GEORGIA DEPARTMENT OF PUBLIC HEALTH

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COVID-19 Test Results Reporting Guidance

Rev. 04.12.2022

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Overview

All physicians, laboratories, and other health providers are legally required to report an actual case of a notifiable disease in Georgia, including COVID-19.[1] The legal authority for notifiable disease reporting is both in Georgia State Code and in Federal Law.[2,3] That legal authority has been expanded for the COVID-19 pandemic to include reporting of negative Nucleic Acid Amplification Test (NAAT) (e.g. PCR) test results and includes any individual, organization, or agency facilitating specimen collection and/or testing, including a specimen collection site or event.[4] In addition to traditional reporters to Public Health such as healthcare providers and laboratories, non-traditional reporters including, but not limited to, schools and universities, long-term care and assisted living facilities, Emergency Medical Services (EMS) and other first responder agencies, employers, and worksites must also report these test results.

Healthcare providers and other individuals, organizations, and agencies do not incur liability for reporting to Georgia Department of Public Health (DPH), as Georgia law specifically states that "[a]ny person . . . submitting in good faith reports or data to the department or county boards of health in compliance with the provisions of this Code section shall not be liable for any civil damages therefor."[5]

The various types of reporters mentioned above are collectively referred to as "facilities" throughout the remainder of this document.

Reporting Requirements

On June 4, 2020, HHS established a list of data elements that must be reported to state or local public health departments for each COVID-19 test performed by a facility, as well as a number of requested data elements. Table 1 shows the minimum data elements required for reporting a COVID-19 test result. Facilities should make every reasonable effort to provide the requested information to DPH in addition to the required elements. As of April 4, 2022, HHS has changed some of the reporting criteria for certain test types.

All positive results for all test types, excluding home tests and antibody tests must be reported. Negative, inconclusive or invalid NAAT (e.g. RT-PCR) test results from laboratories certified under CLIA to perform moderate- or high-complexity tests must be reported. The reporting of negative results for all other tests (e.g., rapid, or antigen test results) are no longer required. Antibody test results, whether negative or positive no longer require reporting. All reportable test results must be reported within 24 hours of testing in order to facilitate timely public health investigations.

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[1] https://dph.Georgia.gov/epidemiology/disease-reporting

[2] O.C.G.A. § 31-12-2(a); Ga. Comp. R. & Regs. 511-2-1-.01(h), -.02(1).

[3] https://www.hhs.gov/about/news/2020/06/04/hhs-announces-new-laboratory-data-reporting-guidance-for-covid-19-testing.html

[4] Public Law 116-136, § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act; Department of Health and Human Services, COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115, June 4, 2020 (https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf); Department of Health and Human Services, Frequently Asked Questions: Laboratory Data Reporting for COVID-19 Testing (https://www.hhs.gov/sites/default/files/laboratory-data-reporting-for-covid-19-testing-faqs.pdf).

[5] O.C.G.A. § 31-12-2(d).

Table 1. Required and Requested Data Elements Established by Georgia Department of Public Health or U.S. Dept. of Health and Human Services

Data Element	Description	Required	Requested	Agency Requiring/Requesting Information
Performing Facility Name	Name of the laboratory or facility that conducted the test	X		DPH, HHS
Performing Facility CLIA Number	CLIA number of the laboratory or facility that conducted the test	X		HHS
Performing Facility Zip Code	Zip code of the laboratory or facility that conducted the test	X		HHS
PatientID	A unique identifier for the person tested. Examples include medical record number or visit number.		X	DPH
Patient Name	Full name of the person tested	X		DPH, HHS
Date of Birth	Date of birth for the person tested	X		DPH, HHS
Age	Age of the person tested	X		HHS
Sex	Sex of the person tested	X		DPH, HHS
Race	Race of the person tested	X		DPH, HHS
Ethnicity	Ethnicity of the person tested	X		DPH, HHS
Patient Street Address	Typical residential street address of the person tested	X		DPH, HHS
City	City in which the person tested typically resides	X		DPH
State	State in which the person tested typically resides	X		DPH
Zip	Zip code in which the person tested typically resides	X		DPH, HHS
County	County in which the person tested typically resides	X		DPH, HHS
Patient Phone	Phone number for the person tested		X	DPH
Patient Email	Email address for the person tested		X	DPH
Employed in Healthcare	Is the person tested employed in a healthcare setting?		X	HHS
Resident in a Congregate Setting	Is the person tested a resident of a congregate setting?		X	HHS
Symptomatic	Is the person tested symptomatic?		X	HHS
Date of Symptom Onset	Date of symptom onset		X	HHS
Hospitalized	Is the person tested hospitalized?		X	HHS
ICU	Is the person tested admitted to an ICU?		X	HHS
Pregnant	Is the person tested currently pregnant?		X	HHS
First Test	Is this the person's first COVID-19 test of any type?		X	HHS
Ordering Facility Name	Name of the facility that ordered the test		X	DPH

