Electronic Laboratory Reporting (ELR)

On-Boarding Handbook

This handbook is intended to be used by potential ELR trading partners of the Tennessee Department of Health (TDH). The documents provided are for trading partner use only, and nothing in this document should be returned to TDH unless specifically requested.

https://tn.gov/health/article/laboratory-reporting

TDH Mission: Protect, promote and improve the health and prosperity of people in Tennessee
TDH Vision: A recognized and trusted leader, partnering and engaging to accelerate Tennessee to one of the nation's 10 healthiest states

ELR On-Boarding Handbook Table of Contents

Terms and Acronyms

This section defines terms and acronyms that are used throughout the on-boarding handbook.

CEDEP: Communicable and Environmental Diseases and Emergency Preparedness Division, the Division within the Tennessee Department of Health that receive electronic lab reports.

CLIA: Clinical Laboratory Improvement Act

CMS: Centers for Medicare & Medicaid Services

Coded element: A message element that consists of a code, a text description, and a code system.

EHR: Electronic health record

ELR: Electronic laboratory reporting

HL7: Health Level 7, a standardized medical message system used for electronic lab reporting to public health. HL7 is one of several American National Standards Institute – accredited Standards Developing Organizations operating in the healthcare arena (http://hl7.org).

IG: Implementation Guide

LIS: Laboratory Information System, also referred to as Laboratory Information Management System (LIMS)

LOINC: Logical Observation Identifiers Names and Codes, which identify the laboratory observation. The LOINC database is maintained by the Regenstrief Institute and is intended to assist in the electronic exchange or clinical results (http://loinc.org).

MIC: Minimum inhibitory concentrations

MQF: Message Quality Framework

MU: Meaningful Use

NIST: National Institute of Standards and Technology

OID: Object Identifier, which is a code number identifying an object used in electronic lab reporting to public health.

PHA: Public Health Agency

PHIN VADS: Public Health Information Network Vocabulary Access and Distribution System

SNOMED-CT: Systematized Nomenclature of Medicine - Clinical Terms, which are used to identify the laboratory results. The clinical terminology is owned and maintained by SNOMED International (formerly IHTSDO).

TDH: Tennessee Department of Health

Trading partner: An entity such as a hospital or laboratory that sends data to the public health department.

TPA: Trading partner agreement

TPRS: Trading Partner Registration System

Introduction

Background

Certain diseases and events are declared to be communicable and/or dangerous to the public and are to be reported to the state or local health departments by all hospitals, physicians, laboratories and other persons knowing of or suspecting a case in accordance with the provision of the statutes and regulations governing the control of communicable diseases in Tennessee (T.C.A. §68 Rule 1200-14-01-.02).

