TEXAS DSHS HEALTH LEVEL 7 (HL7) ELECTRONIC LABORATORY REPORTING (ELR) ONBOARDING GUIDE

VERSION 3.3

TEXAS Health and Human Services
Texas Department of State Health Services

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Definition of Terms

AIMS (Association of Public Health Laboratories Informatics Messaging Services): A secure, cloud-of Public Health Laboratories): An organization that works to strengthen laboratory systems serving the public's health in the United States and globally. APHL represents state and local governmental health laboratories in the United States. Its members, known as "public health laboratories," monitor, detect, and respond to health threats.

ELR (Electronic Laboratory Reporting): The transmission of digital laboratory reports, often from laboratories to state and local public health departments, healthcare systems, and CDC.

EHR (Electronic Health Record): An Electronic Health Record (EHR) is an electronic version of a patient's medical history, that is maintained by the provider over time, and may include all of the key administrative clinical data relevant to that person's care under a particular provider, including demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports.

HIPAA (Health Insurance Portability and Accountability Act)

HL7 (Health Level 7): An interface standard and specifications for clinical and administrative healthcare data developed by the Health Level Seven organization and approved by the American National Standards Institute (ANSI). HL7 provides a method for disparate systems to communicate clinical and administrative information in a normalized format with acknowledgement of receipt.

LOINC (Logical Observation Identifiers Names and Codes)

NBS (NEDSS Base System)

NEDSS (National Electronic Disease Surveillance System)

NIST (National Institute for Standards and Technology)

PHI (Patient Health Information or Protected Health Information)

PIP (Promoting Interoperability Program)

SFTP (Secure File Transfer Protocol)

SNOMED-CT (Systematized Nomenclature of Medicine- Clinical Terms)

Purpose

This document serves as a guide to the step-by-step process and roadmap that an intending facility will need to follow to successfully implement Electronic Lab Reporting (ELR) with the Texas Department of State Health Service (DSHS) Public Health Informatics Data Exchange (PHID) Unit. The intent of this document is to provide a succinct ELR implementation guide for laboratories.

Hospitals participating in the **Centers for Medicare and Medicaid Services (CMS) Promoting Interoperability Program (PIP)** may use this guide to assist in meeting the ELR measure in the Public Health Objective.

There are several steps a facility must complete to successfully submit ELR data. The *Onboarding Process Flow Chart* on page 6 provides a visual representation of the workflow required. Descriptions of the workflow are presented after the chart. DSHS Infectious Disease Informatics (IDI) staff can provide additional explanation as necessary throughout the onboarding process.

Scope

ELR allows laboratories (including hospitals and other facilities) to report test results for reportable diseases through an automated and secure process to Texas NEDSS, the statewide disease surveillance system. Laboratory data are sent in a standard **HL7 2.5.1 ORU message** format electronically from a laboratory information system or electronic health record system through a secure interface to DSHS.

There is no Data Usage Agreement (DUA), Memorandum of Understanding/Agreement (MOU/MOA), or Institutional Review Board (IRB) required for hospitals and other facilities for reporting notifiable conditions to the Texas DSHS as this information are required through regulation. This document is intended to serve as clarification that pursuant to Texas state Statute and Federal Regulation, contract agreements are not necessary for reporting of notifiable diseases by specified entities to the Department of State Health Services.

Chapter 81, Subchapter C of the Texas Health and Safety Code requires reporting of **notifiable disease conditions** to public health authorities. Persons required to report under the statute include, physicians, dentists, veterinarians, local school authorities and individuals in charge of clinical or hospital laboratories. Reporting procedures and notifiable conditions are outlined in the **Texas Administrative Code, Title 25, Chapter 97**. Memorandums are not required under this reporting structure.

The Health Insurance Portability and Accountability Act of 1996's (HIPAA) Privacy Rule authorizes the disclosure of protected health information (PHI) by covered entities, without individual authorization from the patient to public health authorities such as DSHS for public health purposes including, but not limited to, public health surveillance and investigations.

The Privacy Rule, at 45 CFR 164.512(a), allows covered entities to disclose PHI to public health authorities such as DSHS when required by state laws. Chapter 81 of the Texas Health and Safety Code is the applicable state statute for this type of reporting.

