CLIA Waiver by Application Approval Determination
Decision Summary

I. Document Number

CW250001

II. Parent Document Number

K250273

III. CLIA Waiver Type

Dual 510(k) and CLIA Waiver by Application (Dual Submission)

IV. Applicant

Abbott Diagnostics Scarborough, Inc.

V. Proprietary and Established Names

BinaxNOW COVID-19 Ag Card

VI. Measurand (analyte)

Nucleocapsid protein antigen from SARS-Coronavirus 2 (SARS-CoV-2)

VII. Sample Type(s)

Direct anterior nasal swab samples

VIII. Type of Test

Qualitative lateral flow immunoassay

IX. Test System Description

A Overview

The BinaxNOW COVID-19 Ag Card is an immunochromatographic lateral flow assay for detection of SARS-CoV-2 nucleoprotein antigens in human anterior nasal swab specimens without transport media from those who are suspected of COVID-19 withing the first five (5) days of symptom onset.

To initiate testing, a swab provided with the test kit is used to collect anterior nasal swab (ANS) samples from both nostrils of the patient. The user applies six (6) drops of extraction reagent using the pre-filled dropper bottle provided with the test kit to the swab well. Next the user inserts the ANS sample into the test card. The swab is rotated 3 times to elute, lyse and homogenize the sample material from the swab. The card is then closed, bringing the extracted sample into contact with the test strip. As the sample flows along the strip, SARS-CoV-2 antigen first binds to a colloidal gold-conjugated anti-SARS-Cov-2 specific antibody and then is captured by immobilized anti-SARS-CoV-2 antibody, resulting in the presence of a visible line. The control line is formed when colloidal gold-conjugated anti-Chicken antibodies are carried

along the test strip by the sample and captured by immobilized Chicken antibodies. Test results are read visually at 15 minutes without the use of an instrument.

External positive and negative control swabs are provided in each kit of BinaxNOW COVID-19 Ag Card and should be processed according to the instructions for use upon receiving a new lot of test kits or for each untrained operator. The control swabs are intended to be used as quality control samples representative of positive and negative test samples to demonstrate that the reagents are functional, and the assay procedure is performed correctly.

B Test System Components

The assay kit contains all the materials needed to run the test, including external controls, and is available in a 40-test format. Each kit includes:

- Test Cards: A cardboard, book-shaped hinged test card containing one test strip.
- Extraction Reagent: Bottle containing 7.5 mL of extraction reagent.
- Sterile nasal swabs
- Positive Control Swab: Non-infectious recombinant SARS-CoV-2 nucleocapsid antigen dried onto a swab
- Negative Control Swab
- Instructions for Use and Quick Reference Instructions

X. Specific Contents for CLIA Waiver

A Demonstrating "Simple":

- ***Is a fully automated instrument or a unitized or self-contained test.***

  The device is a self-contained test and only requires sample insertion into the device and extraction reagent addition to the test. No instrumentation is required, and the results are visually read based upon two line (one test line and one control line).

- ***Uses direct unprocessed specimens, such as capillary blood (fingerstick), venous whole blood, nasal swabs, throat swabs, or urine.***

  The test uses unprocessed anterior nasal swab specimens directly introduced into the test device.

- ***Needs only basic, non-technique-dependent specimen manipulation, including any for decontamination.***

  An untrained operator can perform the test by performing six (6) basic steps without sample manipulation: (1) remove test card from pouch and open "booklet", (2) add 6 drops of buffer to the extraction buffer port, (3) collect the anterior nasal swab sample, (4) insert the swab sample into the sample port and twist the swab 3 times, (5) peel adhesive liner off and close the test card over swab, and (6) interpret the results at 15 minutes.

  No specialized equipment is needed for sample processing.

- ***Needs only basic, non-technique-dependent reagent manipulation, such as "mix reagent A and reagent B.".***

The test requires only basic reagent handling to obtain accurate results. The provided extraction reagent does not require processing or preparation. The user applies 6 drops of the provided reagent directly to the test card. The kit contains all reagents required for analysis.

