The Children's Care Network

A Pediatric Clinically Integrated Network

COVID-19 Diagnostic Toolkit

A Guide to Pediatric Testing in the Primary Care Setting[1]

As part of the recovery process from this year's pandemic and into 2021, TCCN has developed a guide which provides you with tools to assist your practice if it elects to perform COVID testing for your patients. This guide will outline the equipment, processes, benefits and risks of such testing, and provide other information to identify and track cases of COVID-19 in the community, as well as to improve the safety and security of your patients and families. The identification of both positive and negative test results should also aid to increase parents' awareness of the necessary actions, if needed, to protect their children, their family and their communities.

To begin, it is recommended that a review of the "COVID-19 Pandemic Response , Laboratory Data Reporting: CARES Act Section 18115" be undertaken. Within this document you will also see additional resources provided by the CDC and FDA. Supplementary resources for initiating this diagnostic service into your practice as developed by TCCN are included in this toolkit.

[1] The information provided does not and is not intended to constitute professional, billing or legal advice and is made available for general information purposes only. Members should contact their own advisors to obtain advice with respect to any particular matter. TCCN is not assuming any duty to update or modify this document for specific circumstances.

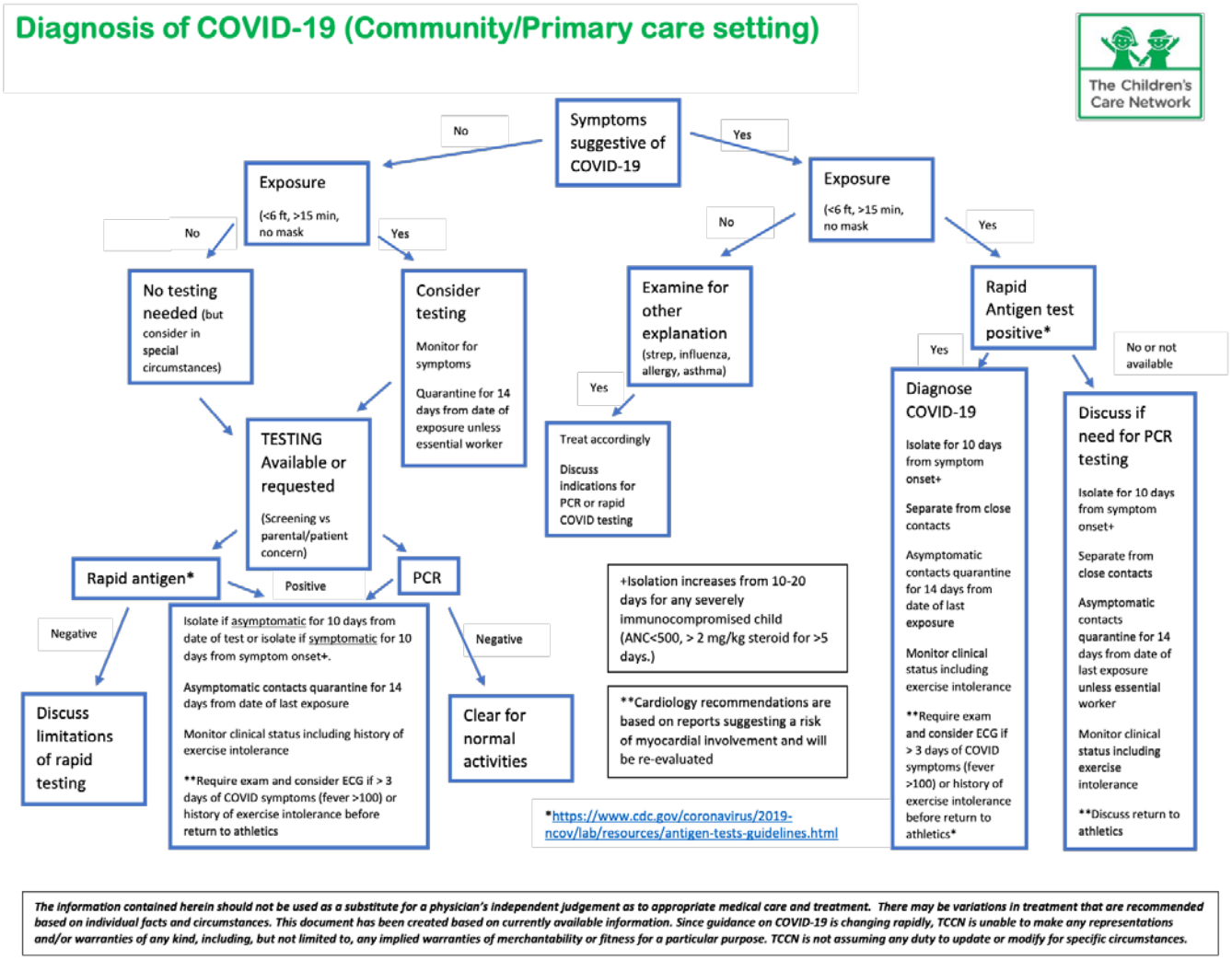
Outline: COVID-19 Diagnostic Toolkit

To our TCCN members:

As we have learned more and more about the novel COVID-19 virus and its implications in pediatric health and wellness, parents today want and need a mechanism for the rapid testing of COVID-19 for their children. Because this is not a simple, one-step process, it is important for you as care providers to understand the different components involved in setting up such a testing program, and the benefits and concerns in doing so.

I. TCCN Quality Guideline

TCCN has recently developed a diagnostic protocol, based on currently available information about COVID-19, to help guide you through that process. As



information about the virus continues to expand, and as guidance on COVID-19 changes rapidly, this recommended treatment protocol should not be used as a substitute for a physician's independent judgement.

