ID NOW COVID-19 Sample Type Labeling Update

ID NOW™ is a point of care molecular testing platform, designed for use in urgent care settings, emergency departments, physicians' office labs, and retail pharmacy settings. Given placement near the site of care, patient samples are normally collected and tested directly on the ID NOW instrument, allowing for patient results delivered in real time.

As new ID NOW COVID-19 customers are onboarded, several hospital and laboratory users have performed clinical validations and patient tests eluted in a viral transport media (VTM).   The use of VTM has been shown to reduce performance in low positive samples, which can potentially lead to ID NOW COVID-19 false negative results as some samples may be diluted below the assay's limit of detection.

In order to maximize point of care performance with the ID NOW COVID-19 test, we intend to amend our EUA submission to exclude the use of samples eluted in VTM.

The following changes are being proposed to FDA and we anticipate the change will be implemented in **ID NOW COVID-19 (PN: 190-000)** the week of April 20th. Abbott will confirm final language, post authorization.

The ID NOW™ COVID-19 product insert will <u>remove</u> the following:
- Intended Use: Nasal, nasopharyngeal or throat swabs eluted in viral transport media
- Specimen Transport and Storage: Use of VTM and the list of acceptable VTMs
- Test Procedure: Nasal, nasopharyngeal or throat swabs eluted in viral transport media
- Materials Provided: Plastic disposable pipettes will no longer be included in the ID NOW COVID-19 kit

Note: Sample type options for COVID-19 testing in ID NOW v6.1.25 software should be updated for Swab Use only. Administrators can update sample types in the settings menu under the home screen. Administrator instructions for this change can be found in Attachment 1.

The ID NOW™ COVID-19 product insert will <u>add</u> the following:
- Specimen Collection and Handling: ID NOW COVID-19 is intended for testing a swab directly without elution in viral transport media as dilution will result in decreased detection of low positive samples that are near the limit of detection of the test.
- Test Procedure: Caution: VTM samples are not an appropriate sample type for the ID NOW COVID-19 test.
- Limitations:
  - ID NOW COVID-19 is intended for testing a swab directly without elution in viral transport media as dilution will result in decreased detection of low positive samples that are near the limit of detection of the test.
  - Swab sample eluted in VTM are not appropriate for use in this test.

The ID NOW™ COVID-19 product insert will <u>continue</u> to include:
- Intended Use: Use of direct nasal, throat and nasopharyngeal swabs.
    - o Note: Patient sterile swabs (foam) for use with nasal or throat patient sample collection will continue to be included.
- Specimen Transport and Storage:
    - o Direct nasal, throat or nasopharyngeal swabs should be tested as soon as possible after collection.
    - o If immediate testing is not possible, the nasal, throat or nasopharyngeal swab can be held in its original package at room temperature (15-30°C) for up to two (2) hours prior to testing. If a direct nasal, throat or nasopharyngeal swab specimen will be held longer than two (2) hours, it must be refrigerated at 2-8°C and tested within 24 hours from the time of sample collection.

Abbott remains confident in our ID NOW COVID-19 test and that use of direct patient samples will allow for maximum performance and guide patient decision making in real time. We appreciate your continued support of Abbott ID NOW™ products.
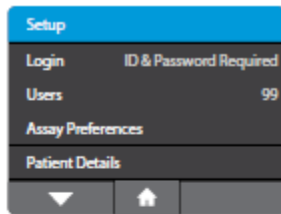
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ID NOW COVID-19 VTM Software Update – Sample Type Selection
(Attachment 1)

Sample Type Selection (Admin Access Only)

- Home>Setup>Assay Preferences> COVID-19 >Sample Type

- Select Swab, and only the swab method will be shown when running a test.

- Press OK to save the settings and return to the Setup Menu.

ID NOW Instrument - User Guide Reference (Page 21):

Home>Setup

Setup	
Login	ID & Password Required
Users	99
Assay Preferences	
Patient Details	
▼	🏠

The **Setup** screen allows the Admin to configure the instrument. Use the up and down arrows to scroll through menus.

Settings are saved even when power is off.

Settings include:
- Login
- Users
- Assay Preferences
- Patient Details
- Date
- Time
- Auto-logout
- Network
- Remote Mode
- Connectivity
- QC Lockout
- Lot Management
- Auto-Print
- Reset to Factory Default

Chosen options are displayed to the right of each setting.