

North Carolina Division of Public Health – NC DPH

Guidelines for Electronic Laboratory Reporting to the North Carolina Division of Public Health

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Electronic Laboratory Reporting

What is electronic laboratory reporting?

Electronic Laboratory Reporting (ELR) is the electronic transmission from laboratories to public health of the laboratory reports which identify reportable conditions. ELR has many benefits, including improved timeliness, reduction of manual data entry errors, and reports that are more complete. Electronic laboratory data from the hospitals, commercial laboratories, and major health departments across North Carolina is critical to timely, accurate, and sensitive disease reporting and intervention for North Carolina residents.

What is NC EDSS?

The North Carolina Electronic Disease Surveillance System (NC EDSS) is a statewide disease surveillance, outbreak/case management, and early detection system. NC EDSS is used by public health professionals to receive, manage and analyze electronic data from public health entities, clinics, laboratories, hospitals and health care providers. NC EDSS services include support for required case or suspect case reporting of reportable diseases, electronic laboratory reporting, outbreak management, emergency situational awareness, and geographic information system mapping capabilities.

Electronic Laboratory Reporting and Promoting Interoperability

Currently, North Carolina Department of Public Health (NC DPH) is accepting electronic laboratory reports from any facility who can maintain compliance of standards.

If you would like to register your intent with NC DPH to initiate electronic laboratory reporting, please complete and submit your registration via North Carolina Division of Public Health Promoting Interoperability Program Registration of Intent Site for hospital facilities.

(<http://ncdphmeaningfuluse.org>).

For non-hospital facilities please submit via this Smartsheet link, [North Carolina Division of Public Health Program Registration of Intent for Non-Hospital Facilities](#).

For steps on the process of implementing an electronic laboratory reporting feed with NC DPH for meeting promoting interoperability, please see Appendix B – NC DPH ELR Onboarding Checklist.

If you have specific questions about Promoting Interoperability, please email them to NCDPHMU@dhhs.nc.gov.

Implementing Electronic Laboratory Reporting

The implementation of electronic laboratory reporting to the NC DPH requires the following steps:

1. Register your facility's intent to submit ELR to NC DPH.
2. Participate in an initial planning discussion with NC DPH and onboard.
3. Enter production with NC DPH.

1. Register your facility's intent to submit ELR

To register your intent with NC DPH to initiate electronic laboratory reporting, please submit your registration via the NC DPH Electronic Health Records (EHR) Promoting Interoperability website (<http://ncdphmeaningfuluse.org>) or [for non-hospital facilities, submit registration via Smartsheet.](#)

2. Participate in an initial planning discussion

It is the preference, of NC DPH, that medical facilities in an ELR interface module obtain laboratory result data directly from their Laboratory Information System (LIS) rather than indirectly via their Electronic Medical Record System. This reduces the risk of loss of detail that may occur when data is transformed from one system to another.

Please include representatives from your facility's laboratory, IT group, and a representative from your LIS vendor in the initial planning discussion with NC DPH.

3. Enter production with NC DPH.

North Carolina General Statutes and Administrative Code require that laboratory tests be reported to the North Carolina Division of Public Health electronically, by mail, by secure telefax, or by telephone. Reporting health information to public health authorities is permitted under both NC state law and HIPAA regulations (NSGS 130A-143 and 42 C.F.R. § 164.512(a)(1)).

The rules for which laboratory results are required by North Carolina law to be reported to the NC Division of Public Health can be found in the North Carolina General Statutes (130A_131.8 and 130A_139) and administrative code (10A NCAC 41a .0101, 10A NCAC 41a .0102 and 10A NCAC 41C .0701). A link to these regulations can be found on the NC DPH Communicable Disease Laws and Rules website (<http://epi.publichealth.nc.gov/cd/laws.html>).

When a laboratory in North Carolina performs a communicable disease or blood lead test and the test result is reportable under NC law, the laboratory is required to report that result to public health authorities in North Carolina, regardless of whether the patient is a resident of North Carolina or of another state. Therefore, the laboratory should include the reportable results for out-of-state patients in their electronic laboratory reporting feed. For out-of-state patients, the NC Division of Public Health will forward laboratory findings that are pertinent to the other state's public health authority.

Please do not include the following results in ELR:

- Laboratory results of tests that were performed at reference laboratory facilities. However, make sure that all patient demographics data are included in laboratory orders to the reference laboratory, so that the reference laboratory can include those in its ELR.
- Laboratory results for CAP or other proficiency testing.
- Laboratory results for internal quality testing (e.g., tests used to test the system, not real patients).

In order to identify the laboratory results that are required by law to be reported from your facility, please complete the Reportable Review tab of the NC ELR Mapping tool (available for download through the http://epi.publichealth.nc.gov/cd/meaningful_use/elr.html).

- i) Complete the Reportable Review tab with the entire menu of services for your facility and indicate which tests are performed in-house versus sent out to a reference lab.
- ii) For each of the tests that are performed in-house, indicate if they are required to be reported under NC law.
- iii) Indicate which tests the facility is willing to voluntarily report to NC DPH. A list of the results that NC DPH will accept for reporting can be found in Appendix A – Additional conditions for reporting to NC DPH.
- iv) Once you have completed the Reportable Review tab, move onto the LOINC Mapping tab.
- v) Add LOINC codes for test mappings. NC DPH will validate codes and insert feedback. Once you have completed the LOINC Mapping tab, move onto the Results Mapping tab.
- vi) Add SNOMED-CT codes for results mappings, NC DPH will validate codes and insert feedback. Once you have completed the Results Mapping tab move onto the Specimen Type Mapping tab.
- vii) Add SNOMED-CT codes for specimen mappings, NC DPH will validate codes and insert feedback. Note: This is for specimen SNOMED-CT codes only, ex 257261003 Swab (Specimen)
Once you have completed the Specimen Type Mapping tab, move onto the Specimen Source Mapping tab.
- viii) Add SNOMED-CT codes for body structures, NC DPH will validate codes and insert feedback. Once you have completed the Specimen Source Mapping tab, please submit it to
NC DPH via the online NC ELR Mapping Tool Submission form

(<https://app.smartsheet.com/b/form?EQBCT=a5631600d8bd4027aef279b2a854fbde>).

