DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 10, 2017

Sara Hallowell, M.S.
Regulatory Affairs Specialist
Alere Scarborough, Inc.
10 Southgate Road
Scarborough, Maine 04074

Re: K162642
Trade/Device Name: Alere BinaxNOW® Influenza A & B Card 2 and Alere™ Reader
Regulation Number: 21 CFR 866.3328
Regulation Name: Influenza virus antigen detection test system
Regulatory Class: Class II
Product Code: PSZ
Dated: February 7, 2017
Received: February 9, 2017

Dear Ms. Hallowell:

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 (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. 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.

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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Steven R. Gitterman -S for

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162642

Device Name
Alere BinaxNOW® Influenza A & B Card 2 and Alere™ Reader

Indications for Use *(Describe)*

The Alere BinaxNOW® Influenza A & B Card 2 is an *in vitro* immunochromatographic assay for the qualitative detection of influenza A and B nucleoprotein antigens in nasopharyngeal (NP) swab and nasal swab specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. Negative test results are presumptive and should be confirmed by cell culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. Alere BinaxNOW® Influenza A & B Card 2 must be read by the Alere™ Reader.

Performance characteristics for influenza A were established during the 2015-2016 influenza season when influenza A/H3N2 and A/H1N1 pandemic were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K162642

SUBMITTER

Alere Scarborough, Inc.
10 Southgate Road
Scarborough, Maine 04074
Establishment Registration Number: 1221359

PRIMARY CONTACT PERSON

Sara Hallowell
(207) 730-5786 (office)
(207) 730-5767 (FAX)
sara.hallowell@alere.com (email)

SECONDARY CONTACT PERSON

Angela Drysdale
(207) 730-5737 (office)
(207) 730-5767 (FAX)
angela.drysdale@alere.com (email)

DATE PREPARED

April 4, 2017

TRADE NAME

Alere BinaxNOW® Influenza A & B Card 2
Alere™ Reader

COMMON NAME

BinaxNOW® Influenza A & B 2, BinaxNOW® Card 2, Alere Influenza A & B 2, BinaxNOW® Flu Card 2/ Reader, Lateral Flow Reader, Card Test Analyzer

CLASSIFICATION NAME

Influenza Virus Antigen Detection Test System (per 21 CFR 866.3328)

CLASSIFICATION

Class II

PRODUCT CODE

PSZ Devices Detecting Influenza A, B, and C Virus Antigens

PANEL

Microbiology (83)

PREDICATE DEVICE

BD Veritor System for Rapid Detection of Flu A+B, K160161.

DEVICE DESCRIPTION

The Alere BinaxNOW® Influenza A & B Card 2 is an immunochromatographic membrane assay that detects influenza type A and B nucleoprotein antigens in respiratory specimens. Influenza specific antibodies and a control antibody are immobilized onto a membrane support as three distinct lines and combined with other reagents/pads to construct a test strip. This test strip is mounted inside a cardboard, book-shaped hinged test card.

Swab specimens require a sample preparation step, in which the sample is eluted off the swab into elution solution. Sample is added to the top of the test strip and the test card is closed. Test results are interpreted at 15 minutes based on the presence or absence of Sample Lines. Alere BinaxNOW® Influenza A & B Card 2 test results must be read by the Alere™ Reader.

The Alere™ Reader is provided separately for result interpretation. The Alere™ Reader enables direct data entry of User ID, Subject ID, and retention of test results, but is intended for result interpretation only. All Alere BinaxNOW® Influenza A & B Card 2 assay steps are performed outside of the reader and the card assay is inserted at the 15 minute read time.