II. Tests and Analyzers: Costs and Availability

TCCN has also negotiated an agreement with Henry Schein Medical to allow its members to purchase both tests and analyzers, which are currently available.[2]

- Discounts on the cost of COVID-19 tests are available through Henry Schein.
- If your practice purchases 60 flu tests, the practice will receive an analyzer at no additional cost
- Discounts on the cost of COVID-19 tests are also available thru BD Veritor
- The Quidel Sofia analyzer is not currently available, however the corresponding tests are ready now.

For more information on the above information or how to apply the tests and equipment, please contact Henry Schein Representative - Robbie Cato 678-549-1449 Robbie.Cato@henryschein.com

III. COVID Testing Process[3]

Prior to administering a COVID test, a patient must complete a visit to determine if COVID testing is needed. This completed visit may be a sick or well-visit, a visit for a flu shot, or for any other presenting issue as identified by the caregiver. Once the need is determined, a COVID test is given. Refer to the TCCN Quality Guideline to assist in the decision-making process.

Testing may take place within the practice, or in a location similar to what is being done in immunization/flu drive-thru clinics.

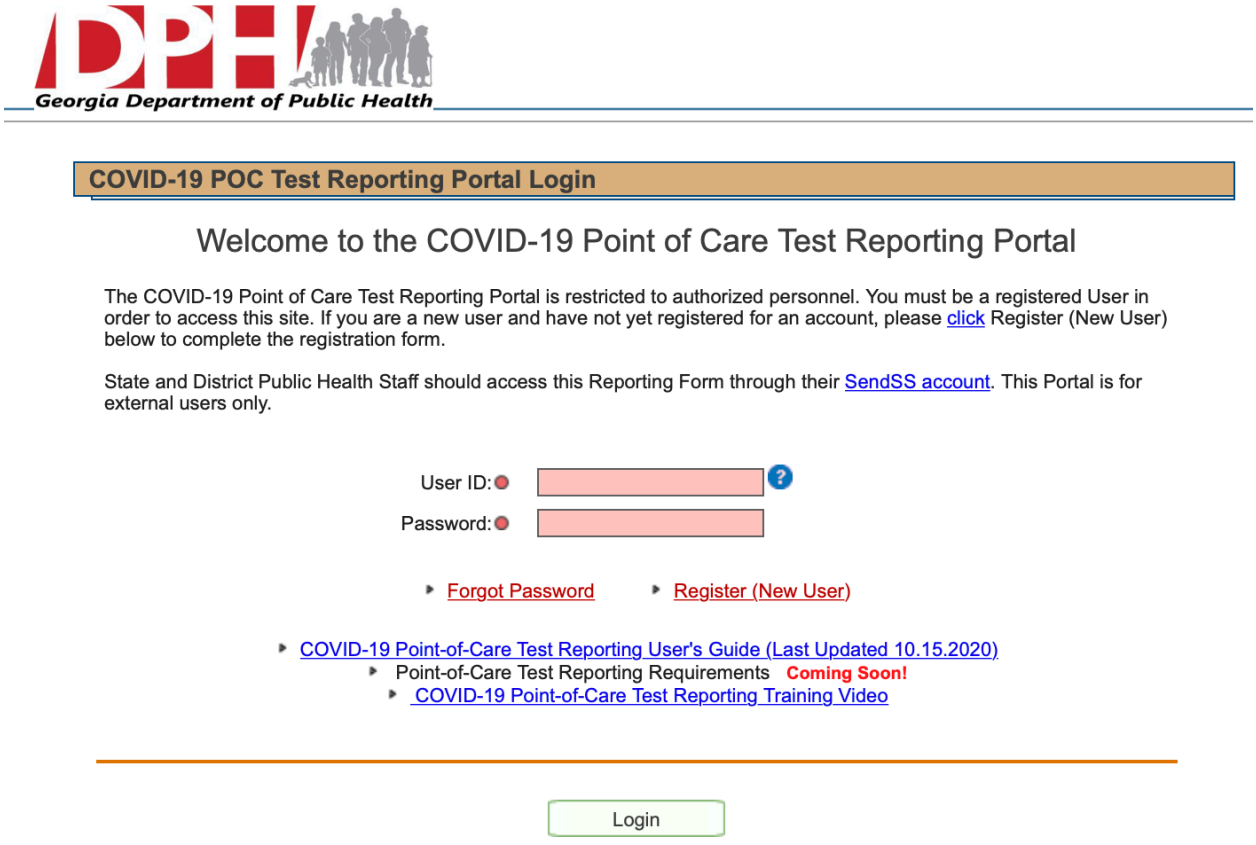
[2] By advising its members of the availability of these items, TCCN is not endorsing any company, equipment, supplies or test, nor is it representing that the equipment, supplies or test kits referenced are merchantable or fit for a particular purpose.

[3] The information provided does not and is not intended to constitute professional, billing or legal advice and is made available for general information purposes only. Members should contact their own attorneys to obtain advice with respect to any particular matter.

For suggestions on how to set up a drive-thru clinic, please reference the Sanofi Flu Clinic guidelines and/or the AstraZeneca FluPlus program. The CDC also has an in-depth, easy to follow tool for satellite and drive thru vaccination clinics—Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations.

Once completed, all COVID-19 tests results must be reported to the Department of Public Health within 24 hours as stated in the CARES Act Section 18115. In Georgia, the results should be reported to the Georgia Department of Public Health which has recently revised the COVID-19 Test Results Reporting Guidance (October 19,2020). This guide provides detailed information on testing as well as a user's guide that provides step-by-step instructions for registering, logging-in and reporting in the portal. The portal can also be used for data entry, searching previously entered results, and exporting data.

You can access this portal, as well as the user's guide and other training materials, by visiting https://sendss.state.ga.us/sendss/!ncov_poc.login.



IV. Coding and Billing

As noted above, all patients **must complete a visit** to be eligible for COVID-19 testing.

