# SPECIAL 510(k): Device Modification
# Decision Summary

**To:** Alere Scarborough, Inc. **RE:** K181853

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This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

**1.** The name and 510(k) number of the SUBMITTER'S previously cleared device:

Alere BinaxNOW Influenza A & B Card 2

510(k) number: K173502

**2.** Submitter'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):**

A software modification has been added to mitigate a low frequency failure mode associated with detectable but not visible dark spots within the Influenza A test line due to non-specific binding. The modification checks for a unique signal-to-noise ratio and implements an additional, parallel quantification algorithm if the specific conditions are detected. Both the original quantification algorithm and the triggered new algorithm must meet certain criteria in this situation to provide a valid result. Failure of the new algorithm to meet the necessary analysis conditions (when triggered) results in an invalid result. The purpose and effect of the change is to reduce the number of false positive Influenza A results. The Alere BinaxNOW Influenza A & B Card 2 assay package insert and Quick Reference Instructions (QRI) have not changed. The instrument user manual has been updated to include the software changes.

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

**5. Comparison Information**

A. Similarities

| | Predicate Device | Modified Device |
|---|---|---|
| Features | Alere BinaxNOW Influenza A & B Card 2 (K173502) | Alere BinaxNOW Influenza A & B Card 2 (K181853) |
| 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 | Same |

| | | |
|---|---|---|
| | 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.<br><br>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.<br><br>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. | |
| Sample Type | Nasopharyngeal and nasal swabs | Same |
| Assay Target | Nucleoprotein Antigen of Influenza A and B | Same |
| Instrumentation | Alere Reader | Same |
| Detection Format | The camera-based Reader detects the presence and identity of the 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. | Same |
| Internally Controlled? | Yes | Same |
| Assay Result | Qualitative | Same |
| Time to Result | 15 minutes | Same |

B. Differences

The Alere Reader user manual has been updated to identify minor changes to the software.

**6. Design Control Activities Summary**:

A risk assessment and hazard analysis of the device modification was conducted and documented according to applicable ISO standards as well as an internal Alere Scarborough Inc. Risk Management Process. The modification made to the software does not affect the assay procedure, and this change

was not expected to impact the performance of the test or its safety and effectiveness. To confirm assay performance was not negatively impacted, Alere Scarborough performed the following validation studies:

A. Design Specification Validation Testing
B. Analytical Study Data Reprocessing
C. Regression Testing of Clinical Study Data

Design Specification Validation Testing
Software design specifications were tested internally to verify the functionality of the requested changes prior to verification studies. Pass/Fail criteria were set for each design input and the results were summarized in the submission. There was one design specification that failed the criteria and cited as an unresolved anomaly. The unresolved anomaly does not affect the performance of the device. All other design specifications passed validation testing.

Analytical Study Data Reprocessing
Saved image files from various analytical studies performed in support of 510(k) clearance and annual reactivity testing were reprocessed by the firmware that includes the new Robust Quant Algorithm. Eight different analytical study data sets comprised of over 2000 individual tests were reprocessed and compared to the results from the original studies. All documented changes to the original results following reprocessing supported the intended functionality of the new algorithm by changing known false positive results into negative results. There were no documented instances of the software modification creating new false results in these studies.

Regression Testing of Clinical Study Data
Saved image files from the 2015-2016 Influenza season clinical study performed in support of 510(k) clearance were reprocessed by the firmware that utilized the new Robust Quant Algorithm. Results of the reprocessing were compared to the results from the original study. Two previously false positive samples changed from Influenza A positive to Influenza A negative resulting in a slightly improved specificity for the test running the new firmware. No other changes to Influenza A results were identified and no changes to Influenza B results were observed after applying the new algorithm. The results of the clinical study data regression testing do not raise any concerns regarding effects of the new firmware on the performance of the device.

**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 submitter'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 submitter 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 device.