Public Health Informatics Data Exchange Electronic Laboratory Reporting (ELR) Promoting Interoperability HL7 Onboarding Guide

Version 2.2

TEXAS Health and Human Services | Texas Department of State Health Services

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Purpose

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

Hospitals participating in the Centers for Medicare and Medicaid Services Electronic Health Record Incentive Programs can use this guide to assist them in meeting the ELR measure in the Public Health Objective.

There are a number of steps a facility must complete to successfully submit ELR data. The Onboarding Process Flow Chart 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.

Scope

ELR allows laboratories (including hospitals and other facilities) to report test results for reportable diseases through an automated and secure process to the statewide disease surveillance system. Laboratory data are sent in a standard **HL7 2.5.1** 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) required for notifiable condition reporting to the Texas DSHS, as this information is required through regulation.

This document is intended to serve as clarification that pursuant to Texas state Statute and Federal Regulation, Memorandums of Agreement (MOA) or Memorandums of Understanding (MOU) are not necessary for reporting of notifiable diseases by specified entities to the Department of State Health Services (“Department”).

Chapter 81, Subchapter C of the Texas Health and Safety Code requires reporting on certain identified diseases to health authorities or the Department. 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 Department rule, 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 the Department for public health purposes including, but not limited to, public health surveillance and investigations. The Electronic Laboratory Reporting program is operated by the Department for public health purposes.

The Privacy Rule, at 45 CFR 164.512(a), allows covered entities to disclose PHI to public health authorities such as the Department, 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 the Department. This reporting does not require the Department to enter into any legal Memorandums.

If onboarding via AIMS, an appropriate chain of trust must be established with the Association of Public Health Laboratories (APHL) using the eHealth Exchange, Care quality, or the APHL participation agreement. The APHL AIMS platform and RCKMS operate through Business Associate or equivalent authorities from the clinical care covered entity.

