Abbott

TECHNICAL BRIEF
August 2023

FDA 510(k) Clearance for ID NOW™ COVID-19 2.0

Supporting Software Version 7.1 and POC Link Connectivity Tool

Abbott has received FDA 510(k) clearance and CLIA waiver on the ID NOW™ COVID-19 2.0 assay. This technical brief provides a summary of the labeling, the supporting software version 7.1 (v7.1), and the new POC Link connectivity tool.

A key new feature of the ID NOW COVID-19 510(k) product and the supporting software update v7.1 provides customers with the flexibility to use a new sequential testing workflow. The sequential workflow will allow customers to have the option to add-on an ID NOW Influenza A & B 2 test after a COVID-19 result is received, using the same patient sample.

Summary of features highlighted in this technical brief:

- Updates to assay labeling
- New sequential workflow – test for COVID-19 with the option to add-on an ID NOW influenza A & B 2 test using the same patient sample
- Extended product dating up to **23 months from date of manufacture**

The new sequential testing workflow feature and the updated 510(k) labeling will apply to existing ID NOW COVID-19 2.0 EUA product after upgrading to software update v7.1. By performing this software update, it enables the sequential workflow for any ID NOW COVID-19 2.0 EUA product you may have in inventory. The upcoming software v7.1 will be available to download remotely through a new connectivity tool, POC Link, starting in October 2023. The v7.1 software update is backwards compatible with all existing ID NOW™ assays.

After the launch of the v7.1 software, all testing must be performed according to the revised 510(k) Instructions for Use. As such, all EUA labeled product in your inventory must be performed in compliance with the 510(k) cleared labeling.

The following sections of this technical brief provide additional details for the following:

ID NOW™ COVID-19 2.0 Assay
510(k) CLIA Waived Labeling & Extended Expiration Dating

Labeling Updates: The details of the 510(k) cleared ID NOW COVID-19 2.0 assay are shown below. The 510(k) cleared labeling will also apply to existing ID NOW COVID-19 2.0 EUA product, including product in possession with customers, distributors and in Abbott inventory.

Product Features	**EUA Authorized Product (Prior Labeling)** ID NOW COVID-19 2.0 PN: 192-000	**510(k) Cleared Product (Updated Labeling)** ID NOW COVID-19 2.0 PN: 192-000
Intended Use	ID NOW™ COVID-19 2.0 assay performed on the ID NOW Instrument is a rapid molecular in vitro diagnostic test utilizing an isothermal nucleic acid amplification technology (NAAT) intended for the qualitative detection of nucleic acid from SARS-CoV-2 in direct anterior nasal (nasal) or nasopharyngeal swab specimens from individuals **who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms.**	ID NOW COVID-19 2.0 performed on the ID NOW Instrument is a rapid molecular in vitro diagnostic test utilizing an isothermal nucleic acid amplification technology (NAAT) intended for the qualitative detection of nucleic acid from SARS-CoV-2 in direct anterior nasal (nasal) or nasopharyngeal swabs from individuals **with signs and symptoms of respiratory tract infection.**
Sequential Testing with ID NOW Influenza A & B 2 Assay	Not a feature in EUA labeling	A single patient specimen can be used to run both an ID NOW COVID-19 2.0 assay and an ID NOW Influenza A & B 2 assay by reusing the Sample Receiver. After receipt of a COVID-19 result, customers will have the option to add-on an Influenza A & B 2 test using the same patient sample. (This feature will also work on existing COVID-19 2.0 EUA-labeled assay. Software v7.1 is required to enable this feature).
Invalid Rate	Initial test invalid rate: **0.71%** Repeat test invalid rate: **0.20%**	Initial test invalid rate: **0.67%** Repeat test invalid rate: **0.19%**
Performance Characteristics	Limit of Detection (LOD): **500 copies/swab** Performance within **7 days of symptom onset** against Patient Infected Status* (Nasal and Nasopharyngeal Swabs Combined) Positive Agreement: 93.3% (95% CI: 89.5% - 96.1%) Negative Agreement: 98.5% (95% CI: 97.2% - 99.3%)	Limit of Detection (LOD): **500 copies/swab or 20 copies/reaction** Performance against Composite Comparator* **(Nasal and Nasopharyngeal Swabs Combined)** Positive Agreement: 91.7% (95% CI: 87.8% - 94.4%) Negative Agreement: 98.4% (95% CI: 97.1% - 99.1%)

