

Guidelines for Onboarding and Reporting COVID-19 Electronic Lab Results via DSHS CSV Submission Template

December 2020

Version 1.0



TEXAS
Health and Human
Services

Texas Department of State
Health Services

Table of Contents

I. Background.....	3
II. Requirements for Reporting SARS-CoV-2 (COVID-19) Laboratory Results in Texas	4
III. Tips for Getting Started on Reporting COVID-19 Tests.....	6
IV. Registration	8
V. sFTP Client	9
VI. Familiarizing Yourself with Reporting Expectations	9
VII. Data Requirements	11
VIII. Test File Transfer using sFTP Client.....	16
IX. File Validation Issues	17
X. Production File Development.....	18
XI. Production File Transfer	19
XII. Frequently Asked Questions	19
XIII. Helpful Websites	22
XIV. Acronym Glossary	23
XV. Data Dictionary	24

I. Background

The ideal standard for reporting electronic laboratory report (ELR) results to the Texas Department of State Health Services (DSHS) is through Health Level 7 International (HL7) data standards. Data submitted via HL7 adhere to strict standards for exchange, integration, sharing, and retrieval of electronic health information. Prior to COVID-19, DSHS only accepted ELRs via HL7 standard to ensure conformance to the highest data quality. The onset of the COVID-19 pandemic led to the need for an alternative method of lab reporting for facilities unable to meet the HL7 reporting standard. Accordingly, DSHS developed an alternative reporting method via the approved comma separated value (CSV) file format.

This document outlines requirements for facilities submitting via the 56-column CSV file format. This guide outlines the requirements and specifications for reporting electronic lab reports to DSHS for import into the Texas National Electronic Disease Surveillance System (NEDSS). NEDSS is the primary public health laboratory management and infectious disease surveillance system in Texas. NEDSS is a secure, collaborative infectious disease integration platform where local, regional, and state public health authorities manage. Data submitted through NEDSS is also transmitted to the Centers for Disease Control and Prevention (CDC).

Currently, there are three main types of tests conducted to identify SARS-CoV-2 including molecular, antigen, and serological (antibody) tests. Each test conducted is reportable to DSHS including positive, negative, and indeterminate results. This guide is designed to help orient both traditional and non-traditional lab facilities (e.g., facilities performing in-house testing that do not typically report to DSHS) through the process of registering, testing, and onboarding to DSHS via the approved comma separated value (CSV) file format.

If a facility is currently submitting via CSV file format and prefers to change submission process to HL7, they should email the Public Health Informatics & Data Exchange Group (**COVID-19ELR@dshs.texas.gov**) to request this change.

Facilities may be able to create and extract reports from an electronic medical record (EMR) software or from a laboratory information management system. ELRs may also be created manually. If completed manually, a facility would typically enter the data into an Excel spreadsheet and save the completed file in the required CSV (MS-DOS) file format. The file is transmitted to DSHS through a secure file transfer protocol (sFTP) connection. Facilities preparing to use this route must have a basic understanding of the standards of reporting and will need technical ability to create and send the daily ELR file successfully.

II. Requirements for Reporting SARS-CoV-2 (COVID-19) Laboratory Results in Texas

State Requirements

On March 24, 2020, **Governor Greg Abbott issued an order** requiring every public and private entity conducting in-house/on-site SARS-CoV-2 (COVID-19) testing utilizing an FDA-approved test, including an emergency use authorization test, for human diagnostic purposes of COVID-19, to submit to the Texas Department of State Health Services (DSHS), as well as to their local health department, daily reports of all test results, including positive, negative, and indeterminate results. Lab results for COVID-19 are required to be reported through the **Texas Administrative Code Chapter 97** and the **Texas Health and Safety Code Chapter 81**.

Federal Requirements

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 and/or local public health department, based on the individual's residence.

Ask on order entry (AOE) questions are additional questions that provide information about the patient's life context. There are seven AOE questions mandated by the CARES Act (**CARES Act Section 18115**). Facilities that order tests electronically must ensure their EMRs can collect and ingest this information. Facilities that do not order tests electronically must ensure they coordinate the collection of AOE info on intake.

Who is required to report?

All facilities or entities conducting in-house/on-site (tests that are not sent to a reference lab) testing for COVID-19 are required to report to DSHS and to their local health department. Facilities required to report include but are not limited to laboratories, hospitals, clinics, pharmacies, long term care facilities, schools, workforce settings, and other entities conducting in-house/on-site testing.

Tests performed by an off-site reference lab should be reported to DSHS by the performing lab.

What information is required to be reported?

All SARS-CoV-2 (COVID-19) test results are required to be reported. All results including positive, negative, and indeterminate results must be reported. This includes all point-of-care (POC) test results as well. Results for all persons tested in the state of Texas must be reported, regardless of the patients' residence. Additionally, results for any Texas residents tested outside of the state must be reported to DSHS.

DSHS provides submitters with resources, including a template and data dictionary, that demonstrate all data fields required for reporting. They also describe other data entry and formatting requirements.

When are lab results required to be reported?

Results are required to be reported **within 24 hours** of test being resultated.

To whom are lab results required to be reported?

Results are required to be reported to both DSHS at the state level and to the local health authority at the local level. All facilities conducting in-house/on-site reporting must register and report to DSHS. If a facility is located in Texas the facility must also contact their **local health authority** to ensure they are compliant with the local directive for reporting. Local health authority directives may vary from faxing to submitting an electronic lab report file directly to them. Note that DSHS does not accept COVID-19 results via fax, phone, or email.

How are lab results required to be reported?

Lab results can either be reported via HL7 message format or via the 56-column CSV reporting template. To report test results, regardless of reporting method, facilities must first register with DSHS and then comply with each step of the process. Facilities will have to understand the required data templates, formatting, and data validity requirements as detailed in the COVID-19 lab reporting template and the COVID-19 lab reporting data dictionary.

Facilities should consult their local health department to ensure they are meeting their local health department directives also.

Why are lab results required to be reported?

Complete and timely lab data is essential to COVID-19 mitigation efforts to reduce the spread of COVID-19.

