# SPECIAL 510(k): Device Modification
# OIR Review Memorandum (Decision Making Document is Attached)

**To:** Alere Scarborough Inc. **RE:** K133637

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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:

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

   Alere™ Influenza A & B Test

   510(k) number: K103610

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):**

The modification presented in this special 510(k) consisted of expanded reactivity table to include reactivity information for the H7N9 influenza A virus. The firm tested the ability of the Alere Influenza A & B Test to detect H7N9 influenza A virus. The virus used (A/Anhui/1/2013) was obtained from the Centers for Disease Control and Prevention as non-infectious beta-propiolactone inactivated virus. A reactivity study was performed with the A/Anhui/1/2013 influenza strain at three dilutions run in triplicate. Each result was interpreted by two operators for a total of six determinations per dilution. The lowest level that generated positive results in all six determinations was identified as the reactivity concentration.

The reactivity concentration was determined to be $8.70 \times 10^6$ $EID_{50}$/ml. The Alere Influenza A & B Test package insert has been updated to include the additional analytical reactivity information.

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

5. **Comparison Information**

Similarities

| | Predicate Device | Modified Device |
|---|---|---|
| | Alere Influenza A & B Test (K103610) | Alere Influenza A & B Test (K133637) |
| **Intended Use** | The Alere Influenza A & B Test is an *in vitro* immunochromatographic assay for the qualitative detection of influenza A and B nucleoprotein antigens in nasopharyngeal (NP) swab, nasal swab, and nasal wash/aspirate specimens. It is intended to | The Alere Influenza A & B Test is an *in vitro* immunochromatographic assay for the qualitative detection of influenza A and B nucleoprotein antigens in nasopharyngeal (NP) swab, nasal swab, and nasal wash/aspirate specimens. It |

| | | |
|---|---|---|
| | aid in the rapid differential diagnosis of influenza A and B viral infections. Negative test results should be confirmed by cell culture. | 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. |
| **Organism Detected** | Influenza A virus and Influenza B virus | Same |
| **Specimen Types** | Nasal swabs | Same |
| **Device Technology** | Lateral flow immunochromatography | Same |
| **Detection Mechanism** | Solid phase immobilized nucleoprotein specific antibodies | Same |

Differences

The package insert has been updated to include detection of the A/Anhui/1/2013 H7N9 virus in the analytical reactivity information section:
A/Anhui/1/2013 - A - H7N9 - $8.7x10^6$ $EID_{50}$/mL

Although this test has been shown to detect H7N9 virus cultured from positive human respiratory specimens, the performance characteristics of this device with clinical specimens that are positive for H7N9 influenza viruses have not been established. The Alere Influenza A & B Test can distinguish between influenza A and B viruses, but it cannot differentiate influenza A subtypes.

6. **Design Control Activities Summary**:

Analytical Reactivity Testing was conducted as described on Page 57 of the submission, “Analytical Reactivity”.

A “Declaration of Conformity” statement was submitted for the manufacturing facility and validation activities and signed by the Senior Vice President of Clinical and Regulatory Affairs. The statements indicate that:

1. The manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
2. The validation activities, as required by the risk analysis, for the modification were performed by the designated individuals and the results demonstrated that the predetermined acceptance criteria were met.

In conclusion, based on the results of the analytical reactivity testing the modified labeling is truthful and accurate. The changes do not affect the performance of the test and it is therefore substantially equivalent to the current cleared test.

**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.