

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

K080380

B. Purpose for Submission:

New device, combining the immunoassay test strips from the individual SAS™ Influenza A and SAS™ Influenza B Tests into one side-by-side plastic cassette

C. Measurand:

Influenza A and influenza B viral nucleoprotein antigens
Influenza types detected: influenza A and influenza B

D. Type of Test:

A rapid immunoassay for the qualitative detection of influenza A and influenza B viral nucleoprotein in nasal washes and nasal aspirates

E. Applicant:

SA Scientific, Ltd.

F. Proprietary and Established Names:

SAS™ FluAlert A & B Test

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
GNX	Class II	21 CFR 866.3330 Antigens, Cf (including Cf controls) influenza virus A, B, C	Microbiology (83)

H. Intended Use:

1. Intended use(s):

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 or 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.

2. Indication(s) for use:
Same as Intended Use
3. Special conditions for use statement(s):
For prescription use only
4. Special instrument requirements:
N/A

I. Device Description:

The SAS™ FluAlert A & B Test is an immunoassay comprised of two strips in one cassette. One strip utilizing monoclonal antibodies against influenza type A nucleoproteins and the second strip utilizing influenza type B viral nucleoproteins. In the presence of influenza A and/or influenza B, the antibody-gold conjugate in the test membranes binds to the nucleoproteins and forms a complex. This complex migrates across the membrane and is captured by influenza A or influenza B antibodies in the membrane and forms visible pink lines. To serve as a procedural control, a pink line will always appear in the control zone of each strip regardless of the presence or absence of influenza A or influenza B nucleoproteins.

J. Substantial Equivalence Information:

1. Predicate device name(s):
SAS™ Influenza A Test (K044141) and SAS™ Influenza B Test (K041439), manufactured by SA Scientific, Ltd., San Antonio, TX.
2. Predicate K number(s):
K044141
K041439
3. Comparison with predicate:

Similarities			
Item	Device	Predicate 1	Predicate 2
	The SAS™ FluAlert A & B Test	SAS™ Influenza A Test (K044141)	SAS™ Influenza B Test (K041439)
Technology	Immunoassay	Immunoassay	Immunoassay
Organism Detected	Influenza A and B	Influenza A	Influenza B
Intended Use	Detection of influenza A and B viral nucleoproteins	Detection of influenza A viral nucleoproteins	Detection of influenza B viral nucleoproteins

Differences			
Item	Device	Predicate 1	Predicate 2
	The SAS™ FluAlert A & B Test	SAS™ Influenza A Test (K044141)	SAS™ Influenza B Test (K041439)
Device Configuration	Two strips in a cassette for detection of influenza A and influenza B	One strip in a cassette for detection of influenza A	One strip in a cassette for detection of influenza B

K. Standard/Guidance Documents Referenced (if applicable):

Guidance on In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labeling and Regulatory Path - <http://www.fda.gov/cdrh/oivd/guidance/1594.pdf>.

L. Test Principle:

The SAS™ FluAlert A & B Test utilizes monoclonal antibodies against influenza Type A and influenza Type B viral nucleoproteins. The test begins with an extraction of nucleoproteins from the clinical specimen. The extracted specimen is then placed into two separate sample wells and observed for the formation of colored lines. The specimen is absorbed and migrates via capillary action through membranes that contain dried gold conjugated antibody specific for either influenza A or influenza B nucleoproteins. If Type A and/or Type B nucleoproteins are present, they bind to the antibody-gold conjugate and form a complex which migrates across the membrane and is captured by influenza A or influenza B antibodies in the membrane. Thus, in the presence of influenza A and influenza B nucleoproteins, an immuno-complex is formed and a visible pink line develops in the specimen zones of the test device, in the A line for influenza A and in the B line for influenza B. In the absence of influenza A and/or influenza B antigens, an immuno-complex is not formed and a negative result is indicated. To serve as a procedural control, a pink line should appear in the control zones regardless of the presence or absence of influenza A and influenza B nucleoproteins.

Interpretation of Results:

Expected Performance of Controls:

Internal Controls

Each test device includes an internal procedural control, a line in the C (control) regions of the test device. Correct procedural technique, specimen flow and test device performance is confirmed when a colored line appears in the C areas of the membrane. If the colored line fails to appear in the C area of either strip, the test result is invalid.

A clear background is an internal negative procedural control. The background color should be white to light pink and should not interfere with the reading of the test result. If a more intensely red background color appears, it may

interfere with the ability to read the test result, therefore the test should be repeated.