Please use the following naming convention when submitting your NC ELR Mapping Tool document.

<Hospital Name> NC ELR <submission#> <Step#> <initials of submitter or reviewer>
<date(YYYY MMDD)>

NC DPH will review your NC ELR Mapping Tool document and give feedback. All the document tabs may be completed at once and NC DPH will review the entirety.

Develop an HL7 Version 2.5.1 Message for ELR

NC DPH currently accepts the messages formatted according to the following implementation guides:

- **HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with Errata** - The implementation is the newest and preferred guide for electronic reporting to NC DPH. This implementation guide is free to download from the HL7 website (www.HL7.org).

The HL7 implementation guide is applicable to communicable disease and blood lead test results. There currently is no comprehensive HL7 implementation guide for the use case of environmental lead test results. If your laboratory performs environmental lead tests, contact the ELR.SupportServices@dhhs.nc.gov to discuss how to report your results.

NC DPH does not have any requirements that conflict with the HL7 implementation guides.

To transmit electronic laboratory results to NC DPH, combine the HL7 transactions for the day into a single batch file per facility or a single file with all facilities per HL7 standards for files and batches. On days with no results, an empty batch file must be sent. Please see below for empty batch file example.

Empty Batch File Example

```
FHS|^~\&|XXX^9.99.999.9.999999.9.9999.9^ISO|XXX  
Lab^9.99.999.9.999999.9.9999.9^ISO|NCDPH  
NCEDSS^2.16.840.1.113883.3.591.3.1^ISO|NCDPH  
EDS^2.16.840.1.113883.3.591.1.1^ISO|202004230100||202004230100||105746688|  
BHS|^~\&|XXX^9.99.999.9.999999.9.9999.9^ISO|XXX  
Lab^9.99.999.9.999999.9.9999.9^ISO|NCDPH  
NCEDSS^2.16.840.1.113883.3.591.3.1^ISO|NCDPH  
EDS^2.16.840.1.113883.3.591.1.1^ISO|202004230100||202004230100||105746688|  
BTS|0|
```

FTS|1|

Every health care system that has multiple laboratories would be required to elect one of the following two choices.

Choice 1

Send a separate file per day per laboratory per health care system.

The SendingFacility in the FHS, BHS and in all the MSH segments must contain the same value, which must be either the CLIA # or OID of the laboratory that that file is for.

For a health care electing Choice 1, a PID-3 repetition for type 'PI' as described under Choice 2 would be allowed but not required.

Choice 2

Send one file per day per health care system, even when there are multiple laboratories within that health care system.

The Sending Facility in the FHS, BHS and in all the MSH segments must all contain the same value, which must be the CLIA # or OID of the laboratory of the primary hospital within that health care system.

Every message must contain a PID-3 repetition with PID-3.5 (ID Type Code) = 'PI' ('PI' means patient internal identifier), PID-3.6.3 (Assigning Facility, Universal ID Type) = 'ISO' and PID-3.6.2 (Assigning Facility, Universal ID) containing an OID that identifies the laboratory of the hospital where the patient is registered. (Note that an OID is required for conformance to the v2.5.1 HL7 Implementation Guide).

NC DPH can only receive one ELR batch file per day (overnight) from each laboratory. If different test results on the same specimen are released by the laboratory at different times of the day between the daily file transmissions, do not send a separate message each time. **It is a NC DPH requirement that a single message per specimen be sent per day, containing a message snapshot that portrays all the reportable test results as they were the last time a laboratory report was released for that specimen.**

Further explanation of the "Snapshot Processing" functionality discussed in the HL7 specifications can be found in Appendix C – Snapshot Processing.

Configure your HL7 messages to use the following field values in the HL7 header segments (FHS, BHS, MSH segments):

Receiving Application: "NCDPH NCEDSS^2.16.840.1.113883.3.591.3.1^ISO"

Receiving Facility: "NCDPH EDS^2.16.840.1.113883.3.591.1.1^ISO"

When messages are sent in an HL7 batch file, the MSH-21 (Message Profile Identifier) field must contain one of:

For ELR Receiver profile, use:

PHLabReport-Batch^^2.16.840.1.113883.9.11^ISO For Lab Sender profile, use:
PHLabReport-Batch^^2.16.840.1.113883.9.10^ISO

Also NC DPH requires that FHS/FileNameID and BHS/BatchNameIDType be populated. NC DPH reconciliation processes require that the two fields above contain the effective date of the file in yyymmdd format somewhere within the field but always at the same fixed location within the field.

eg. if the fixed location is at beginning of the field a value could look like
"201407219160105".

To ensure that your HL7 message is conformant with the applicable HL7 Implementation Guide, you will need to conduct self-service testing of your ELR message using the NIST Tool.

- The National Institute of Science and Technology (NIST) tool

(<https://hl7v2-elr-testing.nist.gov/mu-elr/>)

Your facility and/or your software vendor should try to resolve the error messages, if any, that these tools report. If some of those errors are particularly difficult to resolve, you may consult the technical person assigned to your facility as to whether those errors would prevent acceptance by NC EDSS

Once your facility has successfully completed self-service testing of your ELR message, provide your successful validation results to NC DPH. NC DPH will provide feedback about conformance and content issues that the self-service testing tools are not capable of detecting.

Note, please do not include PII on this site, please send it as txt files not a pdf.

