COVID-19 Lab Reporting Requirements for CSV Submitters

Public Health Informatics and Data Exchange (PHID) Team

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Goal & Outline

Overall Goal:

- Review 56-column template or 60 column (variant) including 7 Ask on Order Entry (AOE) questions

- Improve data quality and timeliness of COVID-19 lab test results in Texas

Outline:

1. Background
   - a. Reporting requirements

2. Review 56 column or 60 column (variant) template with AOE questions

   a. AOE questions

   a. Other changes to previous variables

   b. Lab reporting template and data dictionary review

3. Validation errors and corrections

4. FAQs

5. Resources and tools

6. Questions and comments

ELR Reporting

- Ideal standard: Health Level 7 International (HL7) version 2.5.1
- CSV formatted (MS-DOS) file

**If interested in submitting HL7, please email COVID-19ELR@dshs.texas.gov for instructions regarding the process

Reporting Requirements

Health and Human Services

Texas Department of State Health Services

- State of Texas:
  - Governor's Executive Reporting Order
  - Texas Administrative Code Chapter 97 Subchapter A Control of Communicable Diseases

- Federal:
  - Coronavirus Aid Relief and Economic Security Act (CARES)
    - HHS
    - CDC

Failure to report a notifiable condition is a Class B misdemeanor under the Texas Health and Safety Code §81.049.

Reporting Requirements Fulfilled by Submitting ELRs to NEDSS

Facility Type	Fulfills CARE Federal/CDC Reporting Reqt?	Fulfills DSHS State Reporting Reqt?	Fulfills Local HD or Regional HD Reporting Reqt?	Notes
Hospital lab	Yes	Yes	Check with local jurisdiction to ensure you are in compliance with their local requests.	Clinicians and infection control staff will still need to adhere to local guidance on immediate reporting of COVID-19
Clinic lab	Yes	Yes	Check with local jurisdiction to ensure you are in compliance with their local requests.	Clinicians and infection control staff will still need to adhere to local guidance on immediate reporting of COVID-19
Commercial/ private lab	Yes	Yes	Local health authorities may request a direct feed	
Reference lab	Yes	Yes	Local health authorities may request a direct feed	
Critical Access Care Centers	Yes	Yes	Check with local jurisdiction to ensure you are in compliance with their local requests.	Clinicians and infection control staff will still need to adhere to local guidance on immediate reporting of COVID-19

Reporting by laboratories does not nullify the health care provider's or institution's obligation to report these diseases and conditions, nor does reporting by health care providers nullify the laboratory's obligation to report.
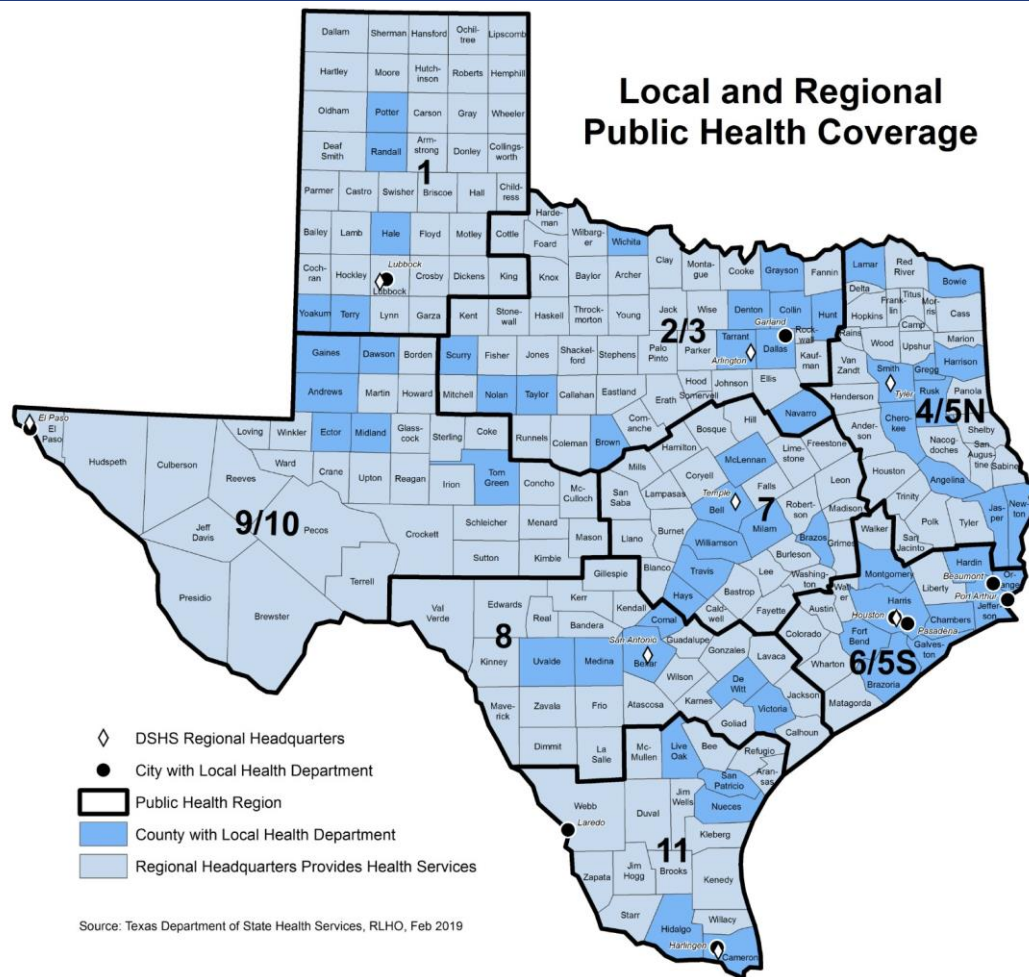
Texas Public Health Jurisdictions