External Controls

Negative and Positive controls for influenza A antigen and influenza B antigen should be tested and the appropriate results obtained. External quality control testing should be performed in conformance with local, state and federal regulations or accreditation organizations as applicable, and should follow the user's laboratory's standard quality control procedures. Controls in the SAS™ FluAlert Control Kit, catalog # 046230, are ready to use; do not dilute with extraction buffer.

Specimen Results and Interpretation:

- The test is negative if a colored line appears only in the C (control) area on both strips.
- The test is positive for Flu A if the line appears under S (specimen) on the Flu A strip and a second line appears under the C on both strips. The test is positive for Flu B if the line appears under S on the Flu B strip and a second line appears under C on both strips. Any pink colored line in the specimen (S) area, regardless of the intensity, is a positive result.
- While co-infections with both influenza A and influenza B viruses are rare and no incidences were observed in the clinical studies, they might occur. If there is a question about the test results, the test may be repeated.
- The test is invalid if no colored line appears in the C area on either strip, even if a colored line appears in either S area. If this occurs, the test should be repeated.

M. Performance Characteristics (if/when applicable):

1. Analytical Performance:

a. Precision/Reproducibility:

The reproducibility of the SAS™ FluAlert A&B Test was evaluated at three clinical sites. Three or four non-professional users per site tested the SAS™ FluAlert A&B Test against a panel of approximately 30 aliquots each of six (6) panel members over a two-week period. Specimens were comprised of pooled nasal aspirates and included two (2) levels of positives for influenza A and two (2) for influenza B and one negative for each virus. The influenza A panel members contained H3N2 A/Hong Kong/8/68 and the influenza B panel members contained B/Allen/45. Negative specimens for influenza A and influenza B were in concentrations below the limit of detection.

Reproducibility Study Summary for the SAS™ FluAlert A & B Test

	Panel Member	Influenza A High Negative	Influenza A Low Positive	Influenza A Moderate Positive	Influenza B High Negative	Influenza B Low Positive	Influenza B Moderate Positive
	Viral Titer Final Conc. TCID ₅₀ /0.2 ml	1.8 x 10 ³	7 x 10 ³	1.4 x 10 ⁴	2.8 x 10 ²	1.1 x 10 ³	2.2 x 10 ³
Agreement with Expected Result	Site 1	29 Neg/30 96.7%	26 Pos/30 86.6%	29 Pos/30 96.7%	28 Neg/29 96.6%	29 Pos/30 96.7%	29 Pos/29 100%
	Site 2	29 Neg/30 96.7%	26 Pos/29 89.7%	29 Pos/29 100%	30 Neg/30 100%	29 Pos/30 96.7%	30 Pos/30 100%
	Site 3	28 Neg/30 93.3%	27 Pos/30 90.0%	30 Pos/30 100%	26 Neg/29 89.7%	29 Pos/30 96.7%	30 Pos/30 100%
	Total Agreement	95.6%	88.8%	98.9%	95.4%	96.7%	100%

b. Linearity/assay reportable range:

Not applicable, qualitative assay

c. Traceability, Stability, Expected values (controls, calibrators, or methods): N/A

d. Detection limit:

The Limit of Detection (LoD) for the SAS™ FluAlert A&B Test was determined using quantified (TCID₅₀ /ml) cultures of five (5) each Influenza A and Influenza B viral strains received from the ATCC. Each strain was serially diluted in SAS™ FluAlert extraction buffer. Strains were assayed using the SAS™ FluAlert A&B Test until no positive signal could be seen. LoD was calculated to determine the lowest detectable concentration range of influenza.

Limit of Detection Summary

Influenza Viral Strain	ATCC	LoD TCID ₅₀ /0.2 ml
H1N1 A/PR/3/34	VR-95	1.2 x 10 ⁵
H3N2 A/Aichi/2/68	VR-547	5.6 x 10 ²
H3N2 A/Hong Kong/8/6/8	VR-544	3.5 x 10 ³
H1N1 A/FM/147	VR-97	7.9 x 10 ³
H3N2 A/Victoria/3/75	VR-822	4.5 x 10 ⁵
Influenza B/Lee/40	VR-101	9.9 x 10 ⁴
Influenza B/Allen/45	VR-102	5.6 x 10 ²
Influenza B/Mass/3/66	VR-523	4.5 x 10 ²
Influenza B/Taiwan/2/62	VR-295	3.5 x 10 ¹
Influenza B/Maryland/1/59	VR-296	1.6 x 10 ²

e. Analytical specificity:

Analytical specificity of the SAS™ FluAlert A&B Test was evaluated for potential cross-reactivity and interference with non-influenza pathogens associated with respiratory tract infections.

