Overview: Hepatitis B and C lab result interpretation resource

June 25, 2025 | 3 pm ET

Welcome! We're glad you can join us

- Today's session will include presentations from HepTAC Advisory Committee members:
  - Eman Addish
  - Sarah New
- And a moderated discussion lead by:
  - Heather Wingate, Tennessee Department of Health and HepTAC Advisory Committee member
- We will begin with presentations followed by discussions/Q&A
- Feel free to use the chat to introduce yourself and ask questions!

Office Hours

- To support jurisdictions on interpreting labs and developing their care cascade, we will be hosting office hours on:
  - July 21 and 28 at 3pm ET
  - Registration: https://nastad.zoom.us/meeting/register/voqmn0X5QnaSkhYpcGPOPg
- Please email hepatitis@NASTAD.org ahead of the office hours with a brief description of your needs to ensure coverage.

LAB INTERPRETATION RESOURCE

Eman Addish, MPH and Sarah New, MPH

AGENDA

Background & Need

Method

Guidance & Applied Steps

Resource

Limitations

Final Takeaway

BACKGROUND & NEED

- **Hepatitis laboratory data can lack critical result interpretation notes.**
  - Ribonucleic acid (RNA) notes like "Detected" or "Not Detected"
- **Data gaps can misclassify results and impact clearance cascades and linkage to care.**
- **Purpose of guidance:**
  - Support surveillance teams in identifying result interpretation fields in HL7 feeds
  - Support collaboration with informatics teams by learning to speak their language
  - Walk through integrating key interpretation notes into surveillance systems
  - Address technical barriers through collaborative problem solving with informatics teams

IN PRACTICE...

- **Quantitative RNA Results Without Interpretation**
  - Some electronic laboratory (ELR) report values like "<15 IU/mL" or "<12 IU/mL" without indicating "Detected" or "Not Detected."

- **When Interpretation is Unclear**
  - Check the **notes field** for interpretive comments
  - Refer to lab-specific guidance (Quest, ARUP, LabCorp, etc.)
  - Use **LOINC.org** to identify test reference ranges

- **Review the Full Panel**
  - Examine all hepatitis-related results from the same panel or timeframe
  - Look for accompanying **qualitative results** (e.g., "Not Detected") to clarify interpretation
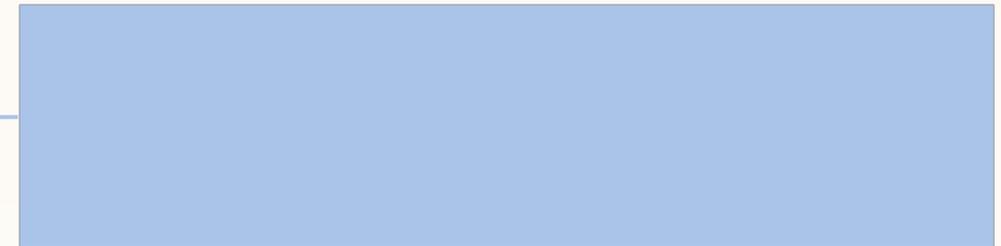
ALMOST 400,000 HCV RNA ELRS REPORTED, 2018 - 2024

Among the 46,446 were reported with an "<" sign,

9.5% were missing qualitative information in one or more fields
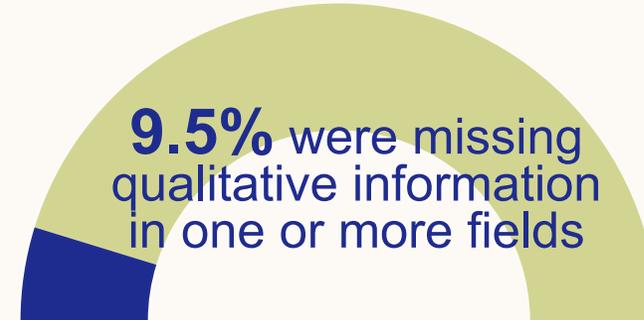
4,418 have quantitative results in the results field without interpretation

