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ID NOW COVID-19 Labeling Updates

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. The availability and ease of access of ID NOW is helping to reduce the risk of infection in society by detecting more positive results than would otherwise be found during this pandemic. 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, where they are needed most.

Questions on the use of the test have been raised by some and studies are being conducted to understand the role of ID NOW in a variety of settings. While we understand no test is perfect, test outcomes depend on a number of factors including specimen type, collection, handling, transport and storage, and conformity to the way the test is designed to be run. Abbott continues to monitor and evaluate the studies that are being reported, consisting of a few with a lower sensitivity and a few with high sensitivity.

In order to maximize point of care performance with the ID NOW COVID-19 test, we are updating the Intended Use to be more specific and enhancing sample collection and handling instructions to reinforce the importance of following Standard Precautions when handling clinical specimens suspected of COVID-19.

Abbott is working with the FDA and the following changes are in-process. We anticipate the change will be implemented in **ID NOW COVID-19 (PN: 190-000)** the week of May 18th and Abbott will provide the updated instructions for use.

The ID NOW™ COVID-19 Intended Use will be updated to state the following:
Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with an alternative molecular assay. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results should be considered in the context of a patient's recent exposures, history, presence of clinical signs and symptoms consistent with COVID-19.

The following Limitation will be expanded:

- Negative results should be treated as presumptive and tested with an alternative FDA authorized molecular assay, if necessary for clinical management, including infection control.
- False negative results may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if amplification inhibitors are present in the specimen or if inadequate levels of viruses are present in the specimen. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.
- As with any molecular test, mutations within the target regions of the Abbott ID NOW COVID-19 test could affect primer and/or probe binding resulting in failure to detect the presence of the virus.

We will <u>add</u> the following Sample Collection and Handling instructions:

- Precautions: Wear clean personal protection equipment and gloves when running each test. Change gloves between the handling of specimens suspected of COVID-19.

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- Specimen Collection and Handling:
  - Follow Standard Precautions when handling clinical specimens, all of which may contain potentially infectious materials. Standard Precautions include hand hygiene and the use of personal protective equipment (PPE), such as laboratory coats or gowns, gloves, and eye protection.
  - To minimize risk of contamination of PPE and swab package during sample collection, it is recommended to widely open the package by pulling from the top down. Carefully remove the swab and perform sample collection.
- Specimen Collection and Handling:
  - If immediate testing is not possible, the nasal, throat or nasopharyngeal swab can be held in its original package or placed in a conical tube and capped tightly at room temperature (15-30°C) for up to two (2) hours prior to 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. If preferred, the swab may also be placed into an uncoated conical tube for storage prior to testing. If placing in a conical tube for storage or transport, ensure the swab fits securely within the tube and the cap is tightly closed.

We will add the following to the Test Procedure instructions:

- Put on a clean pair of gloves.
- To Perform a Test, Step 4:
  - **Mix the swab in the liquid for 10 seconds.** This helps remove the sample from the swab. Lift the swab out of the liquid and press the swab head against the side of the Sample Receiver to remove excess liquid. Once the swab is removed, touch 'OK' to proceed.
  - Discard the swab into a biohazard waste container.
- To Perform a Test, Step 6: Remove and dispose of gloves.

Abbott remains confident in our ID NOW COVID-19 test and these clarification will allow for maximum performance and guide patient decision making in real time. We appreciate your continued support of Abbott ID NOW™ products.