Title: **SARS-CoV-2 CDC Guidelines for Testing on the Abbott/Alere ID Now Analyzer**			SOP #:
Effective Date:	Supersedes:	Author:	
Accreditation Standard:	Review Date:		Date Discontinued:
Laboratory Director Signature:		Date approved by LD:	

POLICY

While specimen processing and testing for the SARS Co V-2 test, the correct personal protective equipment (PPE) must always be used.

- Laboratory staff should always follow the guidance in this procedure.

II. PURPOSE

To define and standardize the PPE to use when performing specimen testing.

Specialized PPE for SARs-CoV-2 Testing is outlined below and must always be followed when testing for SARs-CoV-2.

III. CDC REFERENCE

Decentralized and Point of Care Testing

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 additional information on specimen collection, handling, and testing refer to Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs).

IV. PROCEDURE

A. General Guidelines set for Molecular Diagnostic Testing

- CLIA requires laboratories to have procedures in place to monitor and minimize contamination during the testing process and to ensure a unidirectional workflow for amplification procedures that are not contained in closed systems (42 CFR §493.1101) (36). In this context, a closed system is a test system designed to be fully integrated and automated to purify, concentrate, amplify, detect, and identify targeted nucleic acid sequences. Such a modular system generates test results directly from unprocessed samples without manipulation or handling by the user; the system does not pose a risk for cross-contamination because amplicon-containing tubes and compartments remain completely closed during and after the testing process. For example, according to CLIA regulations, an FDA-cleared or FDA-approved test system that contains amplification and detection steps in sealed tubes that are never opened or reopened during or after the testing process and that is used as provided by the manufacturer (i.e., without any modifications) is considered a closed system. **However, Abbott ID Now manufacturer**

does include additional cleaning procedures to prevent cross-contamination and these must be followed in addition to CDC guidelines due to infectious nature of the COVID-19 virus.

B. General Laboratory Testing – all of the following are worn whenever handling and testing patient specimens:

- Laboratory Coat –
    i. Washable laboratory coats and/or scrubs that are laundered through the designated laundering protocol are the only authorized laboratory coat worn for patient specimen handling. **Laboratory staff DO NOT wear laboratory coats outside the laboratory under any circumstances**. Laboratory coats are placed in the laundry hamper whenever they become soiled, either visibly or suspected, and at least weekly at the end of the week.

    ii. Disposable laboratory coats are preferred and should be tossed into the appropriate biohazardous waste container upon soiling and at the established times set by the institution's guidelines. **Laboratory staff DO NOT wear laboratory coats outside the laboratory under any circumstances.**

- Gloves – all staff are required to wash hands or use hand sanitizer when donning and after doffing gloves, prior to the handling of any specimens and immediately after specimen handling is complete.

NOTE: Gloves must be changed between each patient specimen processed and tested!

C. ***Specialized PPE for SARs-CoV-2 Testing for Laboratory and POCT staff*** - all of the following are worn whenever handling patient specimens for testing for SARs-CoV-2 testing – a positive specimen is highly contagious as it may contain live virus, but the amplified RNA and DNA test cartridge is not infectious but mishandling can cause cross-contamination to other clean reagents and supplies:

- Gown/Lab Coat – disposable paper gowns are worn for the testing of SARs-CoV-2. Gowns are donned and doffed following CDC guidelines prior to the testing of one or multiple specimens. **Staff should not move on to other procedures of laboratory testing without first doffing their SARs-CoV-2 testing gown**.