III. Tips for Getting Started on Reporting COVID-19 Tests

All facilities should follow steps 1-6:

1. Ensure that the tests run by your facility are authorized by the FDA by visiting this page: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>
2. Be sure to register your facility with DSHS to report test results. You can do so on this page: <https://dshs.texas.gov/coronavirus/forms/registerlab.aspx>. You will be contacted by DSHS via email within 3-5 business days with further instructions.
3. Print out a copy of the following documents. These will be in the email we send you or you can find them at <https://www.dshs.texas.gov/coronavirus/submitters.aspx>. This will allow you to quickly and easily refer to resources.
 - a. The CSV reporting guide (this document)
 - b. CSV clean reporting template
 - c. Data dictionary
4. Make a plan for reporting. The plan should clearly define duties and expectations of all team members who will be involved in the lab reporting process.
5. Add the following email addresses to your contacts lists to ensure important communications are not labeled as spam:
 - a. **COVID-19ELR@dshs.texas.gov**
 - b. **IDI@dshs.texas.gov** (for HL7 reporting)
6. If you need help or guidance along the way, feel free to email either of the above addresses.

In addition to the tips above, non-traditional lab facilities and/or facilities primarily conducting Point-of-Care (POC) antigen testing should also complete follow the steps outlined below:

7. Verify that your CLIA number is valid by using one or both of these websites:
 - a. <https://www.cdc.gov/clia/LabSearch.html>
 - b. <https://qcor.cms.gov/main.jsp>
 - c. If your CLIA does not appear on these sites, we will reach back out to you to inform you that the CLIA is not valid. When we do, please send us proof of CLIA registration. Make sure you have this documentation ready.
8. If you are not already conducting tests at your facility, plan a work flow that ensures you are able to capture all the data elements listed in the 56-column CSV template and data dictionary.
 - a. Assemble a team of experts to develop a plan for reporting from your facility. We recommend your team include some or all of the following members:
 - i. Healthcare professionals: e.g., nursing professional who understands the testing process and medical terminology
 - ii. Personnel who are performing testing: e.g., individual who will identify days and times testing is conducted, data to be collected, and recording of data for reporting needs
 - iii. Individual with technical knowledge: e.g., an administrator who can format spreadsheets to meet our requirements and who can enter data daily for reporting

- iv. Report writers: e.g., staff who can interpret the reporting guidelines, data dictionary, different codes, and other required components
 - b. It is always helpful to document the overall workflow of testing at your facility.
 - 9. You can prepare for reporting by:
 - a. Reviewing the required data fields and ensure you know where those data elements will be obtained.
 - b. Reviewing the data dictionary to ensure your data conforms to our requirements.
 - c. Some fields require that you reference websites and other resources. Review the data dictionary to familiarize yourself with those resources.
 - 10. Follow any guidance or instructions you receive from DSHS. You may receive requests for additional data or for corrections. Correspondence will be sent to the email address on file for your facility from the COVID-19ELR@dshs.texas.gov email account.

IV. Registration

In order to begin the reporting of COVID-19 lab results to DSHS, please register online at www.dshs.texas.gov/coronavirus/forms/registerlab.aspx. Complete and submit the form. It is critical that the email addresses you submit are spelled correctly on the form and are actively monitored by your organization. If this information changes, please notify us as soon as possible.

You will need the CLIA number for your facility. Please verify that your CLIA is correct. If you are registering more than one reporting facility, please complete the registration process for each facility with a unique CLIA number. If you have a large number of facilities to register, please email COVID-19ELR@dshs.texas.gov for guidance on how to best proceed.

Next Steps

Once the registration has been completed and submitted, the DSHS Public Health Informatics and Data Exchange Group will email the instructions for the onboarding process to the points of contact listed in the registration form. This is usually within 24 - 72 hours after registration submission.

As you await further instructions you can prepare by identifying your external or public internet protocol IP(s) address.

If you do not know your external or public internet protocol IP(s) address you can find it by doing the following:

- Go to Google
- Type “what is my IP” in the search prompt
- The IP will appear and will look like: 160.45.60.18

Determine what your external/public IP is. After receiving the email you received from DSHS that includes the instructions, reply to all and send your external/public IP info. The reporting facility name and CLIA will be in the email *Subject* line. Please do not remove or change the subject line of the email.

V. sFTP Client

Once we receive the external IP, we will send you an encrypted email containing your username to access our Secure File Transfer Protocol (sFTP). We will also send a separate encrypted email containing your sFTP password. You will need that information to access the DSHS sFTP. Credentialing issuance will take 24 – 72 hours to process.

sFTP is a file protocol for transferring secure files over the web. In order to transfer files to our sFTP, you will need to have an sFTP client installed in order to send data securely.

Downloading sFTP Client

If you don't already have an sFTP client, you will need to obtain one. There are several free sFTP clients available for free download online. If applicable, you should consult with your IT department prior to downloading. If you would like additional instructions on this, please send an email to COVID-19ELR@dshs.texas.gov.

VI. Familiarizing Yourself with Reporting Expectations

Open all the attachments in the “ELR Info” email you received after registering.

If you have not yet received this email and more than 3 business days have passed since you submitted your registration form, send an email to COVID-19ELR@dshs.texas.gov.

There should be at least three attachments included in the email: a DEMONSTRATION template, a CLEAN template, and a DATA DICTIONARY.

Learn more about each field by reviewing the column headers in the DATA DICTIONARY. The data dictionary will explain each field in more detail, including things to avoid and important rules for data entry.

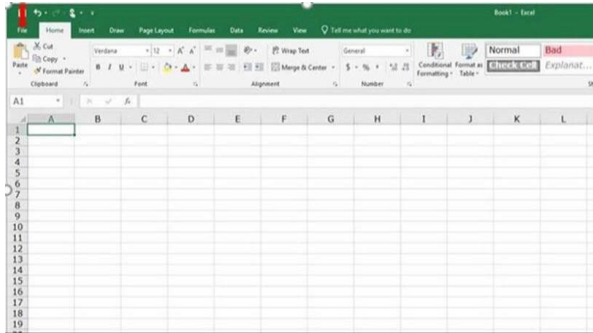
Once you understand the layout of the file, look over the CLEAN template. This file is where you can manually enter all your test entries and real patient results.

Note that the CLEAN template has 56 columns. Your own submissions must have 56 columns – no more, no less.

