



**U.S. FOOD & DRUG
ADMINISTRATION**

January 26, 2017

Alere Scarborough, Inc.
Angela Drysdale
VP, Regulatory Affairs - Infectious Disease
10 Southgate Road
Scarborough, Maine 04074

Re: K173932

Trade/Device Name: Alere i Influenza A & B, Alere i Strep A, Alere i RSV, Alere i Influenza A & B 2
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory viral panel multiplex nucleic acid assay
Regulatory Class: Class II
Product Code: OZE, OOI, PGX, OCC
Dated: December 21, 2017
Received: December 26, 2017

Dear Angela Drysdale:

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 Part 801 and Part 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kristian M. Roth -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

INDICATIONS FOR USE STATEMENT – ALERE™ i INFLUENZA A & B

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.
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510(k) Number (if known)

K173932

Device Name

Alere™ i Influenza A & B

Indications for Use (Describe)

The Alere™ i Influenza A & B assay performed on the Alere™ i Instrument is a rapid molecular *in vitro* diagnostic test utilizing an isothermal nucleic acid amplification technology for the qualitative detection and discrimination of influenza A and B viral RNA in direct nasal swabs and nasal or nasopharyngeal swabs eluted in viral transport media from patients with signs and symptoms of respiratory infection. It is intended for use as an aid in the differential diagnosis of influenza A and B viral infections in humans in conjunction with clinical and epidemiological risk factors. The assay is not intended to detect the presence of influenza C virus.

Negative results do not preclude influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

Performance characteristics for influenza A were established during the 2012-2013 and the 2014-2015 influenza seasons when influenza A/H3 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.

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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
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INDICATIONS FOR USE STATEMENT – ALERE™ i STREP A

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) K173932	
Device Name Alere™ i Strep A	
Indications for Use (Describe) Alere™ i Strep A is a rapid, instrument-based, molecular in vitro diagnostic test utilizing isothermal nucleic acid amplification technology for the qualitative detection of Streptococcus pyogenes, Group A Streptococcus bacterial nucleic acid in throat swab specimens obtained from patients with signs and symptoms of pharyngitis. It is intended to aid in the rapid diagnosis of Group A Streptococcus bacterial infections. All negative test results should be confirmed by bacterial culture because negative results do not preclude infection with Group A Streptococcus and should not be used as the sole basis for treatment.	
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)	

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INDICATIONS FOR USE STATEMENT – ALERE™ i RSV

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) K173932	
Device Name Alere™ i RSV	
Indications for Use (Describe) The Alere™ i RSV assay performed on the Alere™ i Instrument is a rapid molecular <i>in vitro</i> diagnostic test utilizing an isothermal nucleic acid amplification technology for the qualitative detection of respiratory syncytial virus (RSV) viral RNA in direct nasopharyngeal swabs and nasopharyngeal swabs eluted in viral transport media from patients with signs and symptoms of respiratory infection. It is intended for use as an aid in the diagnosis of RSV in children <18 years and adults ≥60 years in conjunction with clinical and epidemiological risk factors.	
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)	

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INDICATIONS FOR USE STATEMENT – ALERE™ i INFLUENZA A & B 2

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) K173932	
Device Name Alere i Influenza A & B 2	
Indications for Use (Describe) The Alere i Influenza A & B 2 assay performed on the Alere i Instrument is a rapid molecular <i>in vitro</i> diagnostic test utilizing an isothermal nucleic acid amplification technology for the qualitative detection and discrimination of influenza A and B viral RNA in direct nasal or nasopharyngeal swabs and nasal or nasopharyngeal swabs eluted in viral transport media from patients with signs and symptoms of respiratory infection. It is intended for use as an aid in the differential diagnosis of influenza A and B viral infections in humans in conjunction with clinical and epidemiological risk factors. The assay is not intended to detect the presence of influenza C virus. Negative results do not preclude influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Performance characteristics for influenza A were established during the 2016-2017 influenza season when influenza A/H3 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 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)	

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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: K173932

SUBMITTER

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

PRIMARY CONTACT PERSON

Angela Drysdale
(207) 415 – 1393 (Mobile)
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Angela.drysdale@alere.com (email)

DATE PREPARED

12/21/2017

TRADE NAME

Alere™ i Influenza A & B
Alere™ i Strep A
Alere™ i RSV
Alere™ i Influenza A & B 2

COMMON NAME

Alere™ i Flu, Alere™ i, Alere™ Influenza A & B
Alere™ i Strep, Alere™ Strep A
Alere™ i RSV,
Alere™ i Flu 2, Alere™ Influenza A & B 2

