North Carolina Division of Public Health – N.C. DPH

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

Table of Contents

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 N.C. EDSS?

The North Carolina Electronic Disease Surveillance System (N.C. EDSS) is a statewide disease surveillance, outbreak/case management, and early detection system. N.C. 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. N.C. EDSS services include support for required case or suspect case reporting of reportable diseases, electronic laboratory reporting, outbreak management, emergency situational awareness, and GIS mapping capabilities.

Electronic Laboratory Reporting and Meaningful Use

Currently, N.C. DPH is only accepting electronic laboratory reports from eligible hospitals. N.C. DPH is not requesting and will not receive electronic laboratory reports from eligible professionals.

If you would like to register your intent with N.C. DPH to initiate electronic laboratory reporting, please complete and submit your registration via the N.C. DPH Meaningful Use Site for Registration of Intent (http://ncdphmeaningfuluse.org).

For steps on the process of implementing an electronic laboratory reporting feed with N.C. DPH for meeting meaningful use, please see Appendix C – N.C. DPH ELR Checklist for meeting Meaningful Use. N.C. DPH will provide documentation at the completion of each step for your records.

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

Implementing Electronic Laboratory Reporting

The implementation of electronic laboratory reporting to the N.C. DPH requires the following steps:
1. Register your facility's intent to submit ELR to N.C. DPH.
2. Participate in an initial planning discussion with N.C. DPH.
3. From the Laboratory Information System, identify the laboratory results that are required by N.C. law to be reported to the N.C. DPH.
4. Translate local codes to standard coding systems.
5. Develop an HL7 Version 2.5.1 message for ELR to N.C. DPH.
6. Set up the secure message transport connectivity with N.C. DPH.
7. Send a batch file containing a test message for initial validation.
8. Participate in structure and content validation with N.C. DPH.
9. Participate in parallel data validation (User Acceptance Testing) with N.C. DPH.
10. Discontinue paper submission of reportable laboratory results to N.C. DPH.

1. Register your facility's intent to submit ELR

To register your intent with N.C. DPH to initiate electronic laboratory reporting, please submit your registration via the N.C. DPH Meaningful Use Site for Registration of Intent (http://ncdphmeaningfuluse.org).

2. Participate in an initial planning discussion

During the initial planning discussion, N.C. DPH will review this document as well as the HL7 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm) that is required for meeting the Stage 2 Meaningful Use objective.

It is the preference of N.C. DPH that hospitals use an ELR interface module that obtains laboratory result data ***directly from the hospital's Laboratory Information System (LIS)*** rather than indirectly via the hospital's 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 N.C. DPH.

3. Identify laboratory results that are required by law to be reported

North Carolina General Statutes and Administrative Code require that positive laboratory tests shall 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 N.C 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 N.C. Division of Public Health can be found in the North Carolina General Statues (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 N.C. DPH Communicable

Disease Laws and Rules website (http://epi.publichealth.nc.gov/cd/laws.html).

In addition to the laboratory results outlined in N.C. General Statues and Administrative Code, the N.C. Division of Public Health can also accept positive laboratory results (via ELR) for the conditions outlined in Appendix B – Conditions accepted for voluntary reporting to N.C. DPH if the hospital laboratory is willing to report those results. The results outlined in Appendix B – Conditions accepted for voluntary reporting to N.C. DPH are not required to be reported to the N.C. Division of Public Health.

When a hospital laboratory in North Carolina performs a communicable disease or blood lead test and the test result is reportable under N.C. 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 hospital laboratory should include the reportable results for out-of-state patients in their electronic laboratory reporting feed. For out-of-state patients, the N.C. 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 "Step 3a: Reportable Review" tab of the N.C. ELR Mapping tool (available for download through the N.C. Electronic Health Records Meaningful Use Requirements for ELR website. http://epi.publichealth.nc.gov/cd/meaningful_use/elr.html).

i) Complete the "Step 3a: 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 N.C. law.
iii) Indicate which tests the facility is willing to voluntarily report to N.C. DPH. A list of the results that N.C. DPH can accept for voluntary reporting can be found in Appendix B – Conditions accepted for voluntary reporting to N.C. DPH.
iv) Once you have completed the "Step 3a: Reportable Review" tab, please submit it to N.C. DPH via the online N.C. ELR Mapping Tool Submission form (https://app.smartsheet.com/b/form?EQBCT=a5631600d8bd4027aef279b2a854fbde).