Ordering Provider Name	Full name of the provider who ordered the test	X		DPH, HHS
Ordering Provider NPI	National Provider Identifier (NPI) of the provider who ordered the test	X		HHS
Ordering Provider Phone	Phone number for the provider who ordered the test	X		DPH, HHS
Ordering Provider/Facility Address	Street address of the facility that ordered the test		X	HHS
Ordering Provider/Facility City	City of the facility that ordered the test	X		DPH, HHS
Ordering Provider/Facility State	State of the facility that ordered the test	X		DPH, HHS
Ordering Provider/Facility Zip	Zip code of the facility that ordered the test	X		DPH, HHS
Specimen ID	A unique identifier for the specimen		X	DPH
Specimen Source	The type of specimen collected	X		DPH, HHS
Date Specimen Collected	Date that the specimen was collected	X		DPH, HHS
Date Specimen Received	Date that the specimen was received at the testing facility		X	DPH
Date Test Ordered	Date that the test was ordered by the facility/provider	X		HHS
Test Result Date	Date that the test was performed	X		DPH, HHS
Test Ordered	LOINC code for the test that was performed	X		HHS
Test Description	Description of the type of test performed	X		DPH
Test Result	Result of the test	X		DPH, HHS
Accession Number or Specimen ID	Accessioning number for the test	X		DPH, HHS
Device Identifier	A unique identifier that indicates the device used for testing	X		HHS

Methods of Reporting Results

At this time, DPH offers three primary methods of reporting COVID-19 test results. Each of these options uses the electronic laboratory reporting (ELR) process to ingest and display the data. This means that data submitted through any of these mechanisms create an electronic 'footprint,' can be viewed and queried in the SendSS ELR Results Query by Public Health staff, automatically link to the Person Under Investigation (PUI) form using pre-determined logic, and contribute to the overall testing data used to determine percent positivity, testing coverage, etc.

Health Level 7 International (HL7) Standards

This option allows for HL7 standardized data elements to be sent automatically and securely from a laboratory or health information system. This is considered the gold standard for reporting public health data, including test results. HL7 data can be sent through a number of mechanisms, including the Public Health Information Network Messaging System (PHINMS), manual upload to a secure folder within the SendSS Public Health Information Portal (PHIP), or, in special circumstances, a secure file transfer protocol (sFTP).

This method of reporting requires a high degree of information technology (IT) capability and support and is most suitable for commercial laboratories, large medical facilities or systems, or providers with a high level of support from the vendor of their information system.

Spreadsheet Template

This option requires a facility to set up an automated file export from their information system, which can be transmitted to DPH through PHINMS or manual upload to a secure folder in PHIP. This file can then be configured for automated ingestion by DPH through a process that creates an HL7 message from the data provided. Configuration typically takes between 20-40 hours per facility.

This method of reporting requires the spreadsheet to adhere to the specifications and template provided by DPH. Otherwise, it cannot be configured for automated processing and must be manually entered by DPH Epidemiology staff, overwhelming the capacity of the available workforce and delaying use of the data for proper case investigation, contact tracing, and follow-up. This method is most suitable for commercial laboratories, medical facilities, systems, or providers that have some degree of IT capability and support, and have the ability to create and modify exports from their information system to adhere to the provided template.

Spreadsheets that are manually generated (i.e., entering data directly into the spreadsheet rather than from an export) result in numerous data quality issues that prevent configuration for automated processing, thus requiring manual data entry by state Epi staff. Consequently, **manually generated spreadsheets will not be accepted by DPH** except under extreme circumstances and in consultation with the Reporting Team.