The Alere™ Reader is an easy to use bench top instrument that can be used near patient and in laboratory settings which will interpret, capture and transmit test results. The Alere™ Reader is a camera based instrument that detects the presence and identity of a completed Alere BinaxNOW® Influenza A & B Card 2 assay, analyzes the intensity of the sample and control line and displays the results (positive, negative or invalid) on a display screen. The screen is intended as a means of user interface informing the user how to operate the reader and to display test result, including any errors. Data can be retrieved and downloaded by the operator at any time after testing and uploaded to the hospital LIS/LIM system, if desired. Operator ID and Subject ID can be entered manually or via the provided barcode scanner. An external printer can be attached via USB to the Alere™ Reader to print test results.

INTENDED USE

The Alere BinaxNOW® Influenza A & B Card 2 is an *in vitro* immunochromatographic assay for the qualitative detection of influenza A and B nucleoprotein antigens in nasopharyngeal (NP) swab and nasal swab specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. Negative test results are presumptive and should be confirmed by cell culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. Alere BinaxNOW® Influenza A & B Card 2 test results must be read by the Alere™ Reader.

Performance characteristics for influenza A were established during the 2015-2016 influenza season when influenza A/H3N2 and A/H1N1 pandemic were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

TECHNICAL CHARACTERISTICS

Alere BinaxNOW® Influenza A & B Card 2 and the predicate device, BD Veritor System for Rapid Detection of Flu A+B, have the same intended use, indications for use, and utilize similar basic principles of operation. They are both chromatographic tests for the qualitative detection of influenza A and B viral antigens.

DEVICE COMPARISON

Alere BinaxNOW® Influenza A & B Card 2 was compared to the legally marketed predicate device, the BD Veritor System for Rapid Detection of Flu A+B.

Parameter	Alere BinaxNOW® Influenza A & B Card 2	BD Veritor System for Rapid Detection of Flu A+B (K160161)
FDA Product Code	PSZ	Same
Assay Target	Influenza A and B nucleoprotein antigens	Same
Intended Use	The Alere BinaxNOW® Influenza A & B Card 2 is an *in vitro* immunochromatographic assay for the qualitative detection of influenza A and B nucleoprotein antigens in nasopharyngeal (NP) swab and nasal swab specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. Negative test results are presumptive and should be confirmed by cell culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. Alere BinaxNOW® Influenza A & B Card 2 test results must be read by the Alere™ Reader. Performance characteristics for influenza A were established during the 2015-2016 influenza season when influenza A/H3N2 and A/H1N1 pandemic were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary. If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.	The BD Veritor System for Rapid Detection of Flu A+B is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasal and nasopharyngeal swabs of symptomatic patients. The BD Veritor System for Rapid Detection of Flu A+B (also referred to as the BD Veritor System and BD Veritor System Flu A+B) is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. A negative test is presumptive and it is recommended that these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Outside the U.S., a negative test is presumptive and it is recommended that these results be confirmed by viral culture or a molecular assay cleared for diagnostic use in the country of use. FDA has not cleared this device for use outside of the U.S. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. The test is not intended to detect influenza C antigens. Performance characteristics for influenza A and B were established during January through March of 2011 when influenza viruses A/2009 H1N1, A/H3N2, B/Victoria lineage, and B/Yamagata lineage were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled “Update: Influenza Activity — United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine.” Performance characteristics may vary against other emerging influenza viruses. If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to the state or local health department for testing. Virus culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.
Intended Environment for Use	Professional use, in a medical laboratory	Professional use, in a medical laboratory or point-of-care
Instrumentation	Alere™ Reader used in conjunction with device.	BD Veritor System Reader

Parameter	Alere BinaxNOW® Influenza A & B Card 2	BD Veritor System for Rapid Detection of Flu A+B (K160161)
Assay Information		
Sample Type	Nasopharyngeal and nasal swabs	Same
Technology	Immunochromatographic	Same
Detection Format	The camera based instrument detects the presence and identity of a completed Alere BinaxNOW® Influenza A & B Card 2 assay, analyzes the intensity of the sample and control line and reports the results (positive, negative or invalid) on a display screen.	An optoelectronic instrument that uses a reflectance-based measurement method to evaluate the line signal intensities at each of the spatially defined test and control line positions, interprets the results using a scoring algorithm, and reports a positive, negative, or invalid result on the LCD screen based on pre-set thresholds.
Internal Control	Yes	Yes
Assay Result	Qualitative	Same
Time to Result	15 minutes	10 minutes

PERFORMANCE SUMMARY

CLINICAL STUDY

The clinical performance of Alere BinaxNOW® Influenza A & B Card 2 was established in a multi-center, prospective clinical study conducted at twelve (12) U.S. study centers during the 2015-2016 respiratory season.