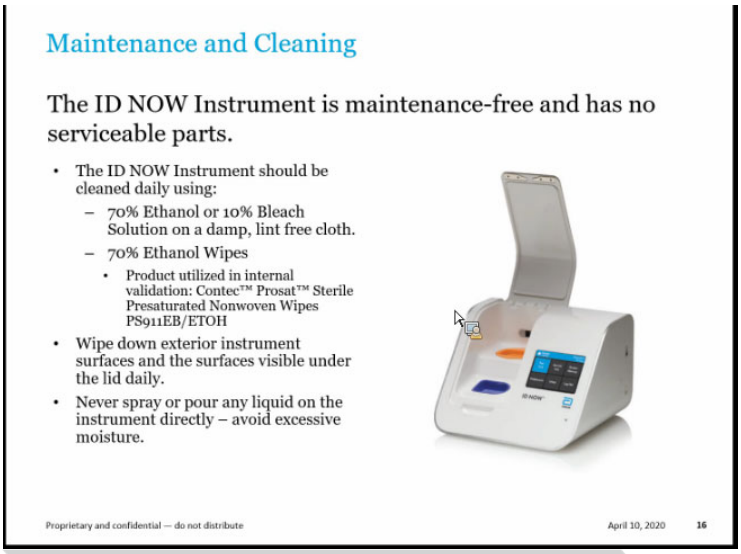
- Gloves – all staff are required to wash hands or use hand sanitizer when donning and after doffing gloves prior to the collection of any specimen. **All staff performing SARs-CoV-2 testing must be double gloved.**

- Barrier – **All SARs-CoV-2 testing must be performed behind a plexi-glass shield or while using a face-shield and mask.** If there is a Biological Safety Cabinet (Microbiology Hood), then wearing a face shield is not required since the cabinet has pull-down shield.

- Cleaning – because this test is a PCR molecular test, contamination from one positive test to the following test has a high likelihood. For this reason, the testing area **must be cleaned** with the approved cleaning product (freshly made 10% bleach solution with a 2 minutes contact, after it dries, follow with a 70% Ethanol solution) **prior to and immediately after testing and processing each individual patient specimen**. This testing area includes the benchtop, analyzer and plexi-glass shield.

- Use of Biohazardous waste container with a closable lid – when discarding spent reagent cartridges containing amplified SARS CoV-2 viruses, the point of care and core clinical laboratory must handle these waste in a special manner and utilize a closed waste container to prevent aerosolization and droplets of the viruses into the ambient air and possibly cross-

contaminate clean items and reagents stored near the analyzer/equipment. Manufacturers recommend discarding the spent cartridge within your used gloves and into the biohazard waste container – see step 3 on the pictorial table at the end of this procedure where you will wrap the glove around the spent reagent container.



Abbott updated their cleaning procedure for the analyzer and recommend thorough cleaning especially after running a positive sample. 4/16/2020

Molecular Considerations

- "Amplicons" are amplified copies of the target DNA or RNA
- Present in the orange test base reaction tubes after the testing process is complete
- If the orange test base is damaged or compromised, these "amplicons" are released, contaminating the workspace and testing environment
- "Amplicons" **cannot make you sick**, but may cause false positive results
- **The risk for amplicon release is very low if test components are handled and discarded appropriately**.

To Avoid Amplicon Release:

- Use caution when opening and handling package #1 – the orange test base
- Discard and DO NOT use any components that are dropped, cracked or found to be damaged.
- Test components must NEVER be discarded individually
- Once the test components are assembled after the test is complete, NEVER disassemble them
- Clean the instrument daily

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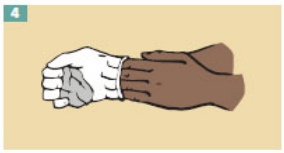
How to Remove Gloves

To protect yourself, use the following steps to take off gloves

1 Grasp the outside of one glove at the wrist. Do not touch your bare skin.

2 Peel the glove away from your body, pulling it inside out.

3 Hold the glove you just removed in your gloved hand.



4 Peel off the second glove by putting your fingers inside the glove at the top of your wrist.

5 Turn the second glove inside out while pulling it away from your body, leaving the first glove inside the second.

6 Dispose of the gloves safely. Do not reuse the gloves.

7 Clean your hands immediately after removing gloves.

Abbott recommends holding the used test cartridge in your hand on slide 2, and then follow slide 3 and 4 to wrap the used test cartridge within the two gloves that were removed and discarded, which will prevent cross-contamination.