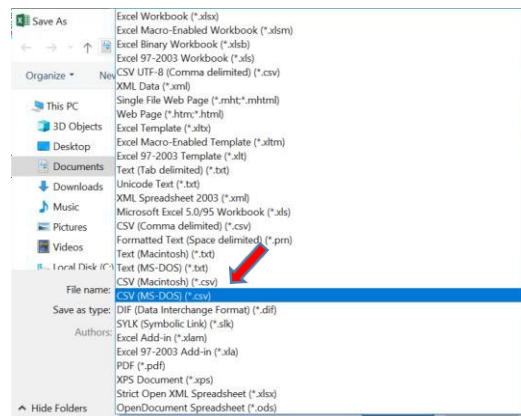
Saving a File in CSV (MS-DOS) Format

Whether you are working on a test file or a production file, if you use Microsoft Excel to enter results into a file, always save your Excel spreadsheet in CSV (MS-DOS) file format. Below are instructions on how to save an Excel file in CSV (MS-DOS) format:

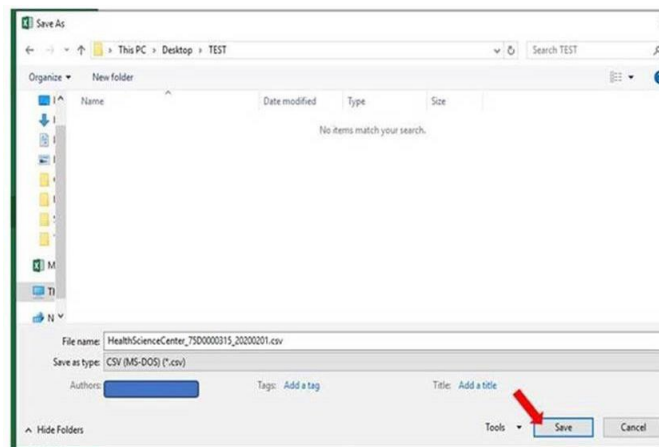
1. Select File



2. Select Save As. Under “Save as type”, select **CSV (MS-DOS)(*.csv)**



3. Select Save



VII. Data Requirements

Per CDC requirements, complete laboratory data must include the following data elements for both state and jurisdictional health departments. **In order to report these data requirements properly, complete the DSHS CSV template in accordance with the DSHS Data Dictionary guidance.**

1. Test ordered – use harmonized (Choose Ctrl and Click to follow link) **LOINC codes provided by CDC**
2. Device Identifier
3. Test result
4. Test Result date
5. Accession Number / 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 code
14. Performing facility name and CLIA number
15. Performing facility zip code
16. Specimen Source – use appropriate LOINC codes
17. Date test ordered
18. Date specimen collected

The following demographic data elements are also required:

19. Patient name (Last name, First name, Middle initial)
20. Patient street address
21. Patient phone number with area code
22. Patient date of birth
23. Ordering provider address
24. Ordering provider phone number

The following are the mandatory Ask on Order Entry (AOE) questions:

25. Patient's first SARS-CoV-2 (COVID-19) test? (Y/N/U)
26. Is patient employed in healthcare? (Y/N/U)
27. Symptomatic as defined by CDC? (Y/N/U)
28. If patient is symptomatic, date of symptom onset? (MM/DD/YYYY)
29. Is patient in Intensive Care Unit (ICU)? (Y/N/U)
30. Is patient a resident in a congregate care setting (nursing home, group home, homeless shelter, etc.)? (Y/N/U)
31. Is patient pregnant? (Y/N/U)

Device ID

- Depending on the type of test used, facilities can use either of the following:
 - Name of the test used
 - Lot number of the testing kit
 - Serial number

Accession Numbers

Facilities can choose several ways to devise accession numbers, but these numbers MUST be unique to each patient for each test for each day. Accession numbers CANNOT be shared or duplicated.

- Accession numbers can be generated several different ways-
 - YYYYMMDD#### - This process helps avoid duplication of accession numbers because of the date that changes every day.
 - If the same patient was tested more than once a day, then an extra number can be added at the end. i.e. YYYYMMDD1234-1

LOINC Code

LOINC code is a unique identifying value for lab tests. If you are unfamiliar with LOINC, think of the code as a unique name that helps our software and epidemiologists distinguish between all the different types of SARS-CoV-2 tests that are being conducted. This is important because epidemiologists use this information to assist in case investigations, and our computer system uses it to catalog every lab result submitted to the state. Below are basic instructions for identifying the LOINC code that corresponds to the lab tests you are conducting.

1. Choose Ctrl and Click to follow link or copy and paste it into your browser:
<https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html>
2. Click on the link next to "Mapping tool" to download the Excel document titled "LIVD SARS-CoV-2 Test Codes.xlsx".

LOINC In Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests

On June 4, 2020, the Department of Health and Human Services (HHS) announced new laboratory data reporting [guidance](#) for COVID-19 testing. Using LOINC and SNOMED-CT to identify and report SARS-CoV-2 test results in electronic reporting systems will facilitate timely and quality data reporting to state and federal public health agencies. The following document (developed per the [LIVD specification](#)) provides LOINC and SNOMED mappings for SARS-CoV-2 diagnostic tests available in the United States. The LIVD mapping catalogue provides coding for these data elements: LOINC test order, LOINC test result, SNOMED-CT test description, SNOMED-CT specimen source, and Device Identifier.

Mapping tool: [LIVD SARS-CoV-2 Test Codes.xlsx](#)
LIVD publication date 2020-10-05.

CDC and its partners will review and update this tool as needed for new or discontinued tests. For more information or to contact CDC about this tool, email DLSinquiries@cdc.gov and use "LIVD Test Code Mapping Tool" in the subject line.

3. You should check back on this website weekly to see if there have been any updates by checking the LIVD publication date underneath the download link.
4. After downloading the file to your computer, open the file in Excel.
5. Look at the bottom of the file – there should be several tabs to choose from. Click on the tab called “LOINC Mapping”. This will take you to a sheet that lists most available devices used for COVID-19 testing and each of their corresponding LOINC codes.

