

SPECIAL 510(k): Device Modification

To: THE FILE

RE: DOCUMENT NUMBER K103610

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class I device requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device:
Clearview Exact II Influenza A & B Test (K092349)
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 and package labeling.
3. This Special 510(k) submission presents a **MODIFIED ANALYSIS** of the clinical performance data (sensitivity and specificity), submitted with the original 510k filing. The modified analysis incorporates the exclusion of eight (8) clinical samples from the final performance analysis, all of which generated dual positive (flu A + flu B) results on the Clearview test. The package insert directs the user to repeat a test with dual positive results. Since the swabs can only be tested once in the test device and another specimen must be collected, these results are not reportable. Therefore, the results for these eight samples have been considered invalid test results in the modified analysis. There were no changes made to the current test system, and there were no new data generated in support of this submission. This modification has not had any effect or caused any changes to the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of this device.

4. **Comparison Information** (similarities and differences):

There were no changes made to the device. The modification was in the data analysis resulting in changes in the performance measures claimed for the device.

Parameter	Modified Claim Clearview Exact II Influenza A & B Test	Clearview Exact II Influenza A & B Test 510(k) Number K092349
INTENDED USE	Detection of Influenza A & B antigens in nasal swab specimens	Same
ANALYTE	Differentiated detection of influenza A & B nucleoprotein antigens	Same
TECHNOLOGY	Lateral flow immunochromatographic membrane assay	Same
SPECIMEN TYPE	Nasal swab specimens	Same
ANALYTICAL REACTIVITY	10^3 to 10^6 TCID ₅₀ /mL for 12 flu A strains and 10 flu B strains; 10^6 EIU ₅₀ /mL for 1 flu A strain	Same
ANALYTICAL SPECIFICITY	Does not cross-react with the 38 bacteria (10^8 to 10^{10} cells/mL, CFU/mL or IFU/mL), 15 viruses (10^5 to 10^8 TCID ₅₀ /mL or CEID ₅₀ /mL) and one yeast (10^9 cells/mL) evaluated	Same

Parameter	Modified Claim Clearview Exact II Influenza A & B Test	Clearview Exact II Influenza A & B Test 510(k) Number K092349
INTERFERING SUBSTANCES	Does not cross-react with the 30 products tested. Visibly bloody samples may be inappropriate for use in this test since analytical studies have shown that 1% whole blood interferes with the correct interpretation of Flu A LOD (C ₉₅) positive samples.	Same
REPRODUCIBILITY	Six individuals; 838 tests. Influenza A detection rates for moderate positive, low positive and high negative samples equal to 99.2%, 94.2%, and 9.2% respectively. Influenza B detection rates for moderate positive, low positive and high negative samples equal to 99.2%, 96.7%, and 7.5% respectively.	Same
SENSITIVITY	94% (95% CI: 83-98%) vs. Viral Culture for the detection of Flu A 77% (95% CI: 67-85%) vs. Viral Culture for the detection of Flu B	Same 78% (95% CI: 68-86%) vs. Viral Culture for the detection of Flu B
SPECIFICITY	96% (95% CI: 93-97%) vs. Viral Culture for the detection of Flu A 98% (95% CI: 96-99%) vs. Viral Culture for the detection of Flu B	94% (95% CI: 91-96%) vs. Viral Culture for the detection of Flu A 97% (95% CI: 95-98%) vs. Viral Culture for the detection of Flu B

5. A declaration of conformity with design controls.

Sponsor provided a signed statement that:

- a) The manufacturing facility, Alere Scarborough, Inc., is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
- b) The modifications presented in this submission do not affect the detection portion of the assay or the components or design of the test system. Therefore, a risk analysis was not required and no verification and/or validation activities were conducted, which would have been performed as a result of a risk analysis.

6. A Truthful and Accurate Statement, a 510(k) Summary and the Indications for Use Enclosure.

The labeling for this modified 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. I recommend the device be determined substantially equivalent to the previously cleared device.