Overview

Detecting and monitoring the occurrence of disease through result reporting of tests indicative of notifiable conditions is a cornerstone of public health surveillance in Texas. The Texas Health and Safety Code specifies that "a person in charge of a clinical or hospital laboratory, blood bank, mobile unit, or other facility in which a laboratory examination of a specimen derived from a human body yields microscopical, cultural, serological, or other evidence of a reportable disease shall report the findings" to the local, regional, or state health authority.

The NEDSS Electronic Laboratory Reporting system at the Texas Department of State Health Services (DSHS) provides a mechanism for clinical and hospital laboratories to send Electronic Laboratory Reports (ELR) in order to fulfill the duty to report tests indicative of notifiable conditions to the public health authority, and is driven by standards based content and markup. Hospital systems will therefore need to develop the capacity to trigger, standardize, and securely transmit appropriate data from their automated data feeds to the NEDSS ELR system at the DSHS.

Suggested framework to implement ELR

Step 1: Registration

- Eligible Hospital or Critical Access Hospital facility registers for ELR intent with DSHS.
  http://www.dshs.state.tx.us/mu/elr.aspx#register
- DSHS sends facility confirmation of registration along with ELR onboarding information to facility.

Step 2: Pre-Testing

- Eligible Hospital/Critical Access Hospital facility reviews the ELR message generated from their certified technology system.
  - Meets Texas ELR Format 251_2014 guidelines
  - Contains LOINC in OBR4 and OBX3
    - Resource: Relma (http://loinc.org/)
  - For results other than structured numeric, contains SnoMed in OBX5.
    - Resource: CDC's PHIN VADS (http://phinvads.cdc.gov)
- Stage 1: When the Eligible Hospital/Critical Access Hospital facility deems the ELR message conforms to all guidelines noted above, proceed to Step 3: Secure Data Transfer so a system generated ELR message can be sent. Upon successful receipt of the test message by DSHS, an email is sent to the Eligible Hospital/Critical Access Hospital facility documenting the successful receipt. This is the final step of Stage 1.
- Stage 2: When the Eligible Hospital/Critical Access Hospital facility deems the ELR message conforms to all guidelines noted above, the Eligible Hospital/Critical Access Hospital facility validates the message using the National Institute of Standards and Technology (NIST) ELR validation tool. When ELR messages conform to all requirements of the NIST validation tool (with the exception of allowed errors), proceed to Step 3: Secure Data Transfer in order to prepare for onboarding.
    - Resource: NIST "Context free Validation" (http://hl7v2-elr-testing.nist.gov/mu-elr)
      ** Allowed errors when using the NIST Validation Tool are located in ***Appendix 3***.

Step 3: Secure Data Transfer

- Selection/installation of a secure data transport mechanism for the data feed to DSHS
  - PHINMS
    - The Public Health Information Network Messaging System (PHINMS) is the Centers for Disease Control and Prevention's (CDC) implementation of the ebXML 2.0 messaging standards.
    - Resource: http://www.cdc.gov/phin/tools/PHINms/installation.html
  - sFTP
    - Secure File Transport Protocol.
- When the secure data transport mechanism is installed and operational at the Eligible Hospital/Critical Access Hospital facility, send an email to NEDSS@dshs.state.tx.us in order to exchange configuration information.

Step 4: Onboarding

- Eligible Hospital/Critical Access Hospital sends batch of self-validated sample messages to DSHS
- DSHS reviews and validates the messages
  - If all messages within the batch do not pass DSHS validation
    - DSHS sends written communication of issues back to Eligible Hospital/Critical Access Hospital and sets timeline for when the next batch of sample messages must be sent.
    - Eligible Hospital/Critical Access Hospital repeats the Onboarding process listed above
  - Eligible Hospital/Critical Access Hospital repeats this onboarding process until all tests indicative of reportable conditions in which they are the testing facility have been submitted and validated

- When all messages within the batch pass DSHS validation, and messages containing all tests indicative of reportable conditions from the Eligible Hospital/Critical Access Hospital have been reviewed and validated, DSHS sends written communication to move the interface into Step 5: Production.