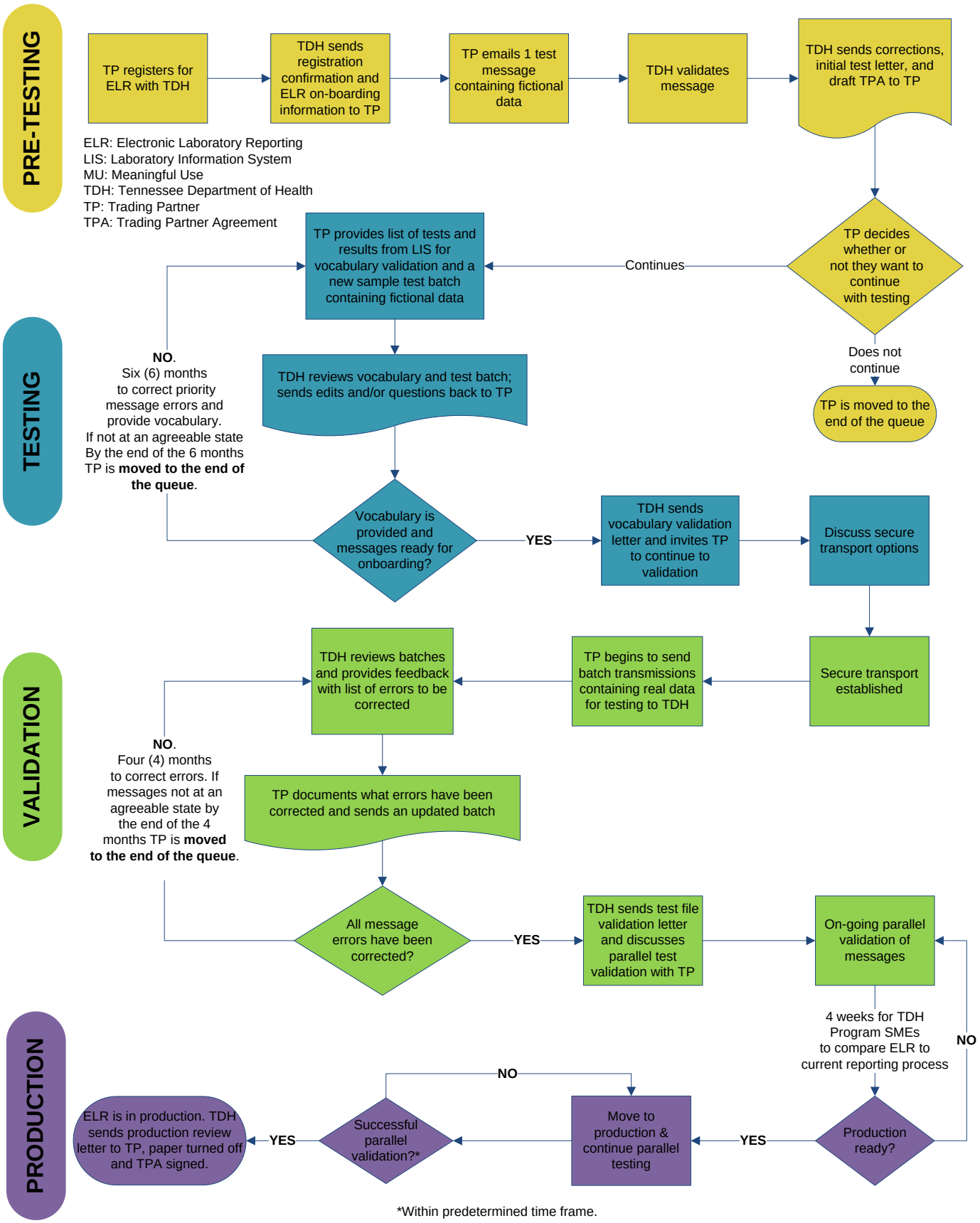
Scope

This handbook should not be used as a tutorial for either HL7 or electronic interfaces. The reader and laboratory trading partners are expected to have a basic understanding of interface concepts, HL7 messaging, and electronic laboratory reporting (ELR) to public health. This handbook is a constraint of the HL7 Implementation Guide, and may be used with either version 2.3.1 or 2.5.1. Please note: hospital-associated laboratories that are sending ELR for Meaningful Use are required to send HL7 2.5.1 messages.

Contact

To learn more about ELR in Tennessee, contact the Surveillance Systems and Informatics Program at (615) 532-6655 or by email at CEDS.Informatics@tn.gov.

On-boarding for HL7 2.3.1 or 2.5.1 ELR from Hospitals and Laboratories



*Within predetermined time frame.

Tennessee Department of Health (TDH) On-boarding for HL7 2.3.1 or 2.5.1 ELR Process Narrative

PRE-TESTING

- In Tennessee, the Electronic Laboratory Reporting (ELR) on-boarding process begins when a potential trading partner registers with TDH expressing their intent to send laboratory information electronically.
- TDH will confirm registration and provide the ELR on-boarding handbook to the potential trading partner.
- The trading partner should obtain a copy of the Health Level Seven (HL7) Standard and HL7 Implementation Guide. Eligible hospitals that are testing with TDH for Meaningful Use **must** use HL7 version 2.5.1 for messaging.
- The trading partner sends the ELR staff at TDH an initial test message through email containing fictional data. The ELR staff at TDH will validate the message structure.
- ELR staff at TDH send the trading partner corrections that need to be made to the initial message, an official letter documenting that they did send a test message to TDH, and the draft Trading Partner Agreement (TPA) with Tennessee-specific requirements.
- A call may be held at this point to discuss whether the trading partner wants to continue with on-boarding, and to outline the next steps of the process. During that call the timeline and business rules will be discussed. (NOTE: this discussion may also occur via email.)

TESTING

- If the trading partner decides to continue with the on-boarding process, they will need to provide TDH with a list of test and results that they plan to report, along with their associated standard and/or local codes. This could be provided in the form of an export from the partner's laboratory information management system (LIMS).
- The trading partner will send the test and result vocabulary along with a sample test batch of messages containing fictional data through email to TDH for validation.
- The ELR staff at TDH will review the vocabulary and send suggested edits to the test batch to the trading partner. **The trading partner will have up to 6 months to correct the priority message errors.** If the messages are not at a state that TDH can accept within 6 months, the trading partner will be moved back to the end of the on-boarding queue in order to free up TDH resources to work with other partners.
- When the vocabulary list has been provided and the messages are ready for validation, TDH will send the trading partner an official email documenting the completion of testing and invite the trading partner to begin validation. TDH will also discuss options for secure transport with the trading partner at this time.

VALIDATION

- Secure transport will be established for batch ELR messages.
- Once the trading partner is sending regular test messages for validation, TDH ELR staff will review the batches and provide the trading partner with feedback and a list of errors that should be corrected.
- The ELR staff at TDH will check-in regularly with the trading partner by phone or email to discuss issues and ensure progress is being made. **The trading partner will have up to 4 months to correct all message errors.** If the test batches are not at a state that TDH can accept within 4 months, the trading partner will be moved back to the end of the queue in order to free up TDH resources to work with other partners engaged in ELR on-boarding.
- When all message errors have been corrected, TDH will send the trading partner an official email documenting the completion of the test file validation and discuss the parallel validation process.
- There will be on-going parallel validation of messages by the CEDEP Program Subject Matter Experts (SMEs) at TDH. During this time, the trading partner will be required to send all lab reports currently being reported on paper to the TDH Central Office. The Program SMEs at TDH will validate paper lab reports and ELR for completeness of ELR messaging to ensure that no paper lab reports or useful information in them is missing from ELR. Once all Programs sign-off, the messages will be deemed production ready.
- Near the end of parallel validation, TDH ELR staff will also send a draft TPA with any additional trading partner-specific business rules and with details regarding message transport. The TPA will not be finalized and signed until after Production.

PRODUCTION

- Once production ready, the ELR batch messages will be sent to TDH's production surveillance systems. The trading partner will continue sending all paper lab reports to the TDH Central Office for post-production parallel validation.
- Once it is determined that no lab reports are missing in the ELR process, TDH will send the trading partner an official letter documenting the successful completion of the production review. Paper lab reporting to TDH by the trading partner may be discontinued for those tests included in ELR, and the TPA will be signed by both TDH and the trading partner.
- The TPA will be reviewed after one year to determine if any updates need to be made.

For more information, please contact the Communicable Disease Surveillance Systems and Informatics team at CEDS.Informatics@tn.gov and please include 'ELR' in the subject line.

