performed.



9. Additional Information

9.1 Updates on Test Results

- 1) Paper Test Requests: Submitters seeking information or updates on specific laboratory test results beyond Laboratory's turn-around-times should call the LRN 24/7 Phone (214) 677-7876 for assistance.
- 2) LabOnline Electronic Test Reports – Refer to the ***DCHHS LabOnline Help Guide*** for information on navigating LabOnline Portal and retrieving final reports.

9.2 Inquiry

- 1) Comments and questions should be directed to the LRN/Bioterrorism Coordinator at (214) 677-7876.

9.3 Select Agent Reporting and Compliance

- 1) In the event of a presumptive positive or confirmed positive result for a Select Agent as identified by the Federal Select Agent Program, the LRN Reference Laboratory will report the result to appropriate public health authorities in accordance with local, state, and federal requirements and will coordinate required follow-up and confirmatory testing:
 - (a) The LRN Reference Laboratory will advise Sentinel Laboratories on the completion of all required forms (e.g., Forms 2, 3, and 4). These forms must be completed within **7 days** of a confirmed identification, unless otherwise specified.
 - (b) Any clinical samples remaining at the Sentinel Laboratory must be destroyed within **7 days** of a confirmed identification.
 - (I) The LRN Reference Laboratory can advise on proper transport or destruction of all samples by calling (214) 677 - 7876.



10. 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.