Please use the following naming convention when submitting your N.C. ELR Mapping Tool document.
<Hospital Name> NC ELR <submission#> <Step#> <initials of submitter or reviewer> <date(YYYY MMDD)>

N.C. DPH will review your N.C. ELR Mapping Tool document and give feedback.

If your annual volume of laboratory results that are required by law to be reported from your facility is low, e.g. < 150/year, N.C. DPH would be willing to consider granting your facility a deferral from implementing an electronic laboratory reporting interface at this time. If N.C. DPH is willing to consider granting your facility a deferral, your facility will be asked to complete the "Step 3b Volume Review" tab of the N.C. ELR Mapping Tool and submit it via the online N.C. ELR Mapping Tool Submission form (https://app.smartsheet.com/b/form?EQBCT=a5631600d8bd4027aef279b2a854fbde).

Please note: If N.C. DPH grants your facility a deferral from implementing ELR at this time, reportable communicable diseases and conditions should continue to be reported to the N.C. DPH via the other mechanisms outlined in 10A NCAC 41A .0102. section (d).

4. Translate local codes to standard coding systems

Translation of code values used locally within the Laboratory Information System to standard coding vocabularies is required for electronic reporting to N.C. EDSS.

A) Laboratory tests or observations should be coded using the Logical Observation Identifier Names and Codes (LOINC®) based on the testing procedure, methodology, and analysis conditions. Further information about this coding system, including a searchable tool, is available on the Regenstrief Institute of Health Care website (loinc.org).

B) Laboratory test results, other than quantitative results, should be coded using Systemized Nomenclature of MEDicine – Clinical Terms (SNOMED-CT®) including organism names and qualitative results such as positive, negative, and undetermined.

C) Specimen types should be coded using Systemized Nomenclature of MEDicine – Clinical Terms (SNOMED-CT®) codes from the SNOMED-CT specimen hierarchy code set.

In order to make sure that N.C. DPH is capable of accepting the LOINC and SNOMED codes sent by your facility, please complete the "Step 4a: LOINC Mapping," "Step 4b: Result Mapping," and "Step 4c: Specimen Type Mapping" tabs of the N.C. ELR Mapping Tool (available for download through the N.C. Electronic Health Records Meaningful Use Requirements for ELR website. http://epi.publichealth.nc.gov/cd/meaningful_use/elr.html). The LOINC and SNOMED codes only need to be provided for laboratory tests, results, and specimen types that have been identified as reportable to N.C. DPH.

Once you have completed the three tabs mentioned above, please submit the N.C. ELR Mapping Tool document to N.C. DPH via the online N.C. ELR Mapping Tool Submission form (https://app.smartsheet.com/b/form?EQBCT=a5631600d8bd4027aef279b2a854fbde).

Please use the following naming convention when submitting your N.C. ELR Mapping Tool document.
<Hospital Name> NC ELR <submission#> <Step#> <initials of submitter or reviewer> <date(YYYY MMDD)>

N.C. DPH will review your N.C. ELR Mapping Tool document and give feedback.

5. Develop an HL7 Version 2.5.1 Message for ELR

N.C. 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 N.C. DPH. Adherence to this guide is required to meet Meaningful Use regulations. This implementation guide is free to download from the HL7 website (www.HL7.org).

- **Implementation Guide for Transmission of Laboratory-Based Reporting of Public Health Information using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol Implementation Guide Update, March 2005** - HL7 transactions that conform to this older guide could be accepted. However, use of this guide would not qualify for Meaningful Use incentive funding. This implementation guide is free to download from the CDC website (https://www.cdc.gov/elr/resources/2-3-1-hlr-standard.pdf)

The HL7 implementation guides named are 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 Project Manager to discuss how to report your results (see Appendix A – Contacts for contact information for the N.C. ELR Implementation Team).

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

To transmit electronic laboratory results to N.C. DPH, combine the HL7 transactions for the day into a single batch within a single file per laboratory per HL7 standards for files and batches.

N.C. 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 N.C. 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 "Snap Shot Processing" functionality discussed in the HL7 specifications can be found in Appendix D – Snap Shot 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 N.C. DPH requires that FHS/FileNameID and BHS/BatchNameIDType be populated. N.C. DPH reconciliation processes require that the two fields above contain the effective date of the file in yyyymmdd 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".

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 <u>all</u> of the MHS segments must contain exactly 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 SendingFacility in the FHS, BHS and in <u>all</u> of the MSH segments must all contain exactly 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).