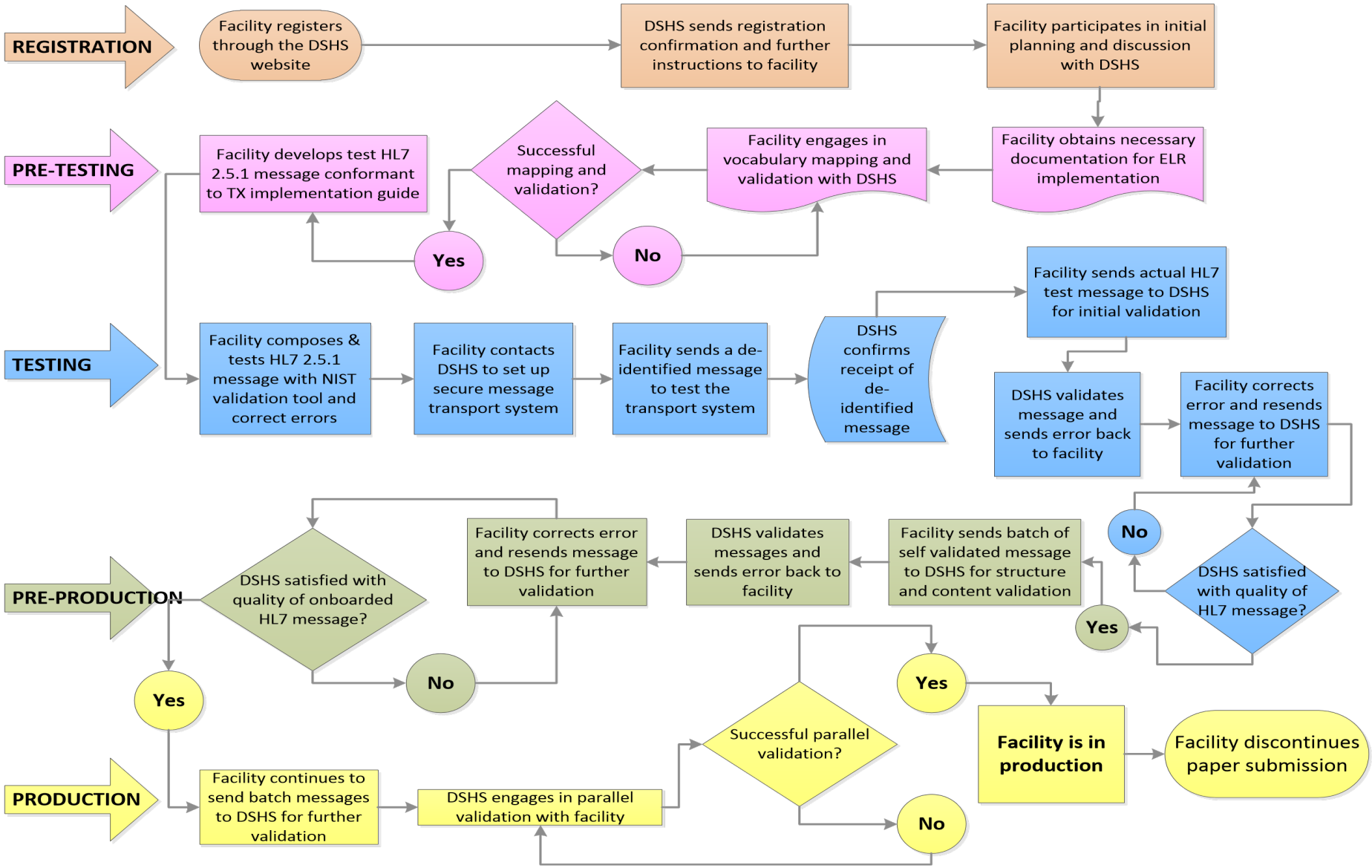
Detailed within are processes to obtain authorization for communicating ELR to the DSHS NEDSS, producing acceptable HL7 messages, and validating these messages for structure and vocabulary constraints. In order to meet the DSHS IDI requirements, the messages must be in HL7 2.5.1 using DSHS-adopted standards.

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 with regard to base HL7 specifications but cannot be relied upon as the sole authority for which all decisions are based.

More information about NEDSS may be found at http://www.dshs.state.tx.us/nedss. Questions about ELR may be directed to IDI@dshs.state.tx.us.

General information about public health reporting and Promoting Interoperability may be found at http://www.dshs.state.tx.us/mu.

Texas HL7 2.5.1 PIP 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 http://oncchpl.force.com/ehrcert. Use the tools provided to determine if your technology is on currently on the list and meets Promoting Interoperability program requirements specific to ELR.	Yes ☐	No ☐
Does the facility have the ability to set up electronic transmission either through SFTP or PHINMS?	Yes ☐	No ☐

Registration

- An Eligible Hospital or Critical Access Hospital facility who wants to engage in ELR for MU with DSHS must register their intent at ELR Provider Registration Form (smartsheet.com)
- DSHS will receive the registration of intent and send registration confirmation with further information/instructions necessary for on-boarding to the facility to the email address included in the registration of intent.
- Facility will participate in an initial planning meeting to discuss the on-boarding 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 Promoting Interoperability program Use objectives with the facility.
- Facility will then decide if they want to continue with DSHS' ELR on-boarding process.

Pre-Testing

- If the facility decides to continue with the on-boarding process, the facility will obtain necessary documentation for ELR on-boarding 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 done, 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.
- If DSHS is **not satisfied with the worksheet after 3 months**, the facility will be moved to the end of the pre-testing queue to free up space for other facilities.
- However, if DSHS is satisfied with the corrections, the facility will proceed to the testing phase.