Electronic Laboratory Reporting (ELR) On-Boarding Checklist

Introduction

The Communicable and Environmental Diseases and Emergency Preparedness Division (CEDEP) within the Tennessee Department of Health (TDH) has programmatic oversight of the diseases and conditions that are reportable to the State of Tennessee and how they are to be reported from hospitals, providers, and laboratories. This on-boarding checklist is intended for those interested in Electronic Laboratory Reporting (ELR), including those interested in obtaining Centers for Medicaid and Medicare Services (CMS) "Meaningful Use" funding. For more information on the ELR on-boarding process in Tennessee, helpful resources, and additional documentation, please visit: https://tn.gov/health/article/laboratory-reporting.

Purpose

The purpose of this document is to provide the reader with the information necessary for successful electronic laboratory reporting to TDH. The on-boarding checklist is for health systems, hospitals, laboratories and their vendors or business associates.

Step 0: Pre-Registration Activities **Before registering with TDH, these items are suggested to accelerate the on-boarding process.**		
Trading Partner Activity	**Complete**	**Comments & Resources**
Download a free copy of the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health Release 1 (US Realm) with Errata.	☐	Available for download from HL7: http://www.hl7.org/implement/standards/product_section.cfm?section=5 NOTE: if not using HL7 version 2.5.1, please make sure to download the appropriate Implementation Guide. Contact TDH ELR staff if you need assistance.
Download the current TN list of reportable diseases for laboratories.	☐	Available for download from the TDH website: https://apps.health.tn.gov/ReportableDiseases
Map local lab test codes to LOINC standard vocabulary.	☐	Reference materials are available from the following websites: LOINC: http://loinc.org Search LOINC terms at: search.loinc.org
Map local, non-numeric lab test result values to SNOMED-CT standard vocabulary.	☐	Reference materials are available from: SNOMED-CT: https://www.nlm.nih.gov/healthit/snomedct/index.html (has information on how to register for ULMS to access their SNOMED-CT browser)
Map other local codes according to the HL7 2.5.1 Implementation Guide.	☐	Public Health Information Network Vocabulary Access Distribution System (PHIN VADS) & Reportable Condition Mapping Table: https://phinvads.cdc.gov/vads/SearchVocab.action
Develop an HL7 message conformant to the HL7 2.5.1 Implementation Guide.	☐	
Test HL7 ELR messages using the NIST HL7 ELR 2.5.1 Validation Suite.	☐	NIST HL7 ELR Validator may be accessed here: http://hl7v2-elr-testing.nist.gov/mu-elr/. For best results, please test all result types that your system produces (coded, numeric, structured numeric, free text).
Resolve message issues found using the NIST HL7 ELR 2.5.1 Validation Suite.	☐	

Step 1: Registration with Tennessee Department of Health (TDH) & Pre-Testing		
Trading Partner Activity	**Complete**	**Comments & Resources**
Set up an account in the Trading Partner Registration System (TPRS): https://apps.tn.gov/tpr/	☐	Trading Partner Registration User Guide is available here: https://apps.tn.gov/tpr/pdf/TPR_Users_Guide.pdf. You may also contact MU.Health@tn.gov for assistance.
Submit ELR registration information via TPRS: https://apps.tn.gov/tpr/	☐	TDH will send trading partner registration confirmation and on-boarding information.
Email test message containing fictional data following HL7 Version 2.5.1 ELR Implementation Guide to CEDS.Informatics@tn.gov .	☐	TDH will review message, send trading partner message corrections, draft Trading Partner Agreement (TPA), and Vocabulary Worksheet.
Step 2: Testing		
Provide TDH with a list of test and results that they plan to report, along with their associated standard and/or local codes.	☐	TDH will review and send trading partner vocabulary edits and questions.
Email test batch of messages containing fictional data following HL7 Version 2.5.1 ELR Implementation Guide to CEDS.Informatics@tn.gov . See Appendix 2 for sample test scenarios that may be used to create test messages.	☐	TDH will review test batch and send an issues list to the trading partner with corrections to be made.
If applicable: return updated vocabulary list and new test batch to TDH (iterative process - continue until at an agreeable state).	☐	
Step 3: Validation		
Establish secure transport and send test file to TDH.	☐	The preferred transport method for ELR is SFTP, but other methods may be discussed. TDH will acknowledge that test file was successfully received and ask trading partner to begin daily transmissions.
Start sending real ELR batch transmissions to TDH.	☐	TDH will review batches and send an issues list with message corrections to be made. Regular calls may be scheduled to discuss messaging issues, if necessary.
If applicable: correct errors and send updated batches to TDH (iterative process – continue correcting until at an agreeable state).	☐	TDH will verify all errors have been corrected and discuss parallel validation with trading partner.
Begin faxing paper lab reports to ELR staff for parallel validation.	☐	TDH ELR staff will work with Program SMEs to compare paper lab reports to ELR for completeness and accuracy of ELR data.
Review draft trading partner agreement (TPA), when provided by TDH.	☐	
Step 4: Production		
Start sending production ELR batch transmissions to TDH and continue sending paper.	☐	
If applicable: correct any issues found during post-production parallel validation.	☐	TDH will alert trading partner when they can stop sending paper labs for parallel validation.
Discontinue paper reporting.	☐	
Review and sign final TPA.	☐	

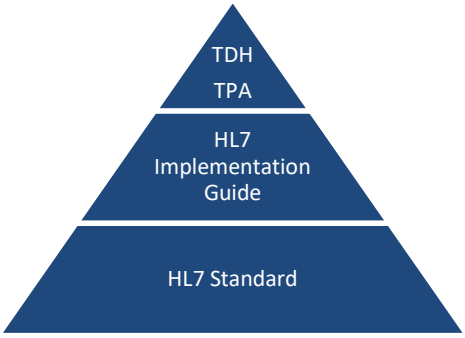
Electronic Laboratory Reporting Frequently Asked Questions

The following are answer to questions commonly asked by trading partners before and during the on-boarding process. If you have additional questions, please contact the ELR team at CEDS.Informatics@tn.gov.