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 one of the following tools:
- The National Institute of Science and Technology (NIST) tool (https://hl7v2-elr-testing.nist.gov/mu-elr/)
- The Message Quality Framework (MQF) tool (https://phinmqf.cdc.gov/)

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 ELR Project Manager as to whether those particular errors would prevent acceptance by N.C.

EDSS (see Appendix A – Contacts for contact information for the N.C. ELR Implementation Team).

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

6. Set up the secure message transport connectivity

N.C. DPH currently supports the Public Health Information Networking Messaging System (PHINMS) as the only transport mechanism to send electronic laboratory results directly to N.C. 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 to the North Carolina Surveillance Systems document.

In addition to receiving results via PHINMS, N.C. 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 the ELR Project Manager (see Appendix A – Contacts for contact information for the NC ELR Implementation Team).

7. Send a batch file containing a test message for initial validation

Transmit the file overnight to N.C. DPH.

N.C. DPH considers a successful test message to include a reportable result conformant to NC Regulations and to the HL7 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm).

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

8. Participate in structure and content validation

When N.C. DPH gives you permission to commence, transmit daily batch files from your Production environment to the N.C. DPH Test environment. N.C. DPH will review and validate the messages to ensure that data received from your facility is conformant to N.C. DPH requirements with regard to format and content, that the data can be processed successfully into N.C. EDSS and that the data meets other data quality requirements.

9. Participate in parallel data validation (User Acceptance Testing)

During parallel validation, your facility shall send N.C. DPH copies of the reports it issued to the ordering clinicians for all test results reportable to public health regardless of whether corresponding ELR was sent. 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 N.C. DPH will review the data imported into N.C. EDSS/ N.C. LEAD to assure that all reportable results that should have been imported into N.C. EDSS/ N.C. 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 ELR Project Manager for discussion with Management regarding an appropriate solution. If changes/fixes to your facility's ELR interface are warranted, the identified issues will be communicated to your facility and/or vendor and are tracked to resolution.

Once the SME from each disease group feels that enough paper laboratory reports have been reviewed and all major 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 signed off their acceptance.

10. Discontinue paper submissions

At the time that N.C. DPH transitions your ELR interface from the test environment to our production electronic surveillance system, your facility will receive a notification stating that that on-going submissions of electronic laboratory reporting of reportable results are being received by N.C. DPH from your facility.

N.C. 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 N.C. DPH that the ELR interface meets the requirement for reporting. At that time, N.C. 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.

When your facility adds new in-house tests or new results which are reportable to public health following the implementation of your ELR interface, your facility must contact the ELR Project Manager to test and validate the sending of any new results via ELR (see Appendix A – Contacts for contact information for the NC ELR Implementation Team).

Appendix A – Contacts

Lina Saintus
ELR Project Manager
Meaningful Use Program Consultant
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Appendix B – Conditions accepted for voluntary reporting to N.C. 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 have to make revisions to 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. That would be simpler for you to implement, and those additional results would be useful for surveillance purposes.

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*

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.*

Coronavirus

Please report *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

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 also report:
- HBV Core total antibody
- HBV HbsAb (antibody to vaccine)

Please do not report:
- HBV eAb (little e antibody)

However note that the following test is reportable by law:
- HBV eAg (little e antigen)

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 contact the ELR Project Manager to discuss how to report your results (see Appendix A – Contacts for contact information for the NC ELR Implementation Team).

Hepatitis C virus (HCV)

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

Hepatitis viral loads

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

Human granulocytic anaplasmosis (HGA)

It was previously known as human granulocytic ehrlichiosis (HGE). It is caused by organism *Anaplasma phagocytophila* (formerly called *Ehrlichia phagocytophila*). *Anaplasma phagocytophila* is reportable, per Administrative Rule criteria similar to *Ehrlichia* spp. Please also report any non-paired sera IgG IFA results expressed as titer ratios that are interpretable as positive.

HIV-1 screening tests (e.g. EIA, Rapid methods)

When a screening test positive result is confirmed by a confirmatory test (e.g. a Western blot), please report the screening test positive result. It may be easier for you to just report all of the screening 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 48 copies/mL, HIV-1 RNA detected*)
- Not Detected, < lower quantitation limit (e.g. *Less than 48 copies/mL, HIV-1 RNA not detected)*

Listeria

Please report any *Listeria* species, not just *Listeria monocytogenes.*

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.

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**.

