## OFFICE OF LABORATORY SERVICES

167 11th AVENUE | SOUTH CHARLESTON, WV 25303

As announced on July 14, 2020, the United States Department of Health and Human Services (HHS) will be distributing one of two rapid SARS-CoV-2 point-of-care test systems and required supplies to all skilled nursing facilities in the country. In order to receive these supplies, each facility must have an active CLIA Certificate of Waiver.

More information regarding this decision can be found in the HHS press release at <a href="https://www.hhs.gov/about/news/2020/07/14/trump-administration-announces-initiative-more-faster-covid-19-testing-nursing-homes.html">https://www.hhs.gov/about/news/2020/07/14/trump-administration-announces-initiative-more-faster-covid-19-testing-nursing-homes.html</a>.

- For those that do not already possess a CLIA Certificate of Waiver, please fill out the CLIA application (CMS-116), found at <a href="https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf">https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf</a>, and be sure to list the exact SARS-CoV-2 (COVID-19) test/instrument that you have been or will be provided.
  Examples of completed CLIA applications are found on our website at
  - Examples of completed CLIA applications are found on our website at <a href="https://dhhr.wv.gov/ols/regulatory/Pages/CLIA.aspx">https://dhhr.wv.gov/ols/regulatory/Pages/CLIA.aspx</a>.
- 2. For those that already have a CLIA Certificate of Waiver, please draft an official letter with your facility name, CLIA number, and the exact test/instrument you will be using. Ensure that the letter is dated and signed by your laboratory director or a designee thereof.

You <u>MAY NOT</u> begin testing until you have been issued a CLIA number (for new applicants) or have made proper notice of the update to your testing menu (for current certificate holders).

Return all requested documents via email to <a href="mailto:dhhrolsclia@wv.gov">dhhrolsclia@wv.gov</a> to ensure the quickest processing. You may also mail or fax these documents, but there will be a delay in processing physical copies. Please contact the CLIA Program at the email address above with any questions you may have regarding completion of the application.

Sincerely,

Dana Stillwagon, MLS(ASCP)cm

Microbiologist Supervisor

Training and Evaluation Section