SPECIAL 510(K): DEVICE MODIFICATION
OIR DECISION SUMMARY

510(k) Number: K173932

This 510(k) submission contains information/data on modifications made to the applicant's own class II or class I devices requiring 510(k). The following items are present and acceptable:

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1. The name and 510(k) number of the applicant's previously cleared device. (For a preamendments device, a statement to this effect has been provided.)

2. Applicant's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

3. Description of the device **MODIFICATION(S):**

   This change was for 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 baselines that are lower than allowed by the algorithm and incorrectly identified as Empty Tube Values. The Norm Window baseline minimum setting was changed from 1.0 mV/s to 0.1 mV/s for each of the assays identified above. This is an algorithm update only, there have been no changes made to the chemistry of the assays.

   The only impact of this change is related to invalid results, the threshold for positive and negative results has not changed and there is no change to assay performance. There are no changes to the user interface and no changes to product labeling are required. The Intended Use of Alere i Influenza A & B, Alere i Strep A, Alere i RSV, and Alere i Influenza A & B 2 as described in the 510k cleared labeling, has not changed because of this modification. The modification does not alter the fundamental technology of the Alere i Influenza A & B, Alere i Strep A, Alere i RSV, and Alere i Influenza A & B 2 assays or the Alere i Instrument.

   The unmodified and modified devices are identical in assay formulation and there has been no change in the test procedure. The only changes are to the software as described above.

4. The **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

5. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including labeling, intended use, physical characteristics, and assay information:

   Similarities

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

Parameter	Alere™ i Influenza A & B (with software modification)	Alere™ i Influenza A & B (K163266)
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.	Same

Parameter	Alere™ i Influenza A & B (with software modification)	Alere™ i Influenza A & B (K163266)
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

Parameter	Alere™ i Strep A (with software modification)	Alere™ i Strep A (K151690)
FDA Product Code	PGX, OOI	Same
Assay Target	*Streptococcus pyogenes*	Same
Intended Use	**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.	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 *Streptococcus* (*Streptococcus pyogenes*)	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

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 *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.	Same
Intended Environment for Use	Professional us, 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 nucleopcapsid 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

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 *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 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.	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	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

Differences

Alere i Influenza A&B

The Alere i Influenza A & B package insert will have the following footnote to the table for the original cross-reactivity study to reflect subsequent additional cross-reactivity information—

*Some cross-reactivity was observed for *Proteus vulgaris* at concentrations greater than 7 $x10^8$, *Moraxella catarrhalis* at concentrations greater than $2x10^9$, and *Serratia marcescens* at concentrations greater than 3 $x10^9$.

Alere i Influenza A&B 2

The Alere i package inserts will be updated to reflect the intended designation for room temperature storage. It will now state 15-30°C for room temperature (previously this was defined as 18-22°C).

6. A **Design Control Activities Summary**:

A risk assessment of the modified Alere i Instrument software was conducted and documented according to the firm's Quality System reqirements. This assessment included a standard Failure Mode and Effects Analysis (FMEA). Base on this risk assessment, the modification made to the software embedded on the Alere i Instrument does not affect the assay procedure and the change is not expected to impact the performance of the test or its safety and effectiveness. Certain validation studies were conducted to confirm that the assay performance was not negatively impacted by the software modification. The following aspects of the system were analyzed:

- Test workflows were verified to ensure they reflect the proper settings and configuration.
- Regression testing was performed to verify that the changes to Baseline values did not impact the core software.
- Code review was performed
- To ensure that changing the baseline did not affect previously collected data used to support regulatory submissions, and thus product claims, CSV and/or JSON files from verification and validations studies that were used to support product claims for each assay were re-analyzed. Each CSV and/or JSON file was processed by the on-board instrument algorithm via the software unit test framework. As an output of the on-board analysis, a summary of the results was generated.

The firm provided a summary of the results from these software validation studies.

7. **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure**.

   The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the applicant's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The applicant has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.