If it is problematic for you to filter the reporting that narrowly, it is acceptable to report based on any of the following increasingly broader criteria:

- Report all vancomycin susceptibility test results (regardless of whether resistant) for *Staphylococcus aureus* susceptibility to vancomycin (along with the culture result).
- Report all susceptibility test results for *Staphylococcus aureus* susceptibility to any drug (along with the culture result).
- Report all *Staphylococcus aureus* culture results, regardless of whether susceptibility tests were performed, including any susceptibility test results.

Streptococcus pneumoniae (only from CSF)

Please report *Streptococcus pneumoniae*, but only when the specimen is CSF.

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 Vibrio

Report these species:

- Grimontia hollisae (formerly called Vibrio hollisae)
- Listonella pelagia (syn. Vibrio pelagia, syn. Vibrio pelagius)
- Photobacterium damselae (formerly called Vibrio damselae)

Appendix C – N.C. DPH ELR Checklist for meeting Meaningful Use

This checklist will prepare you to implement an electronic laboratory reporting interface to the North Carolina Division of Public Health (N.C. DPH) and will assist with meeting the Meaningful Use (MU) Stage 1 and Stage 2 requirements for ELR. Please contact NCDPHMU@dhhs.nc.gov for further assistance.

Step 1: Register Intent to submit ELR			
	Yes	**Date**	**Comments & Resources**
Submit your registration via the N.C. DPH Meaningful Use Site for Registration of Intent (http://ncdphmeaningfuluse.org).	☐		**REQUIRED FOR STAGE 2 OF MU.**
Receive and retain your notification from N.C. DPH that your registration has been completed and received.	☐		

Step 2: Participate in initial planning discussion with N.C. DPH			
	Yes	**Date**	**Comments & Resources**
Download a free copy of HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm).	☐		Available for download through the Health Level Seven (HL7) website. https://www.hl7.org/implement/standards/product_brief.cfm?product_id=98
Download the "Guidelines for Electronic Laboratory Reporting to North Carolina Division of Public Health" document.	☐		Available for download through the NC Electronic Health Records Meaningful Use Requirements for ELR website. http://epi.publichealth.nc.gov/cd/meaningful_use/elr_overview.pdf
Contact N.C. DPH to schedule an initial planning discussion.	☐		Send an email to NCDPHMU@dhhs.nc.gov or contact the ELR Project Manager.
Receive and retain your invitation to initiate on-boarding for electronic laboratory reporting from N.C. DPH.	☐		

Step 3: Identify laboratory results that are required by N.C. law to be reported to N.C. DPH			
	Yes	**Date**	**Comments & Resources**
Download the N.C. ELR Mapping Template.	☐		Available for download through the NC Electronic Health Records Meaningful Use Requirements for ELR website. http://epi.publichealth.nc.gov/cd/meaningful_use/elr.html
Fill in the N.C. ELR Mapping Template with the entire menu of services for your facility and indicate which tests are performed in-house versus sent out to a reference lab.	☐		
Indicate for each of the tests that are performed in-house if they are required to be reported under N.C. law. Also indicate which tests the facility is willing to voluntarily report to N.C. DPH.	☐		The rules for which laboratory results are required by North Carolina law to be reported to N.C. DPH can be found in the North Carolina General Statutes and Administrative code. A link to these regulations can be found on the N.C. DPH Communicable Disease Laws and Rules website. (http://epi.publichealth.nc.gov/cd/laws.html) A list of the results that N.C. DPH can accept for voluntary reporting can be found in Appendix B of the "Guidelines for Electronic Laboratory Reporting to North Carolina Division of Public Health." http://epi.publichealth.nc.gov/cd/meaningful_use/elr_overview.pdf
Once you have completed the "Step 3a: Reportable Review" tab, please submit it to N.C. DPH via the online N.C. ELR Mapping Tool Submission form.	☐		N.C. ELR Mapping Tool Submission form. https://app.smartsheet.com/b/form?EQBCT=a5631600d8bd4027aef279b2a854fbde

Step 4: Translate local codes to standard coding systems			
	Yes	**Date**	**Comments & Resources**
Map local lab orders and tests performed codes to the Logical Observation identifiers Names and Codes (LOINC) standard vocabulary.	☐		Reference materials are available from the following websites: LOINC: loinc.org