6. Now you can search this sheet for the device you are using. The easiest way to do this is to search for the manufacturer of the test – this should be located somewhere on the packaging of the test or on a device itself.
7. Once you have found the manufacturer name, hit Ctrl and F on your keyboard at the same time to pull up a search bar. Alternatively, you can click on the “Find & Select” function on the Excel toolbar, and then click “Find”.

a. Search tool

nasopharyngeal wash (258467004^Nasopharyngeal washings^SCT)
nasopharyngeal aspirate (258411007^Nasopharyngeal aspirate^SCT)

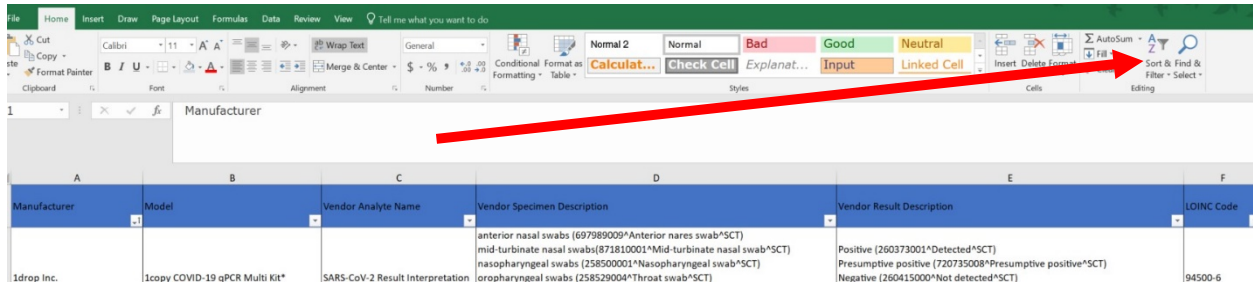
Find and Replace

Find what:

Find All Find Next Close

nasopharyngeal swabs (258529004^Throat swab^SCT)
nasopharyngeal wash (258467004^Nasopharyngeal washings^SCT)
nasopharyngeal aspirate (258411007^Nasopharyngeal aspirate^SCT)

b. “Find & Select”



8. Type in the manufacturer in the search bar and hit Enter on your keyboard. This will take you to the first row on the spreadsheet where your manufacturer is listed. You will see in the second row the models of test kits/devices from the manufacturer.
9. Scroll until you find the test kit or device you are using (and make sure it is next to the right manufacturer). Then, scroll or look to the right until you find the corresponding LOINC code (not LOINC order code). **THIS IS THE LOINC CODE YOU ENTER IN THE LOINC CODE COLUMN OF YOUR CSV FILE.**
10. Look one more cell to the right and you will see the LOINC long name (not LOINC order code long name). **THIS IS THE TEXT YOU ENTER IN THE LOINC TEXT COLUMN OF YOUR CSV FILE (make sure to remove any commas, if any).**

Creating a Test File

Make a copy of the CLEAN template by saving it as a CSV (MS-DOS) file type document. Name this copy using the following naming convention:

Test_YourFacilityName_YourFacilityCLIA#_Date.csv

- DO NOT USE THE DEMONSTRATION TEMPLATE FOR TEST FILES.
- ALWAYS INCLUDE THE WORD "TEST" IN TEST FILE NAMES.

Make sure all 56 column headers are present. In Microsoft Excel, you will see headers all the way right to column BD.

Now, you may begin entering 2-5 lines of mock patient test results. Fill out each required field. This part of the process is like a qualifying event. You must submit a file that is exactly what your real file would look like, but with mock patient name and identifying information (the mock information must still be valid). Do not enter actual, real test results at this time.

When you are finished entering your mock test results, save the document.

At this point, you should review your test data to make sure of the following:

- Are there blank cells?

- If the field is required, the cell should not be blank. See the DATA DICTIONARY for more information on which fields are required and which fields can accept placeholder values if a certain piece of information is unknown.
- Are there 56 columns of data? Does the data go all the way to column BD in Excel?
 - Anything more or fewer than 56 columns will automatically error out.
- Does your test data look like a real patient record?
 - You should not simply type “test” in all the fields. You should pretend that you are submitting a real patient test result and create a name and identifying information.
- Are your dates in the right format?
 - We only accept dates in the MM/DD/YYYY format. It is okay if your dates don’t have leading zeroes.
- Does your LOINC code match the type of test you are conducting?
 - See the DATA DICTIONARY for more guidance on selecting a LOINC code.
- Are state, sex, race, and ethnicity values capitalized and abbreviated?
 - These must be capitalized and abbreviated. See the DATA DICTIONARY for a full list of acceptable values.

Save your test file again, making sure to follow the naming convention in step (1) of these instructions.

Now you may move on to submitting your test file via sFTP for our review.

VIII. Test File Transfer using sFTP Client

Utilizing your sFTP client, connect to our server. The first time you connect, the application will ask you to accept the certificate from our site. Choose Accept.

Next, you will enter the username and password provided by DSHS. The protocol or port is sFTP or 22.

Once you've successfully logged in to your sFTP Client, you are ready to transfer your test file.

Validation of Test File

Once your test file has been validated and approved by DSHS, we will provide your facility the next steps to submit production files. This may take 3-5 days.

DO NOT submit actual lab results until DSHS has approved your facility to do so.

If your test file passed validation, you will receive the following email from **COVID-19ELR@dshs.texas.gov**:

"In order for this site to start submitting "production files", we will need the following from you:

*a) Do you have any backlogged files to report? **If yes**, what is the*

- number of records you will be reporting?*
- number of "positives"?*
- date range of the backlog?*
- test type (PCR, antibody, antigen, etc.)?*

*b) **If no**, then please let us know **immediately!***

Please respond as soon as possible. Once DSHS receives a response, you will receive instruction on when to send the first production file.

If there are problems or errors in the test file, we will contact you to resolve. We will go through this process until the file is corrected and accepted.

IX. File Validation Issues

Facilities that do not adhere to data dictionary and submission template will face file validation issues. Failed validation leads to data resubmission, and backlog of files that can further hinder reporting timelines. Therefore, it is pertinent that facilities adhere to ALL guidelines provided in this document. When records or files fail, facilities can refer to the table below for further guidance to correct identified errors and resubmit the records/files.

Reasons for Failed Files

- File submitted using the demonstration file which is NOT an acceptable format, or all records had missing values in required fields. The demonstration file is ONLY for reference and not to be used for file submissions.
- File was submitted as an Excel (.xlsx) file - All records must be submitted as .csv files and NOT .xlsx files.
- File was not submitted in the 56-column format.
- Commas in any field will automatically reject file. No commas or spaces allowed; special characters should be used minimally.
- Duplicate rows or duplicate columns will cause file errors.
- LOINC codes that do not correspond to the correct test name or vice versa.
- LOINC text describes the LOINC code and is not accepted unless the Code and text are sent together with the file. Each LOINC code must accompany valid text.
- All date fields must conform to the date format MM/DD/YYYY. (Leading zeroes are not required.)
- Specimen ID must have value. Null or missing values are not accepted.
- Non-unique specimen IDs are not accepted.
- Specimen Type value must be present.
- Addresses cannot have null values. Must use “Unknown” value for entry if no address information available.
- Phone number must be a ten-digit number in the following format: ###-###-####. For unknown values, use 999-999-9999.
- Sex must be entered in the accepted abbreviated format (see data dictionary).
- Accession Number must be unique ID for each lab order.
- Same patient cannot have the same test on the same day using the same accession number.

