Indiana Department of Health

REPORTING GUIDANCE – COVID LABORATORY RESULTS

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Overview: COVID Reporting Requirements

- CDC continues to require every COVID-19 testing site to report diagnostic and screening tests performed to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 to the appropriate state or local public health department, based on the individual's residence.
  - New guidance effective April 4, 2022 will no longer require reporting of NEGATIVE results for non-NAAT tests (e.g., rapid, or antigen test results).
  - This includes rapid and antigen testing conducted for screening at schools, correctional facilities, and rapid testing performed in pharmacies, medical provider offices, and drive-through and pop-up testing sites.
- All testing sites must report diagnostics and screening tests within 24 hours of test completion to the appropriate state or local public health department.
- Guidance from Department of Health and Human Services (HHS) continues to require facilities and ordering providers to gather more complete patient demographic information. These data elements should be reported for all COVID laboratory testing reports sent to the appropriate state or local public health department. Please read Technical Guidance for changes in data requirements for up-to-date guidelines
  - CDC COVID Reporting Guidelines: https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html#how- to-report
  - Technical Guidance for ELR Submission for New Data Element Requirements: https://confluence.hl7.org/display/OO/proposed+HHS+ELR+Submission+Guidance+using+HL7+v2+messages

COVID Laboratory Reporting Update

- On March 8, HHS and CDC announced long-planned revisions to HHS COVID-19 laboratory reporting guidance, effective April 4, 2022.

What is the original guidance?

- The original guidance requires the reporting of ALL results (POSITIVE and NEGATIVE) from ALL COVID-19 tests (except home use tests).
- This includes results from Nucleic Acid Amplification Tests (NAAT) like RT-PCR, rapid and antigen tests, and antibody tests.

What is changing with the updated guidance?

- The new guidance will **no longer require reporting of NEGATIVE results for non-NAAT tests** (e.g., rapid, or antigen test results) •
- This includes rapid and antigen testing conducted for screening testing at schools, correctional facilities, employee testing programs, long-term care facilities, and rapid testing performed in pharmacies, medical provider offices, and drive-through and pop-up testing sites.
- It will **no longer require reporting of antibody test results, positive or negative.**

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**Subject to Change*

Please see Technical Guidance:
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COVID Laboratory Reporting Update cont.

What is *not* changing?

- The new guidance still **requires the reporting of ALL POSITIVE results for all test types** (except home tests and antibody tests).
- It still **requires reporting of both POSITIVE and NEGATIVE results from NAAT tests** (e.g., RT-PCR).

What else do we need to know?

- We're making this change because negative test results from antigen and rapid tests are often **unevenly reported and don't inform decision making** and are very **burdensome for testing entities to report and jurisdictions to receive.**
- Making reporting of negative rapid and antigen test results optional will **alleviate some burden** on jurisdictions and testing entities.
- **This change won't affect percent positivity metrics,** which is calculated using PCR and other nucleic acid amplification tests.
- This HHS guidance is the floor for reporting, not the ceiling; **states, territories, local, and Tribal health departments can set additional reporting requirements for their jurisdictions**. `

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COVID Laboratory Data Reporting

Complete Lab Data *Must* Include:

Test Ordered
Device Identifier
Test Result
Test Result Date
Accession # / Specimen ID
Patient Age
Patient Race
Patient Ethnicity
Patient Sex
Patient Residence ZIP Code
Patient Residence County
Ordering Provider Name and NPI
Ordering provider ZIP
Performing Facility Name and CLIA number
Performing Facility ZIP Code
Specimen Source
Date Test Ordered
Date Specimen Collected

Complete Lab Data *Must* Include for the State of Indiana:

- Patient First Name
- Patient Middle Name
- Patient Last Name
- Patient Phone Number with Area Code
- Patient DOB
- Ordering Provider Address
- Ordering Provider Phone Number

HHS "Ask on Entry" Data *Should* Include:

- First Test Y/N/U
- Employed in healthcare Y/N/U
- Symptomatic as defined by CDC? Y/N/U
- If yes, then Date of Symptom Onset mm/dd/yy
- Hospitalized? Y/N/U
- ICU? Y/N/U
- Resident in a congregate care setting (including nursing homes, residential care for people with intellectual and developmental disabilities, psychiatric treatment facilities, group homes, board and care homes, homeless shelter, foster care or other setting) (Y/N/U)
- Pregnant? Y/N/U

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Reporting Options for COVID-19 Results

- Three methods in which testing sites can submit COVID-19 lab results to Indiana Department of Health
    1. **Electronic Laboratory Reporting (ELR)** – automated messaging of lab reports sent using one or more electronic mechanisms. ELR improves the quality of laboratory results received by public health. Indiana Department of Health offers **two methods of ELR onboarding.**
    2. **REDCap "COVID-19 Point-of-Care Test Reporting – Indiana Department of Health" manual entry form** – User access designated to testing sites with **Point-of-Care testing (POC)**
    3. **Fax** complete laboratory reports to 317-234-2812
- Indiana Department of Health has been working with testing sites to determine the best method for your facility to report all COVID-19 lab results. It is our goal to provide your testing site with a secure means for efficient reporting.

