SPECIAL 510(k): Device Modification
Decision Summary

To: SA Scientific **RE:** K132352

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

1. The names and 510(k) numbers of the SUBMITTER'S previously cleared devices:

   Trade Names: SAS™ Influenza A Test
   SAS™ FluAlert A & B Test

   510(k) numbers: K041441
   K080380

2. Submitter's statement that the **INDICATION/INTENDED USES** of the modified devices as described in their labeling **HAVE NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling.
3. A description of the device **MODIFICATION(S).** The modification presented in this 510(k) consisted of **expanded analytical sensitivity (limit of detection; LoD) tables to include reactivity information for** the H7N9 influenza A virus. The ability of the SAS Influenza A Test and the SAS FluAlert A & B Test to detect H7N9 influenza A virus was tested using the (A/Anhui/1/2013) strain obtained from the Centers for Disease Control and Prevention as non-infectious beta-propiolactone inactivated virus. An LoD study was performed with the A/Anhui/1/2013 influenza strain at concentrations:

   - $5x10^7$ EID_{50}/mL
   - $1x10^8$ EID_{50}/mL
   - $2x10^8$ EID_{50}/mL

   The LoD was determined to be $1x10^8$ EID_{50}/mL.

   The package inserts for the SAS Influenza A Test and the SAS FluAlert A & B Test have been updated to include the additional analytical reactivity information

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

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

   Similarities - SAS Influenza A Test (K041441)

Features	SAS Influenza A Test	SAS Influenza A Test
Intended Use	SAS™ Influenza A Test is a visual and rapid assay for the presumptive *in-vitro* qualitative detection of influenza A viral nucleoprotein antigens from nasal washes and nasal aspirates of symptomatic patients. The test is not intended for the detection of Influenza Type B viral antigen or Influenza Type C viral antigen. This test is for professional use	SAS™ Influenza A Test is a visual and rapid assay for the presumptive *in-vitro* qualitative detection of influenza A viral nucleoprotein antigens from nasal washes and nasal aspirates of symptomatic patients. The test is not intended for the detection of Influenza Type B viral antigen or Influenza Type C viral antigen. This test is for professional use

	only. Negative results do not preclude infection with influenza A and should not be used as the sole basis for treatment or other patient management decisions. It is recommended that negative results be confirmed by cell culture.	only. Negative results do not preclude infection with influenza A and should not be used as the sole basis for treatment or other patient management decisions. It is recommended that negative results be confirmed by cell culture.
Read Results	Visual	Visual
Specimen Types	Nasal wash, nasal aspirate	Nasal wash, nasal aspirate
Read Result Time	15 minutes	15 minutes
Internal Controls	Device includes an internal positive and negative procedural control	Device includes an internal positive and negative procedural control

Similarities - SAS FluAlert A & B Test (K080380)

Features	**SAS FluAlert A & B Test**	**SAS FluAlert A & B Test**
Intended Use	SAS™ FluAlert A & B Test is a visual and rapid assay for the presumptive *in-vitro* qualitative detection of Influenza A and Influenza B viral nucleoprotein antigens from nasal washes and nasal aspirates of symptomatic patients. The test is not intended for the detection of Influenza Type C viral antigen. This test is for professional use only. Negative results do not preclude infection with influenza A and/or influenza B and should not be used as the sole basis for treatment or other patient management decisions. It is recommended that negative results be confirmed by cell culture.	SAS™ FluAlert A & B Test is a visual and rapid assay for the presumptive *in-vitro* qualitative detection of Influenza A and Influenza B viral nucleoprotein antigens from nasal washes and nasal aspirates of symptomatic patients. The test is not intended for the detection of Influenza Type C viral antigen. This test is for professional use only. Negative results do not preclude infection with influenza A and/or influenza B and should not be used as the sole basis for treatment or other patient management decisions. It is recommended that negative results be confirmed by cell culture.
Read Results	Visual	Visual
Specimen Types	Nasal wash, nasal aspirate	Nasal wash, nasal aspirate
Read Result Time	15 minutes	15 minutes
External Controls	Device includes an internal positive and negative procedural control	Device includes an internal positive and negative procedural control

Differences

1) The package inserts for the SAS Influenza A Test (K041441) and the SAS FluAlert A & B Test (K080380) have been updated to include detection of the A/Anhui/1/2013 H7N9 virus in the analytical sensitivity (LoD) section:

H7N9 A/Anhui/1/2013* – 2013759189 - 1.00x10^8 EID_{50}/mL

*This viral strain was obtained from the CDC with a known titer. SA Scientific, Ltd. did not verify this titer.

2) The package inserts for the SAS Influenza A Test (K041441) and the SAS FluAlert A & B Test (K080380) have been updated to include the following statement in the limitations section:

Performance characteristics for detecting the 2009 H1N1 and 2013 H7N9 influenza viruses from human specimens have not been established.

3) The package insert for the SAS Influenza A Test (K041441) has been updated to include the following information in the analytical sensitivity (LoD) section:

This test has been shown to detect the Flu A/California/04/09 (H1N1) and Flu A/Anhui/1/2013 viruses cultured from a positive human specimen; however, the performance characteristics of this test with clinical specimens that are positive for the 2009 H1N1 and 2013 H7N9 influenza virus have not been established. The SAS Influenza A Test can detect influenza A viruses, but cannot differentiate influenza subtypes.

4) The package insert for the SAS FluAlert A & B Test (K080380) has been updated to include the following information in the analytical sensitivity (LoD) section:

This test has been shown to detect the Flu A/California/04/09 (H1N1) and Flu A/Anhui/1/2013 viruses cultured from a positive human specimen; however, the performance characteristics of this test with clinical specimens that are positive for the 2009 H1N1 and 2013 H7N9 influenza virus have not been established. The SAS FluAlert A & B Test can distinguish between influenza A and B viruses, but cannot differentiate influenza subtypes.

5) The package insert for the SAS FluAlert A & B Test (K080380) has been updated to include the following information in the cross reactivity section:

Influenza A H7N9 A/Anhui/1/2013 – 2013759189 – 1.00x10^9 EID_{50}/mL – Neg (for cross reactivity with the "B" portion of the SAS FluAlert A & B Test)

6. **Design Control Activities Summary**:

1) Analytical Reactivity Testing was conducted as described in section 3, Device Modifications.

2) Declaration of Conformity

A "Declaration of Conformity" statement was submitted for the manufacturing facility and validation activities and signed by the Quality Assurance/Regulatory Affairs Specialist. The statements indicate that:

a) The manufacturing facility, SA Scientific, Ltd. is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.
b) To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) 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 tests and, therefore, they are substantially equivalent to the currently cleared tests.

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

The labeling for the modified subject devices has been reviewed to verify that the indication/intended uses for the devices are unaffected by the modification. In addition, the submitter's description of the particular modification and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. On this basis, I recommend that the devices are determined to be substantially equivalent to the previously cleared devices.