# **COVID-19 Test Results Reporting Guidance**

#### Overview

All physicians, laboratories, and other health providers are legally required to report an actual or suspected case of a notifiable disease in Georgia, including COVID-19.<sup>1</sup> The legal authority for notifiable disease reporting is both in Georgia State Code and in Federal Law.<sup>2,3</sup> That legal authority has been expanded for the COVID-19 pandemic to include reporting of negative test results and includes any individual, organization, or agency facilitating specimen collection and/or testing, including a specimen collection site or event.<sup>4</sup> 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."<sup>5</sup>

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.

All test results (i.e., positive, negative, inconclusive or equivocal, and invalid) must be reported within 24 hours of testing in order to facilitate timely case investigation, follow-up, and contact tracing. This includes traditional laboratory tests such as RT-PCR and serologic testing, as well as rapid, point-of-care tests performed and resulted on-site during a patient or individual consultation (e.g., Abbott ID Now RNA tests, BinaxNOW antigen tests, rapid antibody tests, and others).

(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).

<sup>5</sup> O.C.G.A. § 31-12-2(d).

<sup>&</sup>lt;sup>1</sup> https://dph.Georgia.gov/epidemiology/disease-reporting

<sup>&</sup>lt;sup>2</sup> O.C.G.A. § 31-12-2(a); Ga. Comp. R. & Regs. 511-2-1-.01(h), -.02(1).

<sup>&</sup>lt;sup>3</sup> https://www.hhs.gov/about/news/2020/06/04/hhs-announces-new-laboratory-data-reporting-guidance-for-covid-19-testing.html

<sup>&</sup>lt;sup>4</sup> 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

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

				Agency
Data Element	Description	Required	Requested	Information
Performing Facility	Name of the laboratory or	X	nequested	DPH. HHS
Name	facility that conducted the			
	test			
Performing Facility	CLIA number of the	Х		HHS
CLIA Number	laboratory or facility that			
	conducted the test			
Performing Facility	Zip code of the laboratory	X		HHS
Zip Code	or facility that conducted			
	the test			
PatientID	A unique identifier for the		X	DPH
	person tested. Examples			
	include medical record			
	number or visit number.			
Patient Name	Full name of the person	X		DPH, HHS
Data of Distle	tested	N N		
Date of Birth	Date of birth for the person	X		DPH, HHS
	Ago of the person tested	v		ППС
Age	Say of the person tested	× ×		
Pace	Page of the person tested	× ×		
Ethnicity	Ethnicity of the person	× ×		
	tested			
Patient Street	Typical residential street	X		DPH, HHS
Address	address of the person			
	tested			
City	City in which the person	Х		DPH
	tested typically resides			
State	State in which the person	Х		DPH
	tested typically resides.			
	Only residents of Georgia			
	or individuals with an			
	unknown address and a			
	Georgia provider should be			
	reported.			
Zip	Zip code in which the	X		DPH, HHS
	person tested typically			
	resides			
County	County in which the person	X		DPH, HHS
	tested typically resides			
Patient Phone	Phone number for the		Х	DPH
	person tested			

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

Date Specimen	Date that the specimen		X	DPH
Received	was received at the testing			
	facility			
Date Test Ordered	Date that the test was	Х		HHS
	ordered by the			
	facility/provider			
Test Result Date	Date that the test was	Х		DPH, HHS
	performed			
Test Ordered	LOINC code for the test	Х		HHS
	that was performed			
Test Description	Description of the type of	Х		DPH
	test performed			
Test Result	Result of the test	Х		DPH, HHS
Accession Number	Accessioning number for	Х		DPH, HHS
or Specimen ID	the test			
Device Identifier	A unique identifier that	Х		HHS
	indicates the device used			
	for testing			

#### **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.

#### 1. 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.

### 2. 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 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.

#### 3. 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. Any facility conducting traditional laboratory testing at an in-house, CLIA-certified laboratory, should report by HL7 or spreadsheet template, even if they are also performing point-of-care testing. Both types of testing can be incorporated into the same reporting method. 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.

A user's guide has been developed that provides step-by-step instructions for registering, logging in, and 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 are able to see all results that are associated with the facility they indicate in the registration form.

A fourth reporting option is available to long-term care facilities. The National Healthcare Safety Network (NHSN) has developed a Point of Care Laboratory Reporting Pathway within the NHSN Long-Term Care COVID-19 Module. Any CMS-certified long-term care facility reporting through this mechanism is in compliance with Federal Law and does not need to report directly to DPH. These data will be shared with states through the APHL Information Messaging Service (AIMS). In order to utilize the new pathway, facilities will need to upgrade their Secure Access Management Service (SAMS) from Level 1 to Level 3. Facilities should complete this enrollment by November 30, 2020 and establish another reporting mechanism through DPH in the interim. NHSN will release its own reporting standards; for further information, email <a href="https://www.nhsn.will.need.co.gov">nhsn.@cdc.gov</a>.

## For State and District Public Health Staff:

The Portal may also be used by state and district public health staff that report point-ofcare 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 by emailing <u>EOCEpidemiology@gets.onmicrosoft.com</u>. <u>Public</u> <u>health staff will be able to access the Portal using their SendSS user ID after being</u> <u>granted access and should NOT use the link above to access the Portal</u>. Public health users can see all results submitted by all users, regardless of facility. It is strongly preferred that facilities utilize one of the four 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.

#### **Reporting of Positive Cases**

Any facility that performs or facilitates collection of a specimen that is **sent to a commercial, hospital, or public health laboratory** for testing is <u>required</u> to report positive results directly to Public Health, preferably through the SendSS Case Report Form.

Any facility that performs or facilitates collection of a specimen that is tested using a **rapid**, **point-of-care test on-site and is reported through one of the four methods describe above** is <u>not required</u> to report positive results through a secondary mechanism, including the SendSS Case Report Form. This is to reduce the burden of reporting on facilities and encourage consistent and comprehensive reporting of test results.

Districts may wish to request or require additional reporting of positive results through a secondary mechanism, such as fax or phone call. This may be done at their discretion through direct communication with facilities but does not supersede the requirement of reporting all test results as described above.

## Additional Information and Resources

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 <u>contactpublichealth@dph.ga.gov</u>, call DPH Epidemiology office at 404-657-2588, or contact your district public health office.