Cross-Reactivity Evaluation

Twenty-two virus strains were obtained from ATCC or other commercial sources. Each cultured viral strain was tested on the SAS™ FluAlert A&B Test at concentrations listed in the table below.

Cross-reactivity Test Results with Common Viral Respiratory Pathogens

Virus	ATTC/Lot #	Concentration	“A” portion of the SAS™ FluAlert A&B	“B” portion of the SAS™ FluAlert A&B
Adenovirus 5	10-198-000	1.2 x 10 ¹⁰ TCID ₅₀ /0.2 ml	Neg	Neg
Adenovirus 7	VR7	3.2 x 10 ³ TCID ₅₀ /0.2 ml	Neg	Neg
Adenovirus 10	VR1087	3.2 x 10 ³ TCID ₅₀ /0.2 ml	Neg	Neg
CoxsackieA9	VR186	3.2 x 10 ² TCID ₅₀ /0.2 ml	Neg	Neg
CoxsackieB5	VR185	3.2 x 10 ⁶ TCID ₅₀ /0.2 ml	Neg	Neg
Cytomegalovirus	021301	20 µg/ml	Neg	Neg
Echovirus11	VR1052	NA	Neg	Neg
Echovirus3	VR1040	1 x 10 ⁴ TCID ₅₀ /0.2 ml	Neg	Neg
Echovirus 6	VR1044	3.2 x 10 ⁶ TCID ₅₀ /0.2 ml	Neg	Neg
HSV-1	2J30000	15 µg/ml	Neg	Neg
HSV-2	8J29502	15 µg/ml	Neg	Neg
Varicella zoster	1102097	12 µg/ml	Neg	Neg
Parainfluenza 1	VR907	5.6 x 10 ⁶ TCID ₅₀ /0.2 ml	Neg	Neg
Parainfluenza 2	VR92	1.8 x 10 ⁵ TCID ₅₀ /0.2 ml	Neg	Neg
Parainfluenza 3	VR93	3.2 x 10 ⁶ TCID ₅₀ /0.2 ml	Neg	Neg
RSV Long	VR26	0.1 x 10 ^{5.5} TCID ₅₀ /0.2 ml	Neg	Neg
RSV B	VR1400	0.1 x 10 ^{5.25} TCID ₅₀ /0.2 ml	Neg	Neg
Influenza B Allen	VR102	3.2 x 10 ³ TCID ₅₀ /0.2 ml	Neg	
Influenza B Lee	VR101	3.2 x 10 ⁶ TCID ₅₀ /0.2 ml	Neg	
Influenza B Mass	VR523	1.8 x 10 ³ TCID ₅₀ /0.2 ml	Neg	
Influenza B Maryland	VR296	1 x 10 ⁴ TCID ₅₀ /0.2 ml	Neg	
Influenza B Taiwan	VR295	5.6 x 10 ² TCID ₅₀ /0.2 ml	Neg	
Influenza A (H1N1) PR	VR95	1.8 x 10 ⁴ TCID ₅₀ /0.2 ml		Neg
Influenza A (H3N2) Aichi	VR547	1.8 x 10 ⁶ TCID ₅₀ /0.2 ml		Neg
Influenza A	VR544	5.6 x 10 ⁴ TCID ₅₀ /0.2 ml		Neg

(H3N2) Hong Kong				
Influenza A FM	VR97	3.2×10^4 TCID ₅₀ /0.2 ml		Neg
Influenza A (H3N2) Victoria	VR822	1.8×10^6 TCID ₅₀ /0.2 ml		Neg

One yeast and fourteen bacterial strains were obtained from ATCC or other commercial sources. Each cultured bacterial or yeast strain was diluted to a concentration of 1×10^8 cfu/ml and tested on the SAS™ FluAlert A&B Test.