A total of twelve (12) investigational sites throughout the U.S. participated in the study. To be enrolled in the study, patients had to be presenting at the participating study centers with flu-like symptoms. Either two nasopharyngeal swabs or two nasal swabs were collected from one nostril from each patient with flu-like symptoms using standard collection methods and tested using the Alere BinaxNOW® Influenza A & B Card 2 assay. An FDA cleared influenza real-time Polymerase Chain Reaction (RT-PCR) assay was utilized as the comparator method for this study.

At all sites, one nasal or nasopharyngeal swab was eluted in elution solution and the other swab was eluted in 1mL of viral transport media (VTM). The swab eluted in elution solution was tested on Alere BinaxNOW® Influenza A & B Card 2, according to product instructions. All twelve (12) sites shipped the VTM sample to a central testing laboratory for RT-PCR.

A total of 585 evaluable specimens were evaluated with Alere BinaxNOW® Influenza A & B Card 2 with results read by the Alere™ Reader. Of the 585 specimens, 565 specimens had valid test results.

Of the total specimens collected, fifty-six percent (56%) of the samples were from females and forty-four percent (44%) from males. Twenty-seven percent (27%) of the population tested was ≤ 5 years of age, twenty-eight percent (28%) was 6-21 years of age, and forty-five percent (45%) was > 21 years.

Compared to the comparator method, the performance of Alere BinaxNOW® Influenza A & B Card 2 for influenza A and influenza B are provided below.

Performance of Alere BinaxNOW® Influenza A & B Card 2 Against the Comparator Method

Influenza Type A

Alere BinaxNOW® Influenza A & B Card 2	Comparator Method		
	Positive	**Negative**	**Total**
Positive	113	23	136
Negative	21	408	429
Total	134	431	565

Sensitivity: 113/134 = 84.3%
(95% CI: 77.2%, 89.5%)

Specificity: 408/431 = 94.7%
(95% CI: 92.1%, 96.4%)

Influenza Type B

Alere BinaxNOW® Influenza A & B Card 2	Comparator Method		
	Positive	**Negative**	**Total**
Positive	51	3	54
Negative	6	505	511
Total	57	508	565

Sensitivity: 51/57 = 89.5%
(95% CI: 78.9%, 95.1%)

Specificity: 505/508 = 99.4%
(95% CI: 98.3%, 99.8%)

ANALYTICAL STUDIES

ANALYTICAL SENSITIVITY

Alere BinaxNOW® Influenza A & B Card 2 limit of detection (LOD or C_{95}), defined as the concentration of influenza virus that produces positive Alere BinaxNOW® Influenza A & B Card 2 results approximately 95% of the time, was identified by evaluating different concentrations of five (5) strains of influenza A and three (3) strains of influenza B. The concentrations identified as the LOD (or C_{95}) levels for each strain are listed below.

Limit of Detection (LoD) Study Results

Strain	Influenza A Subtype or Influenza B Genetic Lineage	Concentration $TCID_{50}$/mL	% Detected
A/Anhui/2013 (Inactivated)*	A/H7N9	1:1500	95%
A/Indiana/10/2011	A/H3N2v	3.67×10^{1}	95%
A/California/7/2009	A/2009 H1N1 (pdm)	5.94×10^{3}	95%
A/Perth/16/2009	A/H3N2	1.68×10^{4}	95%
A/Puerto Rico/8/34	A/H1N1	3.16×10^{4}	95%
B/Massachusetts/02/12	B Yamagata Lineage	1.47×10^{6}	95%
B/Nevada/03/2011	B Victoria Lineage	9.72×10^{3}	95%
B/Malaysia/2506/2004	B Victoria Lineage	4.27×10^{3}	95%

Note: 10µl of each virus dilution was coated onto a swab.

