

# **COVID-19 Pandemic Response, Laboratory Data Reporting**

Request for OMB approval of a New Information Collection

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## **Supporting Statement A**

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- **Goal of the study:** Gather comprehensive laboratory testing data to ensure a rapid and thorough federal response to the COVID-19 pandemic.
- **Intended use of the resulting data:** These data contribute to understanding disease incidence and trends: initiating epidemiologic case investigations, assisting with contact tracing, assessing availability and use of testing resources, and identifying of supply chain issues for reagents and other materials. Laboratory testing data, in conjunction with case reports and other data, also provide vital guidance for mitigation and control activities.
- **Methods to be used to collect:** Daily reports from state health departments via Health Level 7 (HL7) electronic laboratory reporting (ELR) or CSV file.
- **The subpopulation to be studied: Health departments in** fifty states, District of Columbia, and U.S. Territories with electronic reporting capacity
- **How data will be analyzed:** The analyses routinely completed on disease surveillance data would apply to this data set. Since this effort is intended to improve completeness of data across existing variables, this new requirement will enrich and strengthen the current conclusions drawn from the laboratory data, driving public health decision making and interventions.

## 1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests an emergency 6-month approval for a New Information Collection titled COVID-19 Pandemic Response, Laboratory Data Reporting.

Efforts are underway to ensure that laboratory data—including diagnostic viral testing data and serologic testing data—are comprehensive and readily available from laboratories and other facilities providing testing, including point-of-care testing sites for the public health response to SARS-CoV-2 and COVID-19.

Ensuring a rapid and thorough public health response to the COVID-19 pandemic necessitates comprehensive laboratory testing data. These data contribute to understanding disease incidence and trends: initiating epidemiologic case investigations, assisting with contact tracing, assessing availability and use of testing resources, and identifying of supply chain issues for reagents and other material. Laboratory testing data, in conjunction with case reports and other data, also provide vital guidance for mitigation and control activities.

Public Law 116-136 § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act, requires “every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19” to report the results from each such test to the Secretary of the Department of Health and Human Services (HHS).<sup>1</sup>

Through the CARES Act, and other coronavirus supplemental funding packages including [the Paycheck Protection Program and Health Care Enhancement Act, jurisdictions have received funding to accelerate and improve data collection and reporting of SARS-CoV-2](#). Improvements with the laboratory data

<sup>1</sup> <https://www.congress.gov/bill/116th-congress/house-bill/748>

collection and reporting, laboratory information management systems (LIMS) enhancements and expansions, increased completeness of case data reporting, and improvements with timeliness of reporting are among the prioritized activities for implementation with this funding.

This ICR outlines the requirements for data submission to the U.S. Department of Health and Human Services (HHS) as authorized under this law. In an effort to receive these data in the most efficient manner, the Secretary is requiring that all data be reported through existing public health data reporting methods as described below.

As a guiding principle, data will be sent first to the state or local public health agencies (in accordance with state law or policies) to ensure rapid initiation of case investigations by the state and/or local public health agency. At the same time, laboratory order results will be shared with ordering providers or patients if there is not an ordering provider.

Authorizing legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1a) and Public Law 116-136 § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Attachment 1b).

## **2. Purpose and Use of Information Collection**

All laboratories, defined as laboratories, non-laboratory testing locations, and other facilities or locations offering point of care testing or in-home testing related to SARS-CoV-2 shall report data for all testing completed—as well as test types—for each individual tested, within 24 hours of result known or determined, on a daily basis to the appropriate state or local public health agency based on the individual's residence. When data collection starts, states will send line-level data, including a backfill for prior dates. The retrospective data collection will be an optional one-time burden.

Reporting to the state and/or local public health agencies meets the requirement for reporting stated above as this information—under current processes and policies—will then be subsequently provided electronically to the Centers for Disease Control and Prevention (CDC) using an existing pathway and storage location for the data.

For the purposes of this ICR, federal burden is only being placed on fifty states, the District of Columbia, and U.S. Territories with electronic reporting capacity.

The U.S. Government—and particularly CDC—has a long history of partnering with these jurisdictional health departments on surveillance, detection, and reporting activities. The foundations of this data collection and reporting have advanced through legacy cooperative agreement programs at CDC. More recently, jurisdictions have received awards from three congressional acts between February-May 2020, including the Coronavirus Preparedness and Response Supplemental Appropriations Act, the CARES Act, and the Paycheck Protection Program and Health Care Enhancement Act.

Jurisdictions that are poor performing, or where there are barriers to data submission, will be brought to the attention of HHS to assist with intervention at leadership levels. CDC and HHS may also use the tools available from grant and cooperative agreement authorities to intervene and potentially restrict

funding or conduct audits for jurisdictions unable or unwilling to fulfill the requirements laid out in this reporting requirement.