Set up the secure message transport connectivity

NC DPH currently supports the Public Health Information Networking Messaging System (PHINMS) and Health Information Exchange (HIE) as a transport mechanism to send electronic laboratory results directly to NC DPH.

PHINMS is provided free of charge by the CDC and provides strong authentication of the sender and the receiver, as well as very secure and reliable transport. For more information on PHINMS, please visit the CDC's website (<http://www.cdc.gov/phin/tools/PHINms/index.html>).

For information on how to install PHINMS please refer to the Installation and Configuration of PHINMS for Message Submission. ([Implementation Guide - Public Health Information Network Messaging System \(PHINMS\) \(March 31, 2021\) \(cdc.gov\)](#)).

In addition to receiving results via PHINMS, NC DPH can accept ELR messages sent through the North Carolina Health Information Exchange (NC HIE). For more information regarding sending ELR via the NC HIE please contact NC HIEA provider relations team at 919-754-6912 or send an email to HIEA@nc.gov.

Send a batch file containing test messages for initial validation

Transmit the files between the hours of midnight to 6:00 AM Eastern Time to NC DPH. Please avoid sending at 2:00 AM due to time change.

NC DPH considers successful test messages to include reportable results conformant to NC Regulations and to the HL7 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm).

If the messages do not pass initial validation, please continue message development and internal validation.

Participate in structure and content validation

When NCDPH gives you permission to commence, transmit daily batch files from your Production environment to the NC DPH Test environment.

Participate in parallel data validation (User Acceptance Testing)

During parallel validation, your facility shall send NC DPH copies of reports. This reporting is in addition to the regular mechanism through which your facility reports to their Local Health Department.

The Subject Matter Experts (SMEs) at NC DPH will review the data imported into NC EDSS/ NC LEAD to assure that all reportable results that should have been imported into NC EDSS/ NC LEAD were in fact imported correctly and that the imported data is consistent with the original reports.

Any issues that are identified will be reported to the facility for discussion for an appropriate solution. If changes/fixes to your facility's ELR interface are warranted, the identified issues will be reported to your facility, and your facility will oversee fixing the issue.

Once the SME from each disease group feels that enough paper laboratory reports have been reviewed and all significant issues have been identified and corrected, the SME will sign off on the ELR feed for their disease group. This process will continue until the SMEs of all applicable disease groups have validated enough reports and are satisfied with the results.

Discontinue paper submissions

During the time that NC DPH transitions your ELR interface from the test environment to our production electronic surveillance system, NC DPH will continue to perform quality control checks on the ELR messages received from your facility. Your facility is required to continue reporting to the local health departments (according to the regular reporting procedures) until notified by NC DPH that the ELR interface meets the requirement for reporting. At that time, NC

DPH will coordinate with your facility to determine a date to discontinue paper or faxed reporting of laboratory results. On that date, your facility will receive a notification from the North Carolina State Epidemiologist stating that your laboratory can discontinue paper or faxed reporting of reportable laboratory results and solely submit ELR. However, if utilizing eCR, the facility will need to continue to fax.

When your facility adds new in-house tests, new results which are reportable to public health, or a new facility following the implementation of your ELR interface, your facility must contact the ELR.SupportServices@dhhs.nc.gov to test and validate the sending of any new results via ELR.

Appendix A – Additional conditions for reporting to NC DPH

North Carolina law and administrative rules stipulate certain laboratory test results that are required to be reported to public health.

There are additional laboratory results that would be beneficial for public health purposes to have reported via ELR, on a voluntary basis.

- Some of these are in anticipation of proposed changes to the administrative rules. For laboratories just implementing ELR to public health it may be less work to report these to begin with, rather than having to revise software and/or system configurations if/when the administrative rule changes come into force making the reporting mandatory.
- Some of these would reduce the complexity of software rules that the laboratory would have to implement in order to filter which laboratory results to send in the ELR.
- Some of these would have little impact on the laboratory's implementation efforts but would nevertheless be beneficial to public health.

Blood Lead levels

Please send **all** blood lead level results regardless of age and regardless of the level, rather than only the results required by law.

Babesia organisms

Please report any identification, detection or demonstration of any species of Babesia.

Bacillus cereus

Please report any identification, detection or demonstration of Bacillus cereus in a clinical culture sample.

Botulism

In addition to Clostridium botulinum as required by law, please report these species that also cause botulism:

- Clostridium argentinense (formerly C. botulinum type G)
- Clostridium baratii
- Clostridium butyricum

Chancroid

Please report Haemophilus ducreyi.

Clostridium perfringens

Please report Clostridium perfringens only if it is from a stool.

Coronavirus

Please report positive Coronavirus (cause of severe acute respiratory syndrome (SARS)).

Creutzfeldt-Jakob disease (CJD)

Please report:

- presence of the 14-3-3 protein
- presence of Abnormal Prion Protein
- presence of scrapie prion protein (PrP^{Sc})
- PRNP gene mutations found

Enterics

If a GI panel (a PCR) is conducted, we require the laboratory to report any presumptive or final positive results.

If the lab reflexes a PCR to a culture, then we require the positive results of the PCR as well as the positive results of the culture be reported to the state.

Ehrlichia spp.

Please also report any non-paired sera IgG IFA results expressed as titer ratios that are interpretable as positive.

Granuloma inguinale

Please report Klebsiella granulomatis (formerly called or Calymmatobacterium granulomatis).

Haemophilus influenzae

Please report Haemophilus influenzae and all serotypes of Haemophilus influenzae, not just serotype b.

Hepatitis B virus (HBV)

In addition to the HBV tests required by law. Please report preliminary results, also report:

- HBV Core total antibody
 - HBV HbsAb (antibody to vaccine) Please do not report:
-

- HBV eAb (little e antibody)
- Note
- Only report if (+) IgM anti-HBc, HBsAG, HBV DNA, or HBEAG
 - Report Preliminary Results

Hepatitis B virus surface antigen

HBsAg confirmatory results are required by law to be reported. Whether your facility should report HBsAg screening test positive results depends on what practices your laboratory follows for confirming those results.