CLASSIFICATION NAME

Respiratory Viral Pan Multiplex Nucleic Acid System (per 21 CFR 866.3980)
Streptococcus spp Nucleic Acid-Based Assay (per 21 CFR 866.2680)
Instrumentation for Clinical Multiplex Test Systems (per 21 CFR 862.2570)

CLASSIFICATION

Class II

PRODUCT CODE

OCC, OZE, OOI
PGX, OOI

PANEL

Microbiology (83)

PREDICATE DEVICE

Alere™ i Influenza A & B, K163266

Alere™ i Strep A, K151690

Alere™ i RSV, K161375

Alere™ i Influenza A & B 2, K171792

DEVICE DESCRIPTION

Alere™ i Influenza A & B is a rapid, instrument-based isothermal test for the qualitative detection and differentiation of influenza A and influenza B from nasal swabs and nasal or nasopharyngeal swab specimens eluted in viral transport media collected from patients presenting with signs and symptoms of respiratory infection.

Alere™ i Strep A is a rapid, instrument-based isothermal test for the qualitative detection of Group A Strep from throat swab specimens.

Alere™ i RSV is a rapid, instrument-based isothermal test for the qualitative detection and differentiation of respiratory syncytial virus (RSV) viral RNA from direct nasopharyngeal swab (NPS) and NPS eluted in viral transport media from patients with signs and symptoms of respiratory infection.

Alere™ i Influenza A & B 2 is a rapid, instrument-based isothermal test for the qualitative detection and differentiation of influenza A and influenza B from nasal swab or nasopharyngeal swabs tested directly or after elution in viral transport media collected from patients presenting with signs and symptoms of respiratory infection.

All Alere™ i assays utilize isothermal nucleic acid amplification technology and are comprised of:

- Sample Receiver – single use, disposable containing the elution buffer
- Test Base – single use, disposable comprising two sealed reaction tubes, each containing a lyophilized pellet
- Transfer Cartridge – single use, disposable for transfer of the eluted sample to the Test Base, and
- Alere™ i Instrument – repeat use reader

The reaction tubes in the Alere™ i Influenza A & B and Alere™ i Influenza A & B 2 Test Base contain the reagents required for amplification of the target nucleic acid and an internal control. Alere™ i Influenza A & B utilizes a pair of templates (similar to primers) for the specific amplification of RNA from influenza A and B and a fluorescently labeled molecular beacon designed to specifically identify the amplified RNA targets.

The reaction tubes in the Alere™ i Strep A Test Base contain the reagents required for Group A Strep bacterial lysis and the subsequent amplification of the target nucleic acid and an internal control. Alere™ i Strep A utilizes a pair of templates (similar to primers) for the specific amplification of DNA from Group A Strep and a fluorescently labeled molecular beacon designed to specifically identify the amplified nucleic acid target.

The reaction tubes in the Alere™ i RSV Test Base contain the reagents required for amplification of the target nucleic acid and an internal control. Alere™ i RSV utilizes a pair of templates (similar to primers) for the specific

amplification of RNA from RSV A and B and a fluorescently labeled molecular beacon designed to specifically identify the amplified RNA targets.

All Alere™ i assays are performed within the confinement of the Test Base, and no other part of the Alere™ i Instrument has contact with the sample during the amplification process. This reduces the risk of instrument contamination and sample carry-over between measurements.

To perform the assay, the Sample Receiver and Test Base are inserted into the Alere™ i Instrument and the elution buffer is automatically heated by the instrument. The sample is added to the Sample Receiver and transferred via the Transfer Cartridge to the Test Base, resuspending the lyophilized pellets contained within the Test Base and initiating bacterial lysis (for Alere™ i Strep A) and target amplification. Heating, mixing and detection by fluorescence is provided by the instrument, with results automatically reported.

Results are displayed by the Alere™ i Instrument and are also stored in an on-board archive and are assigned to a sample ID that has been entered into the Alere™ i Instrument by the operator, and the date/time the test was performed. Data can be retrieved and downloaded by the operator at any time after testing. An external Alere™ Universal Printer can be attached via USB to the Alere™ i Instrument to print test results.

INTENDED USE

The Alere™ i Influenza A & B assay performed on the Alere™ i Instrument is a rapid molecular *in vitro* diagnostic test utilizing an isothermal nucleic acid amplification technology for the qualitative detection and discrimination of influenza A and B viral RNA in nasal swabs and nasal or nasopharyngeal swabs eluted in viral transport media from patients with signs and symptoms of respiratory infection. It is intended for use as an aid in the differential diagnosis of influenza A and B viral infections in humans in conjunction with clinical and epidemiological risk factors. The assay is not intended to detect the presence of influenza C virus.