- ***Needs no operator intervention during the analysis steps.***

  The test does not require any operator intervention during the analysis step. After insertion of the sample swab into the test cassette, the user applies 6 drops of the extraction reagent, and the test develops without user intervention for 15 minutes. Upon completion of the run time, the user interprets the test results by visual interpretation using the guidance provided in the Instructions for Use/Quick Reference Instructions.

- ***Needs no technical or specialized training with respect to troubleshooting or interpretation of multiple or complex error codes.***

  The test does not require any instrumentation or machinery. The Instructions for Use/Quick Reference Instructions contain information about result interpretation. No technical or specialized training is required for sample collection, sample processing, or result interpretation.

- ***Needs no electronic or mechanical maintenance beyond simple tasks, e.g., changing a battery or power cord.***

  The test does not require any instrumentation or machinery, and therefore does not need any electronic or mechanical maintenance.

- ***Produces results that require no operator calibration, interpretation, or calculation.***

  The test does not require any operator calibration or calculation to interpret results. Operator visual interpretation of test results is required. The Instructions for Use/Quick Reference Instructions provided with the test kit include descriptions of how to interpret test results, including visual examples and indications of next steps to take based on the results.

- ***Produces results that are easy to determine, such as 'positive' or 'negative,' a direct readout of numerical values, the clear presence or absence of a line, or obvious color gradations.***

  The BinaxNOW COVID-19 Ag Card test results are simple to determine results as 'positive', 'negative', or 'invalid' based on the presence or absence of colored test and control lines. The Instructions for Use/Quick Reference Instructions include descriptions and visual examples of test result interpretation. Prescription eyeglasses or contact lenses should be worn by the operator, as applicable.

- ***Contains a quick reference instruction sheet that is written at no higher than a 7th grade reading level.***

  The kit contains a QRI (i.e., procedure card) written at a 7th grade comprehension level.

B Demonstrating "Insignificant Risk of an Erroneous Result"- Failure Alerts and Fail-Safe Mechanisms

1. Risk Analysis:

   Risk management of the BinaxNOW COVID-19 Ag Card has been conducted in accordance with ISO 14971, using the Failure Mode Effects Analysis (FMEA) to assess risk. The FMEA analyzed hazardous situations that may result in false positive, false negative, or invalid results. The FMEA included failures of the device (i.e., manufacturing defects) and failures of the use (i.e., influenced by the user). The probabilities of occurrence for specific failures were assigned during the design phase and later reassessed based on data obtained during performance evaluations, when testing was performed by operators meeting the intended use setting. All risks of harm from the device were mitigated to an acceptable level via modifications in design, manufacturing, or labeling.

   The identified risks which could result in erroneous test results were evaluated in flex studies that stressed the functional units of the test system (Section B.3).

2. Fail-Safe and Failure Alert Mechanisms:

   The BinaxNOW COVID-19 Ag Card was designed to include features and fail-safe mechanisms built into the system to prevent erroneous results.

   Design Features:

   - Each test card is packaged in a foil pouch with desiccant to maintain the integrity of the test device and reagents.
   - The foil pouch of the cassette is printed with the assay name, test analyte, lot number, and expiration date to ensure clarity and appropriate use.
   - Each test card feature distinct position marks to facilitate clear and accurate test performance and results interpretation.
     i. Inside the test card displays images and directional arrows which guides the operator to add six (6) drops of extraction reagent into the top hold of the test card, proper swab insertion and rotation into the bottom hole of the test card, closure of the test card, and to interpret results after 15 minutes.
     ii. On the outside of the test card displays the words, *"Sample"* and *"Control"*, next to the areas of the test card window that visually guides the operator in differently the test result correctly.
   - Each positive control swab included in the kit is clearly marked on the outside labeling with control swab name, lot number, and expiration date to ensure clarity and appropriate use.

     The extraction reagent is contained in a multi-use bottle to maintain the integrity of the reagent.

