



TEXAS

Health and Human Services



Texas Department of State
Health Services

COVID-19 Electronic Lab Reporting Requirements

**Public Health Informatics & Data (PHID) Unit,
Laboratory and Infectious Disease Services (LIDS) Division,
Texas Department of State Health Services**

September 2021

Outline



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II. Laboratory reporting rules overview

- a. COVID-19 laboratory reporting rules
- b. Non-COVID-19 lab reporting rules

III. Legislative updates

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Objectives



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- Understand COVID-19 lab reporting rules
- Be able to denote differences between routine infectious disease lab reporting vs COVID-19 (SARS-CoV-2) lab reporting
- Review latest legislative updates concerning lab reporting
- Identify the program responsible for onboarding lab submitter facilities to NEDSS

Notifiable Conditions



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Texas Notifiable Conditions - 2021

Report all Confirmed and Suspected cases
24/7 Number for Immediately Reportable – 1-800-705-8868

Unless noted by*, report to your local or regional health department using number above or find contact information at <http://www.dshs.texas.gov/idcu/investigation/conditions/contacts/>

A – L	When to Report	L – Y	When to Report
*Acquired immune deficiency syndrome (AIDS) ¹	Within 1 week	Legionellosis ²	Within 1 week
Amebic meningitis and encephalitis ²	Within 1 week	Leishmaniasis ²	Within 1 week
Anaplasmosis ²	Within 1 week	Listeriosis ^{2,3}	Within 1 week
Anthrax ^{2,3,25}	Call Immediately	Lyme disease ²	Within 1 week
Arboviral infections ^{2,4,5}	Within 1 week	Malaria ²	Within 1 week
*Asbestosis ⁶	Within 1 week	Measles (rubella) ²	Call Immediately
Ascariasis ²	Within 1 week	Meningococcal infection, invasive (Neisseria meningitidis) ^{2,3}	Call Immediately
Babesiosis ^{2,5}	Within 1 week	Mumps ²	Within 1 work day
Botulism (adult and infant) ^{2,3,7,25}	Call Immediately ²	Paragonimiasis ²	Within 1 week
Brucellosis ^{2,3,25}	Within 1 work day	Pertussis ²	Within 1 work day
Campylobacteriosis ²	Within 1 week	*Pesticide poisoning, acute occupational ⁸	Within 1 week
*Cancer ⁹	See rules ⁹	Plague (Yersinia pestis) ^{2,3,25}	Call Immediately
Candida auris ^{2,3,10}	Within 1 work day	Polio myelitis, acute paralytic ²	Call Immediately
Carbapenem-resistant Enterobacteriaceae (CRE) ^{2,11}	Within 1 work day	Poliovirus infection, non-paralytic ²	Within 1 work day
Chagas disease ^{2,5}	Within 1 week	Prion disease such as Creutzfeldt-Jakob disease (CJD) ^{2,12}	Within 1 week
*Chancroid ¹	Within 1 week	Q fever ²	Within 1 work day
*Chickenpox (varicella) ¹³	Within 1 week	Rabies, human ²	Call Immediately
*Chlamydia trachomatis infection ¹	Within 1 week	Rubella (including congenital) ²	Within 1 work day
*Contaminated sharps injury ¹⁴	Within 1 month	Salmonellosis, including typhoid fever ^{2,3}	Within 1 week
*Controlled substance overdose ¹⁵	Report Immediately	Shiga toxin-producing <i>Escherichia coli</i> ^{2,3}	Within 1 week
Coronavirus, novel ^{2,16}	Call Immediately	Shigellosis ²	Within 1 week
Cryptosporidiosis ²	Within 1 week	*Silicosis ¹⁷	Within 1 week
Cyclosporiasis ²	Within 1 week	Smallpox ^{2,25}	Call Immediately
Cysticercosis ²	Within 1 week	*Spinal cord injury ¹⁸	Within 10 work days
Diphtheria ^{2,3}	Call Immediately	Spotted fever rickettsiosis ²	Within 1 week
*Drowning/near drowning ¹⁸	Within 10 work days	Streptococcal disease (S.pneumo. ^{2,3}), invasive	Within 1 week
Echinococcosis ²	Within 1 week	*Syphilis – primary and secondary stages ^{1,19}	Within 1 work day
Ehrlichiosis ²	Within 1 week	*Syphilis – all other stages ^{1,19}	Within 1 week
Fascioliasis ²	Within 1 week	<i>Taenia solium</i> and undifferentiated <i>Taenia</i> infection ²	Within 1 week
*Gonorrhea ¹	Within 1 week	Tetanus ²	Within 1 week
<i>Haemophilus influenzae</i> , invasive ^{2,3}	Within 1 week	Tick-borne relapsing fever (TBRF) ²	Within 1 week
Hansen's disease (leprosy) ²⁰	Within 1 week	*Traumatic brain injury ¹⁸	Within 10 work days
Hantavirus infection ²	Within 1 week	Trichinosis ²	Within 1 week
Hemolytic uremic syndrome (HUS) ²	Within 1 week	Trichuriasis ²	Within 1 week
Hepatitis A ²	Within 1 work day	Tuberculosis (Mycobacterium tuberculosis complex) ^{3,21}	Within 1 work day
Hepatitis B, C, and E (acute) ²	Within 1 week	Tuberculosis infection ²²	Within 1 week
Hepatitis B infection identified prenatally or at delivery (mother) ²	Within 1 week	Tularemia ^{2,3,25}	Call Immediately
Hepatitis B, perinatal (HBsAg+ < 24 months old) (child) ²	Within 1 work day	Typhus ²	Within 1 week
Hookworm (ancylostomiasis) ²	Within 1 week	Vancomycin-intermediate Staph aureus (VISA) ^{2,3}	Call Immediately
*Human immunodeficiency virus (HIV), acute infection ^{1,23}	Within 1 work day	Vancomycin-resistant Staph aureus (VRSA) ^{2,3}	Call Immediately
*Human immunodeficiency virus (HIV), non-acute infection ^{1,23}	Within 1 week	Vibrio infection, including cholera ^{2,3}	Within 1 work day
Influenza-associated pediatric mortality ²	Within 1 work day	Viral hemorrhagic fever (including Ebola) ^{2,25}	Call Immediately
Influenza, novel ²	Call immediately	Yellow fever ²	Call Immediately
*Lead, child blood, any level & adult blood, any level ²⁴	Call/Fax Immediately	Yersiniosis ²	Within 1 week

