February 18, 2025

Abbott Diagnostics Scarborough, Inc.
Kristen Cyr
Regulatory Affairs Specialist
10 Southgate Road
Scarborough, Maine 04074

Re: K243518
Trade/Device Name: BinaxNOW COVID-19 Antigen Self Test
Regulation Number: 21 CFR 866.3984
Regulation Name: Over-The-Counter Test To Detect SARS-Cov-2 From Clinical Specimens
Regulatory Class: Class II
Product Code: QYT

Dear Kristen Cyr:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 11, 2025. Specifically, FDA is updating this SE as an administrative correction. The original SE letter incorrectly included an additional trade name. The trade name in this corrected letter reflects the only trade name cleared under K243518 (i.e., BinaxNOW COVID-19 Antigen Self Test).

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Silke Schlottmann, OHT7: Office of In Vitro Diagnostics, (301) 796-9551, Silke.Schlottmann@fda.hhs.gov.

Sincerely,

Silke Schlottmann -S

Digitally signed by Silke Schlottmann -S
Date: 2025.02.18 17:01:40 -05'00'

Silke Schlottmann, Ph.D.
Deputy Assistant Director
Bacteriology Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

February 11, 2025

Abbott Diagnostics Scarborough, Inc.
Kristen Cyr
Regulatory Affairs Specialist
10 Southgate Road
Scarborough, Maine 04074

Re: K243518
Trade/Device Name: BinaxNOW COVID-19 Antigen Self Test; BinaxNOW COVID-19 Ag Card
Regulation Number: 21 CFR 866.3984
Regulation Name: Over-The-Counter Test To Detect SARS-Cov-2 From Clinical Specimens
Regulatory Class: Class II
Product Code: QYT
Dated: November 12, 2024
Received: November 13, 2024

Dear Kristen Cyr:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Silke Schlottmann -S

Digitally signed by Silke Schlottmann -S
Date: 2025.02.11 16:01:26 -05'00'

Silke Schlottman, Ph.D.
Deputy Assistant Director
Bacteriology Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K243518

Device Name
BinaxNOW COVID-19 Antigen Self Test

Indications for Use *(Describe)*
The BinaxNOW COVID-19 Antigen Self Test is a visually read lateral flow immunoassay intended for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal (nares) swab specimens from individuals with signs and symptoms of COVID-19. This test is for non-prescription home use by individuals aged 15 years or older testing themselves, or adults testing individuals aged 2 years or older.

All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment.

Positive results do not rule out co-infection with other respiratory pathogens.

This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.

The performance characteristics for SARS-CoV-2 were established from November, 2020 to July, 2022, when SARS-CoV-2 Delta and Omicron were dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(K) SUMMARY

Preparation Date: February 10, 2025

CONTACT DETAILS

Applicant Name: Abbott Diagnostics Scarborough, Inc.
Applicant Address: 10 Southgate Road, Scarborough, Maine 04074 USA
Applicant Contact: Ms. Kristen Cyr
Applicant Contact Email : kristen.cyr@abbott.com
Applicant Contact Phone : (207) 210-4311

DEVICE NAME

Device Trade Name: BinaxNOW COVID-19 Antigen Self Test
Common Name: BinaxNOW COVID-19 Self Test; BinaxNOW COVID-19
Classification Name: Over-The-Counter Covid-19 Antigen Test
Regulation Number: 866.3984
Product Code: QYT

PREDICATE DEVICE

K231795, QuickVue COVID-19 Test

DEVICE DESCRIPTION SUMMARY

The BinaxNOW COVID-19 Antigen Self Test is an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2 nucleocapsid protein from nasal swab specimens. SARS-CoV-2 specific antibodies and a control antibody are immobilized onto a membrane support as two distinct lines and combined with other reagents/pads to construct a test strip. This test strip and a well to hold the swab specimen are mounted on opposite sides of a cardboard, book-shaped hinged test card.

To perform the test, a nasal swab specimen is collected from the patient, 6 drops of extraction reagent from a dropper bottle are added to the top hole of the swab well. The patient sample is inserted into the test card through the bottom hole of the swab well, and firmly pushed upwards until the swab tip is visible through the top hole. The swab is rotated 3 times clockwise and the card is closed, bringing the extracted sample into contact with the test strip. Test results are interpreted visually at 15 minutes based on the presence or absence of visually detectable pink/purple colored lines. Results should not be read after 30 minutes.