Covered entities operating in Texas are expected to comply with applicable mandatory reporting requirements in Texas' state law and may rely on HIPPA for additional legal basis for disclosing the required information to DSHS. This reporting does not require DSHS to enter any legal memorandums.

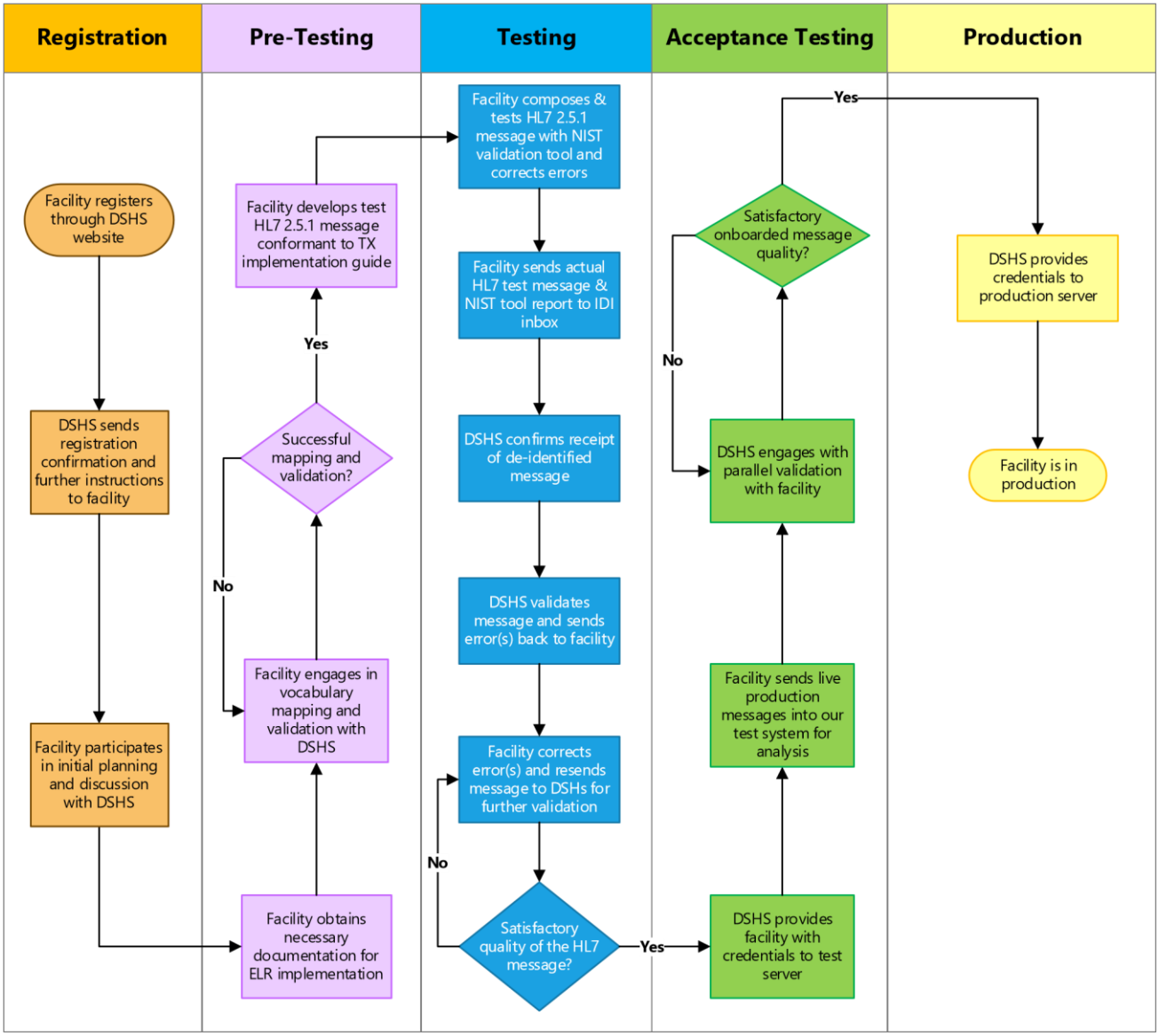
Detailed within are processes to obtain authorization for submitting ELR to the Texas National Electronic Disease Surveillance System (NEDSS), producing acceptable HL7 messages, and validating these messages for structure and vocabulary conformance. To meet the DSHS IDI requirements, the messages must be in HL7 2.5.1 using DSHS adopted standards.