*The LOD is reported as a dilution factor from the inactivated stock. The concentration of the virus stock prior to inactivation was $10^{10.9}$ EID_{50}/mL.

ANALYTICAL REACTIVITY (INCLUSIVITY)

The following influenza A and B strains were tested (3/3) and produced positive Alere BinaxNOW® Influenza A & B Card 2 test results at concentrations ranging from 10^0 to 10^6 $TCID_{50}$/mL.

Influenza Strain	Influenza A Subtype or Influenza B Genetic Lineage	Concentration $TCID_{50}$/mL
A/Brisbane/59/2007	A/H1N1	8.35×10^1
A/California/4/2009	A/H1N1 (pdm)	3.68×10^3
A/Maryland/04/2011	A/H1N1 (pdm)	1.07×10^2
A/New Caledonia/20/1999	A/H1N1	2.08×10^2
A/New Jersey/8/1976	A/H1N1	1.04×10^1
A/New York/18/2009	A/H1N1 (pdm)	1.41×10^2
A/Solomon Islands/3/2006	A/H1N1	5.28×10^1
A/WSN/33	A/H1N1	5.00×10^2
A/Texas/018/2014	A/H1N1	7.90×10^3
A/Texas/002/2014	A/H1N1	1.70×10^3
A/Aichi/2/68	H3N2	7.90×10^3
A/Brisbane/10/2007	H3N2	3.68×10^0
A/Hong Kong/8/68	H3N2	2.41×10^1
A/Port Chalmers/1/73	H3N2	1.58×10^4
A/Texas/50/2012	H3N2	1.06×10^0
A/Victoria/3/75	H3N2	1.58×10^1
A/Victoria/361/2011	H3N2	2.11×10^0
A/Wisconsin/67/2005	H3N2	2.63×10^1
B/Bangladesh/3333/2007	Yamagata Lineage	2.11×10^5
B/Brisbane/60/2008	Victoria Lineage	3.41×10^5
B/Florida/04/2006	Yamagata Lineage	2.97×10^5
B/Lee/40	Victoria Lineage	6.81×10^3
B/Maryland/1/59	Yamagata Lineage	7.90×10^3
B/Montana/05/2012	Victoria Lineage	2.51×10^6
B/Ohio/1/2005	Victoria Lineage	3.40×10^3
B/Russia/69	Yamagata Lineage	5.93×10^5
B/Texas/06/2011	Yamagata Lineage	1.47×10^6
B/Victoria/304/2006	Victoria Lineage	1.58×10^5
B/Victoria/504/2000	Victoria Lineage	6.81×10^4
B/Wisconsin/01/2010	Yamagata Lineage	1.45×10^4

ANALYTICAL SPECIFICITY (CROSS-REACTIVITY)

To determine the analytical specificity of Alere BinaxNOW® Influenza A & B Card 2 test, 58 commensal and pathogenic microorganisms (41 bacteria, 16 viruses and 1 yeast) that may be present in the nasal cavity or nasopharynx were tested. All of the following microorganisms were negative when tested at concentrations ranging from 10^3 to 10^{10} cells/mL or CFU/mL (bacteria), 10^4 to 10^8 $TCID_{50}$/mL or $CEID_{50}$/mL (viruses), and 10^8 cells/mL (yeast).