Point-of-Care Test Reporting Portal

This option uses a web-based portal for direct, manual data entry by the reporting facility and is intended specifically for reporting point-of-care test results. **It should NOT be used for reporting traditional laboratory results** such as RT-PCR testing. The form used for data entry has been streamlined to include only the data elements relevant for point-of-care testing whereas traditional laboratory testing requires additional data elements to be collected and reported. Any facility conducting traditional laboratory testing at an in-house, CLIA-certified laboratory ***and*** point-of-care testing should report all test results by HL7 or spreadsheet template.

A user's guide has been developed that provides step-by-step instructions for registering, logging in, using the Portal for data entry, searching previously entered results, and exporting data. Facilities can access this portal, as well as the user's guide and other training materials, using the following URL:

https://sendss.state.ga.us/sendss/!ncov_poc.login

This method of reporting does not require any IT capability or support, only an Internet connection and a computer. As a result, it is most suitable for providers or facilities that have limited or no IT support, cannot create and modify an export, or do not use an information system to manage testing data. General users of the POC Portal are able to see all results that are associated with the facility they indicate in the registration form.

For State and District Public Health Staff:

The Portal may also be used by state and district public health staff that report point-of-care test results on behalf of multiple facilities (e.g., from faxes or other direct reports). Public Health staff have a different level of user access than reporting facilities and should request access to the Portal within their regular SendSS account by emailing EOCEpidemiology@gets.onmicrosoft.com. **Public Health staff will be able to access the Portal through their SendSS account after being granted access and should NOT use the link above to access the Portal**. Public Health users can see all results submitted by all users, regardless of facility.

It is strongly preferred that facilities utilize one of the three reporting methods described above. However, there may be instances in which a facility will continue to report through other methods (e.g., 866-PUB-HLTH, faxes to district or state public health). This creates a burden on public health to complete data entry, reduces timeliness of reporting, and prevents these results from being included in the overall testing data. While these alternate methods are not encouraged, particularly for reporting of negative results, we recognize that some facilities may prefer to continue reporting in these ways and may accept traditional laboratory results through these methods. **Point-of-care test results will not be accepted by fax; these reports should be made using one of the three ELR methods described above.**

Special Populations and Considerations

Long-Term Care Facilities

The Centers for Medicare and Medicaid (CMS) and the National Healthcare Safety Network (NHSN) have developed a Point of Care Test Reporting Tool within the NHSN Long-Term Care COVID-19 Module. **DPH strongly recommends that CMS-certified facilities report individual point-of-care test results through the NHSN Reporting Tool.** These data will be electronically shared with states through the APHL Information Messaging Service (AIMS). In order to utilize the NHSN Reporting Pathway, facilities must upgrade their Secure Access Management Service (SAMS) from Level 1 to Level 3. Facilities can email nhsn@cdc.gov for additional information about the Reporting Tool and SAMS enrollment or upgrade.

Once a CMS-certified facility has onboarded to the NHSN Point of Care Test Reporting Tool for individual test reporting, they are no longer required to submit results directly to DPH through one of the three methods described above, including the interim spreadsheet upload that was previously offered to some facilities. However, **facilities reporting to NHSN must continue to report positive results to their District Public Health office in a manner determined by the District.** Facilities should confirm the date that they begin reporting all test results to NHSN by emailing contactpublichealth@dph.ga.gov.

Prior to completing the onboarding process and reporting directly to NHSN, CMS-certified facilities should report to DPH using the POC Portal or by spreadsheet if they have previously been given access by the DPH Reporting Team for this interim method of reporting. Any long-term care facility that is not a CMS-certified facility is *not* eligible for reporting through NHSN and should report through the POC Portal. **Interim spreadsheets will be phased out as of September 30th, 2021; all long-term care facilities should transition to reporting either to NHSN, POC Portal, or DPH Specified Spreadsheet template as soon as possible.**

Public Health Staff who Perform Point-of-Care Testing

Some Public Health Staff may be involved in performing point-of-care testing at various locations throughout a county or district but are not typical users of SendSS (i.e., clinical nursing staff who are supporting SPOC or mobile testing initiatives with rapid test kits). The point of entry which these staff use to access the POC Portal is at the discretion of the District Epidemiologist. If the specific location of testing is desired (e.g., SPOC Site A, SPOC Site B), it is recommended that these users access the POC Portal through their SendSS account so that they can enter multiple provider locations in the form. However, if the specific location of testing is not required, it is recommended that these users access the POC Portal using the direct URL provided above and register as a district-wide facility or organization (e.g., District 1-1 Public Health).