Finally, this document serves to facilitate the communication of data in a standard format to DSHS NEDSS. It is assumed that the reader has background knowledge of, and access to the version of HL7 specifications, on which they wish to build a message. DSHS IDI may provide some guidance regarding base HL7 specifications but cannot be relied upon as the sole authority for which all decisions are based.

More information about NEDSS can be found at **https://www.dshs.state.tx.us/PHID/** . Questions about ELR may be directed to **IDI@dshs.texas.gov.**

Please reference the **DSHS ELR webpage** for the latest information and updates. More information on CMS' PIP program may be referenced at **https://www.cms.gov/medicare/regulations-guidance/promoting-interoperability-programs/2023-program-requirements .**

Texas HL7 2.5.1 Onboarding Process Chart



Promoting Interoperability Process Summary

Eligibility Criteria for Onboarding

Is the facility an Eligible Hospital (EH) or Critical Access Hospital (CAH), as defined by the Centers for Medicare and Medicaid Services Electronic Health Records Incentive Programs?	Yes ☐	No ☐
Does the facility have an Electronic Health Record (EHR) system that is certified for 170.314(b) (5) Incorporate Laboratory Test and Values/Results and 170.314(f) (4) Transmission of Reportable Laboratory Tests and Value/Results? For a list of Certified Electronic Health Record Technology (CEHRT) products certified for ELR reporting, visit the Certified Health IT Product List at **Certified Health IT Product List**. Use the tools provided to determine if your technology is currently on the list and meets Promoting Interoperability program requirements specific to ELR.	Yes ☐	No ☐
Has the facility set up electronic transmission either through GlobalScape or PHINMS?	Yes ☐	No ☐

Registration

- An Eligible Hospital or Critical Access Hospital facility who wants to engage in ELR for CMS PIP with DSHS must register their intent by completing the ELR Provider Registration Form.
- DSHS will receive the registration of intent and send registration confirmation with further information/instructions necessary for onboarding to the facility to the email address included in the registration of intent.
- Facility will participate in an initial planning meeting to discuss the onboarding process with DSHS Infectious Disease Informatics (IDI) team. During the initial meeting, DSHS will review necessary documentation as well as the standards in the HL7 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm) that are required for meeting the CMS PIP objectives.
- Facility will then decide if they want to continue with DSHS' ELR onboarding process.

Pre-Testing

- If the facility decides to continue with the onboarding process, the facility will complete necessary documentation for ELR onboarding implementation from DSHS IDI.
- Facility must proceed to do vocabulary mapping and validation with DSHS. The facility will complete the ELR vocabulary mapping worksheet provided by DSHS as much as possible.
- DSHS IDI staff will analyze/validate the ELR vocabulary mapping worksheet and send errors and edits to the facility for correction.
- Once the corrections have been completed, facility will re-send the mapping sheet again to DSHS for validation.
- Once DSHS is satisfied with the validation of the vocabulary mapping sheet, the facility will be notified.
- The facility will need to successfully complete the VMW and not exceed the amount of critical errors allowable.
- After successful completion of the VMW, the facility will proceed to the "testing phase".

Testing

- DSHS will provide the facility with instructions for Globalscape Secure File Transfer connection. The folder will contain a test and production folder to drop files.
- Texas is a dual reporting State. DSHS highly recommends facilities provide sample test messages from the reference labs if available for testing.

- Facility will develop and generate HL7 messages that conform to the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with Errata.
  - The facility will pretest their message(s) using the **National Institute of Standards and Technology (NIST) validation tool**. Examples of result types to be tested include Coded result (CWE), Numeric result, Titer result, structured numeric result, Text result.
- Once the context-free validation reports indicate the test messages are free of errors (Error count is ≤ 10), Facility will Send the message (.txt or. HL7) to the Test folder in GlobalScape and send an email to **IDI@dshs.texas.gov**. to let us know the messages have been dropped and attach the NIST error report.