Information regarding COVID-19 testing is constantly being updated, and practices and their staff should frequently verify regulations, policies and member benefits to ensure accuracy.

For specific information related to diagnosis, CPT codes and other relevant information, please refer to your specific contract for coding information.

V. Risk Management Recommendations

TCCN has outlined several areas you need to consider before initiating a testing program, to help mitigate risk to your practice, your patients and your staff. However, note that this list is not exclusive.

The following is a list of basic guidelines you need to follow when considering a COVID-19 testing program:

Mitigating Risk and Professional Liability

- Follow all organizational policy and procedures
- Ensure all patients receive the same level of quality care
- Require staff to don/doff PPE per the following CDC guidelines
  - Using Personal Protective Equipment (PPE)
  - Managing Operations During the COVID-19 Pandemic
  - Interim Infection Control Guidance for Public Health Personnel Evaluating Persons Under Investigation (PUIs)
- Develop procedures to minimize transmission from patients/visitors
- Require staff to wear face coverings at all times

- Document all interactions, including diagnosis, treatment and all forms of communication in the medical record

- Ensure the practices' orders and results tracking system are in place

- Ensure patients' results are received and communicated efficiently back to the caregiver(s) and the results are documented in the medical record

Patient Safety

- **Standard of Care**

  - Regardless of location of care, the standard of care practiced should be met with the same manner in every location

  - All staff must be appropriately licensed and trained and working within their scope of practice

  - State guidelines must be followed as it relates to training, licensure, supervision, and scope

  - Staff must be adequately trained and deemed competent to provide such care

- **Infection Control: Patients**

  - To reduce risk of infection, all policies, protocols and processes for Safe Injection Practice must be followed

  - Ample time should be allowed for appropriate screening of patients as well as for contraindications/adverse reactions

  - Emergency procedures must be developed to include call for emergency assistance

  - All emergency medical equipment must be available and operational

- **Infection Control: Staff**

  - Policies, protocols and processes for safe needle use and disposal should be followed

- Policies, protocols, and processes for exposure to blood borne pathogens should be followed

- Appropriate PPE must be available and donned/doffed in accordance with practice guidelines

• **Environmental Safety and Security**

- Ensure the staff is performing their duties in an area free from hazards

- Clearly note any hazards which are present

- Post signs and/or create protective barriers, if needed, in designated areas such as in parking lots or in other outdoor spaces

- Ensure protection from the elements, particularly if performing testing in an outdoor area

- Provide lighting and security for all staff, as well as for patients and families

Compliance with Laws, Ordinances and Regulations

- Ensure compliance as noted by federal, state and local authorities

- This compliance should include, but not be limited to the following:

    HIPPA privacy and security

    OSHA

    American with Disabilities Act

    COVID-19 Guidelines

General Liability, EPLI and other Non-malpractice Concerns

Additional measures are recommended to ensure your staff recognizes that one of your primary concerns is keeping them safe during testing. Emphasizing this aspect of the program will help alleviate any concerns they may have as the program unfolds.

If you do not own your practice building, it is recommended that you work with your landlord/leasing company to ensure that they do not have any concerns with your COVID-19 testing program.

This conversation should include a discussion on processes, parking, traffic flow in and out of the parking area, and designated parking, when performing testing outside of the practice's office.

Information about your plan to provide appropriate PPE components to anyone performing testing, your recommendations around social distancing, and hand washing may be also be helpful.

Additional measures to protect you and your staff include:

- Provide a clear process for identifying swabs and labeling specimens quickly and accurately
- Provide specific guidelines on when to change PPE during and after testing, and how to appropriately dispose of used PPE
- Provide open and ongoing communication about the program and the steps the practice is employing to keep them safe

Testing of Parents

Requests from parents to receive COVID-19 may arise during testing of their children. This is not recommended due to potential liability issues around follow-up and test interpretation.

To perform testing on parents, a practice would need to establish a medical record for the adult patient and treat him/her as any other patient. This would create a separate pathway of testing that may or may not be consistent with regulatory guidelines and best practices. Again, this is not recommended.

A practice may provide parents with options for their own COVID testing, such as their respective county's local health department, a retail clinic or other urgent care center advertising COVID-19 testing, or their primary care physician. Providing this information would be for educational purposes and not an endorsement for any of the above options.

VI. Conclusion

We hope that this information has been beneficial and provides you with the information needed to help guide you through the development and launch of a successful COVID-19 testing program.

If you have additional questions or concerns, please contact Barbara Douglas at barbara.douglas@TCCN-CHOA.org or 770-333-0033, Ext. 201.

COVID Testing Purchasing Program

TCCN has entered into an agreement with Henry Schein under which Henry Schein has agreed to offer TCCN practices the ability to purchase COVID Tests and Analyzers at certain discounted prices. There are a few steps in order to complete the account set up for practices.

1. TCCN has sent list of practices to Henry Schein who have signed a TCCN GPO Agreement. If you have not signed a TCCN GPO Agreement, then you will not get the preferred pricing. Please contact Barbara Douglas at Barbara.douglas@tccn-choa.org and send completed GPO agreement to get access to this program.
2. Henry Schein has started the account creation process by inputting your practice name and contact information.
    a. Henry Schein Website: Henry Schein Website
3. Our Henry Schein Account Manager is Robbie Cato. His contact info - phone: 678-549-1449 and email: robbie.cato@henryschein.com
4. To complete Henry Schein account set up – practice will need to submit the following:
    a. CLIA #
    b. Practice Medical Director name and medical license #
5. When practice places 1st order, they will agree to:
    a. Complete Henry Schein Click through link for purchasing agreement and EUA acknowledgement.
    b. Credit Review - online if needed