The below defined data elements related to Laboratory Data Reporting to the Department of Health and Human Services may be reported through the following avenues:

- Submission of laboratory testing data directly to state or local public health agencies, as required by state and/or local law or policy. These entities will then submit these data to the CDC daily using either Health Level 7 (HL7) messaging (attachment 3) or the CDC-provided CSV format (attachments 4).
- Submission of laboratory testing data to state and local public agencies through a centralized platform (such as the Association of Public Health Laboratories’ AIMS platform) where results will then be routed to the appropriate state and local authorities as well as to CDC.
- Submission of laboratory testing data through a state or regional Health Information Exchange (HIE) that may receive, aggregate, store, or facilitate the exchange of data for reporting to the appropriate state or local public health agencies responsible for submitting these data directly to CDC or for submission of such data to CDC.

The following data elements must be collected and reported for SARS-CoV-2 laboratory tests, for the transmission of complete laboratory testing data to the CDC or the Secretary’s designee, including a state or local health agency (note: additional data elements may be requested at a future date. If so, a change request will be submitted to OMB for review).

<b>Data Element Collected</b>	<b>Use</b>
Test ordered – use harmonized <a href="#">LOINC codes provided by CDC</a>	To determine test method, test purpose, test sensitivity and specificity.
Device Identifier – use if LOINC codes do not indicate device/test kit	To determine test sensitivity and specificity.
Test result	For disease rates (Appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests <a href="#">provided by CDC</a> )
Test Result date (date format)	To determine test turn around time
Accession #/Specimen ID	Used for deduplication and tracking (Must have this or Testing_lab_specimen_ID order number assigned by the testing lab)
Age	Assist with population analysis
Patient race (ask patient to self identify)	Assist with population analysis (Allowed Values (allow multiple responses): American Indian or Alaska Native Asian Black or African American Native Hawaiian or Other Pacific Islander White)
Patient ethnicity (ask patient to self	Assist with population analysis

identity	(Allowed Values: Hispanic or Latino; Not Hispanic or Latino)
Patient gender	Assist with population analysis (Allowed Values: Male Female Other Unknown Ambiguous)
Patient residence zip code	Assist with geographic analysis
Patient residence county	Assist with geographic analysis
Ordering provider name and NPI (as applicable)	For analysis by testing setting
Ordering provider zip	For analysis by testing setting
Performing facility name or CLIA number, if known	For analysis by testing setting and for test volume and capacity (Allowed values: CLIA NPI OID)
Performing facility zip code	For analysis by testing setting and for test volume and capacity
Specimen Source - use appropriate LOINC, SNOMED-CT, SPM4 codes, or equivalently detailed alternative <a href="#">codes</a>	For semantic content check of test ordered
Date test ordered (date format)	To determine test turn around time
Date specimen collected (date format)	To determine test turn around time

The following additional demographic data elements must also be collected and reported to state or local health agencies but will not be collected by CDC or the Secretary's designee (note: additional data elements may be requested at a future date. If so, a change request will be submitted to OMB for review).

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

In order to meet this requirement, any person or entity ordering a diagnostic or serologic test, collecting a specimen, or performing a test must make every reasonable effort to collect complete demographic information and must include such data when ordering a laboratory test to enable the entities performing the test to report these data to state and local public health agencies.

When information is not available, ordering health care providers (or their designees), laboratories performing SARS-CoV-2 and associated tests, and State Public Health agencies should query resources like state or regional HIEs and National Health Information Networks (HIN) to obtain missing, required information.

These exchanges and networks have significant capacity to identify missing information as they typically work with a wide range of healthcare provider EHR generated data, as well as a broader array of ADT (admit, discharge, transfer) feeds from local or regional stakeholders.

The following data fields are specific to SARS-CoV-2 and considered “ask on order entry” (AOE) questions for traditional Electronic Health Records or Laboratory Information Management Systems. Recognizing that this goes above and beyond what has been historically requested, this information should be made available in all reporting (including through methods using existing technical infrastructure such as an HIE) to state and local public health agencies and subsequently the CDC as soon as possible, but no later than August 1, 2020. These elements should be collected and conformant with the [HL7 Version 2.5.1 Lab Order Interface Implementation Guide](#) and associated standards, comprehensive of the above data fields.