Bacteria	**Viruses**	**Yeast**
Acinetobacter calcoaceticus	Adenovirus type 1	*Candida albicans*
Bacteroides fragilis	Adenovirus type 7	
Bordetella pertussis	Cytomegalovirus[6A]	
Chlamydia pneumoniae	Human Coronavirus OC43	
Corynebacterium diptheriae	Human Coronavirus 229E[6B]	
Enterococcus faecalis	Enterovirus/Coxsackievirus B4	
Escherichia coli	Human Cytomegalovirus strain AD-169[6C]	
Gardnerella vaginalis	Human metapneumovirus	
Haemophilus influenza	Rhinovirus type 1A	
Haemophilus parainfluenza	Measles virus, strain Edmonston	
Klebsiella pneumonia	Mumps virus, strain Enders	
Lactobacillus casei	Parainfluenza virus 1	
Lactobacillus plantarum	Parainfluenza virus 2	
Legionella pneumophilia	Parainfluenza virus 3	
Listeria monocytogenes[1]	Respiratory Syncytial virus, type B, strain 18537	
Moraxella/Branhamella catarrhalis	Epstein Barr virus, strain P-3	
Mycobacterium avium		
Mycobacterium intracellulare		
Mycobacterium tuberculosis		
Mycoplasma pneumonia[5]		
Neisseria gonorrhoeae		
Neisseria meningitides		
Neisseria mucosa[2]		
Neisseria sicca[3]		
Neisseria subflava		
Peptostreptococcus anaerobius		
Proteus mirabilis		
Proteus vulgaris		
Pseudomonas aeruginosa		
Serratia marcescens[4]		
Staphylococcus aureus		
Staphylococcus epidermidis		
Streptococcus mutans		
Streptococcus pneumonia		
Streptococcus salivarius		
Streptococcus sanguinis		
Streptococcus Group A		
Streptococcus sp. Gp. B		
Streptococcus sp. Gp. C		
Streptococcus sp. Gp. F		
Streptococcus sp. Gp. G		

[1]Flu A positive result obtained at 7.23 x 10^9 cells/mL; concentration diluted to 7.23 x 10^8 cells/mL and generated a negative result.
[2]Flu A positive result obtained at 9.4 x 10^9 cells/mL; concentration diluted to 9.4 x 10^8 cells/mL and generated a negative result.
[3]Flu A positive result obtained at 1.0 x 10^{10} cells/mL; concentration diluted to 1.0 x 10^9 cells/mL and generated a negative result.
[4]Flu A positive Alere™ Reader result obtained at 6.5 x 10^8 cells/mL; concentration diluted to 6.5 x 10^7 cells/mL and generated a negative result.
[5]*Mycoplasma pneumonia* 10^3 was the maximum cfu/mL that could be achieved for growth.
[6]Viruses were tested at concentrations lower than the recommended 10^5 pfu/ml, reflect the stock concentration received from the vendor. Viral stocks were tested at the highest achievable titer allowed by the vendor stock concentration.

- [6A] Cytomegalovirus at 8.89x10^4 $TCID_{50}$/mL
- [6B] Human Coronavirus 229E at 2.81x10^4 $TCID_{50}$/mL
- [6C] Human Cytomegalovirus strain AD-169 at 8.89x10^4 $TCID_{50}$/mL

INTERFERING SUBSTANCES

The following substances, naturally present in respiratory specimens or artificially introduced into the nasal cavity/ nasopharynx were evaluated with Alere BinaxNOW® Influenza A & B Card 2 at the concentrations listed below and were found not to affect test performance.

Substance	Concentration
Mucin	2% (w/v)
Whole Blood	1% (v/v)
Sinus Buster Nasal Spray	20% (v/v)
NeoSynephrine Cold & Sinus Extra Strength Spray	20% (v/v)
Zicam Extreme Congestion Relief	20% (v/v)
4-acetamidophenol	203 µg/mL
Acetylsalicylic acid (aspirin)	652 µg/mL
Albuterol	399 ng/mL
Chlorpheniramine	142 ng/mL
Dexamethasone	0.8 mg/mL
Dextromethorphan	1 µg/mL
Diphenhydramine	5 µg/mL
Doxylamine Succinate	232 ng/mL
Ephedrine	276 ng/mL
Flunisolide	6.8 ng/mL
Guaiacol glycerol ether (pseudoephedrine)	3.58 ng/mL
Mupirocin	12 mg/mL
Oxymetazoline	0.6 mg/mL
Phenylephrine	12 mg/mL
Relenza	284 ng/mL
Rebetol	4.4 µg/mL
Rimantadine	0.28 ng/mL
Tamiflu	1.102 µg/mL
Tobramycin	2.4 mg/mL
Triamcinolone	40 µg/mL

