August 5, 2020

Dear Laboratory Operator,

As clinical and commercial laboratories continue to perform testing for COVID-19 (SARS-CoV-2), the Kentucky Department for Public Health (KDPH) is **issuing updated test reporting guidance as directed by Governor Beshear** to more effectively manage and coordinate the statewide pandemic response.

The **Commonwealth of Kentucky now requires** that all laboratories and facilities offering testing for COVID-19, including rapid testing, among residents of the Commonwealth follow the newly issued guidelines outlined in this mandate, effective immediately.

- LABORATORIES CONDUCTING COVID-19 TESTING AMONG KENTUCKY RESIDENTS MUST -
Report all test results (all positive and non-positive) electronically through the Kentucky Health Information Exchange (KHIE), which serves as the standard route used by KDPH to collect lab reports.

- LABORATORIES ALREADY SUBMITTING LABORATORY RESULTS VIA KHIE MUST -
For **all positive and non-positive** COVID-19 lab reports:

- **Immediately notify** the provider or ordering facility to inform them of the result.
- **Submit electronic laboratory reports (ELR) to KDPH through KHIE.** Reporting of COVID-19 cases to KDPH is required <u>within 24 hours</u> of positive results by statute (902 KAR 2:020).
- **Validate that** all required data elements listed in the "Updated Data Element Requirements" section of this notice are being included in lab reports.
- **Before submitting lab reports with these new variables,** please contact KHIE and coordinate the data submission in order to assure that the full lab data submission process, including new data elements, is working properly and validated.

Onboarded labs shall 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.

- LABORATORIES NOT YET SUBMITTING LABORATORY RESULTS VIA KHIE MUST -
- **Immediately notify** the provider or ordering facility to inform them of the result.

- **Begin the KHIE onboarding process within a time frame determined by KHIE and the facility,** if not already begun. **Once a laboratory has established connectivity with KHIE, it shall be required to be fully onboarded and functional in KHIE within 30 business days.** Receiving ELRs through KHIE will minimize the burden of manual reporting and aid KDPH's critical efforts to quickly identify, track, and slow the transmission of COVID-19. (Please contact the KHIE contact listed below to begin the onboarding process and learn more about how KHIE works closely with labs to provide resources and support throughout the process.)

- **Submit required testing data to KDPH or Local Health Departments until ability to submit ELRs via KHIE is achieved.** By Kentucky statute (902 KAR 2:020), all positive lab reports of COVID-19 cases are required to be reported to KDPH within 24 hours of positive result findings. All non-positive lab results should be submitted at least on a weekly basis, up to daily.

  Select one of these two options to submit COVID-19 testing data:
  1) **Fax/CSV Flat File Option:**
     - **Positive results should be faxed** to KDPH's secure fax (855-568-8601) or sent via secure fax to the Local Health Department of the county of residence for the patient
     - If positives are submitted via fax, **all non-positive results** are required to be submitted via an encrypted or password-protected spreadsheet, formatted correctly to KDPH's standards (attached), to covidKYlab@KY.gov on a weekly basis
  2) **CSV Flat File Only Option:**
     - All **new positive test results (not cumulative)** should be submitted using an encrypted or password-protected spreadsheet, formatted correctly to KDPH's standards (attached), sent to covidKYlab@KY.gov daily; all **new non-positive test results** should be submitted in the same way for each submission.

It is required to fill out the following SurveyMonkey survey daily to report aggregate data until ELR submission via KHIE is achieved: https://tinyurl.com/kytestreports

Once onboarded, **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.

KDPH is currently working on system enhancements, including launching a portal to facilitate the upload of laboratory results to KHIE for low-volume laboratories, as well as a self-service tool for laboratories to begin testing KHIE messaging validations, to facilitate the transition to ELRs via KHIE.

- UPDATED DATA ELEMENT REQUIREMENTS –
In accordance with **federal government and Commonwealth of Kentucky requirements,** all COVID-19 reporting labs are **required** to submit the **following data elements** as part of **all** COVID-19 lab test report submissions:

	NEW REQUIRED ELEMENTS BY CATEGORY	PREVIOUS COMMONWEALTH REQUIREMENT (May 28th)	FEDERAL GUIDANCE?
	Patient Information & Demographics		
1)	Name (first name, middle initial, last name captured separately)	Patient name (elements not captured separately)	
2)	Date of birth (MM/DD/YYYY)	Date of birth	
3)	Gender	Gender	✓
4)	Race	Race	✓
5)	Ethnicity	Ethnicity	✓

6)	Patient address incl. zip code and county of residence	Patient address (zip code not captured separately); County of residence	✓
7)	Patient telephone number	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)	Specimen collection date	✓
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)	Test result	✓
14)	Test result date (MM/DD/YYYY)	Specimen result date	✓
15)	Accession #/Specimen ID	*	✓
16)	Specimen Source (use appropriate LOINC, SNOMED-CT, or SPM4 codes, or equivalently detailed alternative codes)	Specimen source/type (e.g., OP, NP, BAL, sputum, serum)	✓
Ordering Provider / Performing Facility Information			
17)	Date test ordered (MM/DD/YYYY)	*	✓
18)	Ordering provider name	Name of the ordering medical provider or facility	✓
19)	Ordering provider NPI	*	✓
20)	Ordering provider address incl. zip code	Address of the reporting medical provider or facility (zip code not captured separately)	✓
21)	Ordering provider telephone number	Telephone number of the reporting medical provider or facility	✓
22)	Performing facility name and/or CLIA number, if known	*	✓
23)	Performing facility zip code	Address of the reporting medical provider or facility (zip code not captured separately)	✓
24)	Performing facility telephone number	Telephone number of the reporting medical provider or facility	

New data element

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 flat file forms and submission, please contact covidKYlab@KY.gov.

Sincerely,

Eric C. Friedlander
Secretary
Cabinet for Health and Family Services

Steven J. Stack, MD
Commissioner
Department for Public Health