Step 5: Production

- Go Live
  - Batch file format on a daily basis
  - Parallel with production
    - Typically continues for a minimum of 4 weeks; dependent on volume of reports
    - Includes all reportable tests reportable from the Eligible Hospital/Critical Access Hospital facility.
  - After successful parallel with production, move to full production and discontinue legacy, paper-based reporting.
  - Anticipate there will be system maintenance
    - Crosswalk tables
    - Solution upgrades/updates
- Determine ongoing communication protocol when issues need addressed

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 **CE** data types only.
- LOINC (in OBR_4 and OBX_3) and SnoMed (in OBX_5 when OBX2=CE) are required components
- CLIA numbers are preferred over the use of OIDS to identify hospitals and laboratory facilities.

Appendix 1 – Standard Reference Tables

Description	Value Set	Other Available value sets
Abnormal Flags	HL70078	
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	
Resulted Test Name 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	

Appendix 2 – Sample Messages

Culture Result:

```
MSH|^~\&|SendingApp|Reporting Institution Name^99XXXXXXX^CLIA|NEDSS|TX|yyyymmdd||ORU^R01^ORU_R01|msgControlID|P|2.5.1|||||USA
SFT|OrganizationName|VersionNum|SoftwareProductName|SoftwareBinaryID||yyyymmdd
PID|1||999999999^^^Hospital Name&99XXXXX&CLIA^MR^Hospital Name&99XXXXXXX&CLIA~99999999^^^Hospital Name&99XXXXXXX&CLIA^PI^Hospital
Name&99XXXXXX&CLIA~999999999^^^2.16.840.1.113883.4.1^SS||Last Name^First Name^Middle Initial^^^^L||yyyymmdd|Sex||Race Code^Race Description^HL70005|Street
Address^^City^State^Zipcode^USA^C^^||9999999999^PRN^PH^^^999^9999999||||||||Ethnicity Code^Ethnicity Description^HL70189
ORC|RE||999999999^EHR^99XXXXXXX^CLIA||||||||^Ordering Doc Last Name^Doc First Name^DOC Middle Initial^^^MD||9999999999^^^^^999^9999999||||||Ordering Hospital
Name|Ordering Hospital Street Address^^City^State^Zipcode|9999999999^^PH^^^999^9999999|Ordering DOC Street Address^^City^State^Zipcode
OBR|1||999999999^EHR^99XXXXXXXX^CLIA|625-4^Bacteria Stl Cult^LN^CULST^Culture Stool^L|||yyyymmddhhmmss||||||None|||DocID at Hospital^Ordering Doc Last Name^Doc First
Name^Middle Initial^^^^^Hospital Name&99XXXXXX&CLIA^L|^^PH^^^999^9999999|||||yyyymmddhhmmss||LAB|F
OBX|1|CE|625-4^Bacteria Stl Cult^LN^9999^RSLT#1^L|1|L-1712B^Salmonella species^SNM^LocalSalmCode^LocalSalmonella species name^L|||A|||F|||yyyymmdd|99XXXXXXX^Performing
Hospital Name^CLIA|||||||Performing Hospital Name^L^^^^Hospital Name&99XXXXXXX&CLIA|Performing Hospital Street Address^^City^State^Zipcode^USA
NTE|1||Comments
SPM|1|^999999999&EHR&99XXXXXXX&CLIA||STL^Stool=Fecal^HL70487^Stool^Stool/Feces^L||||||||||||yyyymmddhhmmss|yyyymmddhhmmss
```