Please report the preliminary results.

Hepatitis C virus (HCV)

Please report Hepatitis C positive results, regardless of whether the patient has acute hepatitis C or chronic hepatitis C. Please report the preliminary results as well.

We would want anti-HCV results, all HCV (+) results are reportable via ELR. Ideally what we would want:

All positive hepatitis C labs are reportable for laboratories utilizing electronic lab reporting (ELR), which includes the following:

- (A) Hepatitis C virus antibody tests (including the test specific signal to cut-off (s/c) ratio)
- (B) Hepatitis C nucleic acid tests
- (C) Hepatitis C antigen(s) tests
- (D) Hepatitis C genotypic tests

All positive HCV labs (REQUIRED)

(-) HCV RNA's/Viral Loads when associated with a (+) hepatitis C antibody (which is preferred but not required by the law JUST AN ASK)

Hepatitis viral loads

Please report all hepatitis viral load results, even "Not detected," and preliminary results.

Human granulocytic anaplasmosis (HGA)

It was previously known as human granulocytic ehrlichiosis (HGE). It is caused by the organism *Anaplasma phagocytophila* (formerly called *Ehrlichia phagocytophila*). *Anaplasma phagocytophila* is reportable, per Administrative Rule criteria like *Ehrlichia* spp. Please also

report any non-paired sera IgG IFA results expressed as titer ratios that are interpretable as positive.

HIV-1 Tests (e.g. HIV 1+ 2 Ag/Ab, EIA, Rapid methods,)

When a screening test positive result is confirmed by a confirmatory test result, please report the screening test positive result. It may be easier for you to just report all the test positive results, regardless of the outcome of the confirmatory test. Also, if you do the screening test in-house and send the confirmatory test out to a reference laboratory, it may be easier for you to just report all of the screening test positive results.

HIV-1 viral loads

All HIV viral loads are required by law to be reported. When reporting results below the low quantitation limit please include these distinctions:

- Detected, < lower quantitation limit (e.g., *Less than 20 copies/mL, HIV-1 RNA detected*)
- Not Detected, < lower quantitation limit (e.g., *Less than 20 copies/mL, HIV-1 RNA not detected*)

- Common Reference Range is 20 - 10,000,000 copies/mL

Current NC disease reporting law requires all CD4 (Count and Percent (%)) results to be reported.

Listeria

Please report only *Listeria monocytogenes*.

M. Tuberculosis

These results are for all TB samples (pulmonary and extrapulmonary).

Required reporting of TB lab tests - preliminary and final

IGRA's regardless of result (positive, negative, indeterminate, borderline), include T-Spot test and QuantiFERON-Gold test, only via ELR.

Acid-fast bacilli smears and cultures, NAAT (PCR, DNA probe, for example), susceptibilities.

Mycobacteria and Mycobacteria species isolated do need to be reported.

Rifampin resistant

Nocardia species are not reportable.

Ideally what we would want would be 2 things:

Plasmodium

Report all positive results for any species of Plasmodium.

Rocky Mountain Spotted Fever (*Rickettsia rickettsii*)

Please also report any non-paired sera IgG IFA results expressed as titer ratios that are interpretable as positive.

Salmonella

Please report preliminary results and final results

Staphylococcus aureus

Staphylococcus aureus with reduced susceptibility to vancomycin is required by law to be reported. When the vancomycin susceptibility to *Staphylococcus aureus* is “Resistant” or “Intermediately Resistant” **you must report both the culture result and the vancomycin susceptibility test result.**

Streptococcus pneumoniae (only Group A)

Please report *Streptococcus pneumoniae*, but only when the specimen is CSF or a sterile location.

Varicella

- Isolation of varicella-zoster virus (VZV) from a clinical specimen.
- Detection of VZV DNA by direct fluorescent antibody (DFA) or by polymerase chain reaction (PCR) tests from a clinical specimen, ideally scabs, vesicular fluid, or cells from the base of a lesion.
- Varicella IgM

Organisms formerly named Vibrionaceae

Report these species:

- *Grimontia hollisae* (formerly called *Vibrio hollisae*)
 - *Listonella pelagia* (syn. *Vibrio pelagia*, syn. *Vibrio pelagius*)
 - *Photobacterium damsela* (formerly called *Vibrio damsela*)
 - *V. cholerae*
 - *V. vulnificus*
-

Appendix B – NC DPH ELR Onboarding Checklist

This checklist will prepare you to implement an electronic laboratory reporting interface to the North Carolina Division of Public Health (NC DPH) and will assist with meeting the onboarding requirements for ELR. Please contact ELR.SupportServices@dhhs.nc.gov for further assistance.

ELECTRONIC LABORATORY REPORTING (ELR) CHECKLIST		
Step 1: Register Intent to submit ELR		
		Comments & Resources
North Carolina Division of Public Health Promoting Interoperability Program Registration of Intent Site	<input checked="" type="checkbox"/>	REQUIRED
For non-hospital facilities, submit registration via Smartsheet	<input checked="" type="checkbox"/>	REQUIRED
Receive and retain your registration notification from NC DPH	<input checked="" type="checkbox"/>	
Step 2: Pre-testing phase		
Step 2a: Participate in initial planning discussion with NC DPH		
		Comments & Resources
Download a free copy of HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm)	<input checked="" type="checkbox"/>	Available for download through the Health Level Seven (HL7) website
Download the “Guidelines for Electronic Laboratory Reporting to North Carolina Division of Public Health” document	<input checked="" type="checkbox"/>	Available for download through the North Carolina Division of Public Health Promoting Interoperability Program Registration of Intent Site
NC DPH to schedule an initial planning discussion	<input checked="" type="checkbox"/>	To check the status please email ELR.SupportServices@dhhs.nc.gov
Step 2b: Identify laboratory results that are required by NC law to be reported to NC DPH		
		Comments & Resources
Download the NC ELR Mapping Template	<input checked="" type="checkbox"/>	Available for download through the North Carolina Division of Public Health Promoting Interoperability Program Registration of Intent Site
If facility uses Epic Beaker, download the Beaker Mapping Template	<input checked="" type="checkbox"/>	The rules for which laboratory results are required by North Carolina law to be reported to NC DPH can be found in the North Carolina General Statutes and Administrative code
Fill in the NC ELR Mapping Template with your entire menu of services and indicate which tests are performed in-house versus sent to a reference lab	<input checked="" type="checkbox"/>	A link to these regulations can be found on the NC DPH Communicable Disease Laws and Rules website
NC DPH will review the catalogue and provided feedback on what is reportable and voluntarily reportable		A list of the results that NC DPH can accept for voluntary reporting can be found at the