Vendor	**Henry Schein**
Contact	Robbie Cato
Please note: Prices listed do not include tax.	
BD Veritor Plus (Flu A+B, Group A Strep, and RSV with CLIA-waived assays**)**	
Test type	Antigen
CPT Code	87426
Analyzer cost	$300
Analyzer Promo	Free with 2 pk flu test
Cost per test	$32.00
Test cost (per pk-30)	$960.00
Max order	No current allocation - order as many as needed
Analyzer contract/agreement?	No
Quidel Sofia (Influenza A+B and RSV**)**	
Test type	Antigen
CPT Code	87426

Analyzer cost	Placement (Currently new analyzers are not available)
Cost per test	$23.00
Test cost (per pk-25)	$575.00
Max order	No current allocation - order as many as needed
Analyzer contract/agreement?	Yes
PCR - using Abbott IDNow	
Test type	PCR
CPT Code	87635
Analyzer cost	placement
Cost per test	$41.00
Test cost (per pk-30)	$1,230.00
Max order	No current allocation - order as many as needed
Analyzer contract/agreement?	Yes

BY ADVISING ITS MEMBERS OF THE AVAILABILITY OF THESE ITEMS, TCCN IS NOT ENDORSING ANY COMPANY, EQUIPMENT, SUPPLIES OR TEST, NOR IS IT REPRESENTING THAT THE EQUIPMENT, SUPPLIES OR TEST KITS REFERENCED ARE MERCHANTABLE OR FIT FOR A PARTICULAR PURPOSE

COVID-19 Testing Information[1]

Please note that the information regarding COVID-19 testing is constantly being updated and the Providers and their staff should verify regulations, policies, and member benefits regularly.

CPT Coding

86328 - severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]).

86413 - quantitative antibody detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

86769 - Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]).

87426 - infectious agent antigen detection by immunoassay technique of SARS-CoV and SARS-CoV-2.

87428 - - severe acute respiratory syndrome coronavirus (SARS-CoV, SARS-CoV-2, Coronavirus disease [COVID-19]) and influenza virus types A and B.

87635 - Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique.

87636 (Combo test) - Infectious agent detection by nucleic acid (DNA or RNA); Bartonella henselae and Bartonella quintana, amplified probe technique; severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (Coronavirus disease [COVID-19]) and influenza virus types A and B, multiplex amplified probe technique. Approved October 6, 2020. Reimbursement guidelines and rates may not be set by the individual payors.

* Use 87636 to report combined respiratory virus multiplex testing for SARS-CoV-2 with influenza types A and B.

87637 (Combo test) - Infectious agent detection by nucleic acid (DNA or RNA); Bartonella henselae and Bartonella quintana, amplified probe technique; severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (Coronavirus disease [COVID-19]), influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique.

* Use 87637 to report combined respiratory virus multiplex testing for SARS-CoV-2 with influenza types A and B, and RSV. Approved October 6, 2020. Reimbursement guidelines and rates may not be set by the individual payors.

---

[1] The information provided does not and is not intended to constitute professional, billing or legal advice and is made available for general information purposes only. Members should contact their own attorneys to obtain advice with respect to any particular matter.

87651 - Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, amplified probe technique.

87502 - Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or subtypes, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, first 2 types or sub-types.

87426 - Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (e.g., SARS-CoV, SARS-CoV-2 [COVID-19]).

87811 (Combo test) - Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Streptococcus, group B; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]). Approved October 6, 2020 Reimbursement guidelines and rates may not be set by the individual payors.

* Use 87811 to report antigen detection of SARS-CoV-2 by direct optical (i.e., visual) observation.

COVID-19 Related Coding

99072 - Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a Public Health Emergency as defined by law, due to respiratory-transmitted infectious disease.
Please check with each individual payor to determine reimbursement guidelines as some payors consider these items and services to be incidental and not payable.

99211 - Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services.
Centers for Medicare & Medicaid Services (CMS) has approved 99211 for specimen collection for new and established patients; check other payors for reimbursement policies.

Reimbursement Advice[2]

Testing

Use only test approved by the Food & Drug Administration (FDA).
*Be sure that the selected test has been authorized by the FDA and is not still in the process of being approved.

Use tests that are CLIA-waived unless the office has advanced training, the appropriate testing equipment and can follow FDA protocols.

https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2

Please follow additional payor specific reimbursement policies.
*For example, UnitedHealthcare is requesting all physicians and health care professionals who perform and bill for COVID-19 antibody tests to register the test that will be used for their members.

https://www.uhcprovider.com/content/provider/en/resource-library/news/Novel-Coronavirus-COVID-19/covid19-testing.html

Benefits & Eligibility

Be sure to check each patient's eligibility and benefits even if the member ID card looks familiar.
*Call the payor's provider relation's customer service number to clarify benefits.
**Always get a payor representative name, reference number and add the information to the patient's account.

Pay special attention to whether the patient's plan is Fully Insured or Self-Insured (Self-Funded).
*Self-Insured (self-Funded) plans can opt out of payor reimbursement guidelines.

Student, Medicare, and some out of state plans can also have different reimbursement guidelines.

Monitor the payor updates as the additional benefits and liberal reimbursement can end or be reinstated based on government guidelines and/or the state of the pandemic.

Coding

CPT Codes approved by the American Medical Association (AMA) are not automatically covered by the payors. The AMA creates the code and then the payors set their own reimbursement policies and rates. These policies can be superseded by Federal and/or state regulations.

---

[2] The information provided does not and is not intended to constitute professional, billing or legal advice and is made available for general information purposes only. Members should contact their own attorneys to obtain advice with respect to any particular matter.

*There can be weeks and even months before a payor sets their individual reimbursement policies and rates.
**Always review payor specific policies.

Miscellaneous

Pay attention to the extension and termination of the COVID-19 National Public Health Emergency Declaration.
*Declaration was renewed effective October 23, 2020 for an additional 90 days.
**Status influences payors and regulations including the unprecedented HIPAA flexibilities that were approved by the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS).