INTENDED USE/INDICATIONS FOR USE

The BinaxNOW COVID-19 Antigen Self Test is a visually read lateral flow immunoassay intended for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal (nares) swab specimens from individuals with signs and symptoms of COVID-19. This test is for non-prescription home use by individuals aged 15 years or older testing themselves, or adults testing individuals aged 2 years or older.

All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment.

Positive results do not rule out co-infection with other respiratory pathogens.

This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.

The performance characteristics for SARS-CoV-2 were established from November, 2020 to July, 2022, when SARS-CoV-2 Delta and Omicron were dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

INDICATIONS FOR USE COMPARISON

The BinaxNOW COVID-19 Antigen Self Test and the predicate device, QuickVue COVID-19 Test (K231795), have the same intended use. The test systems are intended for the rapid, qualitative detection of SARS-CoV-2 directly in anterior nasal swab specimens as an aid in the diagnosis of SARS-CoV-2 infection.

TECHNOLOGICAL COMPARISON

The BinaxNOW Antigen Self Test (BinaxNOW COVID-19 Ag Card) and the predicate device, QuickVue COVID-19 Test, have the same technological characteristics. Both test systems are visually read lateral flow immunoassays for detection of the nucleocapsid protein antigen from SARS-CoV-2 in clinical specimens.

NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY AND CONCLUSIONS
ANALYTICAL STUDIES

Precision

A precision study was performed to assess the total variability of the BinaxNOW COVID-19 Antigen Self Test across testing days, operators and BinaxNOW COVID-19 Antigen Self Test device lots. The testing panel was prepared using inactivated SARS-CoV-2 (isolate USA-WA1/2020) diluted into clinical nasal matrix and then spiked onto nasal swabs. The testing panel consisted of four members: (1) Negative (no analyte); (2) 0.05X LoD; (3) 1X LoD; and (4) 5X LoD. Each test panel was tested by three Operators across five non-consecutive days, each running three replicates per day (3 operators x 3 lots x 5 days x 3 replicates/panel member) for a total of 135 observations per panel member. The results are presented in the table below.

Precision Study Results

Device Lot	Sample	Percent Agreement with Expected Results (95% Confidence Interval
Lot 1	5X LoD	100% (44/44) (92.0-100.0%)
	1X LoD	100% (42/42) (91.6-100.0%)
	High Negative*	100% (47/47) (92.4-100.0%)
	Negative	100% (46/46) (92.3-100.0%)
Lot 2	5X LoD	100% (43/43) (91.8-100.0%)
	1X LoD	97.8% (44/45) (88.4-99.6%)
	High Negative*	100% (44/44) (92.0-100.0%)
	Negative	100% (47/47) (92.4-100.0%)
Lot 3	5X LoD	100% (47/47) (92.4-100.0%)
	1X LoD	95.8% (46/48) (86.0-98.8%)
	High Negative*	100% (43/43) (91.8-100.0%)

	Negative	100% (41/41) (91.4-100.0%)

*Sample prepared to a concentration 0.05X LOD

Analytical Sensitivity (Limit of Detection)

BinaxNOW COVID-19 Antigen Self Test limit of detection (LoD) was determined by evaluating different concentrations of two inactivated strains of 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.

For each strain, 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 Antigen Self Test LoD in natural nasal swab matrix was confirmed as 3.5×10^3 TCID50/mL for USA-WA1/2020 and 1.6×10^3 TCID50/mL for B.1.1.529 (Omicron). Based upon the testing procedure for this study this LoD equates to 70 $TCID_{50}$/swab for USA-WA1/2020 and 32.06 $TCID_{50}$/swab for B.1.1.529 (Omicron).

Limit of Detection Study Results

Strain	Concentration $TCID_{50}$/mL
USA-WA1/2020	3.5×10^3
B.1.1.529 (Omicron)	1.6×10^3

Testing with International Standard for SARS-CoV-2 Ag (NIBSC 21/368)

A study was performed to also determine the LoD for the BinaxNOW COVID-19 Antigen Self Test in nasal samples using the International Standard for SARS-CoV-2 antigen as a standardized material.