		North Carolina Communicable Disease Manual
Once you have completed the "Reportable Review" tab, please submit it to NC DPH via the online NC ELR Mapping Tool Submission form	<input checked="" type="checkbox"/>	NC ELR Mapping Tool Submission form
Step 2c: Translate local codes to standard coding systems		
		Comments & Resources
Complete the "LOINC Mapping" tab of the NC ELR Mapping Tool with your local codes mapped to the LOINC standard vocabulary	<input checked="" type="checkbox"/>	Logical Observation identifiers Names and Codes (LOINC)
Complete the "Result Mapping" tab of the NC ELR Mapping Tool with your local lab result codes mapped to the (SNOMED-CT) standard vocabulary	<input checked="" type="checkbox"/>	SNOMED CT (Systematized Nomenclature of Medicine--Clinical Terms)
Complete the "Specimen Type Mapping" and "Specimen Sources Mapping" tabs of the NC ELR Mapping Tool with your local specimen types and sources mapped to the SNOMED-CT standard vocabulary	<input checked="" type="checkbox"/>	Submit to NC DPH via the online NC ELR Mapping Tool Submission form
Map other local codes according to the HL7 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm)	<input checked="" type="checkbox"/>	For Example: HL7 defined tables for race, ethnicity, gender, etc
Step 2d: Set up the secure message transport connectivity		
		Comments & Resources
NC DPH accepts ELR messages sent through the Public Health Information Networking Messaging System (PHINMS) or through the North Carolina Health Information Exchange Authority (NC HIEA)	<input checked="" type="checkbox"/>	For more information on PHINMS, please visit the CDC's website
		For more information on NC HIEA, please visit their website
Step 3: HL7 Message Testing		
Step 3a: Develop an HL7 Version 2.5.1 Message for ELR		
		Comments & Resources
Develop an HL7 message conforming to the HL7 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm)	<input checked="" type="checkbox"/>	Available for download through the Health Level Seven (HL7) website
	<input checked="" type="checkbox"/>	

Test ELR messages through the NIST tool, resolve issues found, and provide your successful validation results to NC DPH in a .doc file		National Institute of Science and Technology (NIST) website
NOTE: Do not include PHI, NIST is not a secure tool		
Step 3b: Send a batch file containing a test message for initial validation		
		Comments & Resources
Transmit one batch file with a message containing a reportable result conformant to NC Regulations and to the HL7 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm)	<input checked="" type="checkbox"/>	If the message passes initial validation, coordinate automated daily message transmissions from the test system and/or production system
Transmit one batch file with 0 messages		If the message does not pass initial validation, please continue message development and internal validation
Step 3c: Participate in structure and content validation		
		Comments & Resources
NC DPH will perform structure and content validation	<input checked="" type="checkbox"/>	NC DPH uses Smartsheet in order to track any issues we find with the HL7 message Access is granted by NC DPH to post comments and questions Resolution of issues is expected from the facility
Step 4: Participate in parallel data validation (User Acceptance Testing) with NC DPH		
		Comments & Resources
NC DPH will perform data validation, comparing the electronic submissions from the production system against the existing reporting mechanism (e.g., mail or fax)	<input checked="" type="checkbox"/>	NC DPH will use Smartsheet in order to track any issues found between the HL7 messages and other reports Resolution of issues is expected from the facility
Step 5: Production		
		Comments & Resources
NC DPH will transition your ELR reporting to our production environment	<input checked="" type="checkbox"/>	
NC DPH will perform ELR reconciliation, and track any issues found in the HL7 messages	<input checked="" type="checkbox"/>	NC DPH will use Smartsheet in order to track any issues found in the HL7 messages Resolution of issues is expected from the facility
Coordinate with NC DPH to determine a date to discontinue paper or faxed reporting of laboratory results and solely submit ELR	<input checked="" type="checkbox"/>	

Appendix C – Snapshot Processing

NC DPH requirements for message snapshot

Please see “Excerpts from “HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm)” for the definition of snapshot processing.

The NC DPH requirements for message snapshots are in accordance with that HL7 Implementation Guide; however, these requirements are not merely for the sake of conformance to the HL7 Implementation Guide. There are circumstances and diseases where message snapshots are needed for NC DPH to support disease surveillance optimally, and to avoid extra phone calls from epidemiologists to the laboratory and/or to the physician.

For ELR sent to NC DPH, a message snapshot should include the latest version of all test results which are reportable to NC DPH for the same specimen. There may be other test results on the same specimen that are not reportable to NC DPH and those are not required to be included in the snapshot. Each time a message is sent for a particular specimen the message snapshot is a cumulative report that includes new or changed results as well as previously reported results that have not changed.