   Fail-safe Features:

   - *Internal Quality Control:* The test contains built-in procedural control. This control line area is visible as a blue dyed line in an untested device. In a valid test, the capillary flow of the extraction reagent containing the sample and conjugate will wash the blue dye away and a pink line will form at the control line area. The presence of the pink line on the completed test confirms that the correct procedural technique was used. If the control line remains blue or is not present at all, regardless

of whether a sample line is present, the test is invalid. Testing with a new sample and new device is recommended.

- *External Quality Control:* Testing of one (1) Positive Control Swab (coated with SARS-CoV-2 recombinant antigen) and one (1) Negative Control Swab are provided in each kit. The manufacturer recommends testing of the controls for the following situations:
  i. Each new shipment of BinaxNOW COVID-19 Ag Card kits received.
  ii. Once for each trained operator.
  iii. Additional testing to conform with local, state, and/or federal regulations, accrediting groups, or a laboratory standard Quality Control procedure.

External control swabs are provided ready to use and are extracted and processed using the same procedure as for patient samples except for the number of Extraction Reagent drops required (i.e., 8 drops), which is specified in Procedure Card (QRI). Each control swab should produce the expected positive and negative results to validate the test kit performance. These controls monitor the entire assay and serve to detect product defects or deterioration between the manufacturer's lot release date and the date of use as well as operator use to detect any errors in the performance of the test. If the correct control results are not obtained, users are instructed not to perform patient testing or report patient results. Operators are instructed to contact technical support during normal business hours before testing patient samples.

3. Flex Studies:

The operational limits of the BinaxNOW COVID-19 Ag Card were evaluated in a series of experiments under conditions of stress. Samples used for flex study testing were prepared in negative nasal swab matrix (NSM), which was prepared by pooling negative nasal swabs collected from healthy individuals and eluted in 1 mL of saline. The pooled NCM was confirmed negative by the BinaxNOW COVID-19 Ag Card. Contrived positive samples were prepared at 2X LoD by spiking NCM with inactivated SARS-CoV-2 (USA-WA-1/2020). The contrived negative samples were prepared by spiking NSM onto a nasal swab. External positive and negative Quality Control swabs were tested in replicates of one (1) on each day of flex study testing.

Flex studies were conducted that assessed all major aspects of the test procedure—extraction reagent volume, incorrect assay procedure, test result reading time, incorrect sample type, temperature and humidity conditions, lighting conditions, operating temperature, freeze-thaw conditions, environmental contaminants, and device disturbance. The negative and positive test samples were evaluated under these flex conditions in replicates of five (5). Samples were tested according to the instructions for use protocol, except for the noted deviations dictated by the flex parameter under evaluation. The studies support that the test is robust in the intended use condition with an insignificant risk of erroneous result.

All QC swabs tested obtained expected results. The effect of the following conditions on the performance of the test was evaluated, organized by the potential type of source error:

Human Factors/User Error

1. *Extraction Reagent Volume*

This study evaluated the impact of extraction buffer volume deviations on device performance. Following swab sample insertion into the sample port, a total of 1, 2, 3, 4,

5, 6 (control condition), 7, 8, or 9 drops were added, and results were read according to the Instructions for Use. All samples yielded invalid results with only 1 drop of the extraction buffer. For all other test conditions (2 – 9 drops), all samples yielded the expected results.

2. *Incorrect Assay Procedure*

This study evaluated the effect of incorrect assay procedure (missing steps, performing steps incompletely, or not performing steps in the correct order) on the performance of the BinaxNOW COVID-19 Ag Card. The follow procedure deviations were tested: extraction reagent added out of order, swab inserted into the test out of order, number of swab rotations, and elution time omitted. The results of this study demonstrated false negative results may occur when the swab rotations were omitted and when the extraction reagent/swab insertion occurred out of order. All other samples evaluated under all other procedure deviation conditions produced the expected results.

3. *Test Result Read Time*

This study evaluated the effect of unspecified read times (e.g., a reduced or extended read time) on the performance of the BinaxNOW COVID-19 Ag Card. Positive and negative samples were prepared and randomized by a study operator and then provided to different operators who were blinded to the sample identity to perform the test. Positive and negative samples were tested according to assay procedure except for the modification of results read time (i.e., interpreting test results). Timepoints between 5 – 60 minutes (at various intervals) were evaluated and all samples, at all tested timepoints, produced the expected results.