	Yes	Date	Comments & Resources
Map local lab test result values to the Systemized Nomenclature of Medicine – Clinical Terms (SNOMED-CT) standard vocabulary.	☐		SNOMED-CT: www.nlm.nih.gov/research/umls/Snomed/snomed_main.html Public Health Information Network Vocabulary Access Distribution System (VADS) & Reportable Condition Mapping Table: https://phinvads.cdc.gov/vads/SearchVocab.action
Map local specimen types (sources) to the Systemized Nomenclature of Medicine – Clinical Terms (SNOMED-CT) standard vocabulary.	☐		
Map other local codes according to the HL7 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm).	☐		For Example: HL7 defined tables for race, ethnicity, gender, etc.
Please complete the "Step 4a: LOINC Mapping," "Step 4b: Result Mapping," and "Step 4c: Specimen Type Mapping" tabs of the N.C. ELR Mapping Tool with the mapping of your local codes to these standard coding systems and submit it to N.C. DPH via the online NC ELR Mapping Tool Submission form.	☐		N.C. ELR Mapping Tool Submission form. https://app.smartsheet.com/b/form?EQBCT=a5631600d8bd4027aef279b2a854fbde

Step 5: Develop an HL7 Version 2.5.1 Message for ELR

	Yes	Date	Comments & Resources
Develop an HL7 message conformant to the HL7 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm).	☐		Available for download through the Health Level Seven (HL7) website. https://www.hl7.org/implement/standards/product_brief.cfm?product_id=98
Test ELR messages via self-service online validation tools, resolve issues found, and provide your successful validation results to N.C. DPH.	☐		National Institute of Science and Technology (NIST) website. https://hl7v2-elr-testing.nist.gov/mu-elr/ CDC's Message Quality Framework (MQF) ELR receiver profile. https://phinmqf.cdc.gov/

Step 6: Set up the secure message transport connectivity

	Yes	Date	Comments & Resources
N.C. DPH currently supports the Public Health Information Networking Messaging System (PHINMS) as the transport mechanism to send electronic laboratory results directly to N.C. DPH.	☐		For more information on PHINMS, please visit the CDC's website. http://www.cdc.gov/phin/tools/PHINms/index.html
N.C. DPH can also accept ELR messages sent through the North Carolina Health Information Exchange (NC HIE).	☐		
Contact the ELR Project Manager to request configuration of the transport mechanism at NCDPHMU@dhhs.nc.gov.	☐		

Step 7: Send a batch file containing a test message for initial validation

	Yes	Date	Comments & Resources
Transmit a message containing a reportable result conformant to N.C. Regulations and to the HL7 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm).	☐		If the message passes initial validation, coordinate automated daily message transmissions from the test system and/or production system. If the message does not pass initial validation, please continue message development and internal validation.
Receive and retain your confirmation that a successful test message has been received by N.C. DPH.	☐		

Step 8: Participate in structure and content validation

	Yes	Date	Comments & Resources
N.C. DPH will perform structure and content validation.	☐		N.C. DPH will notify your facility during structure and content validation to discuss and resolve any discrepancies in messaging. If your facility is non-responsive, you many not fulfill the Stage 2 Meaningful Use objective for ELR.

Step 9: Participate in parallel data validation (User Acceptance Testing) with N.C. DPH			
	Yes	**Date**	**Comments & Resources**
N.C. DPH will perform data validation, comparing the electronic submissions from the production system against the existing reporting mechanism (e.g. mail or fax).	☐		N.C. DPH will notify your facility during parallel data validation to discuss and resolve any discrepancies in the data transmission. If your facility is non-responsive, you may not fulfill the Stage 2 Meaningful Use objective for ELR.

Step 10: Discontinue paper submissions to N.C. DPH			
	Yes	**Date**	**Comments & Resources**
N.C. DPH will transition your ELR reporting to the production surveillance system.	☐		
Receive and retain your notification that on-going submissions of electronic laboratory reporting of reportable results are being received by N.C. DPH from your facility.	☐		
Coordinate with N.C. DPH to determine a date to discontinue paper or faxed reporting of laboratory results and solely submit ELR.	☐		N.C. DPH and your facility will perform continual quality control checks. Also, when your facility adds new in-house tests or new results which are reportable to public health, your facility must contact the ELR Project Manager (NCDPHMU@dhhs.nc.gov) to test and validate the sending of any new results via ELR.
Receive and retain your notification from the N.C. State Epidemiologist that your facility can discontinue paper or faxed reporting of laboratory results and solely submit ELR.	☐		

Appendix D – Snap Shot Processing

N.C. 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 N.C. 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 in order for N.C. 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 N.C. DPH, a message snapshot should include the latest version of all test results which are reportable to N.C. DPH for the same specimen. There may be other test results on the same specimen that are not reportable to N.C. 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.