1. **What constitutes ELR in TN?**
   In TN, ELR is the electronic submission of laboratory results thought to be indicative of a reportable condition, disease, or event, as described by the TDH, using interoperability standards (HL7 messaging). Flat file submissions, emails, and other formats are not considered to be ELR in TN, even if transmitted electronically.

2. **How will TDH use the data I send in ELR messages?**
   The ultimate goal of ELR is for the TDH surveillance systems to be able to consume that data so it can be used for public health action. TDH must ensure adequate and reliable information in those systems. Because of this, TDH will not use the data during testing in production surveillance systems. Once the ELR message content and structure is at an agreeable state, TDH will discuss moving the trading partner into production.

3. **What HL7 versions can TDH currently receive for ELR?**
   TDH is currently able to receive both HL7 2.3.1 and HL7 2.5.1 for ELR following the respective standards and implementation guides. TDH expects messages to be formatted based on the following hierarchy, where each document is a constraint upon the one below it.



   The HL7 Standard contains the order and structure of data fields in detail and the HL7 Implementation Guide contains constraints specific to public health reporting and focuses on one type of HL7 message, the ORU^R01 message. This handbook and the TDH TPA contain TDH-specific constraints and exceptions to the HL7 Implementation Guide as well as additional requirements specific to TDH to support electronic exchange of laboratory results of reportable diseases in the State of Tennessee.

   For more information on the HL7 standards and the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health Release 1 (US Realm) with errata, please visit http://www.hl7.org/implement/standards/product_section.cfm?section=5. To obtain a copy of the Implementation Guide for Transmission of Laboratory–Based Reporting of Public Health Information using Version 2.3.1 of the HL7 Standard Protocol (dated March 2005), please visit https://www.cdc.gov/elr/technicalstandards.html. Please contact TDH for a draft copy of the TDH Trading Partner Agreement.

4. **Do you require the use of standard vocabulary?**
   Yes, we require the use of standard vocabulary and value sets, including but not limited to LOINC, SNOMED, and UCUM. LOINC codes and associated descriptions are required for all observation identifiers (OBX-3). TDH expects all coded observations values (OBX-5) to use SNOMED codes and associated descriptions. This applies to all ordinal results such as positive and reactive as well as nominal results for organism names. This does not apply to numeric or structured numeric observation values.

5. **Why am I required to submit a vocabulary list to TDH?**
   TDH has found that vocabulary is one of the most time-intensive aspects of ELR validation. To expedite that process, TDH has worked vocabulary validation into the ELR on-boarding process. During this validation, TDH will work with your facility to ensure only reportable lab results are being sent, verify the tests that are performed in-house and those performed by reference laboratories, confirm that the LOINC and SNOMED codes being sent are valid and descriptions are accurate, check for internal consistency between LOINC code, result type, and specimen source, and work out potential content issues on the front-end.

6. **Will TDH map my local codes? If not, what tools are available for vocabulary mapping assistance?**
   TDH will not map local codes to standard codes. TDH will only accept local codes if sent with the corresponding standard vocabulary. The two best places to find vocabulary mapping assistance include RELMA from the Regenstrief Institute (http://loinc.org/relma) and CDC's PHIN VADS (Vocabulary Access and Distribution System) where you can find a wide variety of vocabulary and tools, including the Reportable Condition Mapping Tables (RCMT) (http://phinvads.cdc.gov/vads/SearchHome.action).

7. **What web based tools are available to assist me in validating my message structure?**
   TDH uses free, online ELR message tools to assist in validation. Examples include the NIST HL7 2.5.1 Validation Suite for certifying 2014 and 2015 Edition Meaningful Use EHR technology (http://hl7v2-elr-testing.nist.gov/mu-elr/) and the CDC's Message Quality Framework (MQF) tool (https://phinmqf.cdc.gov/). TN recommends potential trading partners, including those just interested in testing for Meaningful Use, to first validate their messages using the NIST tool and make any necessary corrections, prior to submitting to TDH for testing. TDH recognizes that not all errors received from the NIST or MQF validation are of equal importance; some may be accepted by TN.

8. **What is reportable in TN?**
   The list of reportable diseases and events is updated annually and can be found on the TDH website: https://apps.health.tn.gov/ReportableDiseases. For information specific to lab events, please see the Reportable Diseases and Events Laboratory Reporting Guidance document: https://apps.health.tn.gov/ReportableDiseases/Common/2017_Detailed_Laboratory_Guidance.pdf.

9. **What methods of transport are available to send ELR to TDH?**
   Secure file transport protocol, or SFTP, is the preferred method of transport for ELR with TDH. This can be set up either by creating a username and password for the account or by exchanging public keys. A username and password is created by default, but utilizing the exchange of public keys is ideal as passwords expire every 90 days. Additional mechanisms may be available and can be discussed upon establishment. TDH does not establish secure transport with trading partners until vocabulary validation is completed and most structural message errors have been resolved. Please see the ELR on-boarding process on page 5 for more information.

10. **If my lab starts to send ELR to TDH, will we have to continue sending paper lab reports?**
    Paper lab reports will only be discontinued once the ELR have been validated against them for a pre-determined amount of time, depending on lab report volume. Paper reporting can only be discontinued for the lab results included in ELR. If your facility is not utilizing ELR to meet all reporting obligations (e.g., not capturing results performed by reference laboratories), those lab reports will still need to be reported on paper. In the event that an ELR is not received, but TDH is notified of lab results from a provider, then TDH will require that paper/manual lab report submission from the lab resume until ELR is validated once again.

