TEXAS
Health and Human Services

Texas Department of State Health Services

Covid-19 Updated Lab Reporting Requirements for CSV Submitters

Public Health Informatics and Data Exchange (PHID) Team

December 11, 2020

Goal & Outline

Overall Goal:

- Review new 56-column template including 7 required 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 new 56-column template with AOE questions
   a. AOE questions
   b. Other changes to previous variables
   c. Lab reporting template and data dictionary review

3. Validation errors and corrections

4. FAQs

5. Resources and tools

6. Questions and comments

ELR Reporting Options

- Ideal standard: Health Level 7 International (HL7) version 2.5.1
- Other option: CSV formatted (MS-DOS) file until able to achieve HL7

**If interested in switching to HL7, please email COVID-19ELR@dshs.texas.gov and we will go over the process

Reporting Requirements

- 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.

What Reporting Requirements Are 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.

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Texas Public Health Jurisdictions
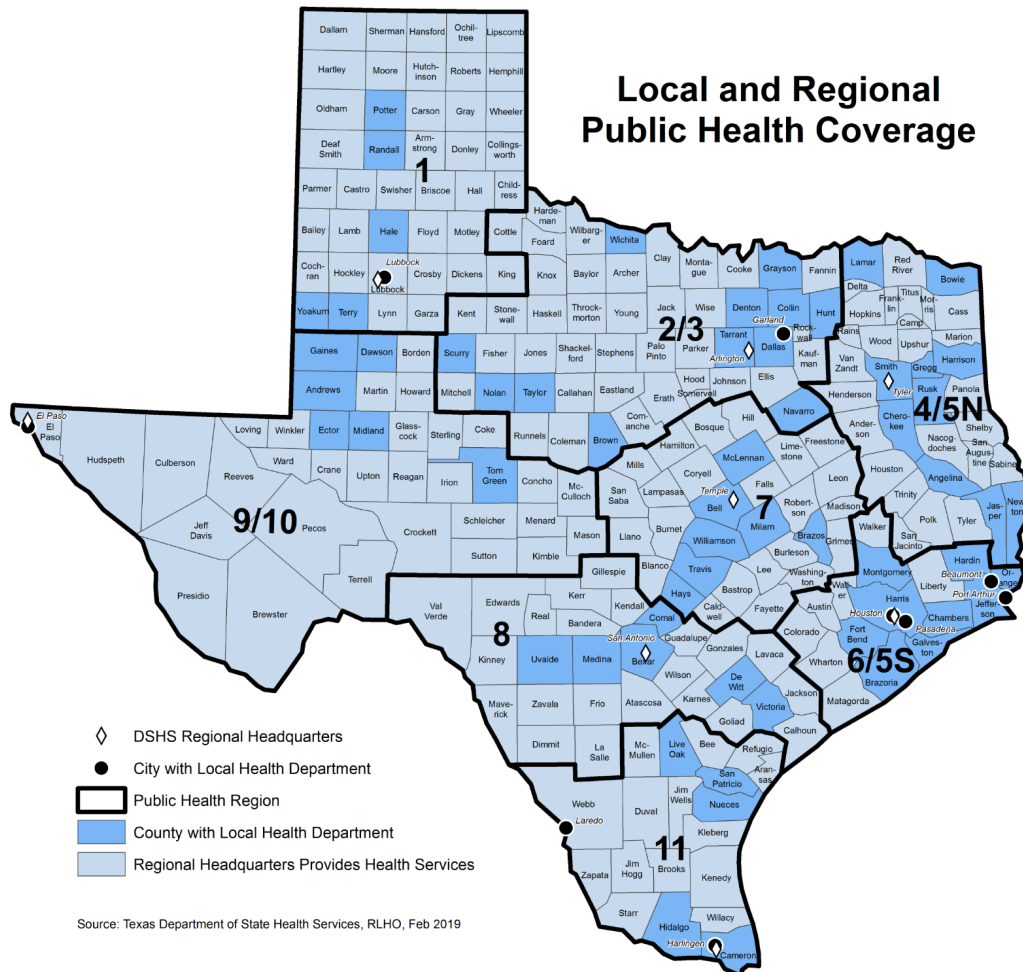
Local and Regional Public Health Coverage

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

https://www.dshs.texas.gov/regions/Coronavirus-(2019-nCoV)-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