REPRODUCIBILITY

A reproducibility study of Alere BinaxNOW® Influenza A & B Card 2 was conducted by operators from three (3) sites using panels of blind coded specimens containing negative, high negative (below the limit of detection), low positive (at the limit of detection), and moderate positive (above the limit of detection) influenza A and B viral samples. Participants tested the sample panels over five (5) different days.

The percent agreement with expected results, across the three sites, for the influenza A moderate positive, low positive, and high negative samples were 100% (90/90), 100% (90/90) and 96.6% (86/89), respectively. The percent agreement with expected result for the influenza B moderate positive, low positive, and high negative samples were 100% (90/90), 100% (89/89) and 97.8% (88/90), respectively. All of the true negative samples (90) generated negative test results.

There were no significant differences observed within run (replicates tested by one operator), between run (five different days), between sites (three sites), or between operators (six operators).

Site-To-Site Qualitative Results – Percent Agreement with Expected Results

Sample Type		Site 1	Site 2	Site 3	Overall % Agreement with Expected Results
Influenza A	Moderate Positive	100% (30/30)	100% (30/30)	100% (30/30)	**100% (90/90)**
	Low Positive	100% (30/30)	100% (30/30)	100% (30/30)	**100% (90/90)**
	High Negative	100% (29/29)[1]	93.3% (28/30)	96.7% (29/30)	**96.6% (86/89)**
Influenza B	Moderate Positive	100% (30/30)	100% (30/30)	100% (30/30)	**100% (90/90)**
	Low Positive	100% (30/30)	100% (30/30)	100% (29/29)[2]	**100% (89/89)**
	High Negative	100% (30/30)	93.3% (28/30)	100% (30/30)	**97.8% (88/90)**
True Negative		100% (30/30)	100% (30/30)	100% (30/30)	**100% (90/90)**

[1]One sample generated an invalid result and was not re-tested.

[2]One sample generated a positive Flu A and Flu B result, was considered invalid and was not re-tested.

INHIBITION BY OTHER MICROORGANISMS

Alere BinaxNOW® Influenza A & B Card 2 test performance in the presence of non-influenza respiratory pathogens was evaluated. Vendor provided stocks of influenza A and B strains were diluted in UTM to approximately 2 times the limit of detection. Contrived influenza A and B positive swab specimens were prepared by coating 10 microliters of virus dilution onto each swab. The following non-influenza viruses were tested (3/3) at the concentration provided in the table below and were found not to affect test performance.

Virus Panel	Concentration ($TCID_{50}$/mL)
Adenovirus Type 1	1.58×10^7
Rhinovirus Type 1A	1.58×10^8
Respiratory Syncytial Virus, Type B, Strain 18537	8.89×10^5

INHIBITION BY HIGH LEVELS OF INFLUENZA A AND B

Alere BinaxNOW® Influenza A & B Card 2 test performance in the presence of high levels of influenza A and B was evaluated. Vendor provided stocks of influenza A and B strains were diluted in UTM to approximately 2 times the limit of detection. Contrived influenza A and B positive swab specimens were prepared by coating 10 microliters of virus dilution onto each swab. To create the co-infection swabs, diluted influenza A (at a concentration approximately 20 times the LoD) was added to

the near LoD Flu B swab. Likewise, diluted influenza B (at a concentration approximately 20 times the LoD) was added to the near LoD Flu A swab. No impact on test performance was observed.