Reasons for Failure Specific to AOE Questions

- Responses do not conform to acceptable responses (Y, N, U); not abbreviated or other invalid values
- Blank required fields – all of the AOE fields are required except for date of symptom onset
 - If the patient is not symptomatic, you should leave date of symptom onset blank
- Date of symptom onset not in correct date format (MM/DD/YYYY)

X. Production File Development

Before creating your production file, answer the following question: Did you receive an email explicitly giving you permission to submit production files?

- a. If yes, continue to step 1 below.
- b. If no, DO NOT SUBMIT A PRODUCTION FILE, as you have yet to pass the testing phase.**

1. Make a copy of the CLEAN template by saving it as a CSV (MS-DOS) document in a folder of your choosing. Name this copy using the following conventions:

YourFacilityName_YourFacilityCLIA#_Date.csv

**** DO NOT USE THE DEMONSTRATION TEMPLATE FOR PRODUCTION FILES.**

2. Make sure all 56 column headers are present. In Microsoft Excel, you will see headers all the way right to column BD.
3. Just like you did with test data, begin entering real patient test results line by line. The only difference is that now you are entering real test results for real patients/staff instead of mock test results for mock patients.
4. When you are finished entering your real test results, save the document.
5. At this point, you should review your production data to make sure of the following:
 - a. Are there blank cells? If the field is required, the cell should not be blank. See the DATA DICTIONARY for more information on which fields are required and which fields can accept placeholder values if a certain piece of information is unknown.
 - b. Are there 56 columns of data? Does the data go all the way to column BD in Excel? Anything more or fewer than 56 columns will automatically error out.
 - c. Are your dates in the right format? We only accept dates in the MM/DD/YYYY format. It's okay if your dates don't have leading zeroes.
 - d. Does your LOINC code match the type of test you are conducting? See the DATA DICTIONARY for more guidance on selecting a LOINC code. Also, browse the official list of valid COVID-19 LOINC codes here (Choose Ctrl and click):
<https://loinc.org/sars-cov-2-and-covid-19/>
 - e. Are state, sex, race, and ethnicity values capitalized and abbreviated? These must be capitalized and abbreviated. See the DATA DICTIONARY for a full list of acceptable values.
6. Save your file again, making sure to follow the naming convention in step (2) of these instructions.

Now you may move on to submitting your production file via sFTP client for validation.

XI. Production File Transfer

You will initiate the transfer of your production file utilizing your sFTP client. Upon prompt, you will enter the username and password provided by DSHS. The protocol or port is sFTP or 22. Once you've successfully logged in to your sFTP Client, you are ready to transfer your production file.

If any issues are identified in your data submission, an email summarizing any errors will be sent. Please be sure to follow any instructions on resubmission of any failed records or files.

XII. Frequently Asked Questions

Please note that the directives given here are in regard to fulfilling your *state* reporting obligations to the Texas Department of State Health Services (DSHS). Be sure to reference your local health authority for any local reporting directives.

Registration

Q: I am already submitting COVID-19 results to my local health department. Do I still have to submit to DSHS?

A: Texas is a dual reporting state, so yes. You must follow local *and* state mandates for reporting.

Q: My facility is already submitting COVID-19 results to National Healthcare Safety Network (NHSN). Do I still have to submit to DSHS?

A: If you are reporting your results to NHSN, you do not need to report to DSHS, as NHSN will report your results to the state.

Q: How do I start the process of submitting COVID-19 results to the state?

A: The first step is to **register** your organization to begin reporting.

Q: I have registered my facility, what next?

A: We will reach out to you with instructions for next steps after we receive your registration form and confirm that your CLIA is valid.

Q: Can I fax you my facility's results?

A: Texas DSHS accepts ONLY Electronic Lab Reporting (ELR), either via HL7 or in the DSHS approved CSV (comma separated value) file format. No other form of reporting is accepted at this time.

Q: Can I email DSHS my facility's results in a spreadsheet?

A: Since e-mail is not a secure method for protected health information (PHI) transfer, Texas DSHS will not accept reports via this method.

Q: My facility is doing point-of-care antigen tests. We are not a traditional lab facility. Do I still have to report test results to the state?

A: Yes. You are required to submit all COVID-19 test results to the state. Facility Onboarding User Guide will clarify how non-traditional facilities can register to report to the state.

Q: Can I phone/mail/fax in to DSHS my facility's COVID-19 results?

A: Texas DSHS DOES NOT does not accept phone, mailed, or faxed reports due to data security issues.

Testing

Q: I registered, submitted my IP, and connected successfully to the sFTP client. Can I start submitting test results?

A: Before we permit you to start sending reports, we first need you to submit a test file. This will help us acknowledge that the submission template guidelines and data dictionary were followed accordingly and successfully.

Q: How should test files be structured?

A: Test files MUST be a .csv file and records MUST resemble real data. Utilize the CSV template and enter test records in accordance with the data dictionary. Once test records are entered in the file, the file should be sent for testing using the correct file naming convention (Test_YourFacilityNameHere_CLIA#_DateofSubmission.csv).

Q: Am I only supposed to submit positive test results?

A: You are required to submit ALL test results, including positive, negative and indeterminates, to DSHS. Contact your local health authority for their requirements for reporting.

Q: What COVID-19 tests can I report to DSHS?

A: Results for all COVID-19 tests must be reported:

- Antigen
- PCR
- Antibody
- POC - Point of Care (can be antigen, PCR, or antibody)
- Panel tests that include COVID-19 tests (e.g., flu A + flu B + SARS CoV 2)

Q: How do I report panel tests?

A: If the panel test you are conducting tests for COVID-19, you should report **all** the results from that test. For example, if the panel tests for flu A, flu B, and SARS antigen, you would have to fill out three rows on the CSV file – one for each result. Each row should have the LOINC code corresponding to the test component. Do not use the LOINC order code when reporting panel tests.

Production

Q: What is LOINC? What LOINC code should I choose?

A: LOINC is a common language (set of identifiers, names, and codes) for identifying health measurements, observations, and documents. The **LOINC** website provides current codes for all reporting.