New 56-Column Template

Previous 48-Column template

+

8 new variables

→

New 56-Column Template
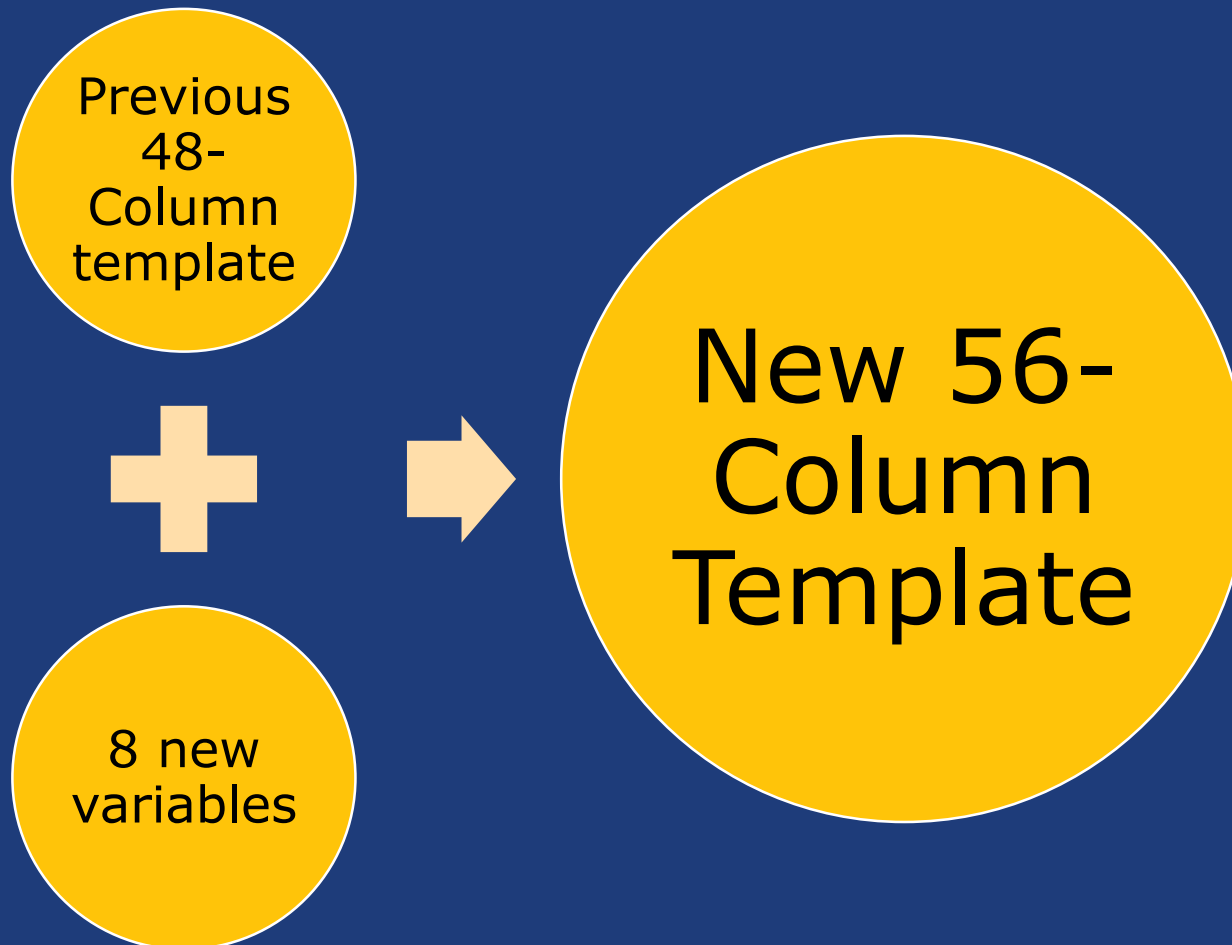
List of Required Fields (56 Variables)

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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

New Questions

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.

New 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.

- Please do NOT include the OPTIONAL AOE questions
  - Additional columns/questions will cause errors
- Only <mark>REQUIRED</mark> AOE questions need to be included
- https://www.hhs.gov/sites/default/files/hhs-guidance-implementation.pdf

DATA DICTIONARY

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- Details for each required data element explained

- New field: Permitted Response Options= Acceptable values for each field described

- Alternative entries for UNKNOWN values

- Links to LOINC Codes look up provided within

New Template Implementation Date

New 56-Column should be implemented in ELR submission files to DSHS by:

January 15, 2021

LOOKING UP LOINC CODES

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

- 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 test name

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

Accession No.

- If the test and collections dates are the same, **accession numbers must be unique** and can't be duplicated in the same file.
  - 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, as long as the ordered test name, LOINC code, and LOINC text are different

- **Can't have unknown values or N/A**

Device ID

- Visit https://accessgudid.nlm.nih.gov/ and search for the device. Use the **primary DI number**
  - Make sure that the value is formatted properly and the value is preserved when being reported
- If you are unable to locate your device, use the model of the device as the device identifier

Submitting Corrected/Updated Files

Only include errored/problematic records in corrected/updated file

Do NOT include good records that were previously successfully processed (this slows overall ELR processing)

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

Corrected_LabABC_45D1234567_20201206.csv

Common Errors to Avoid

Commas

Do not include commas in any columns

Inclusion of commas will cause shifting of data	Be sure to remove commas from address fields

Common Errors to Avoid (cont.)

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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 must be included
Inserting additional columns	• File should only include 56-columns • Do NOT include any other columns
Column order	• Do not change column order

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
Unknowns	• 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

FAQs

1. Do all COVID-19 results for Texas residents need to be reported?

Yes. ALL positive, negative and indeterminate results must be reported.

2. We are unable to report results through our EHR, can we fax or email results instead?

No. If your facility is unable to send results via your EHR (HL7), you may send them via sFTP client using the template provided by us, once we receive your registrations. DO NOT fax or email us any patient results.

3. Do we need to report COVID-19 antibody testing to you as well?

Yes. Positive, negative and indeterminate antibody results should be reported to the state.

4. How often should I submit files?

Files should be submitted daily (one large aggregate file for those using the CSV template), in order to reflect accurate data.

Links to Resources and Tools

1. New DSHS resource webpage for lab submitters: https://www.dshs.texas.gov/coronavirus/submitters.aspx
   a. CSV Reporting Guidelines
   b. New template and data dictionary
   c. Tips/handouts
2. CARES Act: https://home.treasury.gov/policy-issues/cares
3. **LOINC** https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html https://loinc.org/sars-cov-2-and-covid-19/
4. **SNOMED** https://confluence.ihtsdotools.org/display/snomed/SNOMED%2BCT%2BCOVID-19%2BRelated%2BContent
5. **U.S. National Library of Medicine** https://accessgudid.nlm.nih.gov/

Contact Info

Health and Human Services

Texas Department of State Health Services

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

COVID-19ELR@dshs.texas.gov