

Important Product Notice

The INTENDED USE for the ID NOW™ COVID-19 test has changed. Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with different authorized or cleared molecular tests. 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. A limitation regarding false negative results was expanded in light of this change.

The SPECIMEN COLLECTION AND HANDLING for the ID NOW COVID-19 test has changed. The sample collection and handling instructions have been updated to reinforce the importance of following Standard Precautions when handling clinical specimens suspected of COVID-19. Detail has been added to the Precautions, Specimen Collection and Handling, and Test Procedure sections of the Product insert.

The SPECIMEN COLLECTION AND HANDLING for the ID NOW COVID-19 test has changed. Swabs eluted in VTM are no longer an appropriate sample type. 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. Due to this change, disposable transfer pipettes are no longer included in the kit.

The NEGATIVE QUALITY CONTROL swab has been replaced. A specific NEGATIVE CONTROL SWAB is no longer provided in the kit, but rather a sterile swab provided in the test kit should be used as the Negative Control Swab.

For complete instructions, please refer to the updated product insert included in this kit.

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