Probe Result:

```
MSH|^~\&|SendingApp|Reporting Institution Name^99XXXXXXX^CLIA|NEDSS|TX|yyyymmdd||ORU^R01^ORU_R01|msgControlID|P|2.5.1|||||USA
SFT|OrganizationName|VersionNum|SoftwareProductName|SoftwareBinaryID||yyyymmdd
PID|1||999999999^^^Hospital Name&99XXXXX&CLIA^MR^Hospital Name&99XXXXXXX&CLIA~99999999^^^Hospital Name&99XXXXXXX&CLIA^PI^Hospital
Name&99XXXXXX&CLIA~999999999^^^2.16.840.1.113883.4.1^SS||Last Name^First Name^Middle Initial^^^^L||yyyymmdd|Sex||Race Code^Race Description^HL70005|Street
Address^^City^State^Zipcode^USA^C^^||9999999999^PRN^PH^^^999^9999999||||||||Ethnicity Code^Ethnicity Description^HL70189
ORC|RE||999999999^EHR^99XXXXXXX^CLIA||||||||^Ordering Doc Last Name^Doc First Name^DOC Middle Initial^^^MD||9999999999^^^^^999^9999999||||||Ordering Hospital
Name|Ordering Hospital Street Address^^City^State^Zipcode|9999999999^^PH^^^999^9999999|Ordering DOC Street Address^^City^State^Zipcode
OBR|1||999999999^EHR^99XXXXXXXX^CLIA|21613-5^Chlamydia trachomatis Probe^LN^999^Chlamydia Probe^L|||yyyymmddhhmmss||||||None|||DocID at Hospital^Ordering Doc Last Name^Doc
First Name^Middle Initial^^^^^Hospital Name&99XXXXXX&CLIA^L|^^PH^^^999^9999999|||||yyyymmddhhmmss||LAB|F
OBX|1|CE|50387-0^Chlamydia trachomatis rRNA^LN^186134^Chlamydia, Nuc. Acid Amp^L||G-A200^Positive^SNM^P^Positive^L||Negative|A|||F|||yyyymmdd|99XXXXXXX^Performing Hospital
Name^CLIA|||||||Performing Hospital Name^L^^^^Hospital Name&99XXXXXXX&CLIA|Performing Hospital Street Address^^City^State^Zipcode^USA
NTE|1||Comments
SPM|1|^999999999&EHR&99XXXXXXX&CLIA||CVX^Cervix^HL70487^119395005^Cervix^SCT||||||||||||yyyymmddhhmmss|yyyymmddhhmmss
```

Quantifiable Result:

```
MSH|^~\&|SendingApp|Reporting Institution Name^99XXXXXXX^CLIA|NEDSS|TX|yyyymmdd||ORU^R01^ORU_R01|msgControlID|P|2.5.1|||||USA
SFT|OrganizationName|VersionNum|SoftwareProductName|SoftwareBinaryID||yyyymmdd
PID|1||999999999^^^Hospital Name&99XXXXX&CLIA^MR^Hospital Name&99XXXXXXX&CLIA~99999999^^^Hospital Name&99XXXXXXX&CLIA^PI^Hospital
Name&99XXXXXX&CLIA~999999999^^^2.16.840.1.113883.4.1^SS||Last Name^First Name^Middle Initial^^^^L||yyyymmdd|Sex||Race Code^Race Description^HL70005|Street
Address^^City^State^Zipcode^USA^C^^||9999999999^PRN^PH^^^999^9999999||||||||Ethnicity Code^Ethnicity Description^HL70189
ORC|RE||999999999^EHR^99XXXXXXX^CLIA||||||||^Ordering Doc Last Name^Doc First Name^DOC Middle Initial^^^MD||9999999999^^^^^999^9999999||||||Ordering Hospital
Name|Ordering Hospital Street Address^^City^State^Zipcode|9999999999^^PH^^^999^9999999|Ordering DOC Street Address^^City^State^Zipcode
OBR|1||999999999^EHR^99XXXXXXXX^CLIA|24363-4^Hepatitis Panel, Acute^LN^AHepPan^Acute Hepatitis Panel^L|||yyyymmddhhmmss||||||None|||DocID at Hospital^Ordering Doc Last
Name^Doc First Name^Middle Initial^^^^^Hospital Name&99XXXXXX&CLIA^L|^^PH^^^999^9999999|||||yyyymmddhhmmss||LAB|F
OBX|1|SN|20416-4^Hepatitis C virus RNA^LN^140539^Hepatitis C Quantitation^L||^26000|Copies/mL||||| F|||yyyymmdd|99XXXXXXX^Performing Hospital Name^CLIA|||||||Performing
Hospital Name^L^^^^Hospital Name&99XXXXXXX&CLIA|Performing Hospital Street Address^^City^State^Zipcode^USA
NTE|1||Comments
SPM|1|^999999999&EHR&99XXXXXXX&CLIA||Ser^Serum^HL70487^Serum^Serum^L||||||||||||yyyymmddhhmmss|yyyymmddhhmmss
```