In addition to specified reportable conditions, any outbreak, exotic disease, or unusual group expression of disease that may be of public health concern should be reported by the most expeditious means available. This includes any case of a select agent²⁵
 See select agent list at <https://www.selectagents.gov/selectagentsandtoxinslist.html>

*See condition-specific footnotes for reporting contact information

ES9-11364 (Rev. 1/21/21) Expires 1/31/22 – Go to <http://www.dshs.texas.gov/idcu/investigation/conditions/> or call your local or regional health department for updates.

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.

COVID-19 (SARS-CoV-2) Lab Reporting Requirements in Texas



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1. State of Texas Requirements:

- a. Governor Abbot's Executive Order to report COVID-19 lab test results in Texas
- b. Several Texas Health & Safety Codes Chapters 81 Prevention, Control, & Reports of Diseases
- c. Texas Administrative Code Chapter 97 Subchapter A Control of Communicable Diseases

2. Federal Requirements:

- a. Coronavirus Aid Relief and Economic Security Act (CARES)
 - i. HHS
 - ii. CDC

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

Governor's Executive Order



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Every public or private entity that is utilizing an FDA-approved test, including an emergency authorized test, for human diagnostic purposes of COVID-19, shall submit to DSHS, as well as to the local health department, daily reports of all test results, both positive and negative. DSHS shall promptly share this information with CDC.

- Original order issued March 2020
- Renewed July 2021
- Requires direct reporting of lab results to **BOTH**
 1. DSHS Central Office-Austin AND
 2. Local Health Department/PHR

Texas Administrative Code §97.3



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(a)(5) Laboratory reports:

Reports from laboratories shall include

- patient name,
- identification number,
- address,
- telephone number,
- age,
- date of birth,
- sex,
- race and ethnicity;
- specimen submitter name, address, and phone number;
- specimen type;
- date specimen collected;
- disease test and test result;
- normal test range;
- date of test report; and
- physician or practitioner name and telephone number.