<b>Data Element</b>	<b>Use</b>
First test (Y/N/U)	To determine if a new patient (Allowed answers: Yes No Unknown)
Employed in healthcare? Y/N/U	To determine risk exposure (Employed_in_high_risk_setting: These are healthcare workers, first responders, essential services worker Allowed answers: Yes No)
Symptomatic as defined by <a href="#">CDC</a> ? Y/N/U; if yes, then Date of Symptom Onset mm/dd/yy	For infection analysis (Illness_Onset_Date Symptomatic_for_disease: Fever or chills Cough, Shortness of breath or difficulty breathing, Fatigue, Muscle or body aches Headache, New loss of taste or smell Sore throat, Congestion or runny nose, Nausea or vomiting, Diarrhea  Allowed answers: Yes No)
Hospitalized? Y/N/U	For analysis by patient setting (Patient location: Allowed answers: Hospitalized)

	ICU Long term care)
ICU? Y/N/U	For analysis of testing setting
Resident in a congregate care setting (including nursing homes, residential care for people with intellectual and developmental disabilities, psychiatric treatment facilities, group homes, board and care homes, foster care or other setting): (Y/N/U)	For analysis of testing setting
Pregnant? Y/N/U	To determine risk exposure

Laboratory data serve not only as important information to support decision making related to the public health emergency, but also as a critical piece to better understanding the performance of tests in real-world conditions, the effectiveness of clinical interventions, and patient outcomes and interventions.

Better understanding the characteristics and performance of specific tests can help ensure that healthcare providers are equipped with the maximum information necessary to make clinical decisions, develop recommendations and provide the most appropriate care for their patients. Additionally, with widespread use of electronic health records (EHR), closing the loop by incorporating information related to laboratory testing can add to the robustness of data that will eventually serve as the backbone for clinical research to inform treatments, better understand outcomes, improve the quality and performance of diagnostic tests over time, and shape clinical understanding of COVID-19.

To better ensure that data can be captured in the electronic health record (EHR), HHS also recommends that the transmission of laboratory results back to the ordering provider (whenever possible) include the following information.

1. 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
2. Test result date (date format)
3. Unique patient identifier
4. Test ordered – use appropriate LOINC codes
5. Device Identifier – use if LOINC codes do not indicate device
6. Accession #/Specimen ID

These data fields represent the minimum information and any data transmitted should be done in accordance with the HL7 Lab Results Interface (LRI) implementation guide and standard. To ensure that patients receive timely and critical information regarding their own health condition and status, HHS also recommends the transmission of laboratory results be sent directly to the patient (or parent/guardian), either by mail (in writing), email (electronically), and/or via a patient portal or open standard’s based application programming interface (electronically).



LOINC and SNOMED-CT codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC, should be used when possible to help ensure normalization and harmonization of data elements related to laboratory test and results.<sup>2</sup>

### **3. Use of Improved Information Technology and Burden Reduction**

When possible, all information will be collected using health information technology certified to the ONC 2015 Edition certification criteria, and all information should be structured in accordance with the US Core Data for Interoperability (USCDI) when available or when possible.

All data transmission should occur electronically using Health Level 7 (HL7) electronic laboratory reporting (ELR) implementation guides when possible but a predefined flat file format may also be acceptable.

In addition, clinical/point of care testing facilities using electronic health records (EHRs) are encouraged to use electronic case reporting (eCR) standards to report laboratory testing data, at the receiver's discretion, provided the above data elements and timeliness requirements can be met.

For home-based sample collection, including tests that may deliver results at home or through technologies such as personal smartphones and tablets, the test developer or manufacturer of the provided test should provide the data elements above (along with the specimen) to the lab performing the test, which will then be reported to the state and/or local health agency and subsequently HHS or entity designated by the Secretary.

For point of care testing, the device manufacturer should ensure the device is set up and operational to deliver timely and complete electronic results (with identifiers) to the state or local health agency if testing is performed.

### **4. Efforts to Identify Duplication and Use of Similar Information**

There are no other federal efforts underway to collect these data.

### **5. Impact on Small Businesses or Other Small Entities**

This data collection will not involve small businesses.

### **6. Consequences of Collecting the Information Less Frequently**

These data must be collected daily to ensure that the CDC and the federal COVID-19 response is able to make timely decisions on how to deploy resources, update policies and ensure that the needs of local and state governments can be met. Daily data are critical to tracking the trends in local transmission and enable easier identification of spikes. The daily information specifically drives outbreak and "hot spot" interventions in many jurisdictions.

### **7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

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<sup>2</sup> <https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html>

Responses will be required more often than quarterly. Responses will be required daily from all respondents. Otherwise, this request fully complies with the regulation 5 CFR 1320.5.

## **8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

A. Because this is a request for an emergency clearance, CDC asks that the 60-day comment period be waived. However, a 60-day *Federal Register* notice will be submitted to make the public aware of this investigation (Attachment 2).