NC DPH can only receive one ELR batch file per day (overnight) from each laboratory. If different test results on the same specimen are released by the laboratory at different times of the day between the daily file transmissions, do not send a separate message each time. **It is a NC DPH requirement that a single message per specimen be sent per day, containing a message snapshot that portrays all the reportable test results as they were the last time a laboratory report was released for that specimen.**

Example of series of snapshots

Specimen #1111 as of 8/1/2011 11:00 pm the laboratory system has these results to date:

Test	Result	Result Status	Result Date/Time	Comments about example
HIV-1 - HIV-2 - PLUS O (method EIA)	Reactive	Final	8/1/2011 01:00 pm	is reportable to NC DPH
Rapid HIV-1/HIV-2 Antibody	HIV-2	Final	8/1/2011 01:15 pm	is reportable to NC DPH
HepB eAb	Reactive	Final	8/1/2011 02:00 pm	is not reportable to NC DPH

The night of 8/1/2011, an ELR message snapshot for Specimen #1111 is sent to NC DPH containing data for the following within a single message:

Test	Result	Result Status	Result Date/Time
HIV-1 - HIV-2 - PLUS O (method EIA)	Reactive	Final	8/1/2011 01:00 pm
Rapid HIV-1/HIV-2 Antibody	HIV-2	Final	8/1/2011 01:15 pm

On 8/2/2011, the laboratory results the following additional test “HIV-1 WB” on specimen #1111, so the laboratory system now has:

Test	Result	Result Status	Result Date/Time	Comments about example
HIV-1 - HIV-2 - PLUS O (method EIA)	Reactive	Final	8/1/2011 01:00 pm	is reportable to NC DPH
Rapid HIV-1/HIV-2 Antibody	HIV-2	Final	8/1/2011 01:15 pm	is reportable to NC DPH
HepB eAb	Reactive	Final	8/1/2011 02:00 pm	is not reportable to NC DPH
HIV-1 WB	Positive	Final	8/2/2011 11:00 am	is reportable to NC DPH

The night of 8/2/2011, an ELR message snapshot for Specimen #1111 is sent to NC DPH containing data for the following within a single message:

Test	Result	Result Status	Result Date/Time
HIV-1 - HIV-2 - PLUS O (method EIA)	Reactive	Final	8/1/2011 01:00 pm
Rapid HIV-1/HIV-2 Antibody	HIV-2	Final	8/1/2011 01:15 pm
HIV-1 WB	Positive	Final	8/2/2011 11:00 am

On 8/3/2011, the laboratory makes a correction to the result of the “Rapid HIV-1/HIV-2 Antibody” test, changing the result from “HIV-2” to “HIV-1”, so the laboratory now has:

Test	Result	Result Status	Result Date/Time	Comments about example
HIV-1 - HIV-2 - PLUS O (method EIA)	Reactive	Final	8/1/2011 01:00 pm	is reportable to NC DPH
Rapid HIV-1/HIV-2 Antibody	HIV-1	Corrected	8/3/2011 10:00 am	is reportable to NC DPH
HepB eAb	Reactive	Final	8/1/2011 02:00 pm	is not reportable to NC DPH
HIV-1 WB	Positive	Final	8/2/2011 11:00 am	is reportable to NC DPH

The night of 8/3/2011, an ELR message snapshot for Specimen #1111 is sent to NC DPH containing data for the following within a single message:

Test	Result	Result Status	Result Date/Time
HIV-1 - HIV-2 - PLUS O (method EIA)	Reactive	Final	8/1/2011 01:00 pm
Rapid HIV-1/HIV-2 Antibody	HIV-1	Corrected	8/3/2011 10:00 am
HIV-1 WB	Positive	Final	8/2/2011 11:00 am

NC EDSS Import and Deduplication

The information in this section is provided as an illustration of why it is not a problem for NC EDSS to receive and import ELR message snapshots that contain some information that is duplicative of previous ELR messages.

NC EDSS stores data from ELR in this hierarchy and does match/merge/deduplication at each level of the hierarchy:

- Person has 0-n Disease Events (i.e., a case of a disease)
- Person has 0-n Laboratory Specimens (NC EDSS identifies each by the combination of Specimen ID, Collection Date and Specimen Source)
- Person has 0-n Test Results

Notes:

If a particular Test Result from the incoming ELR is an exact duplicate (all field values the same values) of an existing stored Test Result for the same specimen, only one of the duplicates is kept.

If there is any difference, both Test Results are stored and are displayed in descending Result Date sequence. This is like a principle followed in medical records, where superseded information is never deleted, but rather annotated. NC EDSS users are trained to understand that a result with the more recent result date supersedes any results with earlier result dates for the same test.

Also, when an NC EDSS user manually enters new records, NC EDSS also performs detection of potentially duplicate Persons and potentially duplicate Disease Events. If the NC EDSS user invokes a merge of two Person records and then a merge of that merged Person's Disease Event records, the Laboratory Specimens and Test Results are deduplicated within the merged Disease Event the same way as described above for ELR.

When an ELR message snapshot is imported into an NC EDSS Disease Event, all the tests/results in that snapshot are imported into that event regardless of whether all the tests/results are for same disease. The NC EDSS Laboratory Results screen displays all the Test Results for one Laboratory Specimen at a time. Thus, when the user views the NC EDSS Laboratory Results screen, the user is viewing the entire laboratory report.

If the ELR message snapshot contains test results for more than one disease, the same snapshot of all the test results may be imported into more than one Disease Event (i.e. into a different Disease Event for each Disease).

When and why message snapshots matter to NC DPH

The following are some examples of circumstances and diseases where message snapshots are needed for NC DPH to support disease surveillance optimally. The consequences of ELR not sent as message snapshots would be extra work for NC EDSS users, and result in additional phone calls to the laboratory and/or to the physician. This is not an exhaustive list, and the items are not listed in any order of importance.

