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 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 tested 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:

- 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-EUA-Reporting@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 and patient care settings 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."

PERFORMANCE CHARACTERISTICS

CLINICAL PERFORMANCE

Clinical performance characteristics of BinaxNOW COVID-19 Ag Card was evaluated in a multi-site prospective study in the U.S in which patients were sequentially enrolled and tested. A total of seven (7) investigational sites throughout the U.S. participated in the study. Testing was performed by operators with no laboratory experience and who are representative of the intended users at CLIA waived testing sites. In this study testing was conducted by thirty-two (32) intended users. No training on the use of the test was provided to the operators. To be enrolled in the study, patients had to be presenting at the participating study centers with suspected COVID-19. Patients who presented within 7 days of symptom onset were included in the initial primary analysis, as only seven asymptomatic patients were enrolled. Of the seven asymptomatic patients, only two patients were positive for SARS-CoV-2. Two nasal swabs were collected from patients and tested using the BinaxNOW COVID-19 Ag Card at all study sites. An FDA Emergency Use Authorized real-time Polymerase Chain Reaction (RT-PCR) assay for the detection of SARS-CoV-2 was utilized as the comparator method for this study.

At all sites, one nasal swab was tested directly in the BinaxNOW COVID-19 Ag Card test according to product instructions and the other swab was eluted in viral transport media (VTM). Swabs were randomly assigned to testing with the BinaxNOW or RT-PCR testing and were tested by minimally trained operators who were blinded to the RT-PCR test result. All sites shipped the VTM sample to a central testing laboratory for RT-PCR.

External control testing, using BinaxNOW COVID-19 Ag Card Positive and Negative Controls, was performed prior to sample testing each day, at all study sites.

The performance of BinaxNOW COVID-19 Ag Card was established with 102 nasal swabs collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19.

BinaxNOW™ COVID-19 Ag Card Performance within 7 days of symptom onset against the Comparator Method

BinaxNOW™ COVID-19 Ag Card	Comparator Method		
	Positive	Negative	Total
Positive	34	1	35
Negative	1	66	67
Total	35	67	102
Positive Agreement: 34/35	97.1% (95% CI: 85.1% - 99.9%)		
Negative Agreement: 66/67	98.5% (95% CI: 92.0% - 100%)		

Patient Demographics

Patient demographics (gender, age, time elapsed since onset of symptoms) are available for the 102 samples used in the analysis. The table below shows the positive results broken down by age of the patient:

Age	BinaxNOW™ COVID-19 Ag Card		
	Total #	Positive	Prevalence
≤ 5 years	0		
6 to 21 years	0		
22 to 59 years	77	28	36.4%
≥ 60 years	25	7	28.0%

Positive results broken down by days since symptom onset:

Days Since Symptom Onset	Cumulative RT-PCR Positive (+)	Cumulative BinaxNOW™ COVID-19 Ag Card Positive (+)	PPA	95% Confidence Interval	
1	4	4	100.0%	39.8%	100.0%
2	10	10	100.0%	69.2%	100.0%
3	15	15	100.0%	78.2%	100.0%
4	18	18	100.0%	81.5%	100.0%
5	23	22	95.7%	78.1%	99.9%
6	27	26	96.3%	81.0%	99.9%
7	35	34	97.1%	85.1%	99.9%

The following data is provided for informational purposes:

The performance of BinaxNOW COVID-19 Ag Card with positive results stratified by the comparator method cycle threshold (Ct) counts were collected and assessed to better understand the correlation of assay performance to the cycle threshold, estimating the viral titer present in the clinical sample. As presented in the table below, the positive agreement of the BinaxNOW COVID-19 Ag Card is higher with samples of a Ct count <33.

BinaxNOW™ COVID-19 Ag Card Performance against the Comparator Method – by Cycle Threshold Counts

BinaxNOW™ COVID-19 Ag Card	Comparator Method (POS by Ct Category)	
	POS (Ct < 33)	POS (Ct ≥ 33)
Positive	29	5
Negative	0	1
Total	29	6
Positive Agreement (95% CI)	100.0 (88.1, 100.0)	83.3 (35.9, 99.6)

A limited cohort of patients who presented with symptom onset greater than seven days were enrolled in the clinical study (n = 28). Although the sample size was relatively small, the positive agreement in this cohort was 75% (9/12) and negative agreement was 92% (11/12). Therefore, negative results in patients with symptom onset greater than seven days should be treated as presumptive and confirmed with a molecular assay if needed for clinical management.

ANALYTICAL PERFORMANCE:

Limit of Detection (Analytical Sensitivity)

BinaxNOW COVID-19 Ag Card limit of detection (LOD) was determined by evaluating different concentrations of heat inactivated SARS-CoV-2 virus. Presumed negative natural nasal swab specimens were eluted in PBS. Swab eluates were combined and mixed thoroughly to create a clinical matrix pool to be used as the diluent. Inactivated SARS-CoV-2 virus was diluted in this natural nasal swab matrix pool to generate virus dilutions for testing.

Contrived nasal swab samples were prepared by absorbing 20 microliters of each virus dilution onto the swab. The contrived swab samples were tested according to the test procedure.

The LOD was determined as the lowest virus concentration that was detected ≥ 95% of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive).

The BinaxNOW COVID-19 Ag Card LOD in natural nasal swab matrix was confirmed as 22.5 $TCID_{50}$/swab.

Limit of Detection (LoD) Study Results

Concentration $TCID_{50}$/Swab	Number Positive/Total	% Detected
22.5	20/20	100%