COVID Lab Reporting: Facility Infrastructure

Consider the infrastructure of your testing site(s)

1. **What types of tests tools are used to perform COVID-19 test?**
   - Send out/Panel
   - Point of Care (POC)
   - Other
2. **How is reporting currently being done?**
   - Are the results faxed to Indiana Department of Health?
   - Are they submitted directly in NBS application?
   - Is there an existing electronic reporting feed with our electronic health records vendor?
   - Are we a Long-term care or nursing home facility?
   - Do we provide inpatient/outpatient testing?
   - Is another facility/laboratory submitting this data on our behalf?
3. **What is the volume or anticipated volume?**
4. **Who are the partners in which testing is provided?**
   - This can include LTC facilities, hospitals, school/universities, and other labs
5. **Does our IT system support electronic laboratory reporting?**
   - CSV flat file vs HL7 integration

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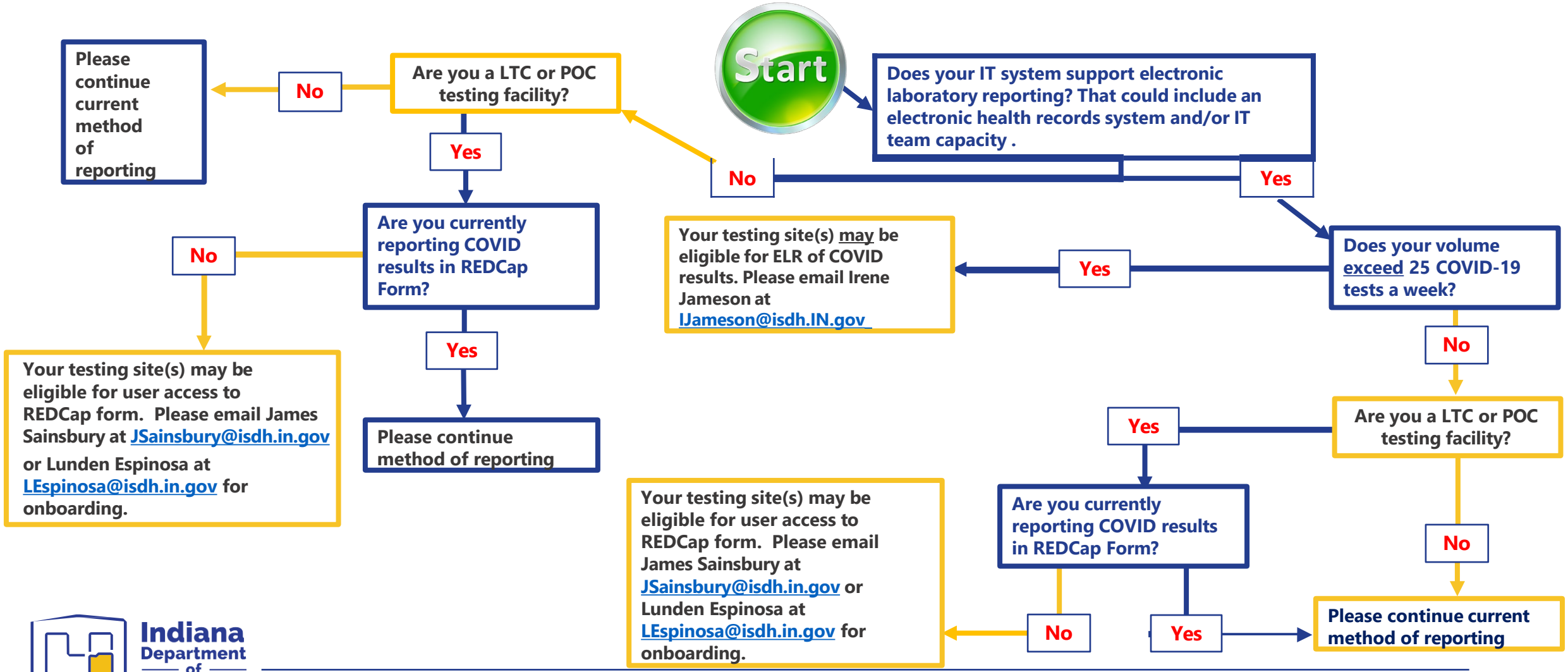
Please follow the "COVID Lab Reporting Methods" Flowchart for reporting guidance

COVID Lab Reporting Methods



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Electronic Laboratory Reporting: Two Options

Comma-separated value (CSV) Implementation

- Pipe-delimited flat file format
- Contains minimum reporting data field requirements. ***Excludes** AOE data fields
- Simple, quick format
- Submitted via SFTP
- Improves timeliness, accuracy, consistency, and completeness of lab and clinical data