Federal CARES Act



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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 SARSCoV-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).

Recently Passed Texas State Legislation



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- Senate Bill 969
- Amends Texas Healthy & Safety Code 81.044 (a) by removing the ability of lab facilities to report in writing or by telephone during public health disasters

SECTION 2. Section 81.044(a), Health and Safety Code, is amended to read as follows:

(a) The executive commissioner shall prescribe the form and method of reporting under this chapter [~~, which may be in writing, by telephone,~~] by electronic data transmission, through a health information exchange as defined by Section 182.151 if requested and authorized by the person required to report, or by other means.

Recently Passed Texas State Legislation (cont.)



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- Senate Bill 969
- Adds Texas Health & Safety Code 81.0495, creating a civil penalty for health care facilities failing to submit reports as required

Sec. 81.0495. FAILURE TO REPORT; CIVIL PENALTY. (a) The department may impose a civil penalty of not more than \$1,000 on a health care facility for each failure to submit a report required under this subchapter.

(b) The attorney general may bring an action to recover a civil penalty imposed under Subsection (a).

Differences



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Non-COVID-19 (Most other notifiable conditions) Lab Reporting	COVID-19 Lab Reporting
<p>Typically, labs are submitted to the local health department to meet reporting requirements</p>	<p>Labs are required to be reported to BOTH the state (DSHS-Central Office) AND to LHD/PHR (may waive this if lab is submitting via NEDSS ELR feed)</p>
<p>Normally, lab submitters include hospitals, commercial labs, or public health labs</p>	<p>Lab submitters include traditional labs, hospitals, commercial labs, and public health. It also includes many non-traditional labs including schools, day cares, work settings, and any facility where FDA-approved COVID lab testing took place</p>
<ul style="list-style-type: none">Laboratories required to submit to NEDSS via Health Level 7 (HL7) International format	<ul style="list-style-type: none">HL7 reporting preferred, butA new alternative method of reporting to DSHS available via an approved comma separated value (CSV) formatted file
<p>Onboarding process may take weeks to months given the complexities of HL7</p>	<p>Depending on lab facility, may be completed in as little as one day</p>
<p>Typically, only positive lab results are required to be reported</p>	<p>Governor's Executive Order and CARES Act require reporting of ALL lab results (positive, negative, and indeterminate) daily</p>

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

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COVID-19 ELRs



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- Unless a facility is brand new, traditional lab submitters (e.g., hospitals, commercial labs) should already be onboarded with NEDSS
 - Before manually entering any labs, please search NEDSS to verify that ELR is not already captured in the system
- Paper lab submitters who have the ability to submit electronically should be referred to PHID team for follow-up to discuss CSV option for reporting

Public Health Informatics & Data Unit



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PHID Unit
encompasses
subject
matter
expertise in
the following
areas:

- Electronic Laboratory Reporting and Electronic Case Reporting Onboarding and Validations,
- NEDSS Helpdesk and Customer Support/Communications,
- Data Analytics and Quality Assurance,
- Data Integration and Interoperability,
- National Electronic Disease Surveillance System (NEDSS)
Base System (NBS) System Design and Implementation

PHID Contact Info



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NEDSS users and other
general questions
related to NEDSS

- For NEDSS related questions, please contact NEDSS@dshs.texas.gov.

Laboratory
submitters/ELR
submitters (Onboarded
and Testing)

- For questions on COVID-19 lab submitter registration, onboarding, resubmitting ELR corrections, and technical assistance please send email to COVID-19ELR@dshs.texas.gov.

Laboratory
submitters/ELR
submitters (Onboarded
and Testing)

- For general informatics or Health Level 7 (HL7) related questions, please contact IDI@dshs.texas.gov.

Contact Info



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For questions on

- COVID-19 case investigations or other epidemiology and surveillance related questions
 - EAIDU-Coronavirus@dshs.texas.gov
- NEDSS
 - NEDSS@dshs.texas.gov