Cross-reactivity Test Results with Common Bacterial Respiratory Pathogens

Bacteria or Yeast	“A” portion of the SAS™ FluAlert A&B	“B” portion of the SAS™ FluAlert A&B
<i>Candida albicans</i>	Neg	Neg
<i>Chlamydia trachomatis</i>	Neg	Neg
<i>Corynebacterium diphtheriae</i>	Neg	Neg
<i>Haemophilus influenza</i>	Neg	Neg
<i>Klebsiella pneumoniae</i>	Neg	Neg
<i>Serratia marcescens</i>	Neg	Neg
<i>Staphylococcus epidermidis</i>	Neg	Neg
<i>Staphylococcus aureus</i>	Neg	Neg
<i>Streptococcus sp gr A</i>	Neg	Neg
<i>Streptococcus sp gr F</i>	Neg	Neg
<i>Streptococcus sp gr G</i>	Neg	Neg
<i>Streptococcus pneumoniae</i>	Neg	Neg
<i>Mycoplasma pneumoniae</i>	Neg	Neg
<i>Neisseria meningitidis</i>	Neg	Neg
<i>Pseudomonas aeruginosa</i>	Neg	Neg

The study demonstrated that the SAS™ FluAlert A&B Test did not cross-react with any respiratory pathogens or commensal organisms tested. The data demonstrated 100% concordance with the expected results.

Interference Study

The analytical specificity of the influenza A portion of the SAS™ FluAlert A&B was evaluated by testing a panel of 22 viruses, 14 bacteria, and one yeast species which may be found in the respiratory tract. For the influenza A portion of the test, influenza whole virus strain A/FM/147 (ATCC VR97) at a titer of 7.9×10^3 TCID₅₀/0.2 ml was added to viral cultures and viral antigens at the concentrations listed in the table below and bacterial and yeast cultures at concentrations of 1×10^8 cfu/ml. For the influenza B portion of the test, whole virus strain B/Mass/3/66 (ATCC VR523) at a titer of 3.2×10^3 TCID₅₀/0.2 ml. was added to viral cultures in the concentrations listed in the table below and bacterial and yeast cultures at 1×10^8 cfu/ml.

SAS™ FluAlert A&B Interference Test Results

Virus	ATTC/Lot #	Concentration	“A” Portion of the SAS™ FluAlert A&B	“B” Portion of the SAS™ FluAlert A&B
Adenovirus 5	10-198-000	1.2×10^{10} TCID ₅₀ /0.2 ml	Pos	Pos
Adenovirus 7	VR7	3.2×10^3 TCID ₅₀ /0.2 ml	Pos	Pos
Adenovirus 10	VR1087	3.2×10^3 TCID ₅₀ /0.2 ml	Pos	Pos
CoxsackieA9	VR186	3.2×10^2 TCID ₅₀ /0.2 ml	Pos	Pos
CoxsackieB5	VR185	3.2×10^6 TCID ₅₀ /0.2 ml	Pos	Pos
Cytomegalovirus	021301	20 µg/ml	Pos	Pos
Echovirus11	VR1052	NA	Pos	Pos
Echovirus3	VR1040	1×10^4 TCID ₅₀ /0.2 ml	Pos	Pos
Echovirus6	VR1044	3.2×10^6 TCID ₅₀ /0.2 ml	Pos	Pos
HSV-1	2J30000	15 µg/ml	Pos	Pos
HSV-2	8J29502	15 µg/ml	Pos	Pos
Varicella zoster	1102097	12 µg/ml	Pos	Pos
Parainfluenza 1	VR907	5.6×10^6 TCID ₅₀ /0.2 ml	Pos	Pos
Parainfluenza 2	VR92	1.8×10^5 TCID ₅₀ /0.2 ml	Pos	Pos
Parainfluenza 3	VR93	3.2×10^6 TCID ₅₀ /0.2 ml	Pos	Pos
RSV Long	VR26	$0.1 \times 10^{5.5}$ TCID ₅₀ /0.2 ml	Pos	Pos
RSV B	VR1400	$0.1 \times 10^{5.25}$ TCID ₅₀ /0.2 ml	Pos	Pos
Influenza B Allen	VR102	3.2×10^3 TCID ₅₀ /0.2 ml	Pos	
Influenza B Lee	VR101	3.2×10^6 TCID ₅₀ /0.2 ml	Pos	
Influenza B Mass	VR523	1.8×10^3 TCID ₅₀ /0.2 ml	Pos	
Influenza B Maryland	VR296	1×10^4 TCID ₅₀ /0.2 ml	Pos	
Influenza B Taiwan	VR295	5.6×10^2 TCID ₅₀ /0.2 ml	Pos	
Influenza A (H1N1) PR	VR95	1.8×10^4 TCID ₅₀ /0.2 ml		Pos
Influenza A (H3N2) Aichi	VR547	1.8×10^6 TCID ₅₀ /0.2 ml		Pos
Influenza A (H3N2) Hong Kong	VR544	5.6×10^4 TCID ₅₀ /0.2 ml		Pos
Influenza A FM	VR97	3.2×10^4 TCID ₅₀ /0.2 ml		Pos
Influenza A (H3N2) Victoria	VR822	1.8×10^6 TCID ₅₀ /0.2 ml		Pos