Please note that Medicaid must establish reimbursement policies and base rates prior to Care Management Organizations (CMOs) establishing their rates.

Website Resources

U.S. Department of Health & Human Services

https://www.hhs.gov/

https://www.hhs.gov/civil-rights/for-providers/civil-rights-covid19/index.html

Food & Drug Administration

https://www.fda.gov/

American Medical Association

https://www.ama-assn.org/

Center for Medicare & Medicaid Services

United Healthcare

https://www.uhcprovider.com/

Aetna

https://www.aetna.com/health-care-professionals.html

Cigna

https://www.cigna.com/health-care-providers/

Humana

https://www.humana.com/provider/

Georgia Medicaid Management Information System

https://www.mmis.georgia.gov/portal/Default.aspx?tabid=26&sessionredirect=true

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.[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 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.

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).

---

[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. Only residents of Georgia or individuals with an unknown address and a Georgia provider should be reported.	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.

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 nhsn@cdc.gov.

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 by emailing EOCEpidemiology@gets.onmicrosoft.com. **Public health staff will be able to access the Portal using their SendSS user ID 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 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 **required** 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 **not required** 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 contactpublichealth@dph.ga.gov, call DPH Epidemiology office at 404-657-2588, or contact your district public health office.

How to Report COVID-19 Laboratory Data

Updated Oct. 16, 2020 Print

Summary:

The Coronavirus Aid, Relief, and Economic Security (CARES) Act and its June 4 implementation guidance require every COVID-19 testing site to report every diagnostic and screening test performed to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (e.g., molecular, antigen, antibody) to the appropriate state or local public health department, based on the individual's residence. Laboratories that currently report directly to CDC should continue sending these data to CDC. Email questions to DLSinquiries@cdc.gov.

The public health response to COVID-19 depends on comprehensive laboratory testing data. These data will contribute to understanding COVID-19's impact and testing coverage and can contribute to the identification of supply chain issues for reagents and other materials. The information below outlines reporting requirements for laboratories.

Who must report

All COVID-19 diagnostic and screening testing sites must

- have a Clinical Laboratory Improvement Amendments (CLIA) certificate – compliance, accreditation, waiver, or provider performed microscopy
- meet all requirements to perform testing, including only using FDA-authorized test systems according to their instructions for use, and
- report the results of the COVID-19 diagnostic and screening tests that they perform to the appropriate state or local public health department.

COVID-19 testing sites are defined as

- laboratories that perform clinical diagnostic or screening testing under CLIA,
- non-laboratory COVID-19 diagnostic or screening testing locations, and
- other facilities or locations offering COVID-19 point-of-care diagnostic or screening tests, or in-home diagnostic or screening tests.

Testing sites must report data for all diagnostic and screening testing completed, which includes molecular, antigen, and antibody testing, for each individual tested. These data must be reported daily, within 24 hours of test completion, to the appropriate local, state , territorial or tribal health department, based on the individual's residence.

Testing sites that perform COVID-19 surveillance testing on de-identified samples, regardless of their CLIA status, should not report the results of their surveillance testing to local, state, territorial, or tribal health departments. If at any time a facility intends to report a patient-specific test result, it must first obtain a CLIA certificate and meet all requirements to perform testing. For more information, see the Center for Medicare and Medicaid Services' (CMS) Research Testing and Clinical Laboratory Improvement Amendments of 1988 (CLIA) Regulations and the CDC Division of Laboratory Systems' CLIA webpage.

For information about the CLIA Certificate application process, see CMS' How to Apply for a CLIA Certificate, Including International Laboratories webpage.

For definitions of COVID-19 diagnostic, screening, and surveillance testing, see CDC's Interim Guidance for Use of Pooling Procedures in SARS-CoV-2 Diagnostic, Screening, and Surveillance Testing.

> The Association of Public Health Laboratories (APHL) has developed the National ELR Flat File and HL7 Generator Tool to assist laboratories with reporting.

How to report

Laboratory data elements may be reported in the following ways:

- Submit laboratory testing data directly to state or local public health departments according to state/or local law or policy. Data must be sent using existing reporting channels to ensure rapid initiation of case investigations, and concurrent reporting of results must be shared with ordering provider or patient, as applicable.
- Submit laboratory testing data to state and local public health departments through a centralized platform (such as the Association of Public Health Laboratories' AIMS platform), where the data will then be routed to the appropriate state and local authorities and routed to CDC after removal of personally identifiable information according to applicable rules and regulations.
- Submit laboratory testing data through a state or regional Health Information Exchange (HIE) to the appropriate state or local public health department and then to CDC as directed by the state.

Public health departments will submit de-identified data to CDC on a daily basis, using either Health Level 7 (HL7) messaging or the CDC-provided CSV format.

> For more information on the data elements included in the June 4 HHS guidance, as well as technical specifications that support implementation, see HHS's COVID-19 Lab Data Reporting Implementation Specifications .

What to report

Complete laboratory data must include the following data elements for state and jurisdictional health departments.

1. Test ordered – use harmonized LOINC codes provided by CDC
2. Device Identifier
3. Test result–use appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC
4. Test Result date (date format)
5. Accession # / Specimen ID
6. Patient age
7. Patient race
8. Patient ethnicity
9. Patient sex
10. Patient residence zip code
11. Patient residence county
12. Ordering provider name and NPI (as applicable)
13. Ordering provider zip
14. Performing facility name and CLIA number
15. Performing facility zip code
16. Specimen Source – use appropriate LOINC, SNOMED-CT, or SPM4 codes, or equivalently detailed alternative codes
17. Date test ordered (date format)
18. Date specimen collected (date format)

The following additional demographic data elements should also be collected and reported to state or local public health departments.