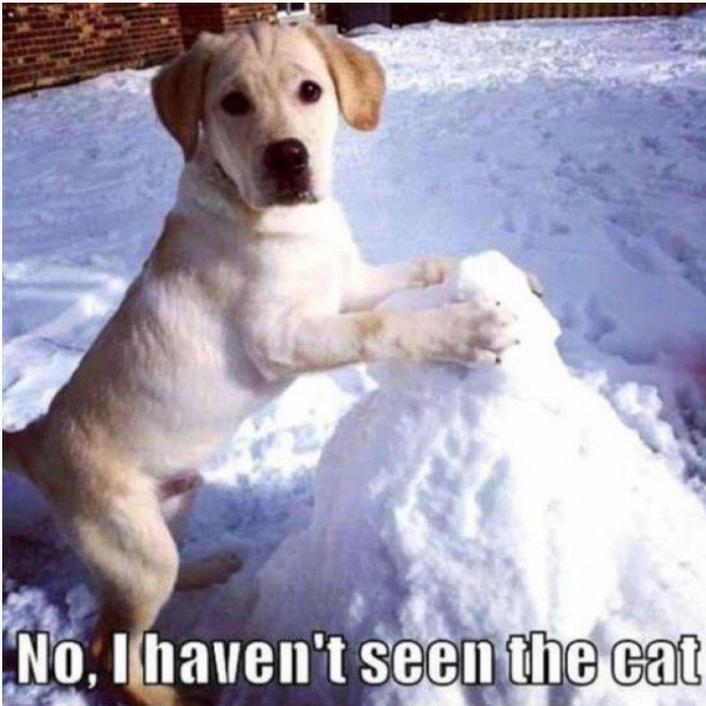**2,510** had no interpretive comments in the notes field

1,881 had no qualitative results in the full panel

4.0% of ELRs with "<" remained ambiguous

?

HAVE YOU EVER RECEIVED LAB RESULTS WITH A "<" SIGN BUT NO ADDITIONAL INFORMATION?

METHODS

- **Reviewed chronic hepatitis B and C ELRs from Quest, LabCorp, and ARUP reported between 2018 – 2024**

- **Documented results for lab test for each test type:**

  - **Hepatitis C:** antibody, RNA, genotype

  - **Hepatitis B:** surface antigen, surface antibody, core antibody total, IGM, little e antigen, little e antibody, genotype, DNA