Over-the-Counter, At-Home Testing

Over-the-counter, at-home test kits to detect SARS-CoV-2 are not covered by the CARES Act and therefore are not subject to the same reporting requirements as other tests that are prescribed or performed by a facility. At-home test kits which do not include a provider component (i.e., prescription-based or facility-supervised distribution and/or a teleproctored health consultation, specimen collection,

or result verification) are not reportable in the state of Georgia and will not be accepted via ELR. Providers are not required to report these at-home tests not covered by the CARES Act to public health even if the patient reports results to you directly. Public health staff may choose to enter these manually into the PUI form as suspect cases. This is optional and not required.

Corrected or Amended Results

If a facility identifies a result that was incorrectly reported or later amended (e.g., the test result was initially reported as negative in error and was, in fact, positive), this information may be reported through the normal mechanism established for that facility but ***must also be reported by encrypted email*** to contactpublichealth@dph.ga.gov. The amended report must include the following fields at a minimum: Patient First and Last Name, Patient Date of Birth, Testing Facility, Specimen Collection Date, Test Type, and corrected Test Result. Additional information should be included if possible (see Table 1). [***Note:*** This does not apply to results that are considered "false positives" or "false negatives," but only to results for which an error in initial reporting was made.]

Reporting of Positive Cases by Providers and Healthcare Facilities

As stated in the Official Code of Georgia,[2] providers and other healthcare facilities are required to report positive cases to DPH according to notifiable disease reporting requirements[1] regardless of whether those results have also been reported by the testing laboratory. This dual method of reporting ensures that Public Health is notified of positive cases of a disease in a timely manner, prevents loss of data due to technical issues, and provides relevant clinical and exposure information that is often not accessible to laboratories.

Any provider or healthcare facility that performs or facilitates collection of a specimen that is **sent to a commercial or public health laboratory or to another healthcare facility laboratory** for testing is **required** to report positive results directly to DPH, preferably through the SendSS Case Report Form. This applies to all notifiable diseases, including COVID-19.

Any provider or healthcare facility that performs or facilitates collection of a specimen that is **tested for COVID-19 on-site and is reported through one of the three primary ELR methods** described above (i.e., HL7, approved spreadsheet, or POC Portal) is **not required** to report positive results directly to DPH in a second manner. However, if a facility identifies or is notified by DPH of an issue preventing timely transmission and use of ELR data, the facility is required to begin manually reporting positive COVID-19 reports through a separate method (e.g. SendSS Case Report Form) within 24 hours. Manual reporting must continue until DPH has notified the facility that the issue has been resolved and alternate reporting methods can cease. [***NOTE***: *This exception applies only to COVID-19 case reporting; all other cases of notifiable diseases should still be reported as described above, regardless of whether data is transmitted through ELR from the facility*.]

If a facility fails to comply with this directive, DPH may refer the facility for consideration of action to require compliance with applicable DPH laws, rules, and regulations. Pending the circumstances of no-compliance, DPH may also refer the facility to the Secretary of the U.S. Department of Health and Human Services (HHS) if the facility is not in compliance with federal law.[4]

Reporting of Sequencing Results and Variant Data

Laboratories sequencing SARS-CoV-2 specimens are strongly encouraged to report patient-specific results to DPH.[6] Laboratories must continue to report results of the initial molecular testing (i.e., PCR testing) to DPH within 24 hours of testing as required by state code. ***Initial positive results should not be held until sequencing data are available***. Upon completion of genetic sequencing, variant data should be reported within 24 hours of testing along with EITHER the original molecular test result (preferred), OR adequate patient identifiers and demographics in order to facilitate linking by DPH to the original specimen and test result. The DPH sequencing specifications for HL7 or spreadsheet template must be used to submit variant data. Table 2 shows the minimum data elements required for reporting a COVID-19 genetic sequencing result. Laboratories should make every reasonable effort to provide the requested information to DPH in addition to the required elements.