N.C. 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 N.C. 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 N.C. DPH
Rapid HIV-1/HIV-2 Antibody	HIV-2	Final	8/1/2011 01:15 pm	is reportable to N.C. DPH
HepB eAb	Reactive	Final	8/1/2011 02:00 pm	is not reportable to N.C. DPH

The night of 8/1/2011, an ELR message snapshot for Specimen #1111 is sent to N.C. 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 N.C. DPH
Rapid HIV-1/HIV-2 Antibody	HIV-2	Final	8/1/2011 01:15 pm	is reportable to N.C. DPH
HepB eAb	Reactive	Final	8/1/2011 02:00 pm	is not reportable to N.C. DPH
HIV-1 WB	Positive	Final	8/2/2011 11:00 am	is reportable to N.C. DPH

The night of 8/2/2011, an ELR message snapshot for Specimen #1111 is sent to N.C. 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 N.C. DPH
Rapid HIV-1/HIV-2 Antibody	HIV-1	Corrected	8/3/2011 10:00 am	is reportable to N.C. DPH
HepB eAb	Reactive	Final	8/1/2011 02:00 pm	is not reportable to N.C. DPH
HIV-1 WB	Positive	Final	8/2/2011 11:00 am	is reportable to N.C. DPH

The night of 8/3/2011, an ELR message snapshot for Specimen #1111 is sent to N.C. 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

N.C. EDSS import and deduplication

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

N.C. 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)

        has 0-n Laboratory Specimens (N.C. EDSS identifies each by the combination of Specimen ID, Collection Date and Specimen Source)

            has 0-n Test Results

Notes:

If a particular Test Result from the incoming ELR is an exact duplicate (all field values exactly 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 similar to

a principle followed in medical records, where superseded information is never deleted, but rather annotated. N.C. 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 N.C. EDSS user manually enters new records, N.C. EDDS also performs detection of potentially duplicate Persons and potentially duplicate Disease Events. If the N.C. 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 N.C. EDSS Disease Event, all of the tests/results in that snapshot are imported into that event regardless of whether all the tests/results are for same disease. The N.C. EDSS Laboratory Results screen displays all of the Test Results for one Laboratory Specimen at a time. Thus, when the user views the N.C. 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 N.C. DPH

The following are some examples of circumstances and diseases where message snapshots are needed in order for N.C. DPH to support disease surveillance optimally. The consequences of ELR not sent as message snapshots would be extra work for N.C. EDSS users, and also 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 particular 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, N.C. EDSS deduplicates test results that are exact duplicates (all field values exactly the same values) and displays the deduplicated Test Results in descending Result Date sequence. This is similar to a principle followed in medical records, where superseded information is never deleted, but rather annotated. N.C. 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 of 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 N.C. 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 N.C. 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 N.C. 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 N.C. 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 N.C. 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 N.C. 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) N.C. EDSS would store that as a new specimen record. It is important that the ELR message contain the snapshot of all results to date for that specimen – otherwise the new specimen record in N.C. EDSS would contain an incomplete report.

4. Antibiotic susceptibility results would be meaningless unless linked to the particular 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 N.C. 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 N.C. EDSS Event. Also, TB cultures and susceptibilities take so long that Person demographics changes may occur in the interim; the effects of which are described above.

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 N.C. EDSS does not already have an HIV or AIDS Disease Event for that Person:

i) If the initial ELR for that specimen is a message snapshot containing both test results, N.C. EDSS would create an AIDS Disease Event. But if the ELR is not a snapshot (i.e. the two results are received in separate messages) and the HIV result gets received/processed first, N.C. EDSS would create an HIV Disease Event, and then when the CD4/CD3 result is received/processed later that would import into the HIV Disease Event. An N.C. EDSS user would then have to review that data and change the HIV Disease Event to an AIDS Disease Event.

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. 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 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 (**continued on P.12)** 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 identifiers3 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 actually 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.

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 of 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 that assigning authorities, so the receiver of the message have to 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, but it's worth noting that non-conformant Laboratories can cause tremendous problems by ignoring this requirement.

This actually 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 actually be required to by state law.

2.1.4.3 Creation of Message Snapshots

The snapshot of data used to construct the message is captured at the time the relevant event (see section 3.4 below) 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.

p. 80
The order group is required and can repeat. 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.

p. 82
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.