GUAM PUBLIC HEALTH LABORATORY GUIDELINES FOR USING ABBOTT BINAXNOW COVID-19 AG CARD

Methodology **CLIA, 42 U.S.C. §263a**	The BinaxNOW™ COVID-19 Ag Card is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasal swabs without viral transport media from individuals suspected of COVID-19 by their healthcare provider within the first **Seven (7)** days of symptom onset. 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.
Specimen Collection & Handling	Specimen collection should be performed by healthcare personnel who have completed training and demonstrated competency on biosafety policies and procedures and appropriate use of personal protective equipment (PPE) that should be worn at all times. Test specimens immediately after collection for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html **Direct Nasal Swab:** Use only the swab provided in the kit for nasal swab collection. To collect a nasal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab 5 times or more against the nasal wall then slowly remove from the nostril. Using the same swab, repeat sample collection in the other nostril.

520 WEST SANTA MONICA AVENUE, DEDEDO, GUAM 96929
www.dphss.guam.gov • Ph.: 1.671.735.7136/7143

Specimen Transport **Note:** **Do not store swab in viral transport media or any other solution that dilutes the sample.**	**Do not return the nasal swab to the original paper packaging.** For best performance, direct nasal swabs should be tested as soon as possible after collection. If immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended the nasal swab is placed in a clean, unused plastic tube labeled with patient information, preserving sample integrity, and capped tightly at room temperature (15-30°C) for up to (1) hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. If greater than 1 hour delay occurs, dispose of sample. A new sample must be collected for testing.
Materials, Reagents & Instruments	**Test Kit Content** The BinaxNOW™ COVID-19 Ag Card kit contains all components required to carry out an assay for SARS-CoV-2. Only a clock, timer or stopwatch is needed (not provided) for measuring the reaction time. No other instrument is required to perform the test.
TEST BASES BASE	The BinaxNOW™ COVID-19 Ag Card is an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2 nucleocapsid protein from nasal swab specimens.
Quality Control	BinaxNOW™ COVID-19 Ag Card has a built-in internal procedural control, showed as a pink/purple Control Line on the test strip, for each of the test. For daily quality control, Abbott suggests that you record these controls for each test run. Kit also provides Positive and Negative Control Swab for external quality control testing. Test these swabs once with each new shipment received and once for each untrained operator to monitor the entire assay.
PATIENT SWABS	Use only the swab provided in the kit for nasal swab collection.
PRODUCT INSERT	QUICK REFERENCE INSTRUCTIONS Refer to the Procedure Card provided with the kit

Storage & Stability	Store kit at 2-30°C. The BinaxNOW COVID-19 Ag Card kit is stable until the expiration date marked on the outer packaging and containers. Ensure all test components are at room temperature before use.

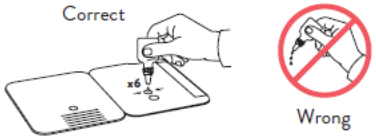
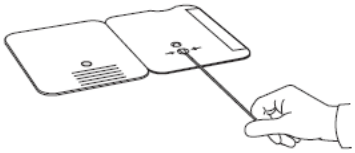
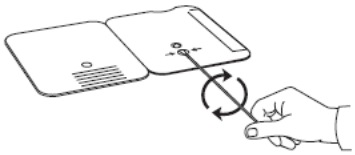
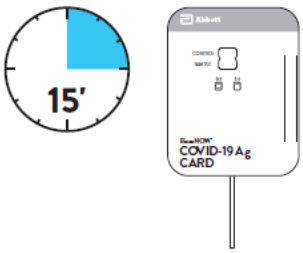
520 WEST SANTA MONICA AVENUE, DEDEDO, GUAM 96929
www.dphss.guam.gov • Ph.: 1.671.735.7136/7143

Procedural Internal Controls	BinaxNOW™ COVID-19 Ag Card has built-in procedural controls. For daily quality control, Abbott suggests that you record these controls for each test run. Procedural Controls: A. The pink-to-purple line at the "Control" position is an internal procedural control. If the test flows and the reagents work, this line will always appear. B. The clearing of background color from the result window is a negative background control. The background color in the window should be light pink to white within 15 minutes. Background color should not hinder reading of the test.
External Positive and Negative Controls	Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed. BinaxNOW™ COVID-19 Ag Card kits contain a Positive Control Swab and Sterile Swabs that can be used as a Negative Control Swab. These swabs will monitor the entire assay. Test these swabs once with each new shipment received and once for each untrained operator. Further controls may be tested in order to conform with local, state and/or federal regulations, accrediting groups, or your lab's standard Quality Control procedures. If the correct control results are not obtained, do not perform patient tests or report patient results. Contact Technical Support during normal business hours before testing patient specimens.
Precautions	1. For *in vitro* diagnostic use. 2. This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate, high or waived complexity tests and 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. 3. Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only). 4. This test has been authorized only for the detection of SARS-CoV-2 antigen, not for any Page **3** of **14** other viruses or pathogens. 5. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests for detection and/or diagnosis of COVID-19 under Section