4. *Patient Swab Testing Delayed*

This study evaluated the impact on the performance of the BinaxNOW COVID-19 Ag Card when patient swab testing was delayed after collection. Contrived positive and negative samples were prepared and randomized by a study operator and then provided to different operators who were blinded to the sample identity to perform the test. The contrived samples were tested according to assay procedure except for the modification of placing the samples into a blank plastic tube and stored at 28-32°C for the following timepoints: 0 (i.e., immediately), 1, 1.5, 2, 3, 4, 5, 6, 7, and 8 hours. After each timepoint the samples were tested per assay procedure. All samples, at all tested timepoints, produced expected results.

5. *Use of Expired Reagents*

This study evaluated the impact on the performance of the BinaxNOW COVID-19 Ag Card, when performing testing with expired and non-expired kit components consisting of test device, extraction reagent, and positive control swab. Contrived positive and negative samples were prepared and randomized by a study operator and then provided to different operators who were blinded to the sample identity to perform the test. The contrived samples were tested according to assay procedure except for the modification of utilizing expired and non-expired components. The expired component timeframes included the following: 36 months, 5 days, 36 months, 14 days, and 36 months, 19 days. As a reference (i.e., control), non-expired components utilized were within the 22 month shelf-life claim of the BinaxNow COVID-19 Ag Card test kit. All samples, at all tested timepoints, produced expected results.

<u>Operational and Environmental Testing Conditions:</u>

6. *Extreme Temperature and Humidity*

This study evaluated the impact of variations in temperature and relative humidity (RH) environmental conditions on test device performance. The temperature and humidity flex conditions required for this study were set up as follows in an environmental chamber:

- Control Condition (30°C ± 2°C / 80% ± 5% RH)
- Low Temperature (5°C ± 3°C) / Low Humidity (5% ± 5% RH)
- Low Temperature (5°C ± 3°C) / High Humidity (71%-89% RH)
- High Temperature (45°C ± 3°C) / Low Humidity (5% ± 5% RH)
- High Temperature (45°C ± 3°C) / High Humidity (95% ± 5% RH)

For each environmental condition described above, BinaxNOW COVID-19 Ag Card components (test device, extraction reagent, and positive control swabs) were placed into the environmental chamber to equilibrate for 30 minutes. Test devices and positive control swabs were then removed from their foil pouches and returned to the environmental chamber for another 30 minutes (for a total of 1 hour exposure). Operators removed the test components from the chamber, initiated the test and returned the test to the chamber for the 15 minute assay run time at which point the results were interpreted. All samples tested across the indicated environmental conditions produced the expected results.

Additionally, to further test the impact of temperature and humidity of storage, pouched kit components were placed into a chamber set to 60°C, 85% RH and stored for 1, 3, 7, and 8 days. After storage 60°C, 85% RH for the required duration, components were removed from the incubator and were tested according to the IFU. All samples tested across the indicated environmental conditions produced the expected results.

7. *Lighting Conditions*

This study evaluated the performance of the BinaxNOW COVID-19 Ag Card when run and interpreted under various lighting conditions. Positive and negative samples were tested according to assay procedure under various lighting conditions: standard LED laboratory lighting, direct sunlight, low light, fluorescent light, and incandescent light. Samples were prepared and randomized by a study operator and then provided to different operators who were blinded to the sample identity to perform the test. All positive and negative controls generated the expected results when run and interpreted under each lighting condition tested.

8. *Test Kit Temperature*

This study evaluated the effects on test performance when test components are

refrigerated and not allowed to reach room temperature before performing the BinaxNOW COVID-19 Ag Card. Kit components (test devices, extraction reagent , and positive control swabs) were placed into refrigerated (2-8°C) storage conditions for at least three (3) hours prior to testing. For the reference condition, kit components were removed from refrigeration and allowed to equilibrate to room temperature for at least 30 minutes. Experimental condition components were removed from refrigeration and tested immediately. Test operators prepared samples and initiated tests, then randomized test devices by sample type and study condition. Tests were then interpreted by a second

group of operators who were blinded to both sample type and study condition. All samples tested across both temperature conditions produced the expected results.