- **Cross referenced with available resources online**

- **Worked with Informatics Team**

- **Reviewed by CDC Division of Viral Hepatitis (DVH)**

- **Currently under review by laboratories**
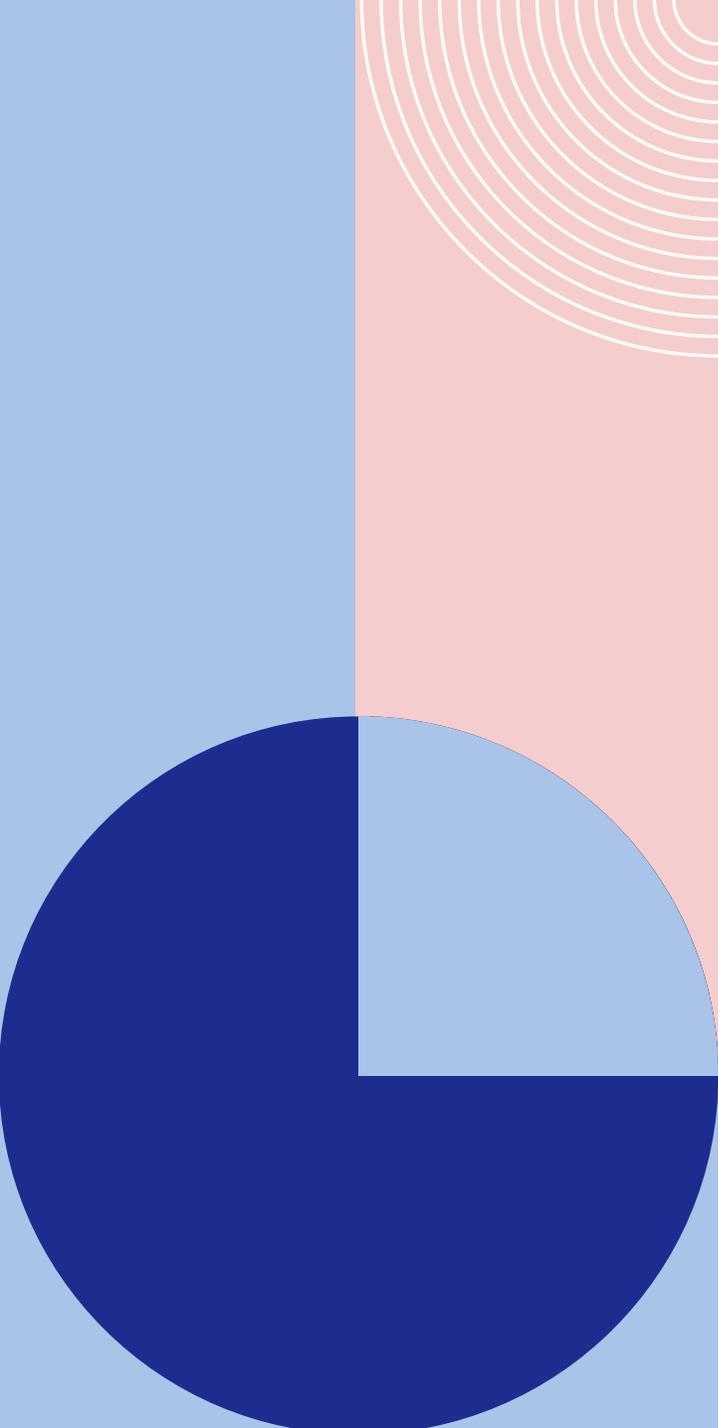
GUIDANCE
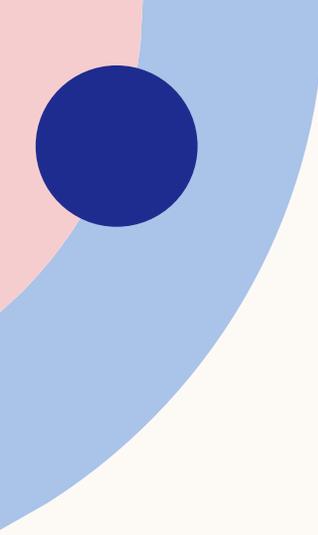
STEP 1: IDENTIFY INTERPRETATION NOTES IN HL7

- **Review the raw HL7 feed**
  - HL7 is a standard way to structure messages so that healthcare systems can exchange information
  - Messages are transmitted electronically and parsed to map to surveillance systems
  - You may not have direct access – reach out to your informatics team to check.

STEP 1: APPLIED

- **Review Observation/Result (OBX) segments in HL7**
  - Each OBX segment is one piece of a result, like a lab result or a clinical observation.
  - Make it possible to automatically interpret and organize data in electronic surveillance systems.
  - Relevant OBX segments:
    - **OBX-5:** Lab result (e.g., "<15")
    - **OBX-6:** Units of measure (e.g., IU/mL)
    - **OBX-7:** Reference range (e.g., "<11.00")
    - **OBX-8:** Abnormal flags (e.g., "N" = Normal, "A" = Abnormal)
    - Use HL7 v2.5.1 ELR Guide (pg. 104+) to explore additional segments

- **Also check note (NTE) segments**
  - Look for interpretation comments like: **"HCV RNA detected" or "HCV RNA not detected"**

DO YOU HAVE EXPERIENCE READING HL7 FEEDS?