One yeast and fourteen bacterial strains were obtained from ATCC or other commercial sources. Each cultured bacterial or yeast strain was diluted to a concentration of 1×10^8 cfu/ml and tested on the SAS™ FluAlert A&B Test.

SAS™ FluAlert A&B Interference Test Results

Bacteria or Yeast	“A” portion of the SAS™ FluAlert A&B	“B” portion of the SAS™ FluAlert A&B
<i>Candida albicans</i>	Pos	Pos
<i>Chlamydia trachomatis</i>	Pos	Pos
<i>Corynebacterium diphtheriae</i>	Pos	Pos
<i>Haemophilus influenza</i>	Pos	Pos
<i>Klebsiella pneumoniae</i>	Pos	Pos
<i>Serratia marcescens</i>	Pos	Pos
<i>Staphylococcus epidermidis</i>	Pos	Pos
<i>Staphylococcus aureus</i>	Pos	Pos
<i>Streptococcus sp gr A</i>	Pos	Pos
<i>Streptococcus sp gr F</i>	Pos	Pos
<i>Streptococcus sp gr G</i>	Pos	Pos
<i>Streptococcus pneumoniae</i>	Pos	Pos
<i>Mycoplasma pneumoniae</i>	Pos	Pos
<i>Neisseria meningitidis</i>	Pos	Pos
<i>Pseudomonas aeruginosa</i>	Pos	Pos

f. Assay cut-off:

N/A

2. Comparison studies:
 - a. *Method comparison with predicate device:*

Prospective Clinical Study

The SAS™ FluAlert A&B Test combines the immunoassay test strips from the individual SAS™ Influenza A and SAS™ Influenza B Tests into one side-by-side plastic cassette. There are no other changes made to this test. In these studies, the users compared the combined test to the individual tests for evaluation of user interpretations. Please see: “Results Summary: SAS™ Influenza A and SAS™ Influenza B Individual Devices compared to cell culture or DFA” chart for comparison of the individual tests to cell culture/DFA.

Four clinical trial sites, in Texas and South Dakota, tested four hundred sixty one (461) nasal clinical specimens blindly and prospectively comparing the SAS™ Influenza A Test and The SAS™ FluAlert A&B (combined) Test performance. The SAS™ Influenza A Test and SAS™ FluAlert A&B Test had a positive percent agreement of 97.2% and a negative percent agreement of 99.7%. Thirteen samples yielded invalid results. .

Four clinical trial sites, in Texas and South Dakota, tested four hundred

sixty one (461) nasal clinical specimens blindly and prospectively comparing the SAS™ Influenza B Test and the SAS™ FluAlert A&B (combined) Test performance. The SAS™ Influenza B test and SAS™ FluAlert A&B Test had a positive percent agreement of 98.7% and a negative percent agreement of 99.7%.

Clinical sites collected the nasal wash samples during the 2007-2008 and 2008 – 2009 influenza seasons from an approximately equal mix of adult (>21 years) and pediatric patients (0-21 years). The nasal aspirate samples were collected predominately from pediatric patients.

Demographics of fresh specimens:

Age (years)	Number of Nasal Wash specimens	% of Total NW Specimens	Number of Nasal Aspirate Specimens	% of Total NA Specimens
0-5	16	5.7%	73	40.1%
6-21	21	7.5%	108	59.3%
22 - 65	25	9.0%	1	0.6%
>65	9	3.2%	0	
Not Determined	208	74.5%	0	
Total	279		182	

Fresh, Prospective Nasal Aspirates:

Influenza A Comparison Results

		SAS™ Influenza A Test		
		+	-	
SAS™ FluAlert A & B Combined Test	+	44	0	44
	-	1	137	138
Total		45	137	182

Positive % Agreement: 97.8% (95% CI 87-100%)
Negative % Agreement: 100% (97% CI 95-100%)

Influenza B Comparison Results

		SAS™ Influenza B Test			
		+	-		
SAS™ FluAlert A & B Combined Test		+	37	0	37
		-	0	145	145
Total			37	145	182