Table 2. Required and Requested Sequencing Data Elements Established by Georgia Department of Public Health

Data Element	Description	Required	Requested	Agency Requiring/Requesting Information
Performing Facility Name	Name of the laboratory or facility that conducted the test	X		DPH, HHS
Performing Facility CLIA Number	CLIA number of the laboratory or facility that conducted the test	X		HHS
Performing Facility Zip Code	Zip code of the laboratory or facility that conducted the test	X		HHS
PatientID	A unique identifier for the person tested. Examples include medical record number or visit number.		X	DPH
Patient Name	Full name of the person tested	X		DPH, HHS
Date of Birth	Date of birth for the person tested	X		DPH, HHS
Age	Age of the person tested	X		HHS
Sex	Sex of the person tested	X		DPH, HHS
Race	Race of the person tested	X		DPH, HHS
Ethnicity	Ethnicity of the person tested	X		DPH, HHS
Patient Street Address	Typical residential street address of the person tested	X		DPH, HHS
City	City in which the person tested typically resides	X		DPH
State	State in which the person tested typically resides	X		DPH
Zip	Zip code in which the person tested typically resides	X		DPH, HHS
County	County in which the person tested typically resides	X		DPH, HHS

[6] https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/reporting-sequencing-guidance.html

Patient Phone	Phone number for the person tested		X	DPH
Patient Email	Email address for the person tested		X	DPH
Employed in Healthcare	Is the person tested employed in a healthcare setting?		X	HHS
Resident in a Congregate Setting	Is the person tested a resident of a congregate setting?		X	HHS
Symptomatic	Is the person tested symptomatic?		X	HHS
Date of Symptom Onset	Date of symptom onset		X	HHS
Hospitalized	Is the person tested hospitalized?		X	HHS
ICU	Is the person tested admitted to an ICU?		X	HHS
Pregnant	Is the person tested currently pregnant?		X	HHS
First Test	Is this the person's first COVID-19 test of any type?		X	HHS
Ordering Facility Name	Name of the facility that ordered the test		X	DPH
Ordering Provider Name	Full name of the provider who ordered the test	X		DPH, HHS
Ordering Provider NPI	National Provider Identifier (NPI) of the provider who ordered the test	X		HHS
Ordering Provider Phone	Phone number for the provider who ordered the test	X		DPH, HHS
Ordering Provider/Facility Address	Street address of the facility that ordered the test		X	HHS
Ordering Provider/Facility City	City of the facility that ordered the test	X		DPH, HHS
Ordering Provider/Facility State	State of the facility that ordered the test	X		DPH, HHS
Ordering Provider/Facility Zip	Zip code of the facility that ordered the test	X		DPH, HHS
Specimen ID	A unique identifier for the specimen		X	DPH
Specimen Source	The type of specimen collected	X		DPH, HHS
Date Specimen Collected	Date that the specimen was collected	X		DPH, HHS
Date Specimen Received	Date that the specimen was received at the testing facility		X	DPH
Date Test Ordered	Date that the test was ordered by the facility/provider	X		HHS
Test Result Date	Date that the test was performed	X		DPH, HHS
Test Ordered	LOINC code for the test that was performed		X	HHS
Test Description	Description of the type of test performed	X		DPH
Test Result	Result of the test	X		DPH, HHS

Accession Number or Specimen ID	Accessioning number for the test		X	DPH, HHS
Device Identifier	A unique identifier that indicates the device used for testing	X		HHS
Sequence Variant	Specialty field just for reporting the lineage result from a COVID Sequence test.	X		DPH
GISAID Sequence ID	Specialty field just for reporting the GISAID ID result from a COVID Sequence test.	X		DPH
GISAID Upload Date	Date when sequence was submitted to GISAID		X	DPH
NCBI Accession	NCBI Genbank or SRA accession number. Any other sequence ID that is not GISAID		X	DPH

Additional Information and Resources

For help determining the appropriate method of reporting for your facility, please refer to Figure 1. This flowchart lists the acceptable methods of reporting based on the type of facility reporting and testing performed. For additional information on any of the three reporting methods described in this guide, or to obtain specifications for reporting by HL7 or spreadsheet template, please email contactpublichealth@dph.ga.gov, call DPH Epidemiology office at 404-657-2588, or contact your District Public Health Office.