Screening test with titer:

```
MSH|^~\&|SendingApp|Reporting Institution Name^99XXXXXXX^CLIA|NEDSS|TX|yyyymmdd||ORU^R01^ORU_R01|msgControlID|P|2.5.1|||||USA
SFT|OrganizationName|VersionNum|SoftwareProductName|SoftwareBinaryID||yyyymmdd
PID|1||999999999^^^Hospital Name&99XXXXX&CLIA^MR^Hospital Name&99XXXXXXX&CLIA~99999999^^^Hospital Name&99XXXXXXX&CLIA^PI^Hospital
Name&99XXXXXX&CLIA~999999999^^^2.16.840.1.113883.4.1^SS||Last Name^First Name^Middle Initial^^^^L||yyyymmdd|Sex||Race Code^Race Description^HL70005|Street
Address^^City^State^Zipcode^USA^C^^||9999999999^PRN^PH^^^999^9999999||||||||Ethnicity Code^Ethnicity Description^HL70189
ORC|RE||999999999^EHR^99XXXXXXX^CLIA||||||||^Ordering Doc Last NameE^Doc First Name^DOC Middle Initial^^^MD||9999999999^^^^^999^9999999||||||Ordering Hospital
Name|Ordering Hospital Street Address^^City^State^Zipcode|9999999999^^PH^^^999^9999999|Ordering DOC Street Address^^City^State^Zipcode
OBR|1||999999999^EHR^99XXXXXXX^CLIA|20507-0^Reagin Ab^LN^999^RPR^L|||yyyymmddhhmmss||||||None|||DocID at Hospital^Ordering Doc Last Name^Doc First Name^Middle
Initial^^^^^Hospital Name&99XXXXXX&CLIA^L|^^PH^^^999^9999999|||||yyyymmddhhmmss||LAB|F
OBX|1|CE|20507-0^Reagin Ab^LN^000111^RPR^L|1|G-A497^REACTIVE^SNM^REA^Reactive^L||NonReactive|A||| F|||yyyymmdd|99XXXXXXX^Performing Hospital Name^CLIA|||||||Performing
Hospital Name^L^^^^Hospital Name&99XXXXXXX&CLIA|Performing Hospital Street Address^^City^State^Zipcode^USA
NTE|1||Comments
OBX|2|SN|31147-2^Reagin Ab^LN^00000^RPR, Quant^L|2|^1^:^4||NonRea<1:1|H|||F|||yyyymmdd|99XXXXXXX^Performing Hospital Name^CLIA|||||||Performing Hospital
Name^L^^^^Hospital Name&99XXXXXXX&CLIA|Performing Hospital Street Address^^City^State^Zipcode^USA
NTE|1||Comments
SPM|1|^999999999&EHR&99XXXXXXX&CLIA||Ser^Serum^HL70487^Serum^Serum^L||||||||||||yyyymmddhhmmss|yyyymmddhhmmss
```

Appendix 3 – Allowed errors when using the NIST Validation Tool

Validation Errors		
Error Details		
1	Type:	Message Structure
	Description:	MSH.2 (Encoding Characters)
	Allowed Values:	^~\&
2	Type:	Message Structure
	Description:	HD Datatypes when identifying a hospital or laboratory facility should contain CLIA identifier.
	Allowed Values:	*Example:* Reporting Institution Name^99XXXXXXX^CLIA