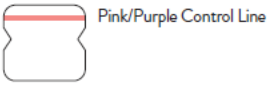
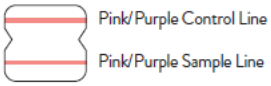
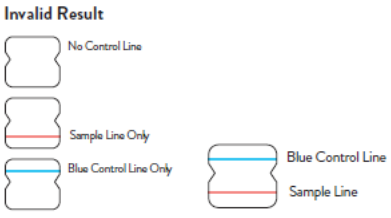
520 WEST SANTA MONICA AVENUE, DEDEDO, GUAM 96929
www.dphss.guam.gov • Ph.: 1.671.735.7136/7143

Precautions (Cont.)	564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. 6. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health laboratories. 7. Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents. 8. Proper sample collection, storage and transport are essential for correct results. 9. Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open. 10. Do not use kit past its expiration date. 11. Do not mix components from different kit lots. 12. Do not reuse the used test card. 13. Inadequate or inappropriate sample collection, storage, and transport may yield false test results. 14. Do not store specimens in viral transport media for specimen storage. 15. All components of this kit should be discarded as Biohazard waste according to Federal, State and local regulatory requirements. 16. Solutions used to make the positive control swab are non-infectious. However, patient samples, controls, and test cards should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal. 17. Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens suspected of COVID-19. 18. INVALID RESULTS can occur when an insufficient volume of extraction reagent is added to the test card. To ensure delivery of adequate volume, hold vial vertically, ½ inch above the swab well, and add drops slowly. 19. False Negative results can occur if the sample swab is not rotated (twirled) prior to closing the card. 20. Swabs in the kit are approved for use with BinaxNOW™ COVID-19 Ag Card. **Do not use other swabs.** 21. The Extraction Reagent packaged in this kit contains saline, detergents and preservatives that will inactivate cells and virus particles. Samples eluted in this solution are not suitable for culture. 22. Do not store the swab after specimen collection in the original paper packaging, if storage is needed use a plastic tube with cap.
Test Procedure	Please refer to the BinaxNOW™ Ag Card User Manual for full instructions, or the Procedure Card for a quick reference with graphic instructions.

520 WEST SANTA MONICA AVENUE, DEDEDO, GUAM 96929
www.dphss.guam.gov • Ph.: 1.671.735.7136/7143

Test Procedure (Cont.)	Open the test card just prior to use, **lay it flat**, and perform assay as follows. **The test card must be flat when performing testing, do not perform testing with the test card in any other position.** 1. Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE,** slowly add **6 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.  2. Insert sample into **BOTTOM HOLE** and firmly push upwards so that the swab tip is visible in the **TOP HOLE**.  3. Rotate (twirl) swab shaft 3 times **CLOCKWISE** (to the right). Do not remove swab.  *Note: False negative results can occur if the sample swab is not rotated (twirled) prior to closing the card.* 4. Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Read result in the window 15 minutes after closing the card. In order to ensure proper test performance, it is important to read the result promptly at 15 minutes, and not before. Results should not be read after 30 minutes.  Note: When reading test results, tilt the card to reduce glare on the result window if necessary. Individuals with color-impaired vision may not be able to adequately interpret test results.

520 WEST SANTA MONICA AVENUE, DEDEDO, GUAM 96929
www.dphss.guam.gov • Ph.: 1.671.735.7136/7143

Test Procedure (cont.)	**Procedure for BinaxNOW™ Swab Controls** Open the test card just prior to use, lay it flat, and perform assay as follows. 1. Hold Extraction Reagent bottle vertically Hovering 1/2 inch above the **TOP HOLE,** slowly add **8 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing. 2. Follow Steps 2 – 4 of the Test Procedure for Patient Specimens.
Results Interpretation	*Note: In an untested BinaxNOW COVID-19 Ag Card there will be a blue line present at the Control Line position. In a valid, tested device, the blue line washes away and a pink/purple line appears, confirming that the sample has flowed through the test strip and the reagents are working. If the blue line is not present at the Control Line position prior to running the test, do not use and discard the test card.* **Negative** A negative specimen will give a single pink/purple colored Control Line in the top half of the window, indicating a negative result. This Control Line means that the detection part of the test was done correctly, but no COVID-19 antigen was detected.  **Positive** A positive specimen will give two pink/purple colored lines. This means that COVID-19 antigen was detected. Specimens with low levels of antigen may give a faint Page **7** of **14** Sample Line. Any visible pink/purple colored line is positive.  **Invalid** If no lines are seen, if just the Sample Line is seen, or the Blue Control Line remains blue, the assay is invalid. Invalid tests should be repeated. 

