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January 10, 2023

Change Notification: CN-0010, Modification of SCoV-2 Ag *Detect*™ Rapid Test Intended Use

Impacted product(s): SCoV-2 Ag *Detect*™ Rapid Test (Catalog Number COVAG-RC, COVAG-20)

Description of change(s):

Effective immediately, the SCoV-2 Ag *Detect*™ Rapid Test Instructions for Use and Quick Reference Instructions will be modified with regards to:

1. Device intended use
2. Interpretation of results
3. Precautions
4. Limitations
5. Performance characteristics (Omicron variant testing)

Please see below for additional information each change.

Device intended use:

Effective immediately, the intended use of the SCoV-2 Ag *Detect*™ Rapid Test will be as seen below. Impactful changes are highlighted in yellow.

The SCoV-2 Ag Detect™ Rapid Test is a lateral flow chromatographic immunoassay intended for the qualitative detection of the SARS-CoV-2 nucleocapsid protein antigen in direct anterior nasal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first 5 days of symptom onset when tested at least twice over three days with at least 48 hours between tests and from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is 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.

The SCoV-2 Ag Detect™ Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

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The SCoV-2 Ag Detect™ Rapid Test is intended for use by medical professionals or operators who are proficient in performing tests in point of care settings. The SCoV-2 Ag Detect™ Rapid Test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

Interpretation of results:

As noted in the updated intended use above, serial testing requirements for the SCoV-2 Ag *Detect*™ Rapid Test have been updated. Effective immediately, the following table should be referenced when interpreting results:

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

There are no changes to how the SCoV-2 Ag *Detect*™ Rapid Test should be read. However, wording for understanding a positive or negative test result has been updated. The new descriptions for these results are as follows:

- Positive result:

  Repeat testing does not need to be performed if patients have a positive result at any time.

  A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and it is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

  Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the SCoV-2 Ag *Detect*™ Rapid Test should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

- Negative result:

  To increase the chance that the negative result for COVID-19 is accurate, you should:
  - **Test again in 48 hours if the individual has symptoms on the first day of testing.**
  - **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

  A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with

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antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be considered presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Precautions and Limitations:

Please review the updated SCoV-2 Ag *Detect*™ Rapid Test Instructions for Use and Quick Reference Instructions available at https://inbios.com/scov-2-ag-detecttm-rapid-test/ for a new list of precautions and limitations.

Performance characteristics:

A performance study was performed by NIH/RADx to evaluate the SCoV-2 Ag *Detect*™ Rapid Test's ability to detect the Omicron variant of SARS-CoV-2. Study design and results are now included in the SCoV-2 Ag *Detect*™ Rapid Test Instructions for Use.

Reason for change(s):

Changes to the SCoV-2 Ag *Detect*™ Rapid Test Instructions for Use and Quick Reference Instructions are based on updated FDA recommendations for all Emergency Use Authorized COVID-19 antigen kits.

Effective date:

The changes listed above are effective as of December 23, 2022. Updated Instructions for Use and Quick Reference Instructions are now accessible on the InBios website (https://inbios.com/scov-2-ag-detecttm-rapid-test/). Physical copies of the updated Instructions for Use and Quick Reference Instructions will be included in all SCoV-2 Ag *Detect*™ Rapid Test kits shipped from InBios International beginning February 8, 2023, or earlier.

Written and approved by:

Shivani Dharmaraja
Sr. Quality Control Manager, Regulatory Special Projects

January 10, 2023
Date