Abbott

Blanchard Valley Health System Site: _____ Location: _____ Form revised 10/5/2023 LTR

Training Checklist for Laboratory Point of Care Testing Date of Hire / Transfer: _____

Method: POCT ID NOW COVID-19 2.0 Date of Initial Training: _____

Test Analyte: SARS-CoV-2 RNA

Associate Name & Title _____ _____ _____ Maiden/Former Name: _____

(print legibly) Associate ID number: _____ Supervisor: _____

ITEM DETAILS		
ID NOW™ - INSTRUMENT OVERVIEW	**USER'S INITIALS**	**DATE**
The user acknowledges being shown and understands the purpose of the following components: • Operator's manual and Quick Start guide • Analyzer on/off power button, temperature indicator, touch screen • Power cord and power port • USB connectors and purpose • Printer (if applicable) with power cords, connectors and paper • Barcode Reader if applicable • Touch screen (Run Test, QC, Review Memory, Logout, Preferences, Setup) • Serial number location and Technical Support contact # • Proper cleaning and maintenance		
ID NOW™ - REAGENT OVERVIEW	**USER'S INITIALS**	**DATE**
The user acknowledges being shown reagent package insert(s), and understands storage conditions, kit components, warm up times, lot #, expiry dates, and early detection for the reagent test kits (as applicable below): • Collection Swabs, original swab packaging, and unused screw top tubes • Orange Test Base –Package #1 • Blue Sample Receiver and White Transfer Cartridge - Package #2 • Quality control swabs (Positive & Negative) • Plastic transfer pipette (Flu and RSV only) • The user has reviewed the "Precautions" listed in the package insert e.g. Handling of used test cartridges and prevention of amplicon. Wears clean personal protection equipment and gloves when running each test. Changes gloves between the handling of specimens suspected of COVID-19. **COVID-19 2.0 192-000***		

ID NOW™ - SAMPLE REQUIREMENTS	USER'S INITIALS	DATE
• User has been provided appropriate sample collection support documents and training resources. • User has reviewed package insert(s) for ACCEPTABLE swabs/transport media types, correct technique to return swab to its package, and sample storage conditions. **COVID-19 2.0 192-000***		

ID NOW™ - QC AND PATIENT TESTING	USER'S INITIALS	DATE
For Quality Control / Patient Test 1. The user follows universal precautions (uses gloves) to handle reagents, QC, Patient swabs/VTM. 2. Demonstrates how to successfully log in to the ID NOW™. 3. The user demonstrates understanding of the "self- test". 4. The user demonstrates how to initiate **Quality control** or **Patient test** from the main menu. 5. The user selects the correct reagent set (package #1 and package #2) for the assay to be performed. 6. The user correctly opens each packet, handles and places reagent components as directed per the user interface displayed on the touchscreen. 7. The user utilizes the quality control swab for the corresponding assay and QC level. OR for patient testing, utilizes correct patient sample type and correctly enters sample identification into the analyzer. 8. The user follows correct timing for the introduction of the sample and 10 second swab rotation in Sample receiver or for VTM, addition of 200 µL. 9. The user demonstrates the initiation of the test by pressing the "OK" key prior to sample transfer. 10. The user OBSERVES the proper positioning of the Transfer Cartridge plunger during the sample transfer. 11. The user completes the Quality control /Patient test process from start to result. 12. User demonstrates understanding of result and procedural control. 13. User demonstrates connecting all reagent pieces for safe and proper disposal.		

ID NOW™ - TEST RESULT INTERPRETATION AND INVALID RESULTS	USER'S INITIALS	DATE
• User has been provided support document(s) for handling an invalid test result. • User demonstrates how to find and interpret QC/PATIENT results on the screen or printout. • The user has been instructed what to do if the QC, patient or procedural control are displayed as invalid or have failed. • The user acknowledges instruction on the main causes of an invalid result and how to repeat an invalid test.		
ID NOW™ COVID-19 2.0* EUA RESULT REPORTING RESPONSIBILITY	**USER'S INITIALS**	**DATE**
• The user acknowledges the responsibilities of reporting results as outlined in the **Limitations** EUA section, if still applicable.		

Associate Signature: _____ Date: _____

Signature of Qualified Trainer/Assessor: _____ Date: _____

Job title of Qualified Trainer/Assessor: _____

* ID NOW COVID-19 2.0 has not been FDA cleared or approved. It has been authorized by the FDA under an emergency use authorization for use by authorized laboratories. The test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens, and is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

TRAINING GRID	ID NOW™ COVID-19 2.0*
PRODUCT PN	192-000
CONTROL KIT PN	192-080
CPT CODE	87635-QW
TESTING TIME	Positive results in as little as 6 minutes Negative results in 12 minutes
SAMPLE TYPES	Direct anterior nasal or nasopharyngeal (NP), swab.
DIRECT SAMPLE STORAGE	**Direct anterior nasal or nasopharyngeal (NP) swab:** Room Temp: for up to 1 hr. prior to testing
TRANSPORT MEDIA SAMPLE STORAGE	NA
BOX CONFIGURATION	24 tests/box 1 (+) control/box test swabs
PATIENT RESULTS MEMORY CAPACITY	999 tests

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