1. Display of multiple test results for the same test on the same day must be unambiguous as to whether all those results still apply or whether a particular result supersedes another from the same day.
 - a) Over time there can be multiple ELR messages received for the same specimen, especially when there are additional or changed test results. As described in the preceding section, NC EDSS deduplicates test results that are exact duplicates (all field values the same values) and displays the deduplicated Test Results in descending Result Date sequence. This is like a principle followed in medical records, where

superseded information is never deleted, but rather annotated. NC EDSS users are trained to understand that a result with the more recent result date supersedes any results with earlier result dates for the same test. If there are multiple results displayed for the same test for the same result date the users interpret that to mean that all those results are applicable at the end of that day (i.e., that none of those results for that day are superseded by other results later that same day). This is one of the reasons why NC DPH requires that only one message per specimen be sent per day and that that message contains a complete snapshot of the status of the results as at the end of that day.

2. Patient demographics changes could occur between a series of ELR reports on the same specimen:
 - a) Patient demographics changes could occur in NC EDSS during the interval between 2 ELR reports on the same specimen and the demographics may not have been correspondingly changed in the laboratory's system. Depending on how extensive the demographics changes are, the 2nd ELR might not match up to the same Person record in NC EDSS as the Person record that was created/updated by the previous ELR for that specimen and may create a new Person record with a new Disease Event record. If the 2nd ELR were to contain only the incremental result rather than a complete snapshot, the new Disease Event in NC EDSS would be missing the previously reported results.
 - b) Patient demographics changes could occur in the laboratory's system during the interval between 2 ELR reports on the same specimen. Depending on how extensive the demographics changes are the 2nd ELR might not match up to the same Person record in NC EDSS as the Person record that was created/updated by the previous ELR for that specimen and may create a new Person record with a new Disease Event record. If the 2nd ELR were to contain only the incremental result rather than a complete snapshot, the new Disease Event in NC EDSS would be missing the previously reported results.
3. When the laboratory changes (corrects) the specimen collection date or specimen source of a previously reported specimen:
 - a) NC EDSS would store that as a new specimen record. It is important that the ELR message contains a snapshot of all results to date for that specimen – otherwise the new specimen record in NC EDSS would contain an incomplete report.
4. Antibiotic susceptibility results would be meaningless unless linked to the previously reported culture result for the same specimen, i.e., to which of the organisms identified in the culture result was tested for susceptibility to the antibiotic). Thus, the culture results need to be in the same snapshot as the susceptibility results.
5. Here are some disease specific scenarios where it especially matters that the ELR be a message snapshot inclusive of other reportable results on the same specimen. This is not an exhaustive list of all such scenarios.
 - a) A Syphilis confirmatory test positive result is meaningful only if it was preceded by a Syphilis screening test positive result on the same specimen. Having the ELR(s) reported as message snapshots ensures that both test results are imported into the same NC EDSS Event.

- b) Testing for tuberculosis typically starts with an AFB smear followed by a culture (that takes additional weeks to perform) on the same specimen. An initial report ELR must be sent for the AFB smear positive result. Weeks later when the culture is resulted, if the culture identifies a reportable organism (such as *M. tuberculosis*), another ELR must be sent for the culture result. It is relevant to know the corresponding AFB smear result. Snapshot processing ensures that both test results are imported into the same NC EDSS Event.
- c) When an HIV detection test is positive and on the same specimen a CD4/CD3 cell count test is below the threshold for AIDS case definition and NC EDSS does not already have an HIV Disease Event for that Person, an HIV event is created in NC EDSS. If the AIDS results are indicated, the HIV result has flags to update to AIDS based on lab results that qualify for AIDS.
- d) Serology panels for tick-borne diseases typically test for multiple diseases at the same time. Positive results for more than one of the diseases can be because of cross reactivity. Therefore, it is useful to the epidemiologist when reviewing a Disease Event for one disease to be aware that there was also a positive result for the other disease. If the ELR is a message snapshot containing the result for both diseases, the entire laboratory report is imported into the Disease Events of both diseases and the epidemiologist would see them no matter which of the Disease Events is being viewed.

Excerpts from “HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm)”

2.1.2 Null Values in Fields Vs. Components

The components and subcomponents of a data type constitute a snapshot of the data. The set of data represented by the data type is handled as a complete set; therefore, using the null value to indicate a missing component or subcomponent is unnecessary.

2.1.4 Snapshot processing

HL7 distinguishes between two methods of update: the "snapshot" and the "action code/unique identifier" modes. Both modes apply to repeating segments and repeating segment groups. For repeating fields, only snapshot processing applies. For the purpose of this guide, only snapshot processing is supported for segments, segment groups, and fields.

2.1.4.0 Repeating Segments

HL7 defines snapshot processing for segments as follows:

In the "snapshot" mode, the information contained in the set of repeating segments or segment groups from the incoming message replaces the corresponding information in the receiving application. This is equivalent to a deletion of the prior information followed by the addition of the newly supplied information. In this mode, everything (all repeating segments and segment groups) must be sent with every subsequent message in the series of messages. There is no other way to indicate which ones changed and which ones did not, the information contained in the set of repeating segments or segment groups from the incoming message replaces the corresponding information in the receiving application. This is equivalent to a deletion of the prior information followed by the addition of the newly supplied information. In this mode, everything (all repeating segments and segment groups) must be sent with every subsequent message in the series of messages. There is no other way to indicate which ones changed and which ones did not. To specify, "delete all of the segments in this repeating group" in the snapshot mode, send a single segment with "delete data" (indicated by a value of "") in all fields. This actively signals the receiver that there is information that needs to be deleted. If no segment were sent, this would equate to "no information". No information should not signal the receiver to take an action. There would be risk that the receiver might misinterpret the sender's intent.

2.1.4.1 Repeating Fields

Snapshot processing for repeating fields requires sending a full list of repetitions for each transaction. If the intent is to delete an element, the element is left off the list. This is analogous to the snapshot mode for repeating segments and segment groups. To delete the whole list, transmit the field once with a |""| (null) in the first component.

