KENTUCKY CABINET FOR HEALTH AND FAMILY SERVICES

TEAM KENTUCKY

Kentucky Public Health
Prevent. Promote. Protect.

COVID-19 Laboratory and Clinical Case Reporting
Frequently Asked Questions
January 25, 2022

1. How does COVID-19 reporting occur in Kentucky?

For most reportable diseases in Kentucky, both a laboratory result and a separate clinical case report are required to be reported to public health. COVID-19 falls into this category, but with certain exceptions.

In the following questions, please note instances where we refer to laboratory result reporting versus clinical case reports.

2. How does the 902 KAR 2:020 regulation change on 1/13/2022 affect the COVID-19 tests that must be reported by laboratories?

Positive and negative SARS-CoV-2 (i.e., COVID-19) antigen and PCR (NAA) tests are still required to be reported by laboratories.

Positive anti-N (nucleocapsid) antibody results are still required to be reported, but positive anti-S (spike protein) antibodies and all negative antibody results are no longer required.

Molecular sequencing results for SARS-CoV-2, previously required by inference, are now explicitly required.

3. How does the 902 KAR 2:020 regulation change on 1/13/2022 affect COVID-19 reporting by healthcare professionals?

Outpatient case reporting obligations have been reduced.

Healthcare professionals are no longer required to submit a COVID-19 case report form (electronic or fax) for patients diagnosed in the outpatient setting *when a separate laboratory report of a COVID-19 (SARS-CoV-2) test result is submitted for the patient*.

Healthcare professionals are still required to submit a COVID-19 case report for all patients they evaluate and diagnose with COVID-19 for whom a separate laboratory report is not submitted either by them or a dedicated laboratory, and for patients admitted to an inpatient treatment facility, and for COVID-19-associated deaths.

4. Do negative results of point-of-care COVID-19 tests need to be reported?

Laboratories are required to report all COVID-19 test results, including point of care tests, as described in #2 above.

If a separate laboratory report of the test result is not concurrently submitted for the patient, healthcare professionals providing point of care COVID-19 testing are required to fulfill the laboratory reporting as described in #2 above.

5. What options are available to fulfill the healthcare professional case reporting requirement?

Healthcare professionals should complete one of the following:

- *Preferred:* Combined EPID 200/CDC PUI case report form for COVID-19. Form should be submitted electronically through the Kentucky Health Information Exchange (KHIE) or faxed to the local health department in the jurisdiction where the patient resides; OR
- CDC COVID-19 PUI Case Report Form along with required patient contact information (e.g., patient face sheet). Both should be faxed to the local health department in the jurisdiction where the patient resides

6. How do I know if I incur the laboratory reporting requirement?

The Commonwealth of Kentucky requires that all laboratories and facilities performing testing for COVID-19, including rapid testing, report COVID-19 test results as described in #2 above.

These reporting requirements do *not* apply to facilities that are sending specimens to external laboratories nor do they apply to clinicians who prescribe tests where the specimen is sent to a laboratory. The laboratory that determines the result is the facility required to report the test result.

Healthcare professionals providing CLIA-waived COVID-19 testing services are required to report the test results in fulfillment of the laboratory reporting requirement if a dedicated laboratory does not report the results on its behalf.

7. Is a COVID-19 case report still required for residents of a long-term care facility?

Long-term care facility and healthcare professional case reports for residents with COVID-19 in long-term care facilities is not necessary *when a separate laboratory report of the test result is concurrently submitted for the patient*.

Long-term care facilities, as well as other residential treatment facilities, are required to report outbreaks of COVID-19 to the local health department and/or KDPH. In the regulation, “outbreak” is

defined as two or more cases, including healthcare associated infections (HAIs), that are epidemiologically linked or connected by person, place, or time. Most cases in congregate settings do not occur in isolation and would be required to be reported to the local health department.

Individual case reports are not required during COVID-19 outbreaks, but a line list of individual cases should be provided to the health department.

8. Are results from at-home COVID-19 tests reportable?

COVID-19 test results involving use of an at-home test kit for which specimen collection is not professionally performed by or monitored by a trained healthcare provider are not reportable.

If the at-home test is professionally observed or "proctored" by a healthcare provider to assure proper specimen collection, the lab test results should be submitted by the lab that results the test or by the healthcare provider professionally performing or validating the test if the at-home test specimen (or result) is not sent to a lab for processing.

9. How are laboratory results reported?

Facilities conducting COVID-19 testing among Kentucky residents must report all test results electronically through the Kentucky Health Information Exchange (KHIE), which serves as the standard route used by KDPH to collect lab reports.

Testing facilities not yet submitting results via KHIE should begin the KHIE onboarding process. KHIE now provides two onboarding options, including registration for an online portal. With this new option, facilities or individual providers can directly enter test results into the online portal; the data are securely submitted electronically via KHIE to public health (both KDPH and local health departments).

- Facilities should communicate with KHIE at KHIElabs@ky.gov to discuss onboarding options and determine a timeframe for onboarding.
    - Option 1: If fully onboarding to KHIE electronically, once a facility has established connectivity with KHIE, facilities are required to be fully onboarded and functional in KHIE within 30 business days.
    - Option 2: Facilities can directly request access to the online portal by following the steps on the Direct Data Entry webpage: https://khie.ky.gov/COVID-19/Pages/Direct-Lab.aspx
- Once onboarded through either option, labs must continue to work with KDPH and KHIE to ensure that appropriate data is being reported in a timely manner, that any internal data problems, as determined by KDPH/KHIE, are addressed by the facility, and that data elements are added, removed, or revised as data requirements evolve.

10. What data elements are required for laboratory test reporting?

In accordance with 902 KAR 2:020, the following data elements are required to be reported as part of all COVID-19 laboratory test submissions:

REQUIRED ELEMENTS BY CATEGORY	
Patient Information & Demographics	
1)	Name (first name, middle initial, last name, captured separately)
2)	Date of birth (MM/DD/YYYY)
3)	Gender
4)	Race
5)	Ethnicity
6)	Patient address incl. zip code and county of residence
7)	Patient telephone number
Testing & Case Information	
8)	First test (Y/N/U)
9)	Test ordered (use harmonized LOINC codes provided by CDC)
10)	Name of testing product
11)	Device identifier
12)	Date specimen collected (MM/DD/YYYY)
13)	Test result (use appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC, or equivalently detailed alternative codes)
14)	Test result date (MM/DD/YYYY)
15)	Accession #/Specimen ID
16)	Specimen Source (use appropriate LOINC, SNOMED-CT, or SPM4 codes, or equivalently detailed alternative codes)
Ordering Provider / Performing Facility Information	
17)	Date test ordered (MM/DD/YYYY)
18)	Ordering provider name
19)	Ordering provider NPI
20)	Ordering provider address incl. zip code
21)	Ordering provider telephone number
22)	Performing facility name and/or CLIA number, if known
23)	Performing facility zip code
24)	Performing facility telephone number

11. Can someone help me with additional questions?

To begin onboarding to KHIE and learn more about the available electronic reporting measures (via the following current available services: Web Services, VPN, HL7/flat file through SFTP), please reach out to KHIElabs@ky.gov or 502-564-7940.

For general inquires or questions regarding laboratory reporting, please contact covidKYlab@KY.gov.

For general inquires or questions regarding healthcare professional reporting, please contact DPH.COVID19PROVIDERS@ky.gov.