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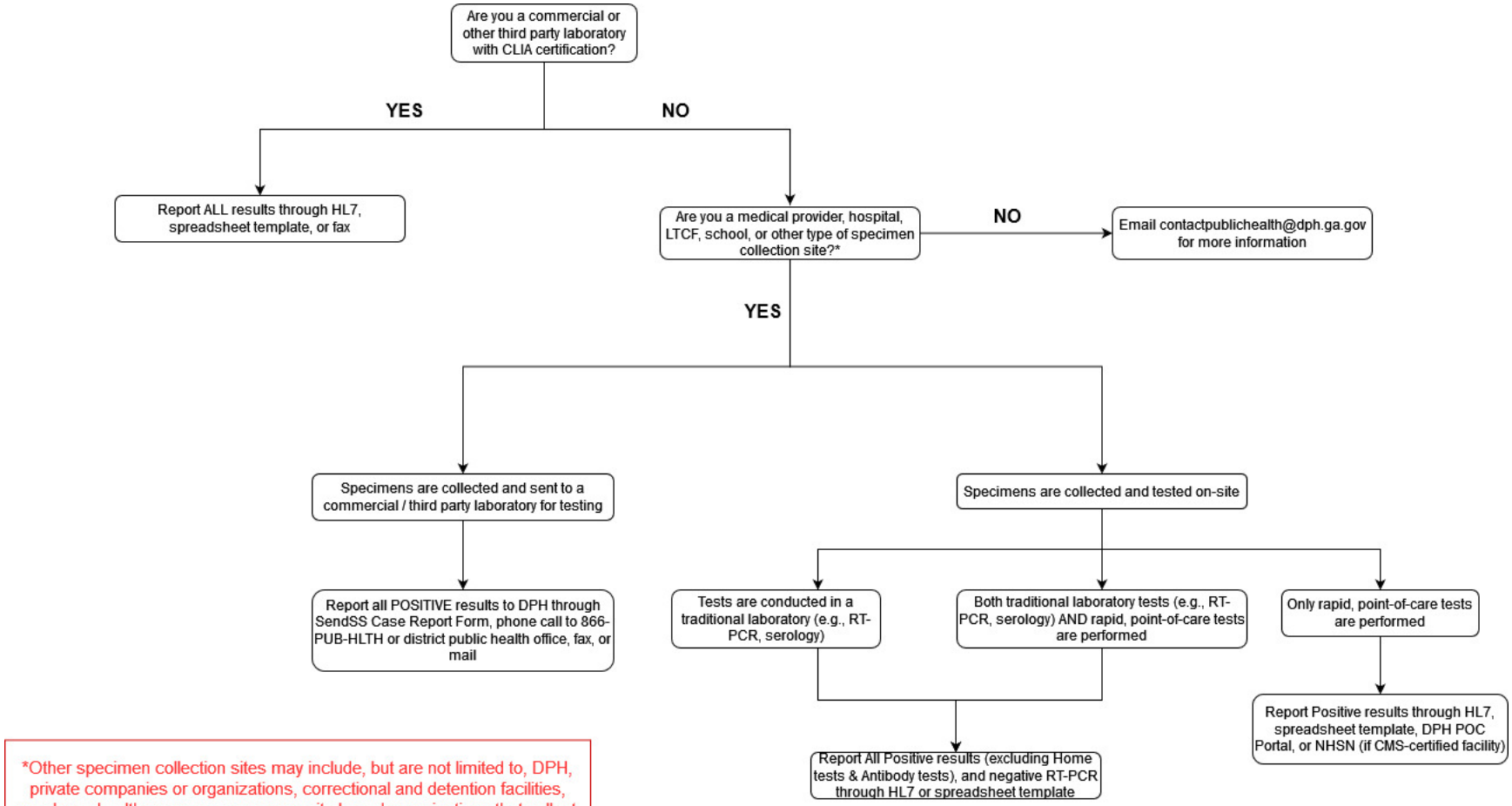
Figure 1. Flowchart to Identify Acceptable Reporting Methods Based on Type of Facility Reporting and Testing Performed



*Other specimen collection sites may include, but are not limited to, DPH, private companies or organizations, correctional and detention facilities, employee health programs, or community-based organizations that collect specimens from individuals seeking COVID-19 testing.