HL7 WALK THROUGH

OBR|1|hepctestpt1^fakeMD^1.2.840.114350.1.13.541.2.7.3.798268.1111^ISO|ConnectionTest^

fakeMD^1.2.840.114350.1.13.541.2.7.3.798268.1111^ISO|11011-4^HCV RNA NAA+probe

Qn^LN^551300^HCV RealTime Abbott^L|||20241202103055-0800||||||pregnancy||

|1234567890^Fake^Doctor^^^^^^NPI&2.16.840.1.113883.4.6&ISO^^^^NPI|^WPN^PH^^1^123^8144

095|||||20241202103055-0800|||F||||||B19.20^Unspecified viral hepatitis C||

OBX|1|SN|11011-4^HCV RNA NAA+probe Qn^LN^551301^Hepatitis C Quantitation^L||<^12|

[IU]/mL^^L||||||F|||||||Abbott RealTime|| 20241202103055-

0800||||TESTLAB^D^^^^CLIA&2.16.840.1.113883.4.7 &ISO^XX^^^05D0123456 |1616 CAPITOL

AVE^^SACRAMENTO^CA^95814|

NTE|1|L|<12

NTE|2|L| HCV RNA not detected

HL7: OBR

| Field	Description
OBR-1	Set ID – unique sequence number for this OBR segment
OBR-3	Filler Order Number – internal lab identifier
OBR-4	Lab Test Order & LOINC
OBR-7	Observation Date/Time – when the test was performed or specimen collected
OBR-13	Relevant Clinical Information Pregnancy note
OBR-16	Ordering Provider / NPI
OBR-25	Result Status – Final result (F = Final, C = Corrected, P = Preliminary, etc.)
OBR-31	Reason for testing ICD-10 Diagnosis Code

HL7: OBX

Field	Description
OBX-1	Set ID – sequence number within the OBR group
OBX-2	Value Type – SN = Structured Numeric, CWE = Coded with Exceptions, FT = Formatted Text, ST = String for text less than 999 characters, TX = Text more than 999
OBX-3	Test (3.1= LOINC & 3.2 Lab test name)
OBX-5	Observation Value – test result value 5.1=SNOMED code& 5.2= Lab result observation
OBX-6	Lab result Units
OBX-7	Reference Range
OBX-8	Abnormal Flags – N = Normal (A = Abnormal, H = High, L = Low, etc.)
OBX-11	Observation Result Status – Final
OBX-19	Result Date
OBX-23	Performing Organizations information
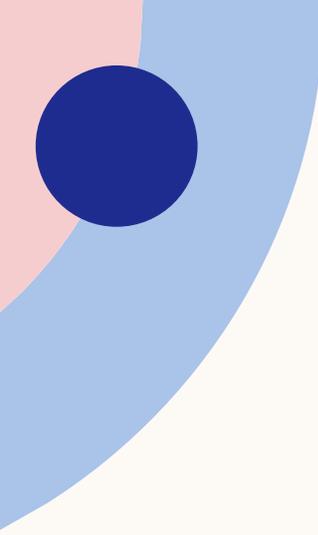
STEP 2: COLLABORATING WITH THE INFORMATICS TEAM

- **Designate Location for Notes**
  - Partner with your informatics team to create a dedicated field in the surveillance system for interpretation notes
  - Ensure it fits within the system's structure and is accessible for future analysis

- **Map Missing Information**
  - If interpretation notes are present in HL7 but not captured in your system, collaborate with informatics to map and populate them in the designated location