Health and Human Services

Texas Department of State Health Services

Local and Regional Public Health Coverage

Source: Texas Department of State Health Services, RLHO, Feb 2019

Coronavirus Disease 2019 (COVID-19) Local Health Entities

COVID-19 Lab Statistics

- <u>Pre-COVID:</u> around **100 labs** submitting labs to DSHS

- <u>Post-COVID:</u> Over **3,600 facilities** have registered

  - **2,000** of them are currently submitting COVID test results

  - **13 million** COVID test results have been submitted to us

  - Average **120k** per day

Templates
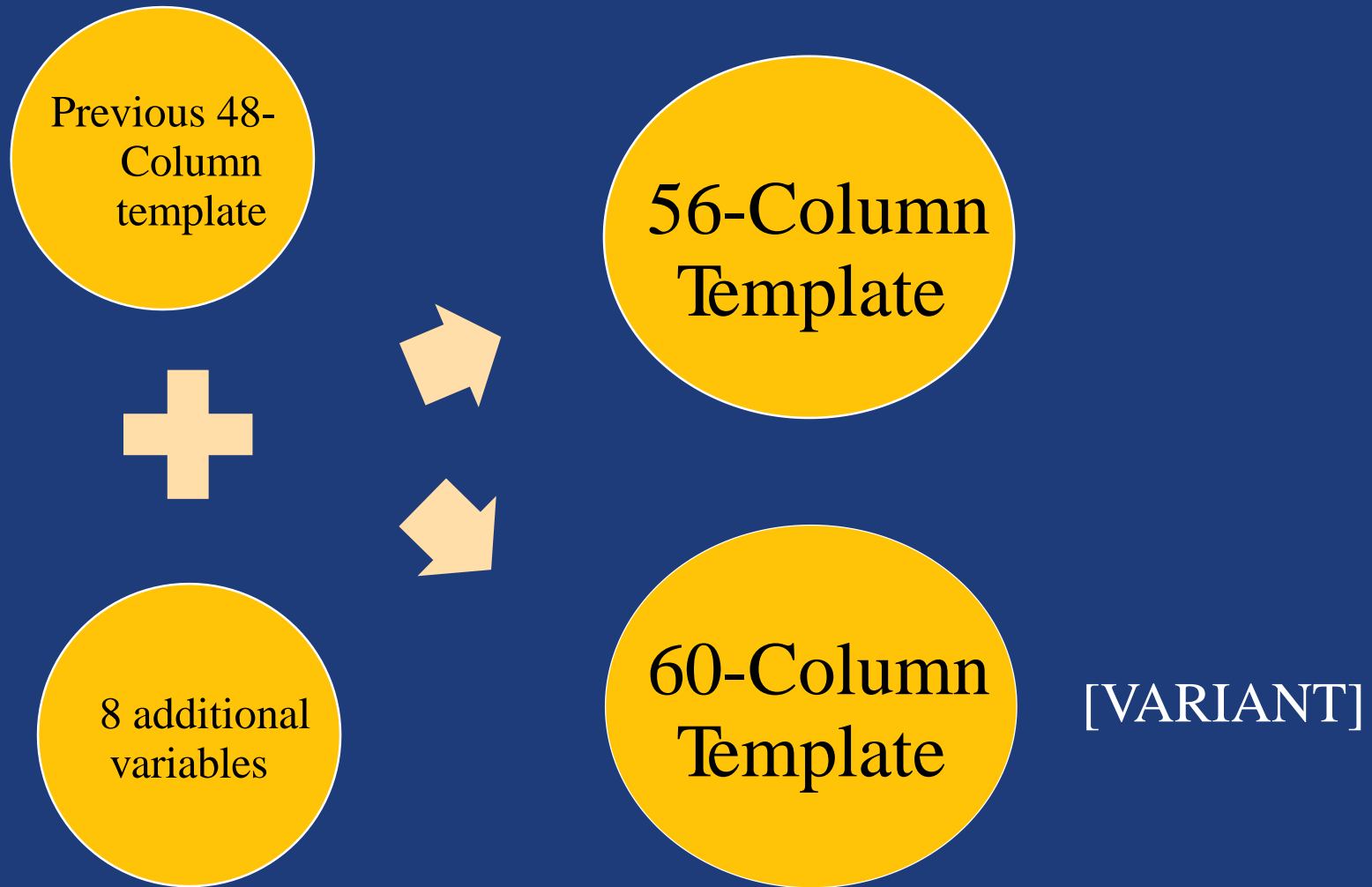
Previous 48-Column template

+

8 additional variables

56-Column Template

60-Column Template

[VARIANT]

Required Fields

A	Reporting_Facility_Name	AC	Pt_Zip
B	CLIA_Number	AD	Pt_County
C	Performing_Organization_Name	AE	Accession_Number
D	Performing_Organization_Address	AF	Ordering_Facility
E	Performing_Organization_City	AG	Ordering_Facility_Address
F	Performing_Organization_Zip	AH	Ordering_Facility_City
G	Performing_Organization_State	AI	Ordering_Facility_State
H	Device_Identifier	AJ	Ordering_Facility_Zip
I	Ordered_Test_Name	AK	Ordering_Provider_Last_Name
J	LOINC_Code	AL	Ordering_Provider_First_Name
K	LOINC_Text	AM	Ordering_Provider_NPI
L	Result	AN	Ordering_Provider_Street_Address
M	Result_Units	AO	Ordering_Provider_City
N	Reference_Range	AP	Ordering_Provider_State
O	Date_Test_Performed	AQ	Ordering_Provider_Zip
P	Test_Result_Date	AR	Ordering_Provider_Phone
Q	Pt_Fname	AS	Specimen_ID
R	Pt_Middle_Initial	AT	Specimen_Type
S	Pt_Lname	AU	Date_Test_Ordered
T	Date_of_Birth	AV	Date_Specimen_Collected
U	Patient Age	AW	Medical_Record_Number
V	Sex	AX	Employed_in_healthcare
W	Pt_Race	AY	Symptomatic_per_cdc