9. *Freeze-Thaw*

This study evaluated the effects on test performance when kit components are subjected to one or three freeze/thaw cycles that may occur during shipment to the end user. Kit components (test devices, extraction reagent, and positive control swabs) were stored per the following storage conditions and parameters:

- One Freeze/Thaw Cycle: Kit components were placed into a -20°C freezer for a minimum of 24 hours. Afterwards, the kit components were transferred to a 30°C incubator for a minimum of 24 hours. After the extraction reagent was thawed, kits were tested according to assay procedure.
- Three Freeze/Thaw Cycles: Kit components were placed into a -20°C freezer for a minimum of 24 hours. Afterwards, the kit components were transferred to a 30°C incubator for a minimum of 24 hours. After the extraction reagent was thawed, kit components were then exposed to two additional freeze/thaw cycles, as described above. Following the third freeze/thaw cycle, kits were tested according to assay procedure.

Operators who were blinded to sample type (positive or negative) performed the kit freeze/thaw steps listed above and then performed tests. Randomized tests were then provided to a second group of operators who were blinded to both sample type and freeze/thaw condition to interpret the results of the test. All positive and negative samples tested across all freeze-thaw conditions produced the expected results.

10. *Environmental Contaminants*

This study evaluated if the presence of environmental contaminants that may be introduced during test operation affects the performance of the BinaxNOW COVID-19 Ag Card. The following environmental contaminants were tested herein:

- 10% Bleach
- 70% Ethanol
- Clorox Wipe
- Glove Powder
- Hydrogen Peroxide Wipe
- 99% Isopropyl Alcohol
- Lysol Spray

Each environmental contaminant was tested in two ways: 1) Wet – while the testing surface was visibly wet/covered with each material; and 2) Dry – after the testing surface was dried/wiped with only the residue of each material remaining. For each condition, the operator placed the unpouched test device test strip side down onto the testing surface, such that it came into contact with the liquid/powder or residue and then returned it face up in one motion. The operator then initiated the test with the positive and negative samples, randomized the test devices, and then provided them to a different group of operators who were blinded to both sample type and study condition for result interpretation.

Negative samples produced erroneous results (i.e., false positives) and/or invalid results with Wet Bleach, Wet Ethanol, Wet Clorox Wipes, and Glove Powder. Positive samples

produced erroneous results (i.e., false negatives) and/or invalid results with Dry Bleach. Dry Clorox Wipes, and 99% Isopropyl Alcohol. All other samples evaluated in the presence of the environmental contaminants produced the expected results.

11. *Device Disturbance and Position*

This study evaluated the impact of disturbing the test device during test operation and the testing surface orientation on the performance of the BinaxNOW COVID-19 Ag Card. Eight different test conditions (including the control condition) were evaluated herein:

- Control condition (performed per the IFU)
- Dropping the test device (before sample addition, after reagent application, after sample application, and after the test booklet was closed)
- Test surface positioning (test device moved horizontally during test development, test device moved to a vertical position during test development, and test device placed face down during test development.)

Operators prepared samples and performed the test disturbance parameters steps listed above and then provided test devices to a second group of operators who were blinded to both sample type and flex condition to interpret test results. All positive and negative samples tested across physical disturbance conditions produced the expected results.

C Demonstrating "Insignificant Risk of an Erroneous Result" - Accuracy

1. Clinical Performance:

The performance of the BinaxNOW COVID-19 Ag Card in detecting SARS-CoV-2 viral nucleoprotein antigen from anterior nasal swab samples was evaluated in a multi-center, prospective study with lay users in the U.S. during two distinct time frames ranging from November 2020 to July 2022. Across six sites, a total of 765 untrained lay users were enrolled into the study and self-tested (or tested another). The study only enrolled subjects with symptoms of respiratory infection consistent with SARS-CoV-2 infection.