- **Reaching out to labs**
  - If HL7 messages lack interpretation notes, ask your informatics team to reach out to the lab's technical contact
  - be added using standard segments like NTE
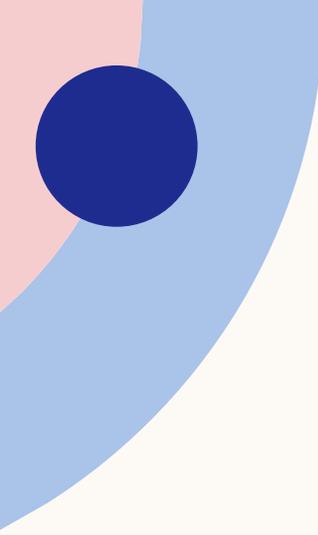
STEP 3: UPDATING SURVEILLANCE SYSTEM & CODE

- **System Configuration**
  - Update system code/config to recognize HL7 notes
  - Ensure notes display clearly for analysts
  - Extend logic to capture reason for testing & pregnancy status (OBX)

- **Testing & Validation**
  - Test to confirm notes appear as expected
  - Verify correct association between notes and corresponding lab results

- **Ongoing Maintenance**
  - Perform regular checks for note inclusion
  - Follow up on ambiguous results with labs
  - Update mappings with informatics team as needed

STEP 2 AND 3: APPLIED

- Collaborate with informatics to map **OBX** and **NTE** fields to appropriate fields in the system

- Test to ensure notes are correctly displayed and linked to the correct lab results
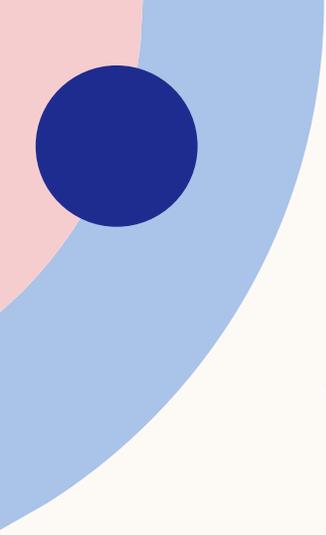
STEP 4: HANDLING MISSING INFORMATION

- **Interim Solutions:**
  - Document gaps when interpretation notes are missing, including what each result means by lab
  - Create logic to interpret ambiguous result + lab combinations as **positive** or **negative** where appropriate

STEP 4: APPLIED

- **Document Known Gaps**
  - Track labs and test types with missing or unclear interpretations

- **Apply Lab-Specific Logic**
  - Use known lab rules to classify results (e.g., "<15 IU/mL" = *Not Detected*)

- **Flag for Manual Review**
  - Identify records that can't be auto-classified for follow-up
  - **Create a Lookup Table for Consistency:**
    - Lab name
    - Reported format (e.g., "<15 IU/mL")
    - Lab-provided interpretation (if available)
    - Surveillance interpretation (e.g., Detected / Not Detected)