Product Features	EUA Authorized Product (Prior Labeling) ID NOW COVID-19 2.0 PN: 192-000	510(k) Cleared Product (Updated Labeling) ID NOW COVID-19 2.0 PN: 192-000
Types of Nasal Collection Swabs	Anterior Nasal (Nasal) Swabs that have been analytically validated, in addition to the swab provided: Puritan Regular **Foam** Tip Swabs, Puritan HydraFlock™ Flock Swabs – Standard Tip, Copan Standard **Rayon Tip** Swab, MRC Technology, Ltd. Foam Tipped Applicator, Foamtec Int'l Swab, Sterile CleanFOAM diagnostic.	Anterior Nasal (Nasal) Swabs that have been analytically validated, in addition to the swab provided: Puritan Regular **Rayon** Tip Swabs, Puritan HydraFlock™ Flock Swabs – Standard Tip, Copan Standard **Flocked** Swab, MRC Technology, Ltd. Foam Tipped Applicator, Foamtec Int'l Swab, Sterile CleanFOAM Diagnostic, and **FA Polyurethane Foam Swabs.** **Note: Puritan™ PurFlock™ Ultra Flocked Swabs-Standard Tip, Copan™ Rayon Standard Tip Swab, and Jiangsu Changfeng Medical Industry (JCF) Polyurethane Foam swabs are not suitable for use in this assay.**

*Three (3) FDA Emergency Use Authorized real-time Polymerase Chain Reaction (RT-PCR) assays for the detection of SARS-CoV-2 were utilized in a composite comparator method for each subject.

** For EUA labeled product, customers should follow the expiration dating listed on the outer box.

Extended Expiration Dating: New extended expiration dating is now available for the ID NOW COVID-19 2.0 assay and the ID NOW COVID-19 Control Swab Kit. Updated expiration dating is also available on certain lots of EUA product that have been reworked with an overlabel to indicate updated expiration.

Product	Expiration Dating
510(k) Product	ID NOW COVID-19 2.0 Test - **23 months** ID NOW COVID-19 Control Swab Kit - **24 months**
EUA Product with an overlabel (reworked product)	**22 months**, if software v7.1 is installed on the instrument. If no software update is performed, instrument will not allow it to run past 13 months.
Existing EUA product (In customer and distributor possession)	**13 months**

For additional support, please reach your Abbott representative or Technical Services at +1.855.731.2288.

ID NOW™ Software Version 7.1
Available through POC Link Connectivity Tool

POC Link is a connectivity tool that delivers remote software updates for the ID NOW™ platform via Abbott's secure servers and is provided at no cost to ID NOW customers. POC Link meets cybersecurity standards and data privacy requirements and does not collect any personal or protected health information.

Starting September 2023, it will be important to register instruments to POC Link to gain access to software v7.1 and future software updates remotely through this tool. Once an instrument is connected to an active Ethernet™ port and registered to POC Link, the user will be able to perform the software update without the need of a USB drive***. If an ID NOW instrument has a middleware connection, please work directly with your middleware provider to complete any necessary steps to enable the new software.

The upcoming ID NOW software update v7.1 can be obtained through POC Link starting in October 2023***. The software update v7.1 is backwards compatible to existing ID NOW™ assays, including the ID NOW COVID-19 2.0 EUA-labeled assay. Important features of software v7.1 include:

- Sequential workflow capability - test for COVID-19 with the option to add-on an Influenza A & B test using the same patient sample
- Cybersecurity updates - to enhance instrument access security

Once the software update is completed, please note the next steps regarding Quality Controls (QC) to continue testing:

- If updating from a recent version of ID NOW software (version 6.1.25 or later), QC will not be required for assays currently in control on the instrument. QC lot information for ID NOW COVID-19 2.0, Influenza A & B 2, Strep A 2 and RSV will be retained.
- If updating from a version prior to version 6.1.25, the update to version 7.1 will clear QC status, and it will be required to run a Positive and Negative QC per assay and per ID NOW instrument.

To learn more about registering your instrument to POC Link, please contact your Abbott Technical Consultant and/or Technical Services at +1.855.731.2288.

***If a USB is required for the software update at your facility, please reach out to your Abbott Technical Consultant.