X	Pt_Ethnicity	*AZ*	*Date_of_Symptom_Onset*
Y	Pt_Phone	BA	Hospitalized
Z	Pt_Str	BB	ICU
AA	Pt_City	BC	Resident_in_Congregate_Care
AB	Pt_ST	BD	Pregnant

Additional Questions

Health and Human Services

Texas Department of State Health Services

1. Medical Record Number
- Optional field; leave BLANK if not available

2. Employed in Healthcare?
- The patient being tested for COVID-19 is in direct contact with patients in a healthcare setting. (Ex: any healthcare provider, physician, physician assistant, dentist, nurse, medical assistant, etc.)

3. Symptomatic per CDC?
- The patient being tested for COVID-19 has experienced at least one or more of the symptoms directly related to the COVID-19 symptoms indicated by CDC.

4. Date of Symptom Onset?
- The date of symptom onset indicates when the patient first started experiencing symptoms of COVID-19.

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Additional Questions

5. Hospitalized?

- The patient being tested for COVID-19 is currently admitted in the hospital. (Ex: inpatient) This does not include outpatients who have visited the emergency room and were released.

6. ICU?

- The patient being tested for COVID-19 is currently admitted into an intensive care unit (ICU).

7. Resident in Congregate Care Setting?

- The patient being tested for COVID-19 resides, meets or gathers in close proximity with other individuals for either a limited or extended period of time (Ex: nursing home, assisted living, residential care for people with intellectual and developmental disabilities, psychiatric treatment facilities, homeless shelters, group homes, foster care, etc.)

8. Pregnant?

- The patient being tested for COVID-19 is actively pregnant or clinically tested positive for pregnancy.

