INTERNATIONAL, INC.
307 Westlake Ave. N.
Suite 300
Seattle, WA 98109
www.inbios.com

Tel. 206 344 5821
Fax. 206 344 5823

**January 10, 2023**

**Change Notification:** CN-0009, Modification of SCoV-2 Ag *Detect*™ Rapid Self-Test Intended Use

**Impacted product(s)**: SCoV-2 Ag *Detect*™ Rapid Self-Test (Catalog Number CAGS-2)

**Description of change(s):**

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

1. Device intended use
2. Interpretation of results
3. Warnings and 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 Self-Test will be as seen below. Impactful changes are highlighted in yellow.

*The SCoV-2 Ag Detect™ Rapid Self-Test is a lateral flow immunoassay device intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus.*

*This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 or older or adult collected anterior nasal (nares) swab samples from individuals aged 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 5 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for 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.*

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

*Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definitive cause of disease. Individuals who test positive with the SCoV-2 Ag Detect™ Rapid Self-Test should self-isolate and seek follow up care with their physician or healthcare provider as additional testing may be necessary.*

*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.*

*Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.*

InBios
INTERNATIONAL, INC.
307 Westlake Ave. N.
Suite 300
Seattle, WA 98109
www.inbios.com

Tel. 206 344 5821
Fax. 206 344 5823

*Individuals should provide all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements, using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Page 2 of 19 Mapping for SARS-CoV-2 Tests provided by CDC.*

*The SCoV-2 Ag Detect™ Rapid Self-Test is intended for non-prescription self-use and/or as applicable, for an adult lay user testing another aged 2 years or older in a non-laboratory setting. The SCoV-2 Ag Detect™ Rapid Self-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 Self-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 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:**

InBios
INTERNATIONAL, INC.
307 Westlake Ave. N.
Suite 300
Seattle, WA 98109
www.inbios.com
Tel. 206 344 5821
Fax. 206 344 5823

- **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 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 diseases should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as 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.

**Warnings, precautions and limitations:**

Please review the updated SCoV-2 Ag *Detect*™ Rapid Self-Test Healthcare Provider Instructions for Use and/or the SCoV-2 Ag *Detect*™ Rapid Self-Test Instructions available at https://inbios.com/scov-2-ag-detect-self-test/ for a new list of precautions, warnings, and limitations.

**Performance characteristics:**

A performance study was performed by NIH/RADx to evaluate the SCoV-2 Ag *Detect*™ Rapid Self-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 Self-Test Healthcare Provider Instructions for Use.

**Reason for change(s):**

Changes to the SCoV-2 Ag *Detect*™ Rapid Self-Test Healthcare Provider Instructions for Use and the SCoV-2 Ag *Detect*™ Rapid Self-Test 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 are now accessible on the InBios website at https://inbios.com/scov-2-ag-detect-self-test/. Physical copies of the updated SCoV-2 Ag *Detect*™ Rapid Self-Test Instructions should be included in all SCoV-2 Ag *Detect*™ Rapid Self-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**