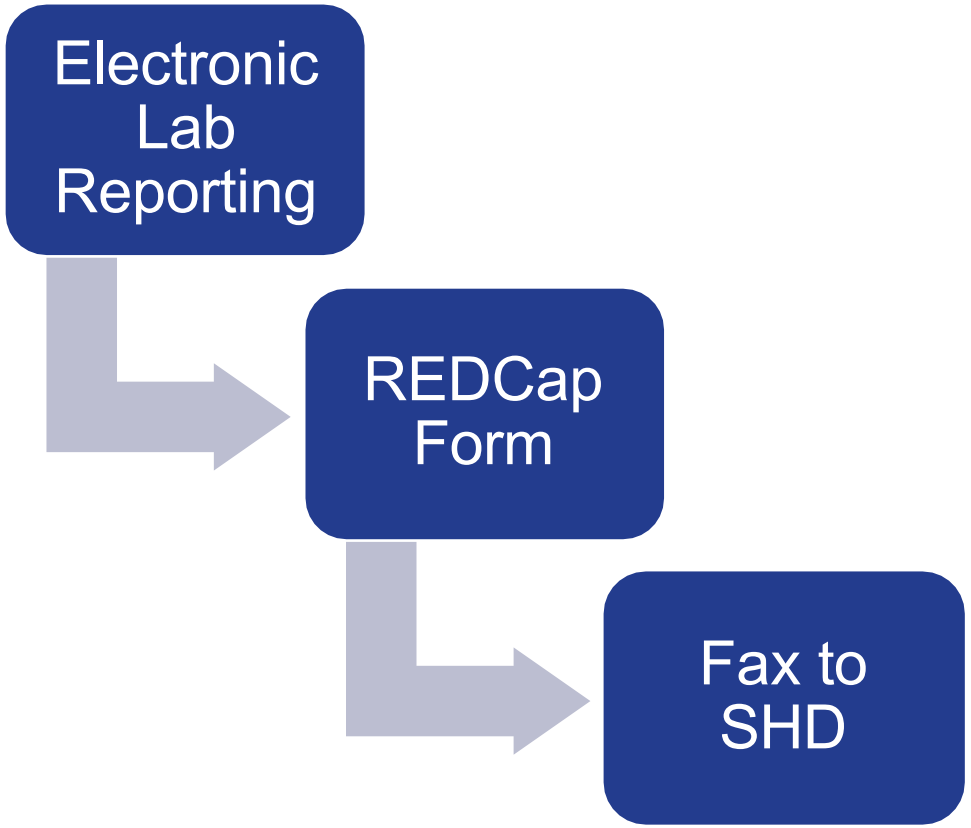
Health Level 7 (HL7) Implementation

- IDOH "Gold standard" preferred method
- For larger lab facilities
- Contains all reporting data field requirements including HHS/CDC
- **Requires mapping of LOINC/SNOMED coding systems prior to HL7 implementation**
- Submitted via SFTP
- Improves timeliness, accuracy, consistency, and completeness of lab and clinical data

Electronic Laboratory Reporting: Implementation Process

- **Prior** to establishing electronic lab reporting, please contact Indiana Department of Health (IDOH) and coordinate electronic file transfer efforts to ensure that complete lab data fields are tested and successfully submitted into our national surveillance system
- Until the ELR process is complete, please **fax only positive Indiana COVID19** lab test results to Indiana Department of Health at 317-234-2812.
- Confirm that all required data elements listed in the "**COVID Laboratory Data Reporting**" section are included in the lab reports
- Once successfully onboarded to submit COVID-19 (SARS-CoV-2) results electronically to IDOH, it will be required that all onboarded labs work with IDOH to report timely, rectify any data quality issues, and modify any data field requirements in **accordance with state/federal guidelines**.

Wrap Up



- **ELR implementation** is ideal method of reporting COVID19 results, which is vital in our public health surveillance and preparedness efforts.
- ***COVID-19 Point-of-Care Test Reporting – Indiana Department of Health*** **REDCap form** allows all sites using point-of-care testing to easily report all results to IDOH and will ensure results are included in surveillance data.
- Facilities already reporting point-of-care testing results through electronic laboratory feeds do not need to report via the ***COVID-19 Point of Care Test Reporting - Indiana Department of Health*** **REDCap form**.

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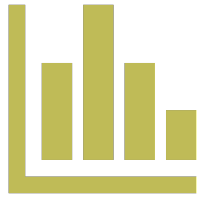
Questions?

Have you reviewed the COVID Lab Reporting Method flowchart and still unsure of the best reporting method for your organization?

Please email **James Sainsbury at JSainsbury@isdh.in.gov, Lunden Espinosa at LEspinosa@isdh.in.gov, or Catherine McQuern at CMcquern@isdh.IN.gov and we will assist you in determining the best method of reporting COVID-19 lab results.**



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