As per the International Standard instructions, the international standard material was reconstituted in 0.25 mL of ultra-pure water. Following reconstitution, the ampule was left at ambient temperature for 20 minutes and then mixed thoroughly, avoiding generation of excess foam. The reconstitution of the material yielded a final stock concentration equal to 2.0×10^4 IU/mL.

For each replicate, 20 µL of virus dilution was applied to a swab and the swab was tested according to the IFU. A preliminary LoD concentration was determined by testing a series of 2-fold dilutions of the antigen spiked into natural nasal swab matrix in replicates of three (3). The lowest concentration with 3 out of 3 positive replicates was considered to be the preliminary LoD. The results of the preliminary LoD study are shown in the Table below:

International Standard for SARS-CoV-2 Ag LoD Range Finding Results

Concentration (IU/ml)	BinaxNOW COVID-19 Ag Card Results	
	# Detected	% Detected
2000	3/3	100
1000	3/3	100
500	**3/3**	**100**
250	0/3	0
125	0/3	0

The preliminary LoD was confirmed by testing an additional seventeen (17) replicates per dilution for a total of (20) until less than 100% positive results were obtained. The results of this testing, as shown in the table below confirmed the LoD for the International Standard Antigen to be 375 IU/mL (7.5 IU/swab).

International Standard for SARS-CoV-2 Ag Confirmatory LoD Results

Concentration (IU/mL)	BinaxNOW COVID-19 Ag Card Results	
	# Detected	% Detected
500	20/20	100
375	**20/20**	**100**
250	4/20	20

Analytical Reactivity (Inclusivity)

An Analytical Reactivity (Inclusivity) study was performed to determine whether the BinaxNOW COVID-19 Antigen Self Test is able to detect a variety of SARS-CoV-2 strains.

Vendor provided stocks of SARS-CoV-2 strains were diluted in natural nasal swab matrix to generate virus dilutions for testing. Contrived swab samples were prepared by coating 20 microliters of virus dilution onto each swab.

Each dilution of virus strain was tested n = 5 replicates. A concentration level was considered "reactive/positive" in this study if all five replicates generated a positive result.

The BinaxNOW COVID-19 Antigen Self Test detected all strains tested at the concentrations indicated in the table below:

Analytical Reactivity Study Results

Variant	Concentration ($TCID_{50}$/ml)
Alpha (B.1.1.7)	2.80×10^5
Beta (B.1.351)	5.60×10^4
Delta (B.1.617.2)	1.40×10^4
Gamma (P.1)	1.40×10^4
Iota (B.1.526)	5.60×10^4
Italy-INMI1	2.80×10^5
Kappa (B.1.617.1)	8.40×10^4
Zeta (P.2)	2.80×10^4

Variant	Concentration ($TCID_{50}$/ml)
Omicron (BA.2.3)	2.10×10^4
Omicron (BA.2.12.1)	1.05×10^4
Omicron (BA.2.75.5)	7.00×10^3
Omicron (BA.4.6)	2.80×10^4
Omicron (BA.5)	4.48×10^5
Omicron (BA.5.5)	8.80×10^2
Omicron (BF.5)	2.80×10^4
Omicron (BF.7)	1.12×10^5
Omicron (BQ.1)	5.60×10^4
Omicron (BQ.1.1)	7.00×10^3
Omicron (XBB)	2.24×10^5
Omicron (JN.1)	2.90×10^3 (IFU/mL)

Analytical Specificity (Cross Reactivity) and Microbial Interference

Cross reactivity and potential interference of BinaxNOW COVID-19 Antigen Self Test was evaluated by testing 29 commensal and pathogenic microorganisms (9 bacteria, 17 viruses, 1 yeast and pooled human nasal wash) that may be present in the nasal cavity. Each organism, virus, and yeast was tested n=5 in the absence or presence of inactivated SARS-CoV-2 virus at 3x LoD (210 TCID50/swab). No cross-reactivity or interference was seen with the microorganisms in the table below when tested at 1×10^6 CFU/mL for bacteria and yeast and at 1×10^5 $TCID_{50}$/mL for viruses.