- The file naming convention for test files is ***TEST_ [YOUR FACILITY LEGAL NAME] _ [YOUR SITE LEGAL CLIA NUMBER] _[CURRENT DATE OF FILE (YYYYMMDD).txt or .HL7.***
- DSHS IDI staff will confirm the receipt of the de-identified message.
- DSHS will validate the message and send errors back to the facility.
- Facility will correct the errors and re-send message to DSHS for further validation and error correction.
  - If necessary, DSHS may schedule a meeting to address errors and solutions.
- Once DSHS is satisfied with the quality of the HL7 message, DSHS will inform the facility to proceed to acceptance phase.

Acceptance Testing

- During acceptance testing phase, the facility will send production messages from the production environment to the test folder in GlobalScape to confirm that the changes made in test have been implemented in production.
- The file naming convention for test files is TEST _ ***[YOUR FACILITY LEGAL NAME] _[YOUR SITE LEGAL CLIA NUMBER]_[CURRENT DATE OF FILE (YYYYMMDD).txt or .HL7.***
- If DSHS is satisfied with the structure and content of the messages and it meets the data quality requirements of DSHS, the facility will go into production phase.

Production

- The facility will use their GlobalScape credentials to log in.
- The facility will upload production messages into the "prod" folder of their GlobalScape account.
- The file naming convention for production files is ***[YOUR FACILITY LEGAL NAME] _[YOUR SITE LEGAL CLIA NUMBER]_[CURRENT DATE OF FILE (YYYYMMDD).txt or .HL7.***
- Any issues with production files are discussed with the DSHS IDI team and communicated to the facility for appropriate action.
- **FACILITIES NEED TO CONSULT WITH THEIR LOCAL/REGIONAL HEALTH DEPARTMENTS TO CONFIRM IF REPORTING THEIR LAB RESULTS TO DSHS WILL MEET THEIR REQUIREMENT FOR LOCAL REPORTING.**

Electronic Laboratory Reporting (ELR) Onboarding Checklist

Before registering with DSHS, these items are suggested to accelerate the on-boarding process.

Facility Activity	Complete	Date
Map local lab test codes to LOINC standard vocabulary	Yes	
Map local, non-numeric lab test result values to SNOMED-CT standard vocabulary	Yes	
Map other local codes according to the HL7 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm)	Yes	
Develop an HL7 message conformant to the HL7 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm)	Yes	
Test ELR messages using the NIST HL7 ELR 2.5.1 Validation Suite	Yes	
Resolve message issues found using the NIST HL7 ELR 2.5.1 Validation Suite	Yes	

The Onboarding Flow-chart Table

Phase 1: Registration with Texas Department of State Health Services

Facility Activity	Complete	Date	DSHS IDI Response	Official Communication
Register for ELR through the DSHS website	Yes		Send confirmation of registration and further instructions to facility	Registration acceptance
Participate in initial onboarding call with DSHS	Yes		Schedule onboarding call with facility	N/A

*Note: All official communication will be done via email to the contact email provided in the registration of intent. To update contact information, please email **IDI@dshs.texas.gov**.*

Phase 2: Pre-Testing

Facility Activity	Complete	Date	DSHS IDI Response	Official Communication
Engage in Vocabulary Mapping and Validation with DSHS	Yes		Confirm successful Vocabulary Mapping and Validation	Yes
Compose HL7 2.5.1 Message	Yes			N/A

Phase 3: Testing

Facility Activity	Complete	Date	DSHS IDI Response	Official Communication
Validate the HL7 2.5.1 message using NIST validation tool, correct errors and send to DSHS.	Yes		Further validation and analysis of the NIST validation report by DSHS.	

Phase 4: Acceptance Testing

Facility Activity	Complete	Date	DSHS IDI Response	Official Communication
Facility will register for a Globalscape account	Yes		DSHS will confirm receipt of test message	N/A
Send live production messages to DSHS for analysis	Yes		Validate message and send errors back to facility	N/A

Phase 5: Production

Facility Activity	Complete	Date	DSHS IDI Response	Official Communication
Start sending production ELR batch transmissions to DSHS and continue parallel validation	Yes		Send Facility any issues that need correction	N/A
Stop parallel validation process	Yes			Letter of completion of onboarding

Best Practices

- Narrative or text results are not accepted in the OBX_5 fields.
- Observation values in OBX_5 (as indicated in OBX_2) are constrained to SN and CWE data types only.
- LOINC (in OBR_4 and OBX_3) and SNOMED (in OBX_5 when OBX2=CWE) are required components.
- Clinical Laboratory Improvement Amendment (CLIA) certificate numbers are preferred over the use of OIDS to identify hospitals and laboratory facilities.