1. Patient name (Last name, First name, Middle Initial)
2. Patient street address
3. Patient phone number with area code
4. Patient date of birth
5. Ordering provider address
6. Ordering provider phone number

To protect patient privacy, any data that state and jurisdictional health departments send to CDC will be deidentified and will not include some patient-level information. The deidentified data shared with CDC will contribute to understanding COVID-19's impact, positivity trends, testing coverage, and will help identify supply chain issues for reagents and other materials.

How to report using standard terminology

CDC has posted a LOINC In-Vitro Diagnostic (LIVD) Test Code Mapping Guide for COVID-19 test results for tests with emergency use authorization from the U.S. Food and Drug Administration (FDA) that can be used by clinical laboratories and instrument manufacturers. This specification supports the use of standardized LOINC and SNOMED Clinical Terms (CT) codes to improve the accuracy of reporting tests for the SARS-CoV-2 virus. Using these harmonized LOINC and SNOMED-CT codes helps ensure that the same type of test is represented uniformly across the United States.

For those COVID-19 tests that have not yet received FDA emergency use authorization, CDC encourages test developers and laboratories that use COVID-19 tests to work together to obtain appropriate and interoperable LOINC and SNOMED-CT codes for reporting purposes.

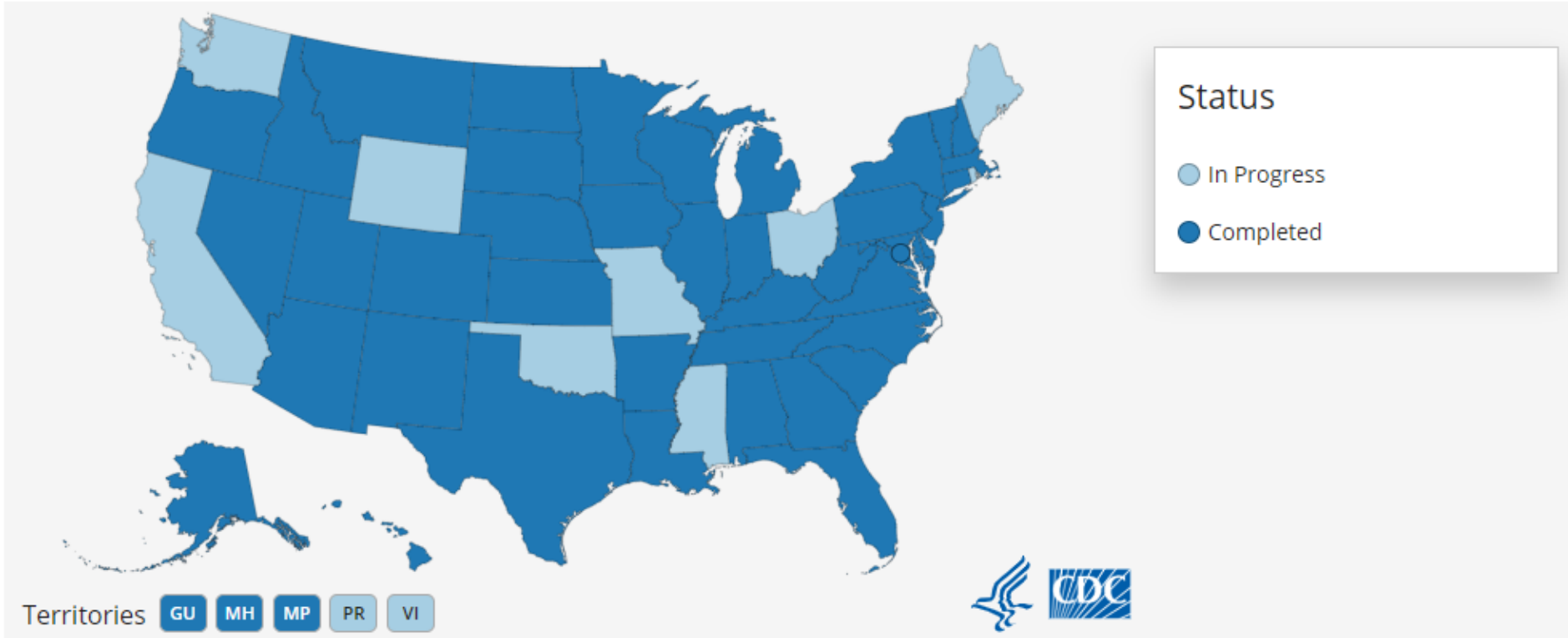
LOINC codes must be used to represent the "question" a viral test asks of a specimen (e.g., does this specimen have SARS-CoV-2 RNA?), and SNOMED-CT codes must be used to represent the diagnostic "answer" (e.g., what was detected?). More background on these terminology standards can be found here:

- LOINC Term
- SNOMED CT

Whenever possible, laboratories must use standard codes that already exist. Before requesting a new code, search the list of currently available LOINC for SARS-CoV-2 tests. If a LOINC test code cannot be identified whose attributes appropriately match the test for which coding is needed, new terms can be submitted, and a new code requested through the LOINC .

Technical assistance for electronic reporting

COVID-19 ELR Implementation



Data Table +

Click map to view the status of electronic laboratory data conversion by state.

Electronic reporting options are available to reduce the burden on providers reporting test results. Laboratories that are not currently reporting electronically to their state or local health department and want assistance in establishing electronic reporting can contact CDC's Emergency Operations Center, Laboratory Reporting Working Group at eocevent405@cdc.gov.

Frequently Asked Questions on Laboratory Data Reporting Guidance for COVID-19 Testing

New guidance from the Department of Health and Human Services (HHS) specifies what data must be reported to comply with the COVID-19 laboratory reporting requirement in CARES Act Section 18115. The new guidance requires facilities and ordering providers to gather more complete patient demographic information to send to state and local public health departments. State and local health departments will then forward the de-identified data to CDC.