Type	Panel Member
Viruses	Human Adenovirus 1
	Human Coronavirus 229E
	Human Coronavirus NL63
	Human Coronavirus OC43
	Human Coronavirus HKU1*
	Enterovirus 70
	Human Metapneumovirus (hMPV)
	Human Parainfluenza virus 1
	Human Parainfluenza virus 2
	Human Parainfluenza virus 3
	Human Parainfluenza virus 4
	RSV A
	Rhinovirus 1A
	MERS-coronavirus
	Human Influenza A/California/07/09
	Human Influenza A/New Caledonia/20/99
	Human Influenza A/Brisbane/02/18
	Human Influenza B/Wisconsin/1/10
Bacteria	*Bordetella pertussis*
	Chlamydia pneumoniae
	Haemophilus influenzae
	Legionella pneumophila
	Mycoplasma pneumoniae

Type	Panel Member
	Staphylococcus aureus
	Staphylococcus epidermidis
	Streptococcus pneumoniae
	Streptococcus pyogenes
Yeast	*Candida albicans*
Other	Pooled Human Nasal Wash

*Four (4) unique clinical specimens were evaluated with Ct counts ranging from 22.3 – 32.0

High Dose Hook Effect

No high dose hook effect was observed when tested with up to a concentration of 1.4 x 10^6 TCID50/mL of inactivated SARS-CoV-2 virus with the BinaxNOW COVID-19 Antigen Self Test.

Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the upper respiratory tract, were evaluated with the BinaxNOW COVID-19 Antigen Self Test at the concentrations listed below and were found not to affect test performance.

Substance	Active Ingredient	Concentration
Throat Lozenge	Menthol, Benzocaine	3 mg/mL
Sore Throat Spray	Phenol	5% w/v
OTC Nasal Spray 1	Mometasone Furoate	15% v/v
OTC Nasal Spray 2	Triamcinolone	15% v/v
OTC Nasal Spray 3	Budesonide	15% v/v
OTC Nasal Spray 4	Fluticasone	15% v/v
OTC nasal gel	Sodium Chloride with Preservatives	15% v/v
OTC Nasal Spray 5	Phenylephrine	15% v/v
OTC Nasal Spray 6	Oxymetazoline	15% v/v
OTC Nasal Spray 7	Cromolyn	15% v/v
OTC Homeopathic Nasal Spray	Zicam *(Galphimia glauca, Histaminum hydrochloricum, Luffa operculate,* sulfur)	15% v/v
OTC Homeopathic Nasal Wash	Alkalol	15% v/v
Hand Sanitizer	Ethyl Alcohol 62%	1% w/v
Hand Soap		1% w/v
Endogenous	Whole Blood	2.5% v/v
Endogenous	Mucin	2.5 mg/mL
Endogenous	Leukocytes	5 x 10^6 cells/mL
Antibiotic, Nasal Ointment	Mupirocin	10 mg/mL
Nasal Corticosteroid 1	Beclomethasone	15% v/v

Substance	Active Ingredient	Concentration
Nasal Corticosteroid 2	Dexamethasone	15% v/v
Nasal Corticosteroid 3	Flunisolide	15% v/v
Anti-Viral Drug 1	Tamiflu (Oseltamivir Phosphate)	5 mg/mL
Anti-Viral Drug 2	Remdesivir	5 mg/mL
Anti-Viral Drug 3	Molnupiravir	5 mg/mL
Antibiotic	Tobramycin	1.44 mg/mL
Anti-Viral Drug	Zanamivir	281.5 ng/mL

Usability Study

A usability study was conducted to assess the lay user's ability to understand the BinaxNOW COVID-19 Antigen Self Test instructions for use and to perform testing using the components provided within the test kit.

The results of the usability testing demonstrated that the users sufficiently comprehend the test procedure as described in the IFU and indicated that the occurrence of user-related errors is low (98% correct execution of procedural steps). Additionally, the usability study showed that the effect of errors was low (100% of participants produced a valid result and interpreted their test result correctly).

Lay User Readability Study

The purpose of this study was to determine whether lay users can adequately interpret BinaxNOW COVID-19 Antigen Self Test devices with varying signal strengths. Trained personnel prepared test devices by running samples at the following concentrations of SARS-CoV-2 recombinant antigen: 2X LoD, 1.5X LoD and ≤1X LoD. Additionally, negative devices (no SARS-CoV-antigen), devices with various types of invalid results, and devices run with a strong positive control were prepared. A total of 30 users across various age ranges and with and without vision impairments participated in the study.