11. **Does ELR fulfill my reporting requirements to TDH?**
    Yes, however, ELR reporting by laboratories does not nullify the health care provider's or institution's obligation to report diseases and events, nor does reporting by health care providers nullify the laboratory's obligation to report reportable lab events. Laboratory reporting, including ELR, is not the same as case reporting by health care providers.

12. **Will my lab need to send the tests performed by reference lab facilities?**
    Yes. According to Tennessee Rules and Regulations, ELR must include lab reports for tests performed in-house and by reference laboratories, with the performing organization appropriately documented in the ELR message. If you are unable to appropriately document the performing organization or utilize standard vocabulary for those results sent to reference labs, paper lab reporting of those lab results will be expected.

13. **How long does the on-boarding process take?**
    For an estimated timeline, please see the ELR on-boarding process on page 5. The actual time to production really depends on the readiness of the trading partner and on how many other trading partners TDH is currently on-boarding. For this reason, we recommend that potential trading partners complete all of the pre-registration activities on page 8 prior to sending their first test message.

14. **How do I get started?**
    The first step in the ELR on-boarding process is registering intent with TDH. To assist trading partners with tracking their progress through the ELR on-boarding process, TDH developed the ELR on-boarding checklist (page 8). This list is recommended for trading partner use, but will not be required to be completed and submitted to TDH. Before starting the on-boarding process, TDH recommends:
    a. Mapping local lab test codes to LOINC standard vocabulary
    b. Mapping local, non-numeric test result values to SNOMED-CT standard vocabulary
    c. Mapping other local codes according to the HL7 2.5.1 Implementation guide: Electronic Laboratory Reporting to Public Health (US Realm)
    d. Obtaining a copy of the HL7 2.5.1 Implementation guide: Electronic Laboratory Reporting to Public Health (US Realm)
    e. Working to develop conformant messages for all result types
    f. Testing those messages using the NIST HL7 ELR 2.5.1 Validation Suite
    g. Resolving message issues found using the NIST HL7 ELR 2.5.1 Validation Suite

15. **I received a letter from Tennessee Department of Health stating my facility/health system is "not a target for continued testing and validation of ELR with TDH and has been placed in the TDH ELR on-boarding queue." What does this mean?**
    This letter is to inform you that you are in our ELR on-boarding queue and will be contacted in the future to continue testing and validation of ELR with TDH. We ask that you continue to report all reportable diseases and events in accordance with your current reporting methods.

16. **What information should I include in the message subject header (MSH)?**
    TDH accepts either CLIAs or OIDs in MSH-4 (Sending Facility). For MSH-5 and MSH-6, TDH expects the OIDs below. For other MSH components please see question 17.
    a. [MSH-5] Receiving Application – 'tdh-ELR^2.16.840.1.113883.3.773.1.1.3^ISO'
    b. [MSH-6] Receiving Facility – 'TDH^2.16.840.1.113883.3.773^ISO'

17. **Does TDH accept batch or real-time message transmission for ELR?**
    Batch transactions will be utilized. Please see table 3-4 in the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health Release 1 (US Realm) with errata for correct Accept Acknowledgement value, Application Acknowledgement value, and Profile ID to be used in MSH-15, MSH-16, and MSH-21, respectively. TDH does not currently accept real-time message transmission for ELR. TDH does not send message or batch acknowledgements for ELR.

18. **When do we sign the Trading Partner Agreement (TPA)?**
    The TPA will remain in draft form and will not be signed by TDH or the trading partner until ELR is in production and paper reporting has been discontinued. TDH will share a draft version of the TPA with the trading partner early in the on-boarding process to help explain business rules.

19. **What is snapshot processing, and do I have to follow it?**
    Any order that results in multiple observations must follow snapshot processing rules as detailed in section 2.1.4 of the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health Release 1 (US Realm) with errata. All information in subsequent message(s) associated with a specific patient and event will replace the corresponding information from the previous message(s) in the receiving application. Because of this, when an observation regarding a particular order is made and an ELR message is sent, any subsequent observations obtained and sent using the same order information must include all previously sent observations for that order.

20. **If something is listed as "RE," do I have to send it to TDH?**
    "RE" stands for "Required, but can be empty". This is <u>not</u> the same as "Optional". For values listed as RE, if the value is known, it is required to be sent. However, if the value is unknown, please leave the field empty. Conformant systems are required to be able to send this information, and the ability to send RE fields will be evaluated during on-boarding.

21. **Can I send more than one message type in the same file to TDH?**
    Although TDH encourages utilizing the same transport method for multiple business areas (e.g., ELR and Immunization Registry), mixed message types in one file will not be accepted. Separate files need to be sent to TDH for each type of message. For ELR, TDH expects only ORU_R01 message types to be sent in a batch that is then sent in a file to TDH.

22. What kind of documentation will TDH provide to me that I can use for Meaningful Use attestation?

TDH will provide official letters documenting each completed step of the ELR on-boarding process. These letters can be used as documentation for your records. Neither TDH nor the Surveillance Systems and Informatics Program are the Meaningful Use regulators or the body which measures compliance. If you have specific questions about your attestation process, please contact representatives within those governing bodies.

Tennessee Department of Health Electronic Laboratory Reporting Business Rules

The following Business Rules will be included in the Trading Partner Agreement between the trading partner and the Tennessee Department of Health (TDH).

1. Specifications for this Agreement are contained in the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health Release 1 (US Realm), with errata. Additional constraints on the reference Implementation Guide can be found on page 18.