Standard Reference Tables

Description	Value Set	Other Available value sets
Abnormal Flags	HL70078	Abnormal Flags
Body Site Value Set	SNOMED CT Anatomical Structure hierarchy	
Diagnostic Services	HL70074	
Ethnic Group	HL70189	PHVS_EthnicityGroup_CDC
Identifier type	HL70203	PH_IdentifierType_HL7_2x
Observation Result Status	HL70085	
Race Category	HL70005	PHVS_RaceCategory_CDC

Result Status	HL70123	
Ordered Test Name	LOINC	
Resulted Test Result	SNOMED	
Patient Sex	HL70001	
Specimen Type	HL70487	PHVS_Specimen_CDC; SNOMED CT Specimen sub-tree
Units of Measure	UCUM	

Texas ELR Issues Resolution Checklist

Common critical areas to address during message pre-testing

Message Header: MSH

Issue #	Item	What does good look like?
1	MSH 4 – Sending Facility -- Verify a CLIA number is used as the ID	Reporting Institution Name^99XXXXXXX^CLIA

Patient Information: PID

Issue #	Item	What does good look like?
2	PID 10 – Patient Race -- Verify standard race codes are used	2131-1^Other^HL70005
3	PID 22 – Patient Ethnicity -- Verify standard ethnicity codes are used	N^Non-Hispanic^HL70189

Observation Request: OBR

Issue #	Item	What does good look like?
4	OBR 4– Verify a LOINC code is used as the UniversalServiceID	24325-3^Hepatic Function Panel^LN
5	OBR 4 – Verify LOINC is in OBR4.1-4.3	**24325-3^Hepatic Function Panel^LN**^321^HEP^L
6	OBR 4 – Verify local codes, if provided, are in OBR4.4-4.6	24325-3^Hepatic Function Panel^LN^**321^HEP^L**

Observation Result: OBX

Issue #	Item	What does good look like?
7	OBX – Verify every OBX segment is only used to provide standardized test results	The following OBX segment should be created as an NTE segment: OBX|2|TX|49580-4^^LN^HIVR^HIV-RAPID TEST^99USI|11|Called to and read back by: |
8	OBX 2 – Verify only SN, CE, or CWE	OBX|1|**CE**|
9	OBX 3 – Verify a LOINC code is used as the Observation Identifier	625-4^Stool Culture^LN
10	OBX 3 – Verify LOINC is in OBX3.1-3.3	**625-4^Stool Culture^LN**^225^Stool Culture^LN
11	OBX 3 – Verify local codes, if provided, are in OBX3.4-3.6	625-4^Stool Culture^LN^**225^Stool Culture^LN**
12	OBX 5 – Verify a SNOMED code is used as the Observation Value for discreet results (CE/CWE)	372342007^Salmonella species (organism)^SCT

13	OBX 5 – Verify SNOMED is in OBX5.1-5.3 for discreet results (CE/CWE)	**11214006^REACTIVE^SCT**^REACTIVE^REACTIVE^L
14	OBX 5 – Verify local codes, if provided, are in OBX5.4-5.6 for discreet results (CE/CWE)	11214006^REACTIVE^SCT^**REACTIVE^REACTIVE^L**
15	OBX 5 – Verify titers are created as structured numeric	|^1^:^16|
16	OBX 5 – Verify all numeric values are created as structured numeric, with comparator (if present) is in OBX5.1	|>^500|

Specimen: SPM

Issue #	Item	What does good look like?
17	SPM 4- Verify a standardized code is used in Specimen Type	119297000^Blood^SCT

List of Test Conditions Required for Submission

Test messages are to be generated and include the following **Texas notifiable conditions** pretested using the NIST tool.