Q: What is a device identifier and where can I find it? Is it an important field to report?

A: The manufacturer and model of the device are adequate device identifiers. You can also use the model number or ID. It is a required field, and it is critical to helping epidemiologists conduct their case investigations.

Q: I don't know the value for a required field. What do I do?

A: See the data dictionary – for some fields, you can use values like Unknown, UN, or 99999, making sure that the values match the expected format of the field.

Q: Can I submit weekly reports instead of daily?

A: Reports **MUST** be submitted daily. Timely reporting is extremely important and necessary. If your facility is not open on a weekend or holiday, reports must be submitted on the next business day.

Q: I am a new staff member replacing someone else on the reporting team/The previous staff member is no longer responsible for reporting. What do I do?

A: Email your question to **COVID-19ELR@dshs.texas.gov** detailing your situation. Make sure to include your facility's CLIA number in the email. We can work to revise and/or correct our contact information for your facility.

Validation

Please refer to the data dictionary for all failed validations. All answers can be found in the data dictionary.

Q: Why are all my date fields causing errors?

A: .csv files accepted **ONLY** in MM/DD/YYYY format and must not have timestamps. If records are not reported in this format they **WILL** fail validation.

Q: My CSV looks fine in Excel with no data entry issues. Why is my file submission still failing?

A: Open the Excel file in Notepad and check for any extra commas at the end of each line, if there are any, then those represent extra columns. Remove the extra columns before resubmission.

Q: How do I report missing date of birth (DOB)?

A: If DOB is not known, it can be left blank. Filling with any other information like "Unknown" or "99" will cause failure. You can also leave age blank if DOB is unknown.

XIII. Helpful Websites

Coronavirus Aid Relief Economic Security (CARES) Act

<https://home.treasury.gov/policy-issues/cares>

This site provides information on the CARES Act

Centers for Disease Prevention and Control (CDC)

<https://www.cdc.gov/coronavirus/2019-ncov/index.html>

This site provides comprehensive COVID-19 information.

Food and Drug Administration (FDA)

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>

This site lists all the FDA authorized tests for COVID-19.

DSHS Lab Submitters Resource Page

<https://dshs.texas.gov/coronavirus/lab-reporting.aspx>

Resource link for facilities submitting lab report data to DSHS.

LOINC

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

<https://loinc.org/sars-cov-2-and-covid-19/>

These sites will help you determine the correct LOINC code to use based on the tests you are using.

SNOMED

<https://confluence.ihtsdotools.org/display/snomed/SNOMED%2BCT%2BCOVID-19%2BRelated%2BContent>

This website discusses SNOMED-related content specific to COVID-19.

U.S. National Library of Medicine

<https://accessgudid.nlm.nih.gov/>

This site will help you determine the Device ID of the test

XIV. Acronym Glossary

- AOE: Ask on Order Entry
- CARES: Coronavirus Aid, Relief, and Economic Security
- CDC: Centers for Disease Control and Prevention
- CLIA: Clinical Laboratory Improvement Amendments
- CSV: Comma Separated Value
- DOB: Date of Birth
- DSHS: Texas Department of State Health Services
- ELR: Electronic Lab Report
- EMR: Electronic Medical Record
- FDA: Food and Drug Administration
- HL7: Health Level Seven (7) International standard
- ICU: Intensive Care Unit
- IP: Internet Protocol
- LIS: Laboratory Information Systems
- LIVD: LOINC In Vitro Diagnostic
- LOINC: Logical Observation Identifiers Names and Codes
- NEDSS: National Electronic Disease Surveillance System
- NHSN: National Healthcare Safety Network
- NPI: National Provider Identifier
- PCR: Polymerase Chain Reaction
- PHIDEG/PHID: Public Health Informatics & Data Exchange Group
- POC: Point of Care Test
- SARS CoV-2: Severe Acute Respiratory Syndrome Coronavirus 2
- sFTP: Secure file transfer protocol
- SNOMED: Systematized Nomenclature of Medicine

XV. Data Dictionary

Data Dictionary for COVID-19 Laboratory Data 56-Column AOE Submission Template

IMPORTANT NOTE: DO NOT INCLUDE COMMAS IN ANY FIELDS AS THIS WILL CAUSE ERRORS IN VALIDATION. All ELR files must be saved and submitted as CSV (MS-DOS) file format type. Files should be submitted using the following naming convention- LegalFacilityName_CLIA_YYYYMMDD(DateofSubmission).CSV. Test files must include the word TEST and should be named like TEST_LegalFacilityName_CLIA_YYYYMMDD(DateFiletoBeAccepted).CSV.

Column	Required Field (Y/N)	Variable Name	Description	Permitted Response Options	Response Descriptions	Notes
A	Y	Reporting_Facility_Name	Name of reporting facility			Enter the legal name of the facility reporting results to DSHS.
B	Y	CLIA_Number	CLIA number of the reporting or sending facility. CLIA = Clinical Laboratory Improvement Amendments number		Valid 10-digit ID required.	Format of CLIA number is ##D##### Example: 12D3456789. https://www.cdc.gov/clia/LabSearch.html https://qcor.cms.gov/index_new.jsp https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/howobtaincliacertificate.pdf
C	Y	Performing_Organization_Name	Name of performing laboratory organization			Enter the name of the performing lab facility actually performing the tests
D	Y	Performing_Organization_Address	Address of performing lab			Do not include any commas in any field, including address fields.
E	Y	Performing_Organization_City	City of performing lab			

Data Dictionary for COVID-19 Laboratory Data 56-Column AOE Submission Template

F	Y	Performing_ Organization_Zip	Zip code of performing lab		ZIP or ZIP+4 (5 or 9 digit) Example: 78756, 787561234, or 78756-1234	Can be 5 or 9 digits Example: 78756, 787561234, or 78756-1234 If performing org zip is outside of the United States, enter 99999.
G	Y	Performing_ Organization_State	State or territory of performing lab		Two-character abbreviation (e.g., TN)	Only the two-letter abbreviations are permitted. Must be uppercase.
H	Y	Device_Identifier	Device Identifier (DI)		-	Use the ID or model number of test kit or instrument used for analysis. You can also call the manufacturer of the test(s) you are using, and they can give you the device ID for the kit/analyzer. If the manufacturer does not yet have the DI for the device you are using, contact SHIELD-LabCodes@fda.hhs.gov for assistance. Unknown is not permissible in this field. https://accessgudid.nlm.nih.gov/
I	Y	Ordered_Test_Name	Name of the ordered test		-	Enter the name of the test ordered by the provider. Ordered test name must be descriptive enough to easily identify the test performed. (Do not enter LOINC code in this field.) Example: COVID 19 Rapid Antigen test. Commas are NOT permitted.