2. The message structure required for this trading partner agreement is ORU^R01^ORU_R01 as described in the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health Release 1 (US Realm), with errata.

3. Batch processing will be utilized. Please refer to Table 3-4 in section 3.3 of the Implementation Guide on Batch Abstract Message Syntax.

4. Any order that results in multiple observations must follow snapshot processing rules as detailed in section 2.1.4 of the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health Release 1 (US Realm), with errata. All information in subsequent message(s) associated with a specific patient and event will replace the corresponding information from the previous message(s) in the receiving application. Because of this, when an observation regarding a particular order is made and an ELR message is sent, any subsequent observations obtained and sent using the same order information must include all previously sent observations for that order.

   An example would be a culture order which results in a final result of *Salmonella* found and sent in an ELR message. If later that culture is also found to have grown *Shigella* and a new ELR message is sent, this second message must also include the original *Salmonella* result. Omitting the original *Salmonella* species result in the subsequent message would indicate that the result is deleted as part of the update that added the *Shigella* species result.

5. Acknowledgement messages will not be sent from TDH.

6. The implementation described in this agreement does not include electronic data exchange with NHSN.

7. The implementation described in this agreement refers to living subjects which does include humans who have died.

8. To determine jurisdiction for reporting: Patient address must be provided in [PID-11] (Patient Address). However, if it is unknown and left empty, then the ordering provider must be documented. If both are unknown and left empty, then the ordering facility is required.

9. Messages are constrained to include only one patient per message. A message containing more than one PID segment will be rejected.

10. Any messages requiring more than one SPM segment per order (OBR segment) must be addressed with TDH prior to sending in production, in order for TDH to make internal processing accommodations.

11. RE fields are required, but can be empty if the information is not known. Conformant systems are required to be able to send this information.

12. Preliminary results (P), final results (F), and corrected results (C) are required to be sent by trading partner and should be properly documented in [OBX-11] (Observation Result Status). TDH is required to process preliminary, final, and corrected results as determined by the State reporting guidelines. Proper serialization must be followed, i.e. a final result cannot precede a preliminary result, and only a corrected result can succeed a final result. Please refer to Table 3-6 in section 3.4 of the Implementation Guide for additional information.

13. Every message must contain one and only one ORC segment.

14. Parent/child relationships include reflex testing and drug susceptibility testing. Parent observations should be appropriately documented in [OBR-26] (Parent Result) and [OBR-29] (Parent) of the child following the data types specified in the Implementation Guide. Known errors in the examples provided in the listed specification should not be referenced as normative content.

15. SFT, PD1, PV1, PV2, TQ1, TQ2, CTD, FTI, and CTI are not required by the State of Tennessee and will be ignored if sent by trading partner. If any of these segments are sent, the segments should be properly formed as described by Table 4-1 of the Implementation Guide.

16. [MSH-11] (Processing ID) can have the values “P” (Production), “T” (Training), or “D” (Debugging), but note that “T” and “D” will be handled in the same way.

17. Standard vocabulary is required. Such vocabulary coding systems include, but are not limited to:
    a. LOINC – Logical Observation Identifiers Names and Codes
    b. SNOMED CT – Systemized Nomenclature of Medicine – Clinical Terms
    c. UCUM – Unified Code for Units of Measure

18. Laboratory reporting including ELR is not the same as case reporting by health care providers. Reporting by laboratories does not nullify the health care provider’s or institution’s obligation to report diseases and conditions, nor does reporting by health care providers nullify the laboratory’s obligation to report lab events.

19. According to Tennessee Rules and Regulations, ELR must include lab reports for tests performed both in-house and by reference laboratories, with the performing organization appropriately documented in the ELR message. If you are unable to appropriately document the performing organization in the ELR message for those labs sent to reference labs, paper lab reporting of those lab results will be expected.

20. The trading partner will notify TDH ahead of changes to the sending application or ELR interface that are expected to affect the ELR messages. These may include, but are not limited to, sending application upgrades and other changes to systems affecting the sending application.

21. As part of the on-boarding process, vocabulary validation will be completed. The vocabulary list provided to TDH is current as of the Production Go-Live date, and therefore reflects the lab results received to date. TDH expects that the vocabulary may change with the addition or deletion of tests and results, and therefore the trading partner will be asked to provide updated vocabulary periodically.

22. TDH will route all blood lead results to the LeadTRK Tennessee program at the University of Tennessee – Knoxville on behalf of the trading partner, fulfilling their requirement for reporting of blood lead to the State of Tennessee.

Tennessee Department of Health Electronic Laboratory Reporting Message Format and Vocabulary

Constraints placed on the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health Release 1 (US Realm), with errata, are specified in this section. This implementation is for Electronic Lab Reporting (ELR) and not Test Order and Results (TOR) reporting or case reporting. Constraints are listed below ordered by message segments. In fields where literal values are expected, the values are indicated below using single quotation marks following an equal sign (e.g. [MSH-12] Version ID = '2.5.1').

Fields in **bold** are required, if available, for all disease reports to public health.

1. FHS – File Header Segment
    a. [FHS-4] File Sending Facility – for the [FHS-4.2] Universal ID, we will accept a Party ID using NPI, CLIA, or OID.
    b. [FHS-11] File Control ID – this field is not supported and should not be sent. If it is sent, it will be ignored.

2. BHS – Batch Header Segment
    a. [BHS-4] Batch Sending Facility – for the [BHS-4.2] Universal ID, we will accept a Party ID using NPI, CLIA, or OID.
    b. [BHS-11] File Control ID – this field is not supported and should not be sent. If it is sent, it will be ignored.