Repetitions of fields shall not have empty repetitions followed by repetitions containing data, except where the HL7 standard clearly reserves certain repetitions for specific purposes. For instance, PID-5 Patient Name is a repeating field, the first repetition of which is reserved by HL7 for the legal name. In the case where a name is known for the patient, but is not the legal name, format the name field as follows: |~|lastname^firstname^mi^^^^A|.

2.1.4.2 Parent Child Linkage

Parent **ORDER** information is located always in the FIRST OBR segment.

Parent **TEST** information is located right after this first OBR in the OBX(s) that follow up until the 2nd OBR

If only 1 OBX exists under the first OBR, then all subsequent tests, i.e., 2nd, 3rd will map to the same Parent OBX.

Parent-Child TEST Linking

Child Segment	Child Location	RELATES TO	Parent Segment	Parent Location	Parent FieldName
OBR 2 -26.1	OBX(s) under 2nd OBR	=	OBX 1 -3	1st OBX under 1st OBR	ObservationIdentifier
OBR 2 -26.2	OBX(s) under 2nd OBR	=	OBX 1 -4	1st OBX under 1st OBR	ObservationSubId

OBR 2 - 26.3	OBX(s) under 2nd OBR	=	OBX 1 - 5.2	1st OBX under 1st OBR	ObservationValue.Text
Parent-Child ORDER Linking					
Child Segment	Child Location	RELATES TO	Parent Segment	Parent Location	Parent FieldName
OBR 2 - 29.1	2nd OBR segment	=	OBR 1 -2	1st OBR segment	PlacerOrderNumber
OBR 2 - 29.2	2nd OBR segment	=	OBR 1 -3	1st OBR segment	FillerOrderNumber

2.1.4.3 Message Snapshots

Snapshot processing for messages simply means that the content of the current message is used to replace the contents from a prior message for the same information object. The primary problem associated with message snapshots is making sure the appropriate information object is updated. In this case, the information object is a laboratory result associated with a specific patient. To do the snapshot update properly, key identifiers must be shared across the messages, and must together uniquely identify the specific laboratory result that is to be updated. In HL7 version 2.7, the key identifiers to tie results together have been identified as the Placer Order Number (ORC-2/OBR-2) and Filler Order number (ORC-3/OBR-3). Unfortunately, some laboratories don't consider the placer or filler number as a unique identifier of the order (and hence the result). Instead, these laboratories use the placer and filler order numbers to identify a group of orders. Typically, in this case, the implementer will need to also look at OBR-4, the universal Service ID in conjunction with the placer or filler order number. Other identifiers in the message that can be used to verify the correct results are being updated include the patient identifiers found in PID-3. If these identifiers don't match across messages, even when the placer and filler order numbers match, then it's very likely the two messages are for different patients.

Another factor complicating the association of results across messages is the fact that many laboratories do not generate unique filler order numbers. In many cases, these laboratories are using an "accession number" as the filler order number. Often these accession numbers are reused by the laboratory system. That means that a particular accession number may be used repeatedly for different orders over time. If this occurs, validating the patient identifiers in PID-3 becomes critical. This guide will call for the use of placer and filler order numbers that are not reused in this fashion. This guide will call for the use of placer and filler order numbers that are not reused in this fashion.

Another issue with matching results from multiple messages is because not all laboratories properly identify the assigning authority associated with an identifier (such as a placer or filler order number). In HL7 terminology, an assigning authority is a component of an identifier that together with the actual ID makes the overall identifier unique. For instance, if Laboratory A creates a filler order number 123, Laboratory B also creates filler order number 123, and both these laboratories send results associated with these orders to a public health department, the

public health department needs to know which laboratory each filler order number is associated with. The assigning authority is used to distinguish between these two laboratories. Not all laboratories provide those assigning authorities, so the receiver of the message must figure out a mechanism for associating the order number with the appropriate laboratory. This guide will require use of some sort of assigning authority to prevent this problem; it's worth noting that non-conformant Laboratories can cause tremendous problems by ignoring this requirement. This becomes a patient safety issue because results can end up being associated with incorrect patients because of this sort of problem.

Finally, for those public health departments that wish to create longitudinal records of laboratory results for patients, the use of patient identifiers to associate results becomes important. Many of the same sorts of issues identified above for placer and filler order numbers exist for patient identifiers. Often, no assigning authority information is provided for these patient identifiers. In this case, personally identifiable information such as name, date of birth, gender, address, etc. become important in trying to match results to the appropriate patient. Certainly, not all public health departments will be trying to do this sort of matching, many are not even allowed to by state law, while others may be required to by state law.

2.1.4.4 Creation of Message Snapshots

The snapshot of data used to construct the message is captured at the time the relevant event occurs. The event triggering creation of the message is distinct from the time of transmission that may occur at some later time, particularly when batch transmission is being used.

The order group is required and can be repeated. This means that multiple ordered tests may be performed on a specimen.

Snapshot processing of the result message involves processing as a snapshot all the repeats of the ORDER_OBSERVATION group together as a group. This is especially important when dealing with parent/child results (such as cultures and sensitivities) which will span multiple ORDER_OBSERVATION groups. All these must be processed from both a message sender and message receiver perspective as a single snapshot.

Multiple results may be associated with an order. There will always be a single OBX in the results group.

Snapshot processing: Since the OBX segment in 2.5.1 does not contain a unique instance identifier, it is assumed that the repeating observation group will contain a complete set of observations (OBXs) associated with the OBR. Where a single OBX is being updated, all the OBXs related to the OBR must accompany the updated OBX, i.e., a full snapshot is sent.
Harmonized condition predicate: May be empty for OBR-25 Result statuses of "O," "I," "S" and "X"; otherwise, it is required.

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