RESOURCES : HEP B & HEP C TAB

Lab name	Test type	Lab Test	Result	Interpretation of result	Notes
Labcorp	Antibody	HCV Antibody (anti-HCV)	Positive/ Reactive	Positive (past or current infection)	
Labcorp	Antibody	HCV Antibody (anti-HCV)	Negative/ Non-Reactive	Negative	
Labcorp	Antibody	HCV Antibody (anti-HCV)	Equivocal	N/A	Recommend retesting
Labcorp	Antibody	HCV s/co (anti-HCV s/co)	0-0.9	Negative	
Labcorp	Antibody	HCV s/co (anti-HCV s/co)	1.0-11.0	Positive (past or current infection)	
Labcorp	Antibody	HCV s/co (anti-HCV s/co)	>11.0	Positive (past or current infection)	
Labcorp	RNA	HCV RNA quant	Positive/ Detected	Positive (current infection)	
Labcorp	RNA	HCV RNA quant	Negative/ Not Detected	Negative	
Labcorp	RNA	HCV RNA quant	QNS	N/A	Quantity not sufficient; recommend retesting
Labcorp	RNA	HCV RNA (IU/mL or Log10 IU/mL)	<12 IU/mL (No additional notes)	Negative	HL7 NTE: HCV RNA not detected
Labcorp	RNA	HCV RNA (IU/mL or Log10 IU/mL)	<12 IU/mL (No additional notes)	Positive (current infection)	HL7 NTE: HCV RNA Detected
Labcorp	RNA	HCV RNA (IU/mL or Log10 IU/mL)	<15 IU/mL	Negative	HL7 NTE: HCV RNA not detected
Labcorp	RNA	HCV RNA (IU/mL or Log10 IU/mL)	<1.18 Log IU/mL	Negative	HL7 NTE: HCV RNA not detected
Labcorp	RNA	HCV RNA (IU/mL or Log10 IU/mL)	<15 IU/mL Not Detected	Negative	HL7 NTE: HCV RNA not detected
Labcorp	RNA	HCV RNA (IU/mL or Log10 IU/mL)	<15 IU/mL Detected	Positive (current infection)	HL7 NTE: HCV RNA Detected
Labcorp	RNA	HCV RNA (IU/mL or Log10 IU/mL)	<1.18 Not Detected Log IU/mL	Negative	HL7 NTE: HCV RNA not detected
Labcorp	RNA	HCV RNA (IU/mL or Log10 IU/mL)	<1.18 Detected Log IU/mL	Positive (current infection)	HL7 NTE: HCV RNA Detected
Labcorp	RNA	HCV RNA (IU/mL or Log10 IU/mL)	Below threshold level	Positive (current infection)	HL7 NTE: HCV RNA Detected
Labcorp	RNA	HCV RNA (IU/mL or Log10 IU/mL)	any result greater than or equal to 12 IU/mL	Positive (current infection)	Assay range: 12 IU/mL to 100,000,000 IU/mL

Lab name	Test type	Lab Test	Result	Interpretation of result	Notes
Labcorp	Surface Antigen	Hepatitis B Surface Antigen (HBsAg)	Positive/ Reactive	Positive	
Labcorp	Surface Antigen	Hepatitis B Surface Antigen (HBsAg)	Negative / Non-Reactive	Negative	
Labcorp	Surface Antibody	Hepatitis B Surface Antibody (anti-HBs)	Positive/ Reactive	Immunity due to past infection or successful vaccination	
Labcorp	Surface Antibody	Hepatitis B Surface Antibody (anti-HBs)	Negative/ Non-Reactive	Lack of immunity; vaccination is recommended.	
Labcorp	Surface Antibody	Hepatitis B Surface Antibody (anti-HBs)	≥10.0 mIU/mL	Immunity due to past infection or successful vaccination	
Labcorp	Surface Antibody	Hepatitis B Surface Antibody (anti-HBs)	<10.0 mIU/mL	Lack of immunity; vaccination is recommended.	
Labcorp	Core Antibody, Total	Hepatitis B Core Antibody (anti-HBc), Total	Positive/ Reactive	Past or current infection	
Labcorp	Core Antibody, Total	Hepatitis B Core Antibody (anti-HBc), Total	Negative/ Non-Reactive	No exposure to hepatitis B	
Labcorp	IGM	Hepatitis B Core Antibody, IGM (anti-HBc IgM)	Positive/ Reactive	Recent infection	
Labcorp	IGM	Hepatitis B Core Antibody, IGM (anti-HBc IgM)	Negative/ Non-Reactive	No infection	
Labcorp	DNA	Hepatitis B Virus (HBV), DNA	Positive/ Detected	Positive	
Labcorp	DNA	Hepatitis B Virus (HBV), DNA	Negative/ Not Detected	Negative	
Labcorp	DNA	Hepatitis B Virus (HBV), DNA	<10 IU/mL/ <1.00 Log IU/mL	Negative	DNA Not Detected
Labcorp	DNA	Hepatitis B Virus (HBV), DNA	<10 IU/mL Detected/ <1.00 Log IU/m Detected	Positive	Comment field has note: <10 HBV DNA Detected
Labcorp	little e Antigen	Hepatitis B e Antigen (HBeAg)	Positive/ Reactive	Positive	
Labcorp	little e Antigen	Hepatitis B e Antigen (HBeAg)	Negative/ Non-Reactive	Negative	
Labcorp	little e Antibody	Antibody to hepatitis B e Antigen (anti-HBe)	Positive	Positive	
Labcorp	little e Antibody	Antibody to hepatitis B e Antigen (anti-HBe)	Negative	Negative	
Labcorp	Genotype	HBV Genotype	Not Detected	Negative	This assay may not be successful when the HBV viral load is <500 IU/mL.
Labcorp	Genotype	HBV Genotype	Recognized genotypes A-I	Positive	This assay may not be successful when the HBV viral load is <500 IU/mL.
Quest	Surface Antigen	Hepatitis B Surface Antigen (HBsAg)	Positive/ Reactive	Positive	With reflex to confirmation; Reference Range(s)Non-Reactive
Quest	Surface Antigen	Hepatitis B Surface Antigen (HBsAg)	Negative / Non-Reactive	Negative	With reflex to confirmation; Reference Range(s)Non-Reactive
Quest	Surface Antibody	Hepatitis B Surface Antibody (anti-HBs)	Positive/ Reactive	Immunity due to past infection or successful vaccination	Reference Range ≥10 mIU/mL
Quest	Surface Antibody	Hepatitis B Surface Antibody (anti-HBs)	Negative/ Non-Reactive	Lack of immunity; vaccination is recommended.	Reference Range ≥10 mIU/mL