Data reporting requirements

1. Why are laboratories being required to collect patient demographic information when conducting COVID-19 testing? +

HHS developed this guidance in response to the CARES Act, which requires every testing site to report every test it performs to detect SARS-CoV-2 or to diagnose a possible case of COVID-19. State and local public health departments have required laboratories to report COVID-19 testing results since the beginning of the COVID-19 public health emergency; however, the requirements for patient information and other data elements have varied across states. The new HHS guidance aims to increase the reporting of important data elements, (e.g., patient age and residence zip code) to inform COVID-19 control and mitigation efforts.

2. How will the laboratory data reported to state and jurisdictional health departments be used? +

Laboratory data reported to state and jurisdictional health departments will be used to help track the spread of COVID-19 and identify areas that are highly impacted by the infection. The data will also be used to track when the spread of infection appears to be slowing down by location.

On a national level, the de-identified data shared with CDC will contribute to understanding national disease incidence and prevalence, positivity trends, and testing coverage, and will help identify supply chain issues for reagents and other materials

3. Are laboratories required to report to *both* state or local public health departments and HHS? +

Laboratories are not required to report to both state or local health departments and HHS. The CARES Act requires laboratories to report all data to state or local public health departments using existing public health data reporting channels (in accordance with state law or policies). The state health departments will provide this data to HHS.

4. Are *all* data elements in the HHS guidance required to be reported by the August 1, 2020 deadline? +

Starting on August 1, 2020, laboratories are expected to make every reasonable effort to report data to the appropriate state or local public health department, as required by HHS guidance.

5. What happens if a laboratory cannot report *all* elements starting on August 1, 2020? +

Anyone who orders a COVID-19 test, collects a specimen, or performs a laboratory test should make every reasonable effort to collect complete demographic information and responses to the "ask on order entry" (AOE questions). Ordering providers should make every effort to collect this critical information from patients during the specimen collection process and provide it to the laboratories performing the test.

When information is not available, the healthcare providers (or their designees) who ordered the COVID-19 test and laboratories performing those tests should consider using other information sources to obtain these data, such as health information exchanges, employee records, and/or school records.

6. Does HHS require the reporting of all laboratory tests, including antibody and antigen tests and negative test results? +

Yes, the CARES Act requires all clinical laboratories and testing providers that perform diagnostic testing under a Clinical Laboratory Improvement Amendments (CLIA) certificate to ***report the results of any test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19*** (e.g., molecular, antigen, antibody)**,** not just positive tests, to state or local public health departments. Results from surveillance testing for SARS-CoV-2 should not be reported to state or local public health departments.

7. My laboratory is testing samples from multiple states. Can this data be sent to the state in which the testing facility is located? +

Laboratories must report results to the appropriate state or local health department based on the individual's residence or the provider location when a patient is out-of-state.

8. Which laboratory is responsible for reporting — the testing lab, referring facility, or both? +

The laboratory that performs the COVID-19 test is responsible for reporting to the appropriate state or local public health department.

9. What are the reporting requirements for samples from individuals from other countries? +

Laboratories need to report test results to the state where the individual is temporarily living or visiting.

10. Where can clinicians and laboratories find more information about reporting requirements? +

Clinicians and laboratories should contact their state or local public health department directly for more information on reporting requirements and the method for reporting.

Technical aspects of reporting

1. Have Logical Observation Identifiers Names and Codes (LOINC) been assigned to COVID-19 tests? +

Yes, information about LOINC codes and the specific harmonized LOINC codes for COVID-19 tests can be found on CDC's website: LOINC In Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests.

2. How can laboratories obtain a LOINC code for the Emergency Use Authorization (EUA) assay their laboratory is using?

CDC's LOINC In Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests website has a mapping catalogue coded for the data elements associated with COVID-19 tests, including the LOINC test order, LOINC test result, SNOMED-CT test description and SNOMED-CT specimen source. Test developers and manufacturers of new tests should contact FDA at SHIELD-LabCodes@fda.hhs.gov for information about obtaining new codes.

3. Will state or local health departments accept COVID-19 electronic laboratory reporting (CELR) extracts if they do not include all required data elements?

Yes, state or local health departments will still accept the data. Public health recognizes this information is not always provided in test orders.

4. Does CDC have the CSV format for reporting?

Laboratories should contact their state or local health department for the CSV format for reporting.

5. What is the device identifier (DI)?

The DI for some tests can be found in the National Institute of Health's (NIH) Access GUDID Database . For a specific DI not located in the Access GUDID Database, contact the device manufacturer to obtain the DI. If the manufacturer does not yet have the DI for the device you are using, contact SHIELD-LabCodes@fda.hhs.gov for assistance.

"Ask on order entry" (AOE) questions and other data elements

1. How should laboratories collect data for AOE questions in the HHS guidance?

If test orders *are placed* electronically, healthcare facilities and laboratories should ensure that the laboratory test order interface can collect or transfer complete demographic data and answers to AOE questions. Healthcare facilities and laboratories should work with their electronic health record or laboratory information management system vendors to improve the order processes and information exchange between the healthcare provider and the laboratory.

If test orders *are not placed* electronically, submission forms (web based or paper) should be updated to include the data elements described in the CARES Act Section 18115 guidance .

2. Will facilities or healthcare providers that order COVID-19 tests be requested to collect the AOE questions?

Every effort should be made to collect this information because these data are critical for state and local public health departments to plan and execute COVID-19 control and mitigation efforts. These elements should be collected and be conformant with the HL7 Version 2.5.1 Lab Order Interface Implementation Guide and associated standards.

3. Should AOE questions be sent to the health department in the electronic laboratory report messages?

Yes, all data related to the AOE questions should be collected and reported to state and local public health departments in the electronic laboratory report messages.