B. In development of the required data elements and mechanism for collection, collaboration across HHS including CDC, ONC, HHS, FDA, CMS and other subject matter experts were consulted. CDC has worked collaboratively with jurisdictions to improve reporting through legacy programs, including on-going consultation, technical assistance, and scientific exchange, which has informed the development of these elements. Additionally, states and cities shared the data elements necessary for their operations and response, and specifically highlighted the need for data completeness and standardization in reporting.

## **9. Explanation of Any Payment or Gift to Respondents**

There are no payments or gifts to respondents.

## **10. Protection of the Privacy and Confidentiality of Information Provided by Respondents**

CDC's Information Systems Security Officer reviewed this submission and determined that the Privacy Act does apply. Limited identifiers will be collected including sex, race, age, and zip code. A signed Privacy Impact Assessment is included with this submission (Attachment 6).

Subsets and summaries of the information collected as part of this submission will be made available to the public in a manner that protects individual privacy. Disclosure of data will be stewarded through a review board to ensure that cell sizes for geography, age, sex, race, ethnicity and other sensitive subgroups will meet criteria sufficient to prevent re-identification.

Data may go to the HHS Protect platform from CDC. To prevent re-identification, states have the option to roll-up data from small counties before sending.

Entities that meet the definition of a covered entity or business associate under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations are permitted to disclose this protected health information under the HIPAA Privacy Rule. Nothing in this guidance changes the existing requirements for HIPAA covered entities and business associates to comply with the applicable HIPAA Privacy, Security, and Breach Notification Rules.

## **11. Institutional Review Board (IRB) and Justification for Sensitive Questions**

Institutional Review Board (IRB)

NCEZID’s Human Subjects Advisor has determined that information collection is not] research involving human subjects. IRB approval is not] required (attachment 5).

Justification for Sensitive Questions

There are no sensitive questions being asked.

**12. Estimates of Annualized Burden Hours and Costs**

**A. Estimated Annualized Burden Hours**

All fifty states, plus the District of Columbia, and U.S. Territories with electronic reporting capacity are required to report data to CDC on a daily basis.<sup>3</sup> Since we are seeking a 6-month OMB approval, the total number of responses per respondent will be 180. The average burden per response is one hour.

There is one-time, four-hour burden associated with retrospective data entry.

There is also a one-time, eight-hour burden for all entities that collect data for an order, place an order, test specimens, reference the specimens to another performer, and/or report the results. This burden is associated with setting-up interfacing with CDC’s Laboratory Information Management System (LIMS) platform for reporting.

Total estimated burden is 65,936 hours.

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
State epidemiologist or informatics staff	CDC-provided CSV file or HL7 messages	54	180	1	9,720
	CDC-provided CSV file or HL7 messages (retrospective data entry)	54	1	4	216
IT professional	LIMS interface configuration	7,000	1	8	56,000
<b>Total</b>					<b>65,936</b>

**B. Estimated Annualized Burden Costs**

The mean hourly wage rate for epidemiologists is \$34.79. The mean hourly wage for Health Information Technologists is \$28.17. Total estimated cost burden is \$1,923,193.40.

<sup>3</sup> As of May 21, 2020, all fifty states, DC, Puerto Rico, U.S. Virgin Islands, and Guam have confirmed capacity to send electronic reporting data to CDC. This rule is expected to apply to additional U.S. territories as those jurisdictions acquire capacity to report electronically.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
State epidemiologist or informatics staff	CDC-provided CSV file or HL7 messages	9,720	\$34.79	\$338,158.80
	CDC-provided CSV file or HL7 messages (retrospective data entry)	216	\$34.79	\$7,514.64
IT professional	LIMS interface configuration	56,000	\$28.17	\$1,577,520.00
<b>Total</b>				\$1,923,193.40

### 13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

Expected cost burden is primarily represented by the annualized burden estimated above, but additional administrative, data collection, and coordination burden are expected. These additional efforts are difficult to quantify and will vary greatly by jurisdiction.

### 14. Annualized Cost to the Government

Estimated Annualized Cost to the Government per Activity	
Cost Category	Estimated Annualized Cost
Contract staff	\$500,000
Partner cooperative agreement	\$1,500,000

### 15. Explanation for Program Changes or Adjustments

This is a new information collection.

### 16. Plans for Tabulation and Publication and Project Time Schedule

Project Time Schedule	
Activity	Time Schedule
On-going collection of information	Daily, starting June 1
Information transmitted to CDC DCIPHER platform	Daily, starting June 1

### 17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB Expiration date is not inappropriate.

### 18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

### Attachments

1A. Authorizing Legislation – Public Health Services Act

1B. Authorizing Legislation – Coronavirus Aid, Relief, and Economic Security (CARES) Act

2. 60-Day FRN
3. CSV format guide
4. HL7 reporting guide
5. Retrospective data entry
6. LIMS interface configuration
7. Non-research determination
8. Privacy Impact Assessment