Requirements and Guidance for Reporting COVID-19 Lab Data to the Maryland Department of Health

This guidance was compiled in response to the COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115 letter sent out by Health and Human Services on June 4, 2020. In order to meet the data reporting requirements outlined in this letter, it is the responsibility of any person or entity ordering a diagnostic or serologic test, collecting a specimen, or performing a test to make every reasonable effort to collect complete data and include such data when ordering a laboratory test so entities performing the test are able to report this data to local and state health departments. This may involve changes to order submission forms, laboratory information systems, or to existing protocols.

All laboratories performing COVID-19 testing—including laboratories, testing locations operating as temporary or remote locations for a laboratory, and other facilities or locations performing point of care testing (POC) or at-home specimen collection must report data for each individual tested, within 24 hours of results being known or determined, on a daily basis to the appropriate state or local public health department based on the individual's residence.

Data can be sent to the Maryland Department of Health (MDH) using either Health Level 7 (HL7) messaging or CSV format using the template provided by the Maryland Department of Health (MDH). Please review the HHS Guidance Implementation document and HL7 Confluence website for HL7 mapping guidance and specifications. The HHS Guidance Implementation document outlines which fields are required, requested, and considered optional by the U.S. Department of Health and Human Services (HHS).

As the guidance from these two documents is applied to your files, please apply these Maryland-specific guidelines:

1. Device Identifier information must be sent in OBX-17
    - Please review and use the Device Identifier information supplied in the LIVD mapping catalogue under the the "Testkit Name ID"
    - The character limit for OBX-17.1= 20 and OBX-17.2 = 48 in the NEDSS Base System (NBS) that is used by MDH. Anything sent in these fields will be truncated to fit the character limit.
2. AOE questions must be sent as OBX segments. The answers to the AOE questions should be sent as coded results (OBX-2 = CWE). OBX-5 will either have HL7 or SNOMED values depending on the question.
3. Refer to the HHS Guidance Implementation document for appropriate SNOMED codes used for the following data elements:
    - Test result values
    - Specimen source
    - AOE: Employed in healthcare (with direct patient contact)--if YES
        - Healthcare Occupation Value Set
    - AOE: Symptomatic per CDC--if YES (optional part of the question)
    - AOE: Hospitalized (at time of testing, for COVID)--if YES (optional part of the question)
    - AOE: ICU (at time of testing, for COVID)--if YES (optional part of the question)
    - AOE: Resident in congregate care/living setting-- if YES (optional part of the question)
    - AOE: Pregnancy status
4. Use the corresponding concept codes for race, ethnicity, and sex codes given by PHIN VADS
5. Use FIPS codes for Patient County

6. NPIs can be found in the [NPI Registry](https://npiregistry.cms.hhs.gov/)
7. CLIA numbers can be found using the [CLIA laboratory search](https://www.cdc.gov/clia/LabSearch.html)

Resources:
https://www.hhs.gov/sites/default/files/hhs-guidance-implementation.pdf
https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html
https://confluence.hl7.org/display/OO/Proposed+HHS+ELR+Submission+Guidance+using+HL7+v2+Messages
https://loinc.org/sars-cov-2-and-covid-19/
https://phinvads.cdc.gov/vads/SearchHome.action
https://www.cdc.gov/clia/LabSearch.html
https://npiregistry.cms.hhs.gov/
https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html