Data Dictionary for COVID-19 Laboratory Data 56-Column AOE Submission Template

J	Y	LOINC_Code	Standard clinical order code (LOINC = Logical Observation Identifier Names and Codes)	Visit https://loinc.org/sars-cov-2-and-covid-19/ for an up-to-date list of valid codes. The only codes we accept are the ones under "SARS CoV 2 lab tests".	The format of COVID LOINC codes is #####-#.	<p>Instructions for selecting correct LOINC code:</p> <ol style="list-style-type: none"> 1) Visit https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html and click the download link next to Mapping tool: LIVD SARS-CoV-2 Test Codes.xlsx. 2) Once downloaded, open the document and click on the LOINC Mapping tab. 3) Search for the manufacturer and model of the instrument/test kit you are using. You can do this by clicking "Find and Select" or using CTRL+F command. 4) Scroll to the column LOINC Code and use the code for the test you are performing. 5) See the CSV guide for more detailed instructions. <p>https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html</p> <p>https://loinc.org/sars-cov-2-and-covid-19/</p>
K	Y	LOINC_Text	Standard clinical order text description	We only accept the "long common name", "short name", or "display name" corresponding to the LOINC code.	-	<p>Instructions for finding LOINC text:</p> <ol style="list-style-type: none"> 1) After the correct LOINC code has been identified, you can visit https://loinc.org/sars-cov-2-and-covid-19/ and click on the code you selected in the previous field. 2) On the popup, you will see the "long common name" at the top. You can also scroll down to "Additional names" and use the "Short" or "Display" name for the LOINC Text. Commas are NOT permitted. Make sure to remove all commas from whichever LOINC text you select. <p>https://loinc.org/sars-cov-2-and-covid-19/</p>

Data Dictionary for COVID-19 Laboratory Data 56-Column AOE Submission Template

L	Y	Result	Either qualitative (results come back as a word like "positive", "negative", etc.) or quantitative (results come back as a number like 0.05) result	Detected Not Detected Positive Negative Indeterminate Invalid	Qualitative tests: Detected, Not Detected, Positive, Negative, Indeterminate, Invalid. Quantitative tests: numerical results like 0.05, etc.	Please use proper spelling and format for qualitative results: +First letter should be uppercase +No abbreviations +Use proper spelling and punctuations
M	Y if Result is Quantitative	Result_Units	Result unit (only if result is quantitative or titer)		You can refer to the package insert or analyzer instructions for more information.	Leave blank IF results are qualitative. Do not enter "N/A", "U", or "Unknown".
N	Y if Result is quantitative or titer	Reference_Range	Only if result is quantitative or titer		You can refer to the package insert or analyzer instructions for more information.	Leave blank IF results are qualitative. Do not enter "N/A", "U", or "Unknown".
O	Y	Date_Test_Performed	Date test was performed	MM/DD/YYYY	Enter date test was performed in the format MM/DD/YYYY	month/day/year Example: 10/10/2020, 5/6/2020 Do not enter a timestamp. Leading zeroes are not necessary.
P	Y	Test_Result_Date	Date test was resulted	MM/DD/YYYY	Enter date test was resulted in the format MM/DD/YYYY	month/day/year Example: 10/10/2020, 5/6/2020 Do not enter a timestamp. Leading zeroes are not necessary.

Data Dictionary for COVID-19 Laboratory Data 56-Column AOE Submission Template

Q	Y	Pt_Fname	Patient first name		-	Commas are NOT permitted.
R	N	Pt_Middle_Initial	Patient middle initial		ONLY first initial of middle name is permitted. Do NOT use punctuations or provide the complete middle name. If unknown, leave blank <u>instead</u> of "U" or "Unknown".	acceptable: A not acceptable: A. not acceptable: Jr
S	Y	Pt_Lname	Patient last name		-	Commas are NOT permitted.
T	Y	Date_of_Birth	Patient date of birth	MM/DD/YYYY	Enter patient's date of birth in the format MM/DD/YYYY	month/date/year Example: 1/1/2020
U	Y	Patient Age	Age of patient	Age in Years (Whole digit- No months, decimals, etc.)	Integer	Value in years, use 0 if age is less than 1 year. Not acceptable: 16 months Not acceptable: 1.5 Acceptable: 3
V	Y	Sex	Patient sex	M F O U A	Male Female Other Unknown Ambiguous	Only the abbreviated values on the left are permitted

Data Dictionary for COVID-19 Laboratory Data 56-Column AOE Submission Template

W	Y	Pt_Race	Patient race	AI A B PI W O U	American Indian Alaska Native Asian Black or African American Native Hawaiian or Other Pacific Islander White Other Unknown	Only the abbreviated values on the left are permitted. Do not enter H for Hispanic in this field.
X	Y	Pt_Ethnicity	Patient ethnicity	H NH U	Hispanic Non-Hispanic Unknown	This is a description of a patient's background - whether they are Hispanic or non-Hispanic. Only the abbreviated values on the left are permitted
Y	Y	Pt_Phone	Patient phone number		###-###-#### 10 digits only. No country codes or extensions.	Do NOT provide extensions or descriptions such as Cell, HOME, WORK, etc. Do not include country codes like +1 or +44. Example: 512-123-4567
Z	Y	Pt_Str	Patient street address		-	Commas are NOT permitted. If the patient lives outside of the United States, enter the Country after address. Example: 123 Green St. - Canada
AA	Y	Pt_City	Patient city		-	If patient lives outside of the United States, enter city name as usual.

Data Dictionary for COVID-19 Laboratory Data 56-Column AOE Submission Template

AB	Y	Pt_ST	Patient state		Two-character abbreviation (e.g., TN)	Only the two-letter abbreviations are permitted. Must be uppercase. If patient lives outside of the United States, enter UN or 99.
AC	Y	Pt_Zip	Patient ZIP		ZIP or ZIP+4 (5 or 9 digit)	Can be 5 or 9 digits Example: 78756, 787561234, or 78756-1234 If patient lives outside of the United States, enter 99999. ZIP Code™ Lookup USPS
AD	Y	Pt_County	Patient County		Only provide the county name: Travis instead of Travis County	If unknown or if patient lives outside of the United States, use Unknown
AE	Y	Accession_Number	Unique filler order number		-	Must be unique number and should not be shared. The assigned accession number should be managed and maintained by your facility since we will reference the accession number when we have questions about a result. If your facility does not use accession numbers, see the CSV guide for instructions on generating your own. Accession number must be unique for each test result, for each patient, on any given day.
AF	Y	Ordering_Facility	Ordering facility/client name		-	Commas are NOT permitted.