DATA DICTIONARY

- Each template data element explained

- Column G "**Permitted Response Options**" details acceptable values for fields

- Alternative entries for UNKNOWN values

- Links to LOINC Codes look up provided

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LOOKING UP LOINC CODES

- In the LIVD section click download the Mapping tool Excel file

- Open the excel file and go to the Mapping tab of the file

- In the tab use the search command (CTRL+ F) to find your facility's test name

- Retrieve the LOINC Code and LOINC text name for data entry

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Accession No.

- Even if the test and collection dates are the same, **accession numbers must be unique** and can't be duplicated in the same file.

  o Even if the same individual was tested twice, on the same day, the accession number must be unique

- For a panel test, the accession numbers can be the same, if the ordered test name, LOINC code, and LOINC text are different

- **Cannot have unknown values nor N/A**

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Device ID

- Visit <u>ACCESS GUDID</u> and search for the device. Use the **primary DI number**
  - o Make sure that the value is properly formatted and value is preserved when reported
- Alternatively, you may use the Manufacturer + Model name for a valid Device_Identifier.

Submitting Corrected/Updated Files

Health and Human Services

Texas Department of State Health Services

Only include invalid records in the corrected/updated file

Do NOT include good records that were successfully processed
(will delay overall ELR processing)

File name should include 'Corrected' in file title, for example:

Corrected_LabABC_45D1234567_20220413.csv

Common Errors to Avoid

Commas

↓

Do not include commas in any columns

| Inclusion of commas will cause data shifting | Please remove commas from address fields |

Common Errors to Avoid (cont.)

File name	• Not properly formatted • Should be *Facilityname_CLIA_ID_YYYYMMDD.CSV*
File type	• Not saved as a CSV (MS-DOS) file format
Missing columns	• All 56-columns or 60 columns (variant) must be included
Inserting additional columns	• File should only include 56-columns or 60 columns (variant) • Do NOT add additional columns
Column order	• Do not change column order

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Common Errors to Avoid (cont.2)

Blanks
- Address and Phone fields cannot be blank
- If address is unknown, enter Unknown
- If Phone is unknown, enter 999-999-9999

Unknown
- Be sure to adhere to the Permitted Values column in Data Dictionary and notes to determine how to capture unknown values

Dates
- MM/DD/YYYY
- Should not include a time stamp

Phone numbers
- Must be in ###-###-#### format
- Do not include extensions or phone types (e.g. home, cell)
- Patient phone is required for expedited follow-up

FAQ

- **My facility is already submitting COVID 19 results to the local health department. Do I still have to submit to DSHS?**

Yes, the State of Texas is a dual reporting state. Facilities must follow both local *and* state mandates for reporting.

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

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.

- **My facility is already submitting COVID 19 results to the Centers for Disease Control and Prevention (CDC)'s Simple Report. Do I still have to submit to DSHS?**

If you are reporting your results via SimpleReport, you do not need to report to DSHS, as USDS will report your results to the state

- **How do I begin the process of submitting COVID 19 results to the state?**

The first step is to register your site(s) <u>here</u>. After registration, we will send you the necessary documents and instructions for reporting your results to DSHS.

- **I have registered my facility/ies; how do we proceed?**

Texas DSHS will reach out to you with instructions for next steps after receiving your registration form and confirming that your CLIA is valid.

- **Can I fax email, mail, or phone you my facility's results?**

Per the Federal CARES Act, sites are required to report results submitting HL7 or CSV files via sFTP.

- **Can I email DSHS my facility's results in a spreadsheet?**

E mail is not a secure method for protected health information (PHI) transfer or patient identifying information (PII), Texas DSHS will not accept reports via this method.

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Resources and Tools

Centers for Disease Prevention and Control (CDC)
https://www.cdc.gov/coronavirus/2019 ncov/index.html

- Comprehensive COVID 19 information

Coronavirus Aid Relief Economic Security (CARES) Act
https://home.treasury.gov/policy issues/cares

- Information on the CARES Act

Food and Drug Administration (FDA)
https://www.fda.gov/medical devices/coronavirus disease 2019 covid 19 emergency use authorizations medical devices/vitro diagnostics euas

- Lists all the FDA authorized tests for COVID 19

LOINC
https://www.cdc.gov/csels/dls/sars cov 2 livd codes.html https://loinc.org/sars cov 2 and covid 19/

- Help facilities 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

- Discusses SNOMED related content specific to COVID 19

Texas DSHS Lab Submitters Resource Page
https://dshs.texas.gov/coronavirus/lab reporting.aspx

- Resource link for facilities submitting lab report data to DSHS

U.S. National Library of Medicine
https://accessgudid.nlm.nih.gov/

- Help facilities determine the Device ID of the test

Questions

For any questions or concerns with lab reporting, please contact:

COVID-19ELR@dshs.texas.gov