A summary of the results of the study is shown in the Table below by age and visual condition. Overall, the study demonstrated that lay user participants can correctly perceive and interpret the test card results when sample lines are clear. When sample lines are faint, the accuracy decreases as detectability diminishes. In this study, this effect appeared to be influenced by age and visual capabilities of the person reading the results. It is therefore recommended that users with conditions affecting their vision are encouraged to seek assistance to interpret results accurately. A related warning statement is included in the IFU.

Summary of Results by Visual Condition (Correct Interpretations)

Visual Condition	Positive Control	Positive 2xLoD	Positive 1.5xLoD	Positive ≤1xLoD	Negative Control	Invalid 1	Invalid 2	Invalid 3	Invalid 4
Good (n=10)	10/10 (100%)	10/10 (100%)	8/10 (80%)	9/10 (90%)	10/10 (100%)	9/10 (90%)	9/10 (90%)	10/10 (100%)	10/10 (100%)
Other* (n=20)	20/20 (100%)	15/20 (75%)	12/20 (60%)	9/20 (45%)	(19/20) (95%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	19/20 (95%)
Overall (n=30)	30/30 (100%)	25/30 (83%)	20/30 (67%)	18/30 (60%)	29/30 (97%)	29/30 (97%)	29/30 (97%)	30/30 (100%)	29/30 (97%)

*Far/near-sighted or wear bifocals

Summary of Results by Age (Correct Interpretations)

Visual Condition	Positive Control	Positive 2xLoD	Positive 1.5xLoD	Positive ≤1xLoD	Negative Control	Invalid 1	Invalid 2	Invalid 3	Invalid 4
15-40 (n=8)	8/8 (100%)	8/8 (100%)	8/8 (100%)	7/8 (88%)	8/8 (100%)	8/8 (100%)	7/8 (88%)	8/8 (100%)	8/8 (100%)
41-65 (n=13)	13/13 (100%)	11/13 (85%)	9/13 (69%)	7/13 (54%)	13/13 (100%)	12/13 (92%)	13/13 (100%)	13/13 (100%)	13/13 (100%)
65+ (n=9)	9/9 (100%)	6/9 (67%)	3/9 (33%)	4/9 (44%)	8/9 (89%)	9/9 (100%)	9/9 (100%)	9/9 (100%)	8/9 (89%)
Overall (n=30)	30/30 (100%)	25/30 (83%)	20/30 (67%)	18/30 (60%)	29/30 (97%)	29/30 (97%)	29/30 (97%)	30/30 (100%)	29/30 (97%)

CLINICAL STUDIES

Clinical performance characteristics of the BinaxNOW COVID-19 Antigen Self Test were evaluated in two prospective studies conducted with symptomatic individuals within the United States. In the first study, conducted across five (5) investigational sites from November, 2020 through March, 2021, each subject either self-collected one (1) nasal swab (from both nostrils) or had one sample collected from him/her by another individual and performed the BinaxNOW COVID-19 Antigen Self Test.

In the second study, an additional all comers, real world, prospective clinical study was performed at a high-volume COVID community testing site from March 2022 to July 2022 when Omicron and its variants were prevalent in the United States. This study was led by Johns Hopkins Medicine in collaboration with the University of Maryland Medical Center and Maryland Department of Health. In this study, participants independently performed the BinaxNOW COVID-19 Antigen Self Test, from nasal swab collection to result interpretation.

In each study, a matched anterior nasal swab sample was taken from each study subject by a healthcare professional for testing on an FDA Emergency Use Authorized real-time Polymerase Chain Reaction (RT-PCR) assay for the detection of SARS-CoV-2 as the comparator method in each study. In the first study, the swab for the comparator method was collected after the swab for the BinaxNOW COVID-19 Antigen Self Test and in the second study, the swab for the comparator method was collected prior to the swab for the BinaxNOW COVID-19 Antigen Self Test.

Across both studies, the performance of BinaxNOW COVID-19 Antigen Self Test was established with a total of 604 nasal swabs from symptomatic patients (within 5 days of symptom onset) who were suspected of COVID- 19. Performance is shown in the tables below combined for both studies and individual by study.

