Dear Health Care Provider,

As clinicians and facilities expand testing for COVID-19 (SARS CoV2) across Kentucky this letter serves to inform and remind that within the Commonwealth of Kentucky healthcare providers are **required by law and regulation to report all positive laboratory results for SARS-CoV-2** in a Kentucky resident to the Kentucky Department for Public Health (KDPH). As a clinician or facility that offers COVID-19 testing to the public, you are responsible for reporting every positive result you have identified through laboratory testing to public health authorities (local or state) within 24 hours. This includes patients with positive PCR, NAA, antigen and antibody results. Rapid and point-of-care testing is included in this requirement.

Clinician/facility reporting is required **in addition to** laboratory reporting to fulfill Kentucky’s reporting requirements. If COVID-19 testing is performed within your facility (e.g., a pharmacy) and/or there is no “ordering clinician,” the reporting duty falls upon the facility staff. For any lab-positive results of COVID-19 testing, providers/clinicians/facilities must submit a CDC Person Under Investigation (PUI) Form (also called a, “COVID-19 Case Report Form”) and Kentucky’s Reportable Disease Form, an EPID 200, to KDPH or your local health department. An **updated version of the PUI form can be found on CDC’s website and an updated version of the EPID 200 can be found on the Commonwealth’s website**.

It is critical for KDPH to collect accurate and complete data from healthcare providers and laboratories. Without this information, KDPH and local health authorities cannot conduct essential outbreak management activities, such as contact tracing, isolation, and quarantine, to mitigate the spread of COVID-19.

**Per Commonwealth regulation 902 KAR 2:020 (detailed below), the following data elements are required to be reported by health care providers and/or facilities providing testing:**

Section 4(16) Information to be reported. Except as provided in subsections (3) and (7) of this section, a report required by this administrative regulation shall include:

(a) Patient name;
(b) Date of birth;
(c) Gender;
(d) Race;
(e) Ethnicity;
(f) Patient address;
(g) County of residence;
(h) Patient telephone number;
(i) Name of the reporting medical provider or facility;
(j) Address of the reporting medical provider or facility; and
(k) Telephone number of the reporting medical provider or facility.

(17) A reporting health professional shall furnish the information listed in subsection (16) of this section and Section 2(6)(b) of this administrative regulation.

Section 2(6)(b) Clinical, epidemiologic, and laboratory information pertinent to the disease including sources of specimens submitted for laboratory testing.


Please note, submitting a CDC PUI form and/or EPID 200 form as described above does not apply to testing-only events where a formal medical evaluation does not also take place. This exemption is allowed to facilitate public access to testing-only services in the midst of the current COVID-19 public health emergency and should not be interpreted as a general exemption from CDC PUI and EPID 200 reporting obligations required of clinicians who provide a medical evaluation of a patient and order COVID-19 testing in relation to their evaluation. These reporting obligations are an essential element of the public health system and clinician compliance with them is important and appreciated.

For any inquiries or questions, please contact DPH.COVID19Providers@KY.gov. Thank you for your commitment to reporting COVID-19 cases promptly so that effective public health action can be taken. Without your active participation in this process, Kentucky residents would be at increased risk of COVID-19.

Sincerely,

Eric C. Friedlander
Secretary
Cabinet for Health and Family Services

Steven J. Stack, MD
Commissioner
Department for Public Health
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 Andy 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 within 24 hours 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](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:

<table>
<thead>
<tr>
<th>NEW REQUIRED ELEMENTS BY CATEGORY</th>
<th>PREVIOUS COMMONWEALTH REQUIREMENT (May 28th)</th>
<th>FEDERAL GUIDANCE?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Information &amp; Demographics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1) Name (first name, middle initial, last name captured separately)</td>
<td>Patient name (elements not captured separately)</td>
<td></td>
</tr>
<tr>
<td>2) Date of birth (MM/DD/YYYY)</td>
<td>Date of birth</td>
<td></td>
</tr>
</tbody>
</table>
| 3) Gender | Gender | ✓
| 4) Race | Race | ✓
| 5) Ethnicity | Ethnicity | ✓
<table>
<thead>
<tr>
<th></th>
<th>6) Patient address incl. zip code and county of residence</th>
<th>Patient address (zip code not captured separately); County of residence</th>
<th>✓</th>
</tr>
</thead>
<tbody>
<tr>
<td>7)</td>
<td>Patient telephone number</td>
<td>Patient telephone number</td>
<td>✓</td>
</tr>
</tbody>
</table>

**Testing & Case Information**

<table>
<thead>
<tr>
<th></th>
<th>8) First test (Y/N/U)</th>
<th>*</th>
<th>✓</th>
</tr>
</thead>
<tbody>
<tr>
<td>9)</td>
<td>Test ordered (use harmonized LOINC codes provided by CDC)</td>
<td>*</td>
<td>✓</td>
</tr>
<tr>
<td>10)</td>
<td>Name of testing product</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>11)</td>
<td>Device identifier</td>
<td>*</td>
<td>✓</td>
</tr>
<tr>
<td>12)</td>
<td>Date specimen collected (MM/DD/YYYY)</td>
<td>Specimen collection date</td>
<td>✓</td>
</tr>
<tr>
<td>13)</td>
<td>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)</td>
<td>Test result</td>
<td>✓</td>
</tr>
<tr>
<td>14)</td>
<td>Test result date (MM/DD/YYYY)</td>
<td>Specimen result date</td>
<td>✓</td>
</tr>
<tr>
<td>15)</td>
<td>Accession #/Specimen ID</td>
<td>*</td>
<td>✓</td>
</tr>
<tr>
<td>16)</td>
<td>Specimen Source (use appropriate LOINC, SNOMED-CT, or SPM4 codes, or equivalently detailed alternative codes)</td>
<td>Specimen source/type (e.g., OP, NP, BAL, sputum, serum)</td>
<td>✓</td>
</tr>
</tbody>
</table>

**Ordering Provider / Performing Facility Information**

<table>
<thead>
<tr>
<th></th>
<th>17) Date test ordered (MM/DD/YYYY)</th>
<th>*</th>
<th>✓</th>
</tr>
</thead>
<tbody>
<tr>
<td>18)</td>
<td>Ordering provider name</td>
<td>Name of the ordering medical provider or facility</td>
<td>✓</td>
</tr>
<tr>
<td>19)</td>
<td>Ordering provider NPI</td>
<td>*</td>
<td>✓</td>
</tr>
<tr>
<td>20)</td>
<td>Ordering provider address incl. zip code</td>
<td>Address of the reporting medical provider or facility (zip code not captured separately)</td>
<td>✓</td>
</tr>
<tr>
<td>21)</td>
<td>Ordering provider telephone number</td>
<td>Telephone number of the reporting medical provider or facility</td>
<td>✓</td>
</tr>
<tr>
<td>22)</td>
<td>Performing facility name and/or CLIA number, if known</td>
<td>*</td>
<td>✓</td>
</tr>
<tr>
<td>23)</td>
<td>Performing facility zip code</td>
<td>Address of the reporting medical provider or facility (zip code not captured separately)</td>
<td>✓</td>
</tr>
<tr>
<td>24)</td>
<td>Performing facility telephone number</td>
<td>Telephone number of the reporting medical provider or facility</td>
<td></td>
</tr>
</tbody>
</table>

*New data element*

To begin onboarding to KHE 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 KHElabs@ky.gov or 502-564-7940. For general inquiries 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