Negative results do not preclude influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

Performance characteristics for influenza A were established during the 2012-2013 and the 2014-2015 influenza seasons when influenza A/H3 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.

Alere™ i Strep A is a rapid, instrument-based, molecular *in vitro* diagnostic test utilizing isothermal nucleic acid amplification technology for the qualitative detection of *Streptococcus pyogenes*, Group A *Streptococcus* bacterial nucleic acid in throat swab specimens obtained from patients with signs and symptoms of pharyngitis. It is intended to aid in the rapid diagnosis of Group A *Streptococcus* bacterial infections.

All negative test results should be confirmed by bacterial culture because negative results do not preclude infection with Group A *Streptococcus* and should not be used as the sole basis for treatment.

The Alere™ i RSV assay performed on the Alere™ i Instrument is a rapid molecular *in vitro* diagnostic test utilizing an isothermal nucleic amplification technology for the qualitative detection of respiratory syncytial virus (RSV) viral RNA in direct nasopharyngeal swabs and nasopharyngeal swabs eluted in viral transport media from patients with signs and symptoms of respiratory infection. It is intended for use as an aid in the diagnosis of RSV in children <18 years and adults ≥60 years in conjunction with clinical and epidemiological risk factors.

The Alere™ i Influenza A & B 2 assay performed on the Alere™ i Instrument is a rapid molecular *in vitro* diagnostic test utilizing an isothermal nucleic acid amplification technology for the qualitative detection and discrimination of influenza A and B viral RNA in direct nasal or nasopharyngeal swabs and nasal or nasopharyngeal swabs eluted in viral transport media from patients with signs and symptoms of respiratory infection. It is intended for use as an aid in the differential diagnosis of influenza A and B viral infections in humans in conjunction with clinical and epidemiological risk factors. The assay is not intended to detect the presence of influenza C virus.

Negative results do not preclude influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

Performance characteristics for influenza A were established during the 2016-2017 influenza season when influenza A/H3 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.

COMPARISON TO THE PREDICATE

The purpose of this Special 510k submission is to bring to market a modification of the software contained on the Alere™ i Instrument. A modification of the Alere™ i Influenza A & B, Alere™ i Strep A, Alere™ i RSV, and Alere™ i Influenza A & B 2 algorithm was made to mitigate issues with false invalid results due to baseline values that are lower than allowed by the algorithm and incorrectly identified as Empty Tube Values. This is an algorithm update only, there have been no changes made to the chemistry of the assays.

Alere™ i Influenza A & B incorporating the software modification was compared to the legally marketed predicate device, the 510(k) cleared Alere™ i Influenza A & B test.

Parameter	Alere™ i Influenza A & B (with software modification)	Alere™ i Influenza A & B (K163266)
FDA Product Code	OCC,OZE, OOI	Same
Assay Target	Influenza A, Influenza B	Same
Intended Use	The Alere™ i Influenza A & B assay performed on the Alere™ i Instrument is a rapid molecular <i>in vitro</i> diagnostic test utilizing an isothermal nucleic acid amplification technology for the qualitative detection and discrimination of	Same

Parameter	Alere™ i Influenza A & B (with software modification)	Alere™ i Influenza A & B (K163266)
	influenza A and B viral RNA in nasal swabs and nasal or nasopharyngeal swabs eluted in viral transport media from patients with signs and symptoms of respiratory infection. It is intended for use as an aid in the differential diagnosis of influenza A and B viral infections in humans in conjunction with clinical and epidemiological risk factors. The assay is not intended to detect the presence of influenza C virus. Negative results do not preclude influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Performance characteristics for influenza A were established during the 2012-2013 and the 2014-2015 influenza seasons when influenza A/H3 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.	
Intended Environment for Use	Professional use, in a medical laboratory or point of care	Same
Instrumentation	Alere™ i Instrument	Same
Assay Information		
Sample Type	Nasal Swab and Nasal or Nasopharyngeal Swabs Eluted in Viral Transport Media	Same
Influenza A Viral Target	PB2 segment	Same
Influenza B Viral Target	PA segment	Same
Technology	Isothermal nucleic acid amplification	Same
Internal Control	Yes	Same
Result Interpretation	Automated	Same
Assay Result	Qualitative	Same
Time to Result	< 15 minutes	Same

Alere™ i Strep A incorporating the software modification was compared to the legally marketed predicate device, the 510(k) cleared Alere™ i Strep A test.