BinaxNOW™ COVID-19 Antigen Self Test Performance within 5 days of symptom onset against the Comparator Method – Overall/Combined

BinaxNOW COVID-19 Antigen Self Test	Comparator Method		
	Positive	**Negative**	**Total**
Positive	186	6	192
Negative	28	384	412
Total	214	390	604
Positive Agreement: 186/214 86.9% (95% CI: 81.7, 90.8)			
Negative Agreement: 384/390 98.5% (95% CI: 96.7, 99.3)			

Note: Five (5)samples generated an invalid BinaxNOW COVID-19 Ag Card result and are not included in the analysis. The invalid rate is 5/730, or 0.68% (95% CI from 0.29% to 1.59%). The denominator for the invalid rate is based on total study enrollment.

BinaxNOW COVID-19 Antigen Self Test Performance within 5 days of symptom onset against the Comparator Method – Original Study (November 2020 – March 2021)

BinaxNOW COVID-19 Antigen Self Test	Comparator Method		
	Positive	**Negative**	**Total**
Positive	71	3	74
Negative	16	205	221
Total	87	208	295
Positive Agreement: 71/87 81.6% (95% CI: 72.2, 88.4)			
Negative Agreement: 205/208 98.6% (95% CI: 95.8, 99.5)			
Overall Agreement: 93.6% (95% CI: 90.2, 95.8)			

Note: Three (3) samples generated an invalid BinaxNOW COVID-19 Antigen Self Test result and are not included in the analysis. The invalid rate is 3/397, or 0.76% (95% CI from 0.26% to 2.20%). The denominator for the invalid rate is based on total study enrollment.

BinaxNOW COVID-19 Antigen Self Test Performance within 5 days of symptom onset against the Comparator Method – Omicron Study (February 2022 – July 2022)

BinaxNOW COVID-19 Antigen Self Test	Comparator Method		
	Positive	**Negative**	**Total**
Positive	115	3	118
Negative	12	179	191
Total	127	182	309
Positive Agreement: 115/127 90.6% (95% CI: 84.2, 94.5)			
Negative Agreement: 179/182 98.4% (95% CI: 95.3, 99.4)			

Note: Two (2) samples generated an invalid BinaxNOW COVID-19 Antigen Self Test result and are not included in the analysis. The invalid rate is 2/327, or 0.61% (95% CI from 0.17% to 2.20%). The denominator for the invalid rate is based on total study enrollment.

BinaxNOW COVID-19 Antigen Self Test Positive Agreement (PPA) against the Comparator Method – Stratified by Days Post Symptom Onset (DPSO)

DPSO	PPA - Original Study (November 2020-March 2021)	PPA - Omicron Study (February 2022-July 2022)
Day 0	N/A (0/0)	69.23% (9/13)
Day 1	94.12% (16/17)	88.24% (45/51)
Day 2	73.33% (22/30)	97.22% (35/36)
Day 3	76.00% (19/25)	100.00% (20/20)
Day 4	88.89% (8/9)	66.67% (2/3)
Day 5	100.00% (6/6)	100.00% (4/4)

Serial Testing

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular tests were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 – 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection.

Performance of the antigen test with serial testing in individuals is described in the table below.

Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

Days After First PCR Positive Test Result	Symptomatic On First Day Of Testing		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)		
	1 Test	2 Tests	3 Tests
0	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	4/9 (44.4%)	3/7 (42.9%)	

1 Test = one (1) test performed on the noted days after the first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.
2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.
3 Tests = three (3) tests performed an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

The data presented in this 510(k) premarket notification demonstrate that the subject device (BinaxNOW COVID-19 Antigen Self Test) is substantially equivalent to the predicate device (QuickVue COVID-19 Test, K231795). The differences in the BinaxNOW COVID-19 Antigen Self Test (proposed device) and the Quidel QuickVue COVID-19 Test (predicate device, K231795) are limited to the Intended Use population (individuals aged 15 years or older vs. individuals aged 14 years or older). This difference does not affect the overall substantial equivalence of the proposed device to the predicate device in terms of the technological similarity, intended use, safety, and effectiveness. Furthermore, the information contained within this notification demonstrates BinaxNOW COVID-19 Antigen Self Test compliance with the special controls applicable to an over-the-counter test to detect SARS-CoV-2 from clinical specimens.

There is no known potential adverse effect to the operator when using this in vitro device according to the BinaxNOW COVID-19 Antigen Self Test package insert.