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 5-10), send copies of the validation reports to IDI@dshs.texas.gov.
- After the facility has met the message applicable criteria, they will contact DSHS to set up a secure message transport system.
- The facility will send a de-identified message to DSHS in order to test the transport system.
- DSHS IDI staff will confirm the receipt of the de-identified message.
- Facility will then send an actual HL7 message (test) that is conformant to the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with Errata for initial validation by DSHS.
- DSHS will validate the message and send errors back to the facility.

- Facility will have up to **3 months** to correct the errors and re-send message to DSHS for further validation and error correction.
- If the messages are not at a satisfactory state as determined by DSHS, the facility will be put at the end of the testing queue.
- Once DSHS is satisfied with the quality of the HL7 message, DSHS will inform the facility to proceed to onboarding/acceptance phase.

Acceptance Testing

- The facility will begin to send live batch transmission of messages to DSHS for structure and content validation.
- DSHS will review and validate the messages and send errors and corrections back to the facility. Facility will correct the errors and resend the messages for further validation.
- If DSHS is satisfied with the structure and content of the messages and it meets the data quality requirements of DSHS IDI, the facility will go into production phase.
- However, if DSHS is not satisfied with the messages structure, content and quality, the facility will have **3 months** to correct any errors and resend the messages to DSHS for further review.

Production

- Facility will continue to send batch messages to DSHS for validation.
- DSHS will give permission to engage the facility in **parallel validation**, a process whereby the Subject Matter Experts (SMEs) at DSHS will perform gap analysis to compare the data submitted into DSHS IDI with the content of the paper laboratory report to make sure the content are similar and synonymous.
- Any issues with parallel validation are discussed with the DSHS IDI team and communicated to the facility for appropriate action if there is any necessity.
- Once parallel validation is concluded, DSHS will inform the facility when to discontinue paper submission of reportable disease events.

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	

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.state.tx.us.

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.	
Contact DSHS to set up secure message transport	Yes		Provide secure transport options	N/A
Send de-identified message to test the transport system	Yes		Confirm receipt of de- identified message	N/A
Send actual HL7 **test** message to DSHS for initial validation	Yes		Validate message and send errors back to facility	N/A

Phase 4: Onboarding

Facility Activity	Complete	Date	DSHS IDI Response	Official Communication
Send batch of validated message to DSHS for structure and content	Yes		Validate message and send errors back to facility	N/A
Facility correct error and resend message back to DSHS	Yes		State whether message is free of error not	UAT test completion

Document what errors have been corrected and send updated batch to DSHS	Yes		Verify all errors corrected and discuss parallel test validation with facility	
Participate in parallel test validation process as decided during discussion with DSHS	Yes		Discuss moving to production with facility	

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		Inform facility about the end of the onboarding process	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	MSH4 – 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	PID10 – Patient Race -- Verify standard race codes are used	2131-1^Other^HL70005
3	PID22 – Patient Ethnicity -- Verify standard ethnicity codes are used	N^Non-Hispanic^HL70189

Observation Request: OBR

Issue #	Item	What does good look like?
4	OBR4– Verify a LOINC code is used as the UniversalServiceID	24325-3^Hepatic Function Panel^LN
5	OBR4 – Verify LOINC is in OBR4.1-4.3	**24325-3^Hepatic Function Panel^LN**^321^HEP^L
6	OBR4 – 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 actually 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	OBX2 – Verify only SN, CE, or CWE	OBX|1|**CE**|
9	OBX3 – Verify a LOINC code is used as the Observation Identifier	625-4^Stool Culture^LN
10	OBX3 – Verify LOINC is in OBX3.1-3.3	**625-4^Stool Culture^LN**^225^Stool Culture^LN
11	OBX3 – Verify local codes, if provided, are in OBX3.4-3.6	625-4^Stool Culture^LN**^225^Stool Culture^LN**
12	OBX5 – Verify a SNOMED code is used as the Observation Value for discreet results (CE/CWE)	372342007^Salmonella species (organism)^SCT
13	OBX5 – Verify SNOMED is in OBX5.1-5.3 for discreet results (CE/CWE)	**11214006^REACTIVE^SCT**^REACTIVE^REACTIVE^L

