Laboratory Directors and Supervisors,

The current global health crisis highlights the extraordinary risk that personnel in the Public Health field take on a daily basis. Your willingness to provide care, education, leadership, and selfless service are what makes this mission possible. Our public servants, across the world, are putting themselves on the front lines of this pandemic to provide calm, steady care in the face of adversity. Your dedication to our shared mission "to raise the physical, mental, social, and spiritual health of American Indians and Alaska Native (AI/AN) to the highest level" is palpable and provides the backbone to our entire agency. Please know that safety is of paramount importance for all staff that continue taking the risk of working in healthcare. The testing procedures are to be performed in accordance with the most current guidance from the CDC. While it is recognized that test procedures for pathogens that require the open manipulation of patient samples are recommended to be performed in a BSC, it is acceptable to perform this testing with enhanced PPE as directed by the CDC.

Information of particular interest in this pandemic and the subsequent testing requirements should be discussed at each site with the Laboratory Director, Laboratory Supervisor, Medical Director, Clinical Director, and Chief Executive Officer as follows:

Test complexity under the FDA EUA authorization for COVID-19: The Abbott ID NOW is considered a WAIVED analyzer for use in close proximity to the patient, also known as Point of Care. Waived testing can be performed outside of the clinical laboratory with the adherence to Universal and Standard precautions as defined by CLIA '88 and the CDC.

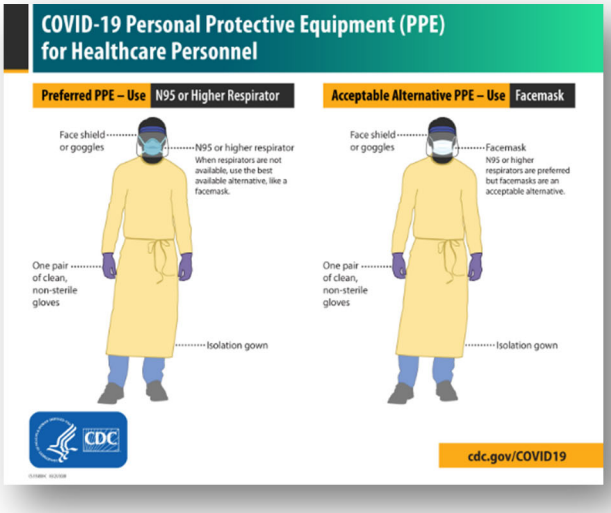
Methodology: This testing platform performs the SARS-CoV-2 identification using nucleic acid amplification technology (NAAT) from a single sample's viral RNA in a closed testing system. NAAT is non-propagative diagnostic testing, meaning that the sample virus is rendered noninfectious during the testing process and identification is performed on a snippet of the viral RNA.

Maintaining the disinfection and directionality of the work area in accordance with the manufacturer's instructions is imperative as contamination from previous samples or controls can lead to both false-positive and false-negative results.

Safety concerns: Pre-analytic criteria, specimen collection and handling, provide the greatest risk of exposure to personnel. Collection has the single highest risk of exposure due to the potential for aerosols and droplets created by coughing, sneezing, and/or vomiting reactions. Sample preparation for testing is the next highest risk with the potential for droplet creation when mixing the sample swab in the testing device.

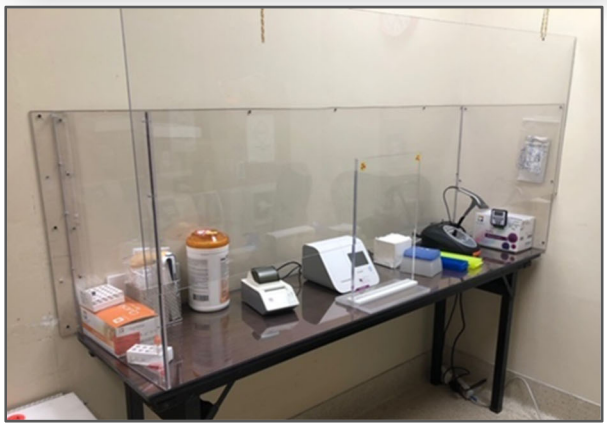
Testing and PPE: For diagnostic testing of specimens conducted outside of a BSL-2 laboratory, such as rapid respiratory testing performed at the point of care, use Standard Precautions to provide a barrier between the specimen and personnel during specimen manipulation.

For procedures with a high likelihood to generate aerosols or droplets, use either a certified Class II Biological Safety Cabinet (BSC) **or** additional precautions to provide a barrier between the specimen and personnel. Examples of these additional precautions include personal protective equipment (PPE), such as a surgical mask or face shield, or other physical barriers, like a splash shield (see COVID-19 PPE for HCP image to the right).



The following is an example of local creation for primary containment. Information on this setup can be obtained from:

Roger Martinez, Laboratory Director
Acoma-Canoncito-Laguna Service Unit
Email: Roger.Martinez2@ihs.gov



If your site was selected for an analyzer there are criteria that **MUST** be met in order to conduct testing in accordance with Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) regulations, and CDC Guidelines.

- **MUST** be a CLIA '88 certified testing site: Waived, PPM, Moderate, or High
- **MUST** perform Risk Assessment of: (APHL, WHO, CLSI M29A4E, Appendix B)
    - Workforce
    - Risk Characterization
    - Risk Mitigation
- **MUST** attend Abbott ID NOW training as provided by IHS HQ through the National Laboratory Professional's Council.
- **MUST** maintain training records, analyzer maintenance and use records, quality control and validation studies (if applicable), testing area, and results in accordance with manufacturer's instructions, CDC guidelines, and CLIA '88 regulations.
- **MUST** report patient results to Area Office, State Health Departments, and FDA.

The following are resources and additional guidelines you can refer to for more information on COVID-19 testing:

- Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) regulations
- Federal Expert Security Advisory Panel (FESAP)
- Clinical and Laboratory Standards Institute documents (copyrighted)
- CDC guidelines
- World Health Organization guidelines