CLIA Frequently Asked Questions

What is CLIA?

- A federal law issued by CMS in 1988 requiring any facility performing any testing from specimens from the human body for the purpose of providing information for the diagnosis, prevention or treatment of a disease, or for the assessment of health have a CLIA certificate.
- The facility's federal tax ID number is tied to the CLIA certificate and it is important for facilities to ensure this, demographic information, and director name is updated with the CLIA office.

When should a facility be considered a lab?

- A facility is considered a lab when they perform any type of testing from FSBS to complicated tests such as genetic testing and must have a CLIA certificate to correspond to the complexity of testing they are performing.

What is a Certificate of Waiver (COW)?

- For the purpose of our discussion, we will talk about the Certificate of Waiver.
    - All tests are categorized by the FDA and with a COW, the facility can only perform those tests categorized by the FDA as waived.
    - The COW is the only certificate type that does not have any personnel requirements.

How are COVID-19 test being released?

- All COVID-19 tests are currently being released under an EUA (emergency use authorization).

How are the test categorized by the FDA?

- They are categorized by the FDA with an EUA status of Waived, Moderate, or High complexity.

Which Rapid Point of Care Antigen Test have been sent to Long Term Care Facilities?

- The Rapid Point of Care Antigen tests that are being sent to the nursing homes by HHS have an FDA EUA status of waived are:
    - BinaxNOW COVID-19 Ag Card: 08/26/20
    - BD Veritor System for Rapid Detection of SARS- CoV-2: 08/18/20
    - Sofia SARS Antigen FIA: 05/08/20

- The first distribution by HHS consisted of either the BD Veritor System or the Quidel Sofia test system.
- Some nursing home are receiving a second Antigen test which is called the Abbott Binax NOW.

Can facilities share their testing system with other facilities including sister facilities?

- No. HHS distributed the analyzer and materials for the intended use of the residents and staff under that nursing home's CLIA number only.

How will facilities be trained to use testing equipment?

- When a nursing home receives their analyzer and materials, it is very important for them to read the manufacturer's instructions and utilize the training materials they provide. The manufacturer's website provides online training and all staff who will be performing the COVID-19 Antigen testing should participate in this and have documented training prior to performing testing (ensure accuracy of test results).
    - Follow manufacturer's instructions for performing testing (this is a CLIA regulation for waived testing)
    - Ensure analyzer and test supplies are maintained at the temperature range required by the manufacturer (document on daily temperature logs)

How do we report information collected?

- There is a lot of confusion with reporting the COVID-19 results. In addition to the long term care requirements and CMS/CDC requirement, there are specific laboratory requirements (Facilities that perform COVID-19 antigen testing in-house or even a FSBS are considered a laboratory by CLIA).
- When the CLIA department approves applications to add COVID-19 testing, the facility will receive an email to explain the COVID-19 reporting information which consists of: Qualtrics Report and OSDH Acute Disease reporting using the PHIDDO system.

What is the Qualtrics Report?

- Qualtrics Report is per the Governors Fourth Amended Executive Oder 2020-20.
- The Qualtrics Report is NOT a CLIA report.
- William Huffman (WilliamBH@health.ok.gov) is the contact person for this report.

How does one set up PHIDDO Enrollment?

- Tony McCord (TonyWM@health.ok.gov) us the contact person for Acute Disease.
- PHIDDO report requires the facilities to enter their positive cases. The negatives can be compiled on a spreadsheet (ask Tony McCord for the template), then uploaded through PHIDDO (there is certain information needed for the negative patients as required by the CARES ACT).
- The PHIDDO reporting satisfies the CLIA regulation of reporting in-house COVID-19 testing to the state.

What if a Long Term Care Facilities cannot perform in-house testing?

- If a nursing home cannot perform in-house testing, whether it is routine testing, outbreak, and/or a lack of supplies, the facility can collect samples and send them to a reference laboratory for testing.
- Long-term-care facilities are required to meet the testing requirements in their facility.
- The long-term-care facility would need to contact the reference lab and work with them to ensure they can provide the 48 hour turn-around-time.
- Collection of specimens and payment for services are between the facility and the reference laboratory.