14	OBX5 – Verify local codes, if provided, are in OBX5.4-5.6 for discreet results (CE/CWE)	11214006^REACTIVE^SCT^**REACTIVE^REACTIVE^L**
15	OBX5 – Verify titers are created as structured numeric	|^1^:^16|
16	OBX5 – 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	SPM4 – Verify a standardized code is used in Specimen Type	119297000^Blood^SCT

Examples of Some Conditions

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

	Condition	Organism	Test
1.	Amoeba,anaplasma or any other reportable hemolytic parasite	Entamoeba histolytica, Anaplasma phagocytophilum 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
2.	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
3.	Ascariasis	*Ascaris*	microscopic detection and identification of organism (eggs, larvae, or worms)
4.	Campylobacteriosis	*Campylobacter* spp.	isolation or antigen detection
5.	Carbapenem-resistant Enterobacteriaceae (CRE)	*Klebsiella* species and *E. coli* that are resistant to any Carbapenem, including meropenem, imipenem, doripenem, or ertapenem	isolation of *Klebsiella* species and *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)
6.	Ebola hemorrhagic fever	Ebola virus	antigen detection

7.	Hepatitis A, acute	Hepatitis A virus	IgM antibody detection
8.	Hepatitis B, acute	Hepatitis B virus	antigen or core IgM antibody detection

9.	Hepatitis B virus infection in pregnant women	Hepatitis B virus	antigen or antibody*** detection (excluding HBV surface antibody)
10.	HIV	HV	All HIV positive results, CD4 (CD4 Tlymphocyte) counts, viral loads, HIV DNA Tests and HIV Western Blots, HIV 1,2 AB (antibody) tests, HIV IFA (Immunofluorescent Assay) tests
11.	Human prion disease including Creutzfeldt-Jakob disease	Prions	positive *RT-QuIC or* Tau protein
12.	Legionellosis	*Legionella*	isolation of *Legionella,* detection of Legionella pneumophila serogroup 1 antigen in urine, or detection Legionella pneumophila serogroup 1 antibody
13.	Multidrug-resistant Acinetobacter (MDR-A)	*multidrug-resistant Acinetobacter spp.*	isolation of Acinetobacter spp. that are nonsusceptible (i.e., resistant or intermediate) to at least one antibiotic in at least 3 antimicrobial classes of the following 6 antimicrobial classes: βeta-Lactam (Piperacillin, Piperacillin/Tazobactam), Aminoglycosides (Amikacin, Gentamicin, Tobramycin), Carbapenems (Imipenem, Meropenem, Doripenem), Fluoroquinolones (Ciprofloxacin, Levofloxacin), Cephalosporins (Cefepime, Ceftazidime), Sulbactam (Ampicillin/Sulbactam)
14.	Rabies, human	Lyssavirus	isolation, antigen detection, or antibody detection
15.	Rickettsia, unspecified	*Rickettsia* spp.	antibody detection
16.	Rubella	Rubella virus	isolation, antigen detection, IgM antibody detection, or significant change in IgG titer

17.	Rubella, congenital syndrome (CRS)	Rubella virus	isolation, antigen detection, or antibody detection in infant
18.	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
19.	Shigellosis	*Shigella* spp.	isolation or antigen detection

20.	STD	*Chlamydia,Gonorrheoa, Treponema(Syphilis),Trichomona,*	All tests.
21.	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.
22.	Vancomycin-intermediate Staphylococcus aureus (VISA)	vancomycin- intermediate (MIC: 4-8 µg/ml) *Staphylococcus aureus*	isolation
23.	Vancomycin-resistant Staphylococcus aureus (VRSA)	vancomycin-resistant (MIC: > 16 µg/ml) *Staphylococcus aureus*	isolation