Clinical research trial reporting

1. For an Institutional Review Board (IRB) approved clinical research trial, are laboratories required to report laboratory testing data from CLIA-certified COVID-19 testing (molecular, antigen, or antibody) if the specimens are de-identified and results are not returned to the ordering clinician?

In general, no. Laboratories are not responsible for reporting these data. However, state health department rules and regulations apply and may differ from this general guidance.

2. For an IRB-approved clinical research trial, what are the requirements for reporting laboratory testing data from CLIA-certified COVID-19 testing (molecular, antigen, or antibody) if the specimens are de-identified and results are being returned to the ordering clinician for patient care?

The reporting requirements differ for laboratories and research clinicians:

Laboratories

Laboratories are not responsible for reporting these data since they do not have the patient-identifying information required to comply with reporting requirements. However, state health department rules and regulations apply and may differ from this general guidance.

Research Clinicians

In clinical trials, research clinicians who are responsible for clinical care of trial participants are responsible for linking de-identified specimen test results to participant demographic information and are required to report the positive results daily to the appropriate state or local public health department based on the patient's residence. Demographic information required for reporting is detailed in HHS's June 4, 2020 guidance .

Research clinicians are not required to report negative test results. However, state health department rules and regulations apply and may differ from this general guidance.

If a clinician receives COVID-19 test results from duplicate specimens that were collected in the same manner and tested with different test methods (e.g., different platforms) or in different CLIA laboratories, the clinician should not report both results. In the case of two positive test results, the clinician should report the result that is provided first. In the case of discrepant test results, the clinician should report the positive result. However, state health department rules and regulations apply and may differ from this general guidance.

If the clinician requests COVID-19 testing for study participants independent of research activities or for clinical management, results should be reported to the appropriate state or local public health department.

Last Updated Oct. 16, 2020

Risk Management Concerns

There are several different Risk Management areas of concern when providing COVID Testing in pediatric practices.

Malpractice – Professional Liability Concerns

Ruth Wood, Director of Patient Safety, from MagMutual has given the following guidance for COVID Testing in TCCN practices:

- General recommendations for practices to minimize risk when offering COVID testing. At a minimum, it's important to:
  - Follow all the organizations policies and procedures.
  - Ensure all patients are receiving similar quality care.
  - Require staff to don/doff PPE per CDC guidelines. Have procedures in place to minimize transmission from patients/visitors, i.e. require that they wear face coverings at all times when possible.
  - Document all interactions, treatment, communications, etc. in the medical record.
  - Ensure all orders, results tracking system is in place and patients' results are being received and communicated efficiently.

- Providing testing to Parents
  - I strongly recommend that Pediatric providers only provide testing to pediatric patients. COVID-19 testing involves interpreting and follow-up which establishes a patient/provider relationship. This is outside the scope of practice for pediatricians and requires regulatory compliance. Having separate pathways of testing/treatment/notification/documentation can open a practice to additional liability.

- Testing utilizing drive through vs. designated parking spots processes
  - No specific recommendation for one versus the other. Either way, thorough planning is important for mitigating risks with these types of vaccination clinics. The CDC has an in-depth, easy to follow tool for satellite and drive through vaccination clinics, Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations.

- Recommended PPE
  - Recommendation is to strictly follow CDC guidelines and documenting those efforts.
    - CDC – Using Personal Protective Equipment (PPE)
    - CDC - Managing Operations During the COVID-19 Pandemic
    - CDC - Interim Infection Control Guidance for Public Health Personnel Evaluating Persons Under Investigation (PUIs)

- Additional recommendations for safety with external testing clinics
  - Regardless of the location of where testing is administered, there are constants that must remain to prevent risk to patients and staff and mitigate liability:
    - Standard of care: Regardless of the location of care, it is expected that the standard of care will be met in the same manner as it is within the practice.

- Appropriately licensed and trained staff working within their scope: State guidelines must be followed as it relates to licensure, supervision and scope. Staff must also be adequately trained and deemed competent to provide such care.
- Safety:
    - **Patient**
        - Infection Control: Policies, protocols and processes for Safe Injection Practices must continue to be followed to reduce the risk of infection in patients.
        - Screening for Contraindications/Adverse Reactions: Allowing time and tools for appropriate screening of patients as well as monitoring for adverse reactions.
        - Having a process for emergencies, including calling for assistance and having emergency medical equipment available.
        - Clear pathways, egress signs, etc. to prevent accidents.
    - **Staff**
        - Infection Control: Policies, protocols and processes for safe needle use and disposal and blood borne pathogens should continue to be followed. Appropriate PPE must also be donned/doffed and available in accordance with practice guidelines.
        - Environmental Safety & Security: Ensuring the area staff are working in is free of hazards, any hazards are clearly noted and signage and barriers create a protective area for staff to work. Also ensure appropriate protection from the elements, lighting and security for staff.
    - **Compliance with federal, state and local laws and ordinances, such as:**
        - HIPAA Privacy and Security
        - OSHA
        - American with Disabilities Act
        - COVID-19 guidelines

General Liability, EPLI and other non-Malpractice Concerns

The information below is from our Broker, Bill Reese, for items to consider to minimize risk for your practice that is not malpractice related.

- Ensure that any employee involved in COVID testing is using recommended PPE components.

- If you do not own your practice building, work with your landlord/leasing company and ensure they do not have any concerns with your COVID Testing Plans.
    - For instance, having lines in your parking lot that do not affect their safe traffic flow, or interfere with other tenants.

- In your protocol process, if doing drive through testing, ensure cars are in park when doing the test.
- Having designated parking spots may be a better option, rather than a line of cars.

- In your protocol process, ensure that there is a process of identifying swabs and specimens are labeled correctly as quickly as possible.

- Ensure all staff is practicing safe distancing throughout the process to keep them safe.
- Ensure staff is changing PPE as per recommendations. Stress that this is about keeping them safe.