An anterior nasal (AN) swab was self-collected by each study subject and immediately tested with the BinaxNOW COVID-19 Ag Card according to the test device's quick reference instructions. A second swab was collected by the study operator (either an anterior nasal swab or mid-turbinate swab), placed into a transport tube containing viral transport media, refrigerated, and shipped to a central lab for testing with a highly sensitive RT-PCR comparator assay. The investigational sample was collected first, followed then by the comparator swab. Demographics, symptom information, and health history were also collected from each subject.

There were 604 evaluable subjects with an average age of 37 years. Approximately 43% (262/604) were male and 56% (342/604) were female (2 subjects were undisclosed; 0.33%). A total of 161 subjects of the total 765 enrolled were excluded because they did not meet the inclusion criteria, or their samples had invalid or missing comparator results. Results obtained with the BinaxNOW COVID-19 Ag Card were compared to the results obtained with a highly sensitive RT-PCR comparator test to determine agreement with the true clinical status of the patient.

The BinaxNOW COVID-19 Ag Card demonstrated a positive percent agreement (PPA) of 86.9% (186/214; 95% CI: 81.7% - 90.8%) and a negative percent agreement (NPA) of 98.5% (384/390; 95% CI: 96.7% - 99.3%) when compared to the comparator method.

Table 1. *Performance of BinaxNOW COVID-19 Ag Card against RT-PCR Comparator*

		RT-PCR Comparator		
		Positive	**Negative**	**Total**
BinaxNOW COVID-19 Ag Card	**Positive**	186	6	192
	Negative	28	384	412
	Total	214	390	604

PPA: 86.92% (186/214; 95% CI: 81.7% - 90.8%)
NPA: 98.46% (384/390; 95% CI: 96.7% - 99.3%)

Table 2. *Performance Metrics of BinaxNOW COVID-19 Ag Card stratified by Days Post-Symptom Onset (DPSO)*

Days Post-Symptom Onset	PPA by DPSO	NPA by DPSO
Day 0	69.23% (9/13)	100.00% (24/24)
Day 1	89.71% (61/68)	98.92% (92/93)
Day 2	86.36% (57/66)	100.00% (97/97)
Day 3	86.67% (39/45)	97.78% (88/90)
Day 4	83.33% (10/12)	96.61% (57/59)
Day 5	100.00% (10/10)	96.30% (26/27)

Table 3. *Performance of the BinaxNOW COVID-19 Ag Card stratified by sample collection timeframe.*

Dominant Variant	Study Date Range	PPA	NPA
Pre-Omicron (n=295)	November 2020 – March 2021	81.61% (71/87)	98.56% (205/208)
Omicron (n=309)	February 2022 – July 2022	90.55% (115/127)	98.35% (179/182)

2. Reproducibility/Near Cut-Off Study:

A reproducibility/near cut-off study was conducted with the BinaxNOW CoVID-19 Ag Card at three (3) CLIA-waived external sites by a total of nine (9) untrained operators (3 operators per site). Each operator tested six (6) samples comprised of four (4) panel members (Table 1), two (2) times a day (AM and PM), across five (5) non-consecutive days. Contrived samples were prepared utilizing inactivated SARS-CoV-2 (USA-WA1/2020) diluted into negative nasal swab matrix (NSM) to Moderate Positive (5X LoD), Low Positive (1X LoD), and High Negative (0.05X LoD). True negative (TN) samples consisted of NSM only. Contrived samples were applied to individual dry nasal swabs which were blinded, randomized, and tested across three (3) reagent lot numbers. Results were generated from a total 540 samples (3 sites x 3 operators/site x 2 times a day x 5 non-consecutive days x 6 replicates/operator/day). Over the course of the study, each operator tested fifteen (15) samples per panel member.

Table 4. *Contrived Positive and Negative Panel Members*

Sample	SARS-CoV-2 Concentration	Expected Results

Moderate Positive (5X LoD)	2187.5 $TCID_{50}$/mL	Positive
Low Positive (1X LoD)	437.5 $TCID_{50}$/mL	
High Negative (0.05X LoD)	23.03 $TCID_{50}$/mL	Negative
True Negative	NSM Only	

A summary of percent agreement with expected results for each panel member by operator, site, and reagent lot number is presented in Tables 2 and 3 below. All daily controls performed by each operator generated the expected results on each day of testing (data not shown).