3. MSH – Message Header
    a. [MSH-2] Encoding Characters – literal value: '^~\&'
    b. [MSH-3] Sending Application – we ask that [MSH-3.1] Namespace ID be limited to 13 characters.
    c. [MSH-4] Sending Facility - for [MSH 4.2] Universal ID, we will accept a Party ID using CLIA or OID.
    d. [MSH-5] Receiving Application – literal value: 'tdh-ELR^2.16.840.1.113883.3.773.1.1.3^ISO'
    e. [MSH-6] Receiving Facility – literal value: 'TDH^2.16.840.1.113883.3.773^ISO'
    f. [MSH-9] Message Type – literal value: 'ORU^R01' for 2.3.1 or 'ORU^R01^ORU_R01' for 2.5.1
    g. [MSH-10] Message Control ID – this value must be unique.
    h. [MSH-11] Processing ID - may have the values 'P' (Production), 'T' (Training), or 'D' (Debugging), but note that 'T' and 'D' will be handled in the same way.
    i. [MSH-12] Version ID – literal values: '2.5.1' or '2.3.1', but note that '2.5.1' is required for Meaningful Use.
    j. [MSH-15] Accept Acknowledgment Type - literal value: 'NE' (or left empty)
    k. [MSH-16] Application Acknowledgment Type – literal value: 'NE' (or left empty)
    l. [MSH-21] Message Profile Identifier – for [MSH-21.1], the literal value 'PHLabReport-Batch' should be used.

4. SFT – Software Segment
    This segment is optional. If it is sent, it should be properly formatted following Table 5-2 of the Implementation Guide.

5. PID – Patient Identification Segment
    a. [PID-3] Patient Identifier List – may be populated with social security number, medical record number, and/or other internal patient identifiers.
    b. **[PID-5] Patient Name** – [PID-5.7] Patient Name Type Code must contain the literal value 'L', indicating a legal name.
    c. **[PID-7] Date/Time of Birth** – should be a minimum of YYYYMMDD.
    d. **[PID-8] Administrative Sex** – this field is required by TDH.
    e. **[PID-10] Race** – race values indicating "Hispanic" should not be included in this field, but should be reflected in the ethnicity field ([PID-22] Ethnic Group).
    f. **[PID-11] Patient Address** – this field, including street address, city, state, zip code, and county are required by TDH.
    g. **[PID-13] Phone Number – Home** – this field is required by TDH.
    h. **[PID-22] Ethnic Group** – this field is required by TDH.

6. NK1 – Next of Kin Segment
    This segment is optional. If it is sent, it should be properly formatted following Table 5-6 of the Implementation Guide.

7. ORC – Common Order Segment
    a. [ORC-4] Placer Group Number – if sent, [ORC-4.1] Placer Group Number ID should equal the requisition number.
    b. **[ORC-12] Ordering Provider** – this field is required by TDH, and must contain the same value as [OBR-16].
    c. **[ORC-21] Ordering Facility Name** – this field is required by TDH.
    d. **[ORC-22] Ordering Facility Address** – this field is required by TDH.
    e. **[ORC-23] Ordering Facility Phone Number** – this field is required by TDH.

8. OBR – Observation Request Segment
    a. [OBR-4] Universal Service Identifier – may use LOINC and/or local codes to identify the ordered test. If only sending local codes, use [OBR-4.4], [OBR-4.5], and [OBR-4.6].
    b. **[OBR-16] Ordering Provider** – this field is required by TDH, and must contain the same value as [ORC-12].
    c. [OBR-25] Result Status – use "F" for Final Results, "P" for Preliminary Results, or "C" for Correction to Results. This status should pertain to the entire order.
    d. [OBR-26] Parent Result – this field is used for parent/child linking. It should only be filled for Orders pertaining to a generated or reflex order with parent order/observation group in the same message. For Public Health lab results parent result is populated for drug susceptibility test orders. See the appendix on page 22 for additional discussion and guidance on sending these types of results.
    e. [OBR-29] Parent – this field should be filled in for the same reasoning as [OBR-26] above. See the appendix on page 22 for additional discussion and guidance on sending these types of results.

9. OBX – Observation/Result Segment
    a. [OBX-2] Value Type – this field is required and should appropriately correspond to the observation being made in [OBX-5] Observation Value (i.e. a structured observation result should not be reported as TX). Expected data types are SN, NM, CE, and CWE.

b. **[OBX-3] Observation Identifier** – local values and descriptions may be supplied; however, LOINC codes and their associated descriptions are required. It is expected that observation identifiers are appropriately coded to convey the actual test being performed, the method, the result yielded, and the specimen, when applicable.
c. [OBX-4] Observation Sub-ID – this field is required for all OBX segments. When linked to a child order segment, it should appropriately correspond to the observation sub-ID contained in the [OBR-26] Parent Result.
d. **[OBX-5] Observation Value** – all coded observation values should include SNOMED CT codes and associated descriptions. Local values and descriptions may also be supplied. This does not apply to numeric or structured numeric observation values.
e. [OBX-6] Units – UCUM codes are expected for all quantitative observation values (NM or SN). Local values and descriptions may also be supplied.
f. [OBX-7] References Range – expected for all quantitative observation values (NM or SN). We anticipate some reference ranges to be missing. To account for this, we expect abnormal flags to be in all observations and to be used appropriately. The reference range will similarly be used to document cut point values, index values, and any other information used to interpret a quantitative observation value.
g. [OBX-8] Abnormal Flag – though listed as CE in the Implementation Guide, we expect this value to be supplied and to follow the appropriate codes listed in the HL70078 table. The Abnormal Flag field should be used to document the interpretation of the observation value and correspond to the information provided in [OBX-5] and [OBX-7] (Observation Value and Reference Range, respectively).
h. [OBX-11] Observation Result Status - use "F" for Final Results, "P" for Preliminary Results, "C" for Correction to Results.