Positive % Agreement: 100% (95% CI 97-100%)

Negative % Agreement: 100% (95 % CI 88-100%)

Fresh, Prospective Nasal Washes:

Influenza A Comparison Results

		SAS™ Influenza A Test		
		+	-	
SAS™ FluAlert A & B Combined Test	+	26	1	27
	-	1	251	252
	Total	27	252	279
Positive % Agreement: 96.3% (95% CI 79-100%)				
Negative % Agreement: 99.6% (95% CI 97-100%)				

Influenza B Comparison Results

		SAS™ Influenza B Test		
		+	-	
SAS™ FluAlert A & B Combined Test	+	40	1	41
	-	1	237	238
	Total	41	238	279
Positive % Agreement: 97.6% (95% CI 86-100%)				
Negative % Agreement: 99.6% (95% CI 97-100%)				

Results Summary: Fresh Nasal Washes and Aspirates

Influenza A Comparison Results

		SAS™ Influenza A Test		
		+	-	
SAS™ FluAlert A & B Combined Test	+	70	1	71
	-	2	388	390
	Total	72	389	461
Positive % Agreement: 97.2% (95% CI 879-100%)				
Negative % Agreement: 99.7% (95% CI 98-100%)				

Influenza B Comparison Results

		SAS™ Influenza B Test		
		+	-	
SAS™ FluAlert A & B Combined Test	+	77	1	78
	-	1	382	383
	Total	78	383	461
Positive % Agreement: 98.7% (95% CI 92-100%)				
Negative % Agreement: 99.7% (95% CI 98-100%)				

Note: Performance characteristics for detecting the 2009 H1N1 influenza virus from human specimens have not been established

Retrospective Study

To supplement the prospective study, 191 frozen, archived, nasal wash samples from a children's hospital in Texas were blindly assayed comparing the individual SASTM Influenza A Test and the individual SASTM Influenza B Test to the SASTM FluAlert A&B (combined) Test. For these samples, the positive percent agreement with the influenza A Test is 100% and negative percent agreement is 99.3%, while positive percent agreement with the Influenza B Test was 94.7% and negative percent agreement is 98.0%

SASTM Influenza

A Test

SAS TM FluAlert A&B Combined Test	A Test		
	+	-	
+	27	1	28
-	0	163	163
Total	27	164	191

Positive % Agreement: 100% (95% CI 84-100%)

Negative % Agreement: 99.3% (95% CI 96-100%)

SASTM Influenza

B Test

SAS TM FluAlert A & B Combined Test	B Test		
	+	-	
+	36	3	39
-	2	150	152
Total	38	153	191

Positive % Agreement: 94.7% (95% CI 81-99%)

Negative % Agreement: 98.0% (95% CI 94-99%)

b. Matrix comparison:

Not applicable

3. Clinical studies:

a and b. Clinical Sensitivity and Specificity:

SASTM Influenza A and SASTM Influenza B individual devices compared to cell culture or DFA.

The performance of the SASTM Influenza A and SASTM Influenza B individual devices was established during the 2002-2003 and 2003-2004 flu seasons, at clinical sites in Iowa, Virginia, and South Dakota. A total of 263 and 255 clinical specimens, respectively, were tested using the SAS Influenza A and Influenza B devices and the results were compared to cell culture or DFA. Specimens were comprised of leftover nasopharyngeal

washes, nasal washes and nasopharyngeal aspirates, and were tested blindly and prospectively. Results are shown in the following table.

All Specimens		SAS™ Influenza A Test			SAS™ Influenza B Test		
		+	-		+	-	
Cell Culture/DFA	+	57	4	61	19	0	19
	-	18	184	202	2	234	236
		75	188	263	21	234	255
Sensitivity		76%			90.5%		
95% CI		65-85%			68-98%		
Specificity		97.9%			100%		
95% CI		94-99.9%			98-100%		

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Influenza prevalence varies year to year, with the highest number of cases in the fall and winter months in the US. During the period of September 30, 2007 to April 5, 2008, prevalence in the US for both influenza A and influenza B was 18.5%, with 74% of those cases attributed to influenza A and 26% attributed to influenza B. For studies conducted on the SAS™ FluAlert A&B Test, during the 2007-2008 and 2008-2009 seasons, prevalence for fresh, prospective nasal washes and nasal aspirates was 15.1% for influenza A and 16.5% for influenza B.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.