Table 5. *Precent Agreement with Expected Results by Untrained Operators*

Sample	**Positive Percent Agreement / Total**									
	Site: 1			**Site: 2**			**Site: 3**			**Totals**
	Operators			**Operators**			**Operators**			
	X_{1A}#	**Y_1**	**Z_1**	**X_2**	**Y_2**	**Z_2**	**X_3**	**Y_3**	**Z_3**	**95% CI**
Moderate Positive (5X LoD)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (135/135) 97.2%-100%
Low Positive (1X LoD)	100% (15/15)	86.7% (13/15)	93.3% (14/15)	100% (15/15)	93.3% (14/15)	100% (15/15)	80% (12/15)	93.3% (14/15)	100% (15/15)	94.1% (127/135) 88.7%-97.0%
High Negative (0.05X LoD)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	92.3%* (12/13)	99.2% (132/133) 95.9%-99.9%
True Negative	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	93.3% (14/15)	99.3% (134/135) 95.9%-99.9%

Operator X_{1A} replaced Operator X_1 who did not participate in study due to time constraints.
* Two samples excluded: Interpreted before 15 minutes was completed.

Table 6. *Lot-to-Lot Precision Results*

Untrained Operators					
Sample	**Lot 1 (381213)**	**Lot 2 (391213)**	**Lot 3 (371213)**	**% Agreement**	**95% CI**
Moderate Positive (5X LoD)	100% (45/45)	100% (45/45)	100% (45/45)	100% (135/135)	97.2% - 100.0%
Low Positive (1X LoD)	93.3% (42/45)	90.9% (40/44)	97.8% (45/46)	94.1% (127/135)	88.7% - 97.0%
High Negative (0.05X LoD)	100%* (44/44)	97.8% (44/45)	100%* (44/44)	99.2% (132/133)	95.9% - 99.9%
True Negative	100% (45/45)	97.8% (44/45)	100% (45/45)	99.3% (134/135)	95.9% - 99.9%
* Excluded Sample: Interpreted before 15 minutes was completed.					

The results obtained from these studies demonstrated that the BinaxNOW COVID-19 Ag Card produces reproducible results with untrained operators in CLIA waived settings and consistent performance across multiple lots with organism concentrations near the assay LoD.

3. Operator Questionnaire:

   At the end of the reproducibility/precision study a total of nine (9) untrained operators (3 operators per site) completed a questionnaire to provide feedback on the ease of the use of the BinaxNOW COVID-19 Ag Card. The questionnaire had six (6) questions which evaluated the following general topics:

   - Ease of use to follow the Quick Reference Instructions
   - Ease of use of the test and test kit components
   - Ease of processing sample
   - Ease of interpreting results
   - Ability to read the Control Line

   Based on the feedback from the nine (9) untrained operators, the BinaxNOW COVID-19 Ag Card was found to be easy to set up, operate, and interpret results. Operators also found the Quick Reference Instructions easy to use and understand.

D Labeling for Waived Devices

The labeling for the BinaxNOW COVID-19 Ag Card consists of:

1. Instructions for Use (IFU)
2. Procedure Card (i.e., Quick Reference Instructions)
3. Quality Control Swab Instructions for Use

The following elements are appropriately present:

- The IFU and Procedure Card are written at no higher than a 7th grade reading level.
- The IFU, Procedure Card, and Outer Box identify the test as CLIA waived.
- The IFU and Procedure Card contain a statement that a Certificate of Waiver is required to perform the test in a waived setting.
- The IFU and Procedure Card contain a statement that laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test per 42 CFR 493.15(e)(1).
- The IFU and Procedure Card provide instructions for conducting quality control procedures.

The labeling is sufficient and satisfies the requirements of 21 CFR 809.10.

XI. Conclusion

The submitted information in this CLIA waiver application supports a CLIA waiver approval decision.