Data Dictionary for COVID-19 Laboratory Data 56-Column AOE Submission Template

AG	Y	Ordering_Facility_Address	Ordering facility/client Address		-	Street address of ordering facility. Commas are NOT permitted.
AH	Y	Ordering_Facility_City	Ordering facility/client City		-	
AI	Y	Ordering_Facility_State	Ordering facility/client State		Two-character abbreviation (e.g., TN)	Only the two-letter abbreviations are permitted. Must be uppercase.
AJ	Y	Ordering_Facility_Zip	Ordering facility/client ZIP code		ZIP or ZIP+4 (5 or 9 digit)	Can be 5 or 9 digits Example: 78756, 787561234, or 78756-1234 If patient lives outside of the United States, enter 99999.
AK	Y	Ordering_Provider_Last_Name	Ordering Provider's last name			Commas are NOT permitted. Acceptable: Smith M.D. Not acceptable: Smith, M.D.
AL	Y	Ordering_Provider_First_Name	Ordering provider's first name			Commas are NOT permitted. Acceptable: John Not acceptable: John, Jr.
AM	N	Ordering_Provider_NPI	Ordering provider NPI number		NPI = National Provider Identifier. A 10-digit numerical value.	If unknown, leave blank <u>instead</u> of "Unknown" or "N/A" or 9999999999.
AN	Y	Ordering_Provider_Street_Address	Ordering provider street address			Commas are NOT permitted.
AO	Y	Ordering_Provider_City	Ordering provider city			
AP	Y	Ordering_Provider_State	Ordering provider state		Two-character abbreviation (e.g., TN)	Only the two-letter abbreviations are permitted. Must be uppercase.

Data Dictionary for COVID-19 Laboratory Data 56-Column AOE Submission Template

AQ	Y	Ordering_Provider_Zip	Ordering provider ZIP		ZIP or ZIP+4 (5 or 9 digit)	Can be 5 or 9 digits Example: 78756, 787561234, or 78756-1234 If ordering provider is outside of the United States, enter 99999.
AR	Y	Ordering_Provider_Phone	Ordering provider phone number		###-###-#### 10 digits only. No country codes or extensions.	Do NOT provide extensions or descriptions such as Cell, HOME, WORK, etc. Example: 512-123-4567 Not acceptable: 512-123-4567 ext. 13
AS	Y	Specimen_ID	Unique Id for the specimen		A unique ID given to every specimen taken from a patient or individual.	You are allowed to utilize the same value for accession and specimen ID.
AT	Y	Specimen_Type	Specimen type (e.g., blood/serum, nasopharyngeal, oropharyngeal, sputum, etc.)		Text description of where the specimen originated from the patient. Use the examples on the left for guidance or refer to the package insert of your test kit or device.	Do NOT use numerical SNOMED (Systemic Nomenclature of Medicine) values. You may not use Unknown in this field.
AU	Y	Date_Test_Ordered	Date test was ordered	MM/DD/YYYY	Enter date test was ordered in the format MM/DD/YYYY	Do not include timestamps. month/date/year Example: 1/1/2020

Data Dictionary for COVID-19 Laboratory Data 56-Column AOE Submission Template

AV	Y	Date_Specimen_Collected	The date the specimen was collected	MM/DD/YYYY	Enter date specimen was collected in the format MM/DD/YYYY	Do not include timestamps. month/date/year Example: 1/1/2020
AW	N	Medical_Record_Number	Medical Record Number (MRN)		The medical record number applies only if the person being tested is a patient in your facility. If the person being tested is not a patient, leave this field blank.	The medical record number is organization specific. The number is used by the hospital as a systematic documentation of a patient's medical history and care during each hospital stay.
AX	Y	Employed_in_healthcare	Ask on Order Entry (AOE): Employed in healthcare	Y N U	Yes No Unknown	Is the patient employed in healthcare with direct patient contact ? Use only the abbreviated values on the left
AY	Y	Symptomatic_per_cdc	AOE: Symptomatic per CDC?	Y N U	Yes No Unknown	Was the patient symptomatic per CDC? Official list of COVID-19 symptoms from CDC
AZ	<i>conditional</i>	<i>Date_of_Symptom_Onset</i>	<i>AOE: Date of symptom onset</i>	<i>MM/DD/YYYY</i>	<i>The date that the patient started experiencing symptoms of COVID-19. MM/DD/YYYY</i>	<i>If yes, then date of symptom onset. If patient does not have symptoms, then leave this field blank.</i>
BA	Y	Hospitalized	AOE: Hospitalized (at time of testing, for COVID)?	Y N U	Yes No Unknown	Is the patient being tested currently hospitalized? To determine if the individual is hospitalized for any reason at time of testing. Use only the abbreviated values on the left. When ordered during ER duration, the answer would be N.

Data Dictionary for COVID-19 Laboratory Data 56-Column AOE Submission Template

BB	Y	ICU	AOE: ICU (at time of testing, for COVID)?	Y N U	Yes No Unknown	To determine if the individual is in the ICU for any reason at time of testing. Use only the abbreviated values on the left.
BC	Y	Resident_in_ Congregate_Care	AOE: Resident in a congregate care setting	Y N U	Yes No Unknown	Does patient reside in a congregate setting (including nursing homes, residential care for people with intellectual and developmental disabilities, psychiatric treatment facilities, group homes, board and care homes, homeless shelter, foster care or other setting)? This is at time of exposure where they normally live. Use only the abbreviated values on the left.
BD	Y	Pregnant	AOE: Pregnant?	Y N U	Yes, Pregnant Not Pregnant Unknown	Is the patient pregnant? Current pregnancy status of the patient.

Note: Please refer to the full version of the dictionary for more information.



TEXAS

Health and Human Services

**Texas Department of State
Health Services**

Texas Department of State Health Services
Laboratory and Infectious Disease Services Division
Public Health Informatics and Data Exchange Group
1100 West 49th Street
Austin, Texas 78756
Email: COVID-19ELR@dshs.texas.gov