10. NTE – Notes and Comments Segment
    This segment is optional. If it is sent, it should be properly formatted following Table 5-14 of the Implementation Guide. The NTE segment should only be used to convey additional comments regarding the associated segment. Please do not send results in the NTE segment.

11. SPM – Specimen Segment
    a. **[SPM-2] Specimen ID** – this field is required by TDH.
    b. [SPM-4] Specimen Type – this field is required and should be populated with either SNOMED codes and descriptions or codes and descriptions from the HL70070 or HL70487 tables.
    c. [SPM-8] Specimen Source Site – this field should be populated with either SNOMED codes and descriptions or codes and descriptions from the HL70163 or HL70070 tables.
    d. **[SPM-17] Specimen Collection Date/Time** – this field is required by TDH.

12. FTS – File Trailer Segment
    a. [FTS-1] File Batch Count = '1'

13. BTS – Batch Trailer Segment
    a. [BTS-1] Batch Message Count – should be the total number of messages contained in the batch with a limit of 2000 messages per Batch.

14. Additional Comments:
    a. Value types of ED (Encapsulated Data) and RP (Reference Pointer) will not be accepted.
    b. Observation Identifiers: LOINC codes and their published long name descriptions or agreed upon descriptions by the signatories to this document are required.
    c. Observation Values: SNOMED concept codes and their published descriptions or agreed upon descriptions by the signatories to this document are required for qualitative observation values.
    d. For values listed as RE (Required but may be empty), if the value is known, then it is required to be sent. However, if the value is unknown, please leave the field empty.
    e. Observations about a specimen will follow the SPM segment. Observations about an order will follow the OBR segment.

Appendix 1: Guidance for Sending Antimicrobial Resistance Test Results via ELR

To fully assess antimicrobial resistance and categorize resistance properly, TDH needs to receive enough information about resistance testing for specific organisms. This includes:

1. The antimicrobial/bactericidal agent being tested
2. The method of testing (Kirby-Bauer, MIC, etc.)
3. The actual quantitative and qualitative results and interpretations

This information is used to monitor for multi-drug resistant organisms that require stronger antibiotics to treat infections.

Specific fields in the HL7 message allow for the antimicrobial susceptibilities to be reported to public health. The messages used to report susceptibilities should contain the organism, antibiotic susceptibilities, and the specimen source. The parent observation is the identified observation and the child observation is the antibiotic susceptibility result. The child observations should list all antibiotics tested against the organism, the measured MIC values, and the phenotypic interpretation.

See the diagram below for a simple example of how to link the parent-child observations:

Message Type (HL7 2.5.1)
MSH
PID
ORC
OBR|1|Placer|Filler
OBX|1||Observation^Identifier|ObservationSubID|ObservationValue
SPM
OBR|2||||||||||||||||||||||||||||Observation&Identifier^ObservationSubID^ObservationValue|||Placer^Filler
OBX|1
OBX|2
OBX|3
SPM

Example [OBR-26] Parent Result:
|600-7&Microorganism identified&LN&CULT&Culture&L^1^Streptococcus pneumoniae|

The first component <600-7&Microorganism identified&LN&CULT&Culture&L> consists of the test codes and descriptions for a microbial culture that appeared in the parent observation [OBX-3]. The second component <1> is the sub-ID in the parent organism [OBX-4]. The third component <Streptococcus pneumoniae> is the result description of the parent observation. The result description should come from [OBX-5.2] of the parent observation, but may come from [OBX-5.5] if [OBX-5.2] is empty.

Additional information and message examples can be found in Appendix A of the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health Release 1 (US Realm), with errata.

Appendix 2: Test Scenarios for ELR Structural Validation

The following scenarios may be used to create test HL7 messages. These may be sent to TDH during Step 2 of the on-boarding process.

1. Order: Lead level (patient 7 years old)
   Specimen: Blood
   Qualitative result: Elevated
   Quantitative result: 15 µg/dl

2. Order: Bacterial culture
   Specimen: Stool
   Result: *Salmonella enterica* subspecies *enterica* serovar Typhi.

   For this result, please provide as much speciation/typing information as your lab has the ability to determine.

3. Order: Bacterial culture
   Specimen: Body fluid
   Result: *Streptococcus* Lancefield Group B, *Streptococcus agalactiae*

   Reflex Order 2: Bacterial susceptibility panel by MIC
   Result 1: Ampicillin ≤0.25 µg/dl (Susceptible)
   Result 2: Cefotaxime ≤0.12 µg/dl (Susceptible)
   Result 3: Vancomycin =0.5 (Susceptible)

   For this result, please provide as much speciation/typing and susceptibility information as your lab has the ability to determine.

4. Order: Rocky Mountain Spotted Fever group Ab
   Specimen: Blood
   Result 1: Rickettsia spotted fever group Ab IgG titer of 1:128
   Result 2: Rickettsia spotted fever group Ab IgM titer of <1:64

5. Order: Prenatal panel
   Specimen: Blood
   Result 1: HIV positive by DNA PCR
   Result 2: Reagin Ab titer in serum by RPR of 1:128

6. Order: Hepatitis C virus RNA viral load by Probe and target amplification
   Specimen: Serum
   Result: Undetected

   For this result, please also provide your quantitative cut-off value for an undetectable viral load, and present it as results from your lab would be presented.

7. Order: Gonorrhea and Chlamydia by Probe and target amplification
   Specimen: Genital swab
   Result 1: *Neisseria gonorrhea* Positive
   Result 2: *Chlamydia trachomatis* Negative