Technical Brief - September 2020
ID NOW COVID-19 Labeling Updates

Over the past several months, Abbott has been working closely with the FDA on post-authorization clinical studies for our on-market ID NOW COVID-19 product. As these interim results have been reviewed, data indicates that molecular testing using ID NOW performs best when used within 7 days of symptom onset, affirming the critical role played by rapid tests in helping to slow the spread of COVID-19 in early detection of the SARS CoV-2 virus.

Given Abbott's intention for ID NOW to be used at the point of care, our sample collection guidance on our product insert has been modified to one hour at room temperature and guides customers to test immediately or store in a clean unused tube for best performance.

The following Product Insert change will be effective immediately. We anticipate this change to be implemented in **ID NOW COVID-19 (PN: 190-000)** labeling the week of September 28th with the following four areas updated and detailed below.

1. **The ID NOW™ COVID-19 Intended Use will be updated to state the following:**
   ID NOW COVID-19 assay performed on the ID NOW Instrument is a rapid molecular in vitro diagnostic test utilizing an isothermal nucleic acid amplification technology intended for the qualitative detection of nucleic acid from the SARS-CoV-2 viral RNA in direct nasal, nasopharyngeal or throat swabs from individuals who are suspected of COVID-19 by their healthcare provider **within the first seven days of the onset of symptoms.** Testing is authorized for laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate complexity/high complexity tests. The ID NOW COVID-19 assay is also authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

2. **The ID NOW COVID-19 Specimen Storage and Transport will be updated to state the following:**
   For best performance, direct nasal, throat or nasopharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible, **and to maintain best performance, it is highly recommended the nasal, throat or nasopharyngeal swab is placed in a clean, unused tube labeled with patient information, and capped tightly at room temperature (15-30°C) for up to one (1) hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. If greater than one (1) hour delay occurs, dispose of sample. A new sample must be collected for testing.**

   If the swab is to be returned to its package for transport, carefully return to allow the swab head to only come into contact with the lower portion of the packaging. Avoid touching the outside of the wrapper with the swab.

3. The ID NOW COVID-19 Conditions of Authorization language was updated to reflect recent EUAs with no change to the conditions.

4. The ID NOW COVID-19 Analytical Studies now includes the results of an ID NOW evaluation of FDA SARS-CoV-2 Reference Panel. All 58 EUA manufacturers were asked by the FDA to participate in this evaluation and results are now publicly available as of September 16, 2020 on the FDA website.

FDA SARS-CoV-2 Reference Panel Testing

The evaluation of sensitivity and MERS-CoV cross-reactivity was performed using reference material (T1), blinded samples and a standard protocol provided by the FDA. The study included a range finding study and a confirmatory study for LoD. Blinded sample testing was used to establish specificity and to confirm the LoD. The results are summarized in the table below.

Summary of LoD Confirmation Result using the FDA SARS-CoV-2 Reference Panel

Reference Materials Provided by FDA	Specimen Type	Product LoD	Cross-Reactivity
SARS-CoV-2	Nasopharyngeal Swab	$3.0x10^5$ NDU/mL	N/A
MERS-CoV		N/A	ND

NDU/mL = RNA NAAT detectable units/mL
N/A: Not applicable
ND: Not detected

After completion of our post-authorization clinical study, we will update the ID NOW COVID-19 Product Insert with final clinical study results and will provide additional customer communications at that time.

We appreciate your continued interest and support of Abbott ID NOW products to help fight the COVID-19 pandemic.