RESOURCES: SAS & R CODE

```
SAS Code
/* Process the lab data – After coding for the test type and the results that are easy to interpret */
data clean_lab_results;
   set Lab_data;
   if HCVRNA = 1 and result = ' ' then do;
   /* Identify whether 'not detected' in the comments field refers to the result or the reference range*/
   if index(lab_comment, "not detected") > 0 then do;
/* If 'not detected' appears with 'reference range', flag it as part of the reference range */
if index(lab_comment, "reference range") > 0 then do;
        reference_range_flag = 1;
        test_result_flag = 0;
        final_RNA_result = "Check Comments";
      end;
 /* "RNA not detected" indicates the actual result */
else if index(lab_comment, "not detected") > 0 then do;
     reference_range_flag = 0;
```

```
R Code
# Load required libraries
library(dplyr)
library(stringr)


# Process the lab data – After coding for the test type and the results that are easy to interpret
clean_lab_results <- Lab_data %>%
 mutate(
   # Convert lab_comment to lowercase for consistent pattern matching
   lab_comment = str_to_lower(lab_comment),

   # Initialize all flags and final result
   reference_range_flag = NA_integer_,
   test_result_flag = NA_integer_,
   Positive_result_flag = NA_integer_,
   final_RNA_result = NA_character_
 ) %>%
 rowwise() %>%
```

LIMITATIONS

Interpretations are highly site- and lab-specific

Does not include all labs

The resource includes LabCorp, Quest, and ARUP

Labs change assays and retire labs over time

ARUP retired some tests (but interpretation still holds)

LabCorp now reports HCV RNA results using a threshold of <12 IU/mL, in addition to <15 IU/mL

TAKEAWAYS

- Enhances **case classification**, **clearance cascade metrics**, and **linkage to care**

- Strengthens HL7 data interpretation to improve:
    - **Surveillance quality**
    - **Data usability**
    - **Public health action**

- Scalable to other interpretation fields (e.g., **pregnancy status**)

- **Collaboration** between surveillance programs, informatics, and labs

THANK YOU

Rosie Glenn Finer, CDPH

Isabel Lechuga, NASTAD

Zakiya Grubbs, NASTAD

CDC DVH

Quest, LabCorp, and ARUP partners

Discussion/Q&A with the audience

Feel free to raise your hand or
pop your questions into the chat

Office Hours

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