Condition	Organism	Test
Amoeba or any other reportable hemolytic parasite	Entamoeba histolytica or any other reportable hemolytic parasite	Microscopic detection and identification of organism (cysts or trophozoites) or antigen detection isolation, microscopic detection and identification of organism, antigen detection, or antibody detection
Arbovirus, Neuroinvasive and Nonneuroinvasive including but not limited to:	Arboviruses including but not limited to: Cache Valley virus; California serogroup virus; Chikungunya; Dengue; Eastern equine encephalitis virus; Flavivirus, unspecified; Jamestown Canyon virus; Japanese encephalitis virus; Powassan virus; St. Louis encephalitis virus; Venezuelan equine encephalitis virus; West Nile; Western equine encephalitis virus; Yellow fever; Zika virus	Isolation, antigen detection, or antibody detection
Ascariasis	Ascaris	Microscopic detection and identification of organism (eggs, larvae, or worms)
Botulism	Clostridium botulinum	PCR, culture, toxin typing
Campylobacteriosis	Campylobacter spp.	Isolation, PCR, or antigen detection

Carbapenemase producing Carbapenresistant Enterobacterales (CP-CRE)	Klebsiella species and E. coli that are resistant to any Carbapenem, including meropenem, imipenem, doripenem, or ertapenem	Isolation of Klebsiella species, E. aerogenes, or E. coli that are resistant to any Carbapenem, including meropenem, imipenem, doripenem, or ertapenem, or production of a carbapenemase (i.e., KPC, NDM, VIM, IMP, OXA-48) demonstrated by a recognized test (i.e., polymerase chain reaction, metallo- βlactamase test, modified Hodge test, Carba NP)
Diphtheria	*Corynebacterium diphtheriae*	Isolation AND Confirmation of toxin-production by Elek test or by another validated test capable of confirming toxinproduction (this part is done at CDC)
Ebola hemorrhagic fever	Ebola virus	Antigen detection
Hepatitis A, acute	Hepatitis A virus	IgM antibody detection
Hepatitis B, acute	Hepatitis B virus	Antigen or core IgM antibody detection
Hepatitis B virus infection in pregnant women	Hepatitis B virus	Antigen or antibody*** detection (excluding HBV surface antibody)
Human immunodeficiency virus (HIV)	HIV	All HIV positive results, CD4 (CD4 T-lymphocyte) counts, viral loads, HIV DNA Tests and HIV Western Blots, HIV 1,2 AB (antibody) tests, HIV IFA (Immunofluorescent Assay) tests

Human prion disease including CreutzfeldtJakob disease	Prions	Positive RT-QuIC or Tau protein
Legionellosis	Legionella	Isolation of Legionella, detection of Legionella pneumophila serogroup 1 antigen in urine, or detection Legionella pneumophila serogroup 1 antibody

Monkeypox	Monkeypox virus	PCR testing for *Orthopoxvirus*, nonvariola *Orthopoxvirus,* or *Monkeypox virus*
Mumps	Mumps virus	Isolation or PCR
Rabies, human	Lyssavirus	isolation, antigen detection, or antibody detection
Rickettsia, unspecified	Rickettsia spp.	Antibody detection
Rubella	Rubella virus	Isolation, antigen detection, IgM antibody detection, significant change in IgG titer, or PCR
Rubella, congenital syndrome (CRS)	Rubella virus	Isolation, antigen detection, or antibody detection in infant, or PCR
Shiga toxin-producing Escherichia coli (STEC)	Escherichia coli O157:H7 and Shiga toxin-producing Escherichia coli	Isolation of Escherichia coli O157:H7 or detection of Shiga toxin by PCR or EIA

Shigellosis	Shigella spp.	Isolation, PCR, or antigen detection; Whole genome sequencing
Sexually transmitted disease (STD)	Chlamydia, Gonorrhea, Treponema (Syphilis)	All tests.
Tuberculosis	Mycobacterium tuberculosis M. bovis, M. africanum, M. microti, M. canetii, M. caprae, and M. pinnipedii	Isolation of M. tuberculosis complex from a clinical specimen, OR Demonstration of M. tuberculosis complex from a clinical specimen by nucleic acid amplification test, OR Demonstration of acid-fast bacilli in a clinical specimen when a culture has not been or cannot be obtained.
Vancomycin-intermediate Staphylococcus aureus (VISA)	Vancomycin-intermediate (MIC: 4-8 µg/ml) Staphylococcus aureus	Isolation
Vancomycin-resistant Staphylococcus aureus (VRSA)	Vancomycin-resistant (MIC: > 16 µg/ml) Staphylococcus aureus	Isolation

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