Limitations	• This test detects both viable (live) and non-viable, SARS-CoV, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not

520 WEST SANTA MONICA AVENUE, DEDEDO, GUAM 96929
www.dphss.guam.gov • Ph.: 1.671.735.7136/7143

Limitations (Cont.)	correlate with viral culture results performed on the same sample. • A negative test result may occur if the level of antigen in a sample is below the detection limit of the test. • The performance of the BinaxNOW™COVID-19 Ag Card was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test. • False negative results may occur if a specimen is improperly collected, transported, or handled. • False results may occur if specimens are tested past 1 hour of collection. Specimens should be test as quickly as possible after specimen collection. • False negative results may occur if inadequate extraction buffer is used (e.g., <6 drops). • False negative results may occur if specimen swabs are not twirled within the test card. • False negative results may occur if swabs are stored in their paper sheath after specimen collection. • Positive test results do not rule out co-infections with other pathogens. • Positive test results do not differentiate between SARS-CoV and SARS-CoV-2. • Negative test results are not intended to rule in other non-SARS viral or bacterial infections. • The presence of mupirocin may interfere with the BinaxNOW™ COVID-19 Ag test and may cause false negative results. • Negative results, from patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. • If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
Conditions of Authorization for Laboratory and Patient Care Settings	The BinaxNOW™ COVID-19 Ag Card Letter of authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas . However, to assist clinical laboratories using the BinaxNOW™ COVID-19 Ag Card, the relevant Conditions of Authorization are listed below:

520 WEST SANTA MONICA AVENUE, DEDEDO, GUAM 96929
www.dphss.guam.gov • Ph.: 1.671.735.7136/7143

Conditions of Authorization for Laboratory and Patient Care Settings (Cont.)	• Authorized laboratories[1] using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media. • Authorized laboratories using your product will use your product as outlined in the "BinaxNOW™ COVID-19 Ag Card" Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted. • Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing. • Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate. • Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAReporting@ fda.hhs.gov) and Abbott Diagnostics Scarborough, Inc. (via email: ts.scr@abbott.com, or via phone by contacting Abbott Diagnostics Scarborough, Inc. Technical Service at 1-800-257-9525) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware. • All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling. • Abbott Diagnostics Scarborough, Inc., authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request. [1] The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, 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." as "authorized laboratories."

520 WEST SANTA MONICA AVENUE, DEDEDO, GUAM 96929
www.dphss.guam.gov • Ph.: 1.671.735.7136/7143

Result Notification **Note:** **Report to Guam DPHSS Territorial Epidemiologist 671-888-WARN (9276) of any confirmed COVID-19 or disease cases with potential for serious public health impact or which may merit epidemiologic investigation.**	Results at the Patient Care Settings are reported to patients within 15-30 minutes of testing specimen(s) by the medical provider or designee. Copies of results shall be forwarded to DPHSS GPHL. Results at the Laboratory are reported to the submitting healthcare facility and or medical provider. Healthcare facility and or medical provider will be responsible for reporting all test results to patients. Any other request for copies of result reports, apart from that stipulated above will not be accepted.
Laboratory Contact Information	Alan Mallari, Microbiologist II (671) 300-9080 (671) 687-8374 alan.mallari@dphss.guam.gov Lea Nisay, Microbiologist I, (Alternate) (671) 300-9088 (671) 300-7355 FAX lea.nisay@dphss.guam.gov Anne Marie Santos, Central Laboratory Administrator (671) 300-9085/9084 (671) 988-4788 annemarie.santos@dphss.guam.gov

Attachment:

1. GPHL Submission Form DPHSS_FRM_03.11.2020
2. Abbott BinaxNOW™ COVID-19 Ag Card User Manual
3. Abbott BinaxNOW™ COVID-19 Ag Card Procedure Card
4. BinaxNOW™ COVID-19 Ag Card Fact Sheet for Healthcare Providers
5. BinaxNOW™ COVID-19 Ag Card Fact Sheet for Patients

References:

1. Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-nCov/index.html. Accessed October 29, 2020.
2. bioRxiv. (https://www.biorxiv.org/content/10.1101/2020.02.07.937862v1). Accessed October 29, 2020.
3. https://www.fda.gov/media/141570/download, Accessed October 29, 2020.
4. Manual of Clinical Microbiology, 11th Edition, Vol. 1, ASM. (2015) pg. 279.