Parameter	Alere™ i Strep A (with software modification)	Alere™ i Strep A (K151690)
FDA Product Code	PGX, OOI	Same
Assay Target	<i>Streptococcus pyogenes</i>	Same
Intended Use	Alere™ i Strep A is a rapid, instrument-based, molecular <i>in vitro</i> diagnostic test utilizing isothermal nucleic acid amplification technology for the qualitative detection of <i>Streptococcus pyogenes</i>, Group A <i>Streptococcus</i> bacterial nucleic acid in throat swab specimens obtained from patients with signs and symptoms of pharyngitis. It is intended to aid in the rapid diagnosis of Group A <i>Streptococcus</i> bacterial infections. All negative test results should be confirmed by bacterial culture because negative results do not preclude infection with Group A <i>Streptococcus</i> and should not be used as the sole basis for treatment.	Same
Intended Environment for Use	Professional use, in a medical laboratory or point of care	Same
Instrumentation	Alere™ i Instrument	Same
Assay Information		
Sample Type	Throat Swab	Same
Target Analyte	Group A <i>Streptococcus</i> (<i>Streptococcus pyogenes</i>)	Same
Technology	Isothermal nucleic acid amplification	Same
Internal Control	Yes	Same
Result Interpretation	Automated	Same
Assay Result	Qualitative	Same
Time to Result	< 8 minutes	Same

Alere™ i RSV incorporating the software modification was compared to the legally marketed predicate device, the 510(k) cleared Alere™ i RSV test.

Parameter	Alere™ i RSV (with software modification)	Alere™ i RSV (K161375)
FDA Product Code	OCC, OOI	Same
Assay Target	RSV	Same
Intended Use	The Alere™ i RSV assay performed on the Alere™ i Instrument is a rapid molecular <i>in vitro</i> diagnostic test utilizing an isothermal nucleic acid amplification technology for the	Same

Parameter	Alere™ i RSV (with software modification)	Alere™ i RSV (K161375)
	qualitative detection of respiratory syncytial virus (RSV) viral RNA in direct nasopharyngeal swabs and nasopharyngeal swabs eluted in viral transport media from patients with signs and symptoms of respiratory infection. It is intended for use as an aid in the diagnosis of RSV in children <18 years and adults ≥60 years in conjunction with clinical and epidemiological risk factors.	
Intended Environment for Use	Professional use, in a medical laboratory or point-of-care	Same
Instrumentation	Alere™ i Instrument	Same
Assay Information		
Sample Type	Nasopharyngeal Swab, Nasopharyngeal Swab eluted in Viral Transport Media	Same
RSV Target	NS2 gene and nucleocapsid gene N	Same
Technology	Isothermal nucleic acid amplification	Same
Internal Control	Yes	Same
Result Interpretation	Automated	Same
Assay Result	Qualitative	Same
Time to Result	< 13 minutes	Same

Alere™ i Influenza A & B 2 incorporating the software modification was compared to the legally marketed predicate device, the 510(k) cleared Alere™ i Influenza A & B 2 test.

Parameter	Alere™ i Influenza A & B 2 (with software modification)	Alere™ i Influenza A & B 2 (K163266)
FDA Product Code	OCC,OZE, OOI	Same
Assay Target	Influenza A, Influenza B	Same
Intended Use	The Alere™ i Influenza A & B 2 assay performed on the Alere™ i Instrument is a rapid molecular <i>in vitro</i> diagnostic test utilizing an isothermal nucleic acid amplification technology for the qualitative detection and discrimination of influenza A and B viral RNA in direct nasal or nasopharyngeal swabs and nasal or nasopharyngeal swabs eluted in viral transport media from patients with signs and symptoms of respiratory infection. It is intended for use as an aid in the differential diagnosis of influenza A and B viral infections in humans in conjunction with clinical and epidemiological risk factors. The assay is not intended to detect the presence of influenza C virus.	Same

Parameter	Alere™ i Influenza A & B 2 (with software modification)	Alere™ i Influenza A & B 2 (K163266)
	Negative results do not preclude influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Performance characteristics for influenza A were established during the 2012-2013 and the 2014-2015 influenza seasons when influenza A/H3 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.	
Intended Environment for Use	Professional use, in a medical laboratory or point of care	Same
Instrumentation	Alere™ i Instrument	Same
Assay Information		
Sample Type	Nasopharyngeal Swab, Nasal Swab and Nasal or Nasopharyngeal Swabs Eluted in Viral Transport Media	Same
Influenza A Viral Target	PB2 segment	Same
Influenza B Viral Target	PA segment	Same
Technology	Isothermal nucleic acid amplification	Same
Internal Control	Yes	Same
Result Interpretation	Automated	Same
Assay Result	Qualitative	Same
Time to Result	< 15 minutes	Same