510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K212623

B Applicant

Healgen Scientific, LLC

C Proprietary and Established Names

Healgen Strep A Rapid Test Strip (Throat Swab)

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
GTY	Class I	21 CFR 866.3740 - Streptococcus Spp. Serological Reagents	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

This is a new 510(k) submission to obtain substantial equivalence for the Healgen StrepA Rapid Test.

B Measurand:

Group A *Streptococcus* Antigen

C Type of Test:

Lateral flow chromatographic immunoassay.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Strep A Rapid Test Strip (Throat Swab) is a rapid chromatographic immunoassay for the qualitative detection of Streptococcus pyogenes (Group A β-hemolytic Streptococcus, Strep A) antigen from throat swab specimens of symptomatic patients to aid in the diagnosis of Group A Streptococcus bacterial infection.

All negative test results should be confirmed by bacterial culture because negative results do not preclude infection with Group A Streptococcus and should not be used as the sole basis for treatment.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

For in vitro diagnostic use only
A negative result must be confirmed by culture. A negative result may be obtained if the concentration of the Group A Streptococcus antigen present in the throat swab is not adequate or is below the detectable level of the test.

D Special Instrument Requirements:

None

IV Device/System Characteristics:

A Device Description:

Healgen Strep A Rapid Test Strip (Throat Sdfwab) is a qualitative, lateral flow immunoassay for the detection of Strep A carbohydrate antigen from a throat swab. In this test, a throat swab is collected from the patient and the Strep A antigen is extracted in the extraction tube. This test uses a strip with antibody specific to Strep A carbohydrate antigen coated on the test line region of the test. The test strip is immediately placed in the sample solution that migrates up through the test strip to generate a color line in the test line region. The presence of a colored line in the test line region indicates a positive result for detection of Strep A antigen, while its absence indicates a negative result. To serve as a procedural control, a red line should always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred. If the red control line does not appear, or remains blue, the test result is invalid.

Device Contents:

- 25 Test strips
- 25 Sterile swabs
- 25 Disposable extraction tubes (one tube for each test strip)
- 1 Reagent A (10mL; 2M Sodium Nitrite)
- 1 Reagent B (10mL; 0.2M Acetic Acid)
- 1 Positive control (1mL; Non-viable Strep A; 0.05% Proclin300)
- 1 Negative control (1mL; Non-viable Strep C; 0.05% Proclin300)
- 1 Package insert

B Principle of Operation:

Group A *Streptococcus* antigen reacts with the anti-Strep A antibody conjugated to the gold particle. The complex is then bound by the anti-Strep A capture antibody and a visible red test line appears, indicating a positive result. To serve as an onboard procedural control, a control line observed at the control site prior to running the assay will turn red, indicating that the test has been performed properly.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Wondfo Rapid Strep A Test

B Predicate 510(k) Number(s):
K133343

C Comparison with Predicate(s):

Device & Predicate Device(s):	K212623	K133343
Device Trade Name	Healgen Strep A Rapid Test Strip (Throat Swab)	Wondfo One Step Strep A Swab Test
General Device Characteristic Similarities		
Intended Use	The Strep A Rapid Test Strip (Throat Swab) is a rapid chromatographic immunoassay for the qualitative detection of *Streptococcus pyogenes* (Group A β-hemolytic *Streptococcus*, Strep A) antigen from throat swab specimens of symptomatic patients to aid in the diagnosis of Group A *Streptococcus* bacterial infection. All negative test results should be confirmed by bacterial culture because negative results do not preclude infection with Group A *Streptococcus* and should not be used as the sole basis for treatment.	The Wondfo Strep A Rapid Test is a chromatographic immunoassay for the qualitative detection of Strep A antigen from throat swab specimens from symptomatic patients to aid in the diagnosis of Group A Streptococcal infection. All negative test results should be confirmed by bacterial culture because negative results do not preclude Group A Strep infection and should not be used as the sole basis for treatment. This test is intended for professional and laboratory use, only.

Device & Predicate Device(s):	K212623	K133343
Specimen	Throat swab	Same
Assay technical	Immunochromatographic	Same
Control Antibodies	Goat polyclonal anti-Rabbit IgG	Same
Test Antibody	Rabbit Polyclonal Anti-Strep A	Same
Indication for Use	Prescription Use	Same
General Device Characteristic Differences		
Test format	Strip	Cassette
Analytical sensitivity	7.2×10^3 CFU/mL (360 organisms/test)	1.5 x 10^5 organisms/mL
Clinical Sensitivity	97.1%: 95% Cl (93.7-98.8%)	95%: 95% Cl (88-98%)
Clinical Specificity	99.4%: 95% Cl (96.2-100.0%)	98%: 95% Cl (96-99%)
Results Reading Time	5 minutes	10 minutes

VI Standards/Guidance Documents Referenced:

Not applicable

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

Precision/Reproducibility:

To demonstrate the reproducibility of the Healgen StrepA Rapid Test, a four-member test panel consisting of *Streptococcus pyogenes* ATCC 19615 prepared at 2 × LoD, 1 × LoD and 0.5 × LoD concentrations, as well as a negative (diluent only) sample, was tested. The panel was tested at three sites by two operators at each site. Each operator tested each panel member, in duplicate, over 5 days using three lots of the device (2 operators × 3 sites × 2 replicates × 3 lots × 5 days = 180 results/panel member). The results are summarized in Table 1.

Table 1. Reproducibility of Healgen Strep A Rapid Test.

Target Level	Site A %Detection (Positive/Tested)	Site B %Detection (Positive/Tested)	Site C %Detection (Positive/Tested)	Combined %Detection (Positive/Tested)
Negative	0% (0/60)	0% (0/60)	0% (0/60)	0% (0/180)
2 × LoD	100% (60/60)	100% (60/60)	100% (60/60)	100% (180/180)
1 × LoD	98.3% (59/60)	93.3% (56/60)	95% (57/60)	95.6% (172/180)
0.5 × LoD	48.3% (29/60)	43.3% (26/60)	41.7% (25/60)	44.4% (80/180)

There were no significant differences in the test results obtained between different users, different sites, and different lots on different days. The Healgen StrepA Rapid Test reproducibility is acceptable.

1. Linearity:

   Not applicable. This is a qualitative detection assay.

2. Analytical Specificity/Interference:

A. Analytical specificity (Cross-reactivity and Microbial interference)
To evaluate the potential for cross-reactivity with the Healgen Strep A Rapid Test Strip, microorganisms likely to be found in the respiratory tract were tested by three operators using three lots of the device for a total of nine results for each microorganism. The test organisms, concentrations and cross-reactivity results are shown in Table 2.

To evaluate the potential for microbial interference of Healgen Strep A Rapid Test Strip performance, potential interfering organisms likely to be found in the respiratory tract were tested in the presence of *Streptococcus pyogenes* at 2× LoD. Samples were randomized and blinded for single replicate testing by three (3) operators with three (3) device lots . The test organisms, concentrations and interference results are shown in Table 2.

Table 2. Analytical specificity (Cross-reactivity & Microbial interference) for Healgen Strep A Rapid Test

Test Microorganisms	Concentrations	Test Result (Positive/Tested)	
		Absence of *S. pyogenes*	Presence of *S. pyogenes*
Arcanobacterium haemolyticum	2.6×10^8 CFU/mL	0/9	3/3
Bordetella pertussis	7.5×10^8 CFU/mL	0/9	3/3
Candida albicans	9.5×10^8 CFU/mL	0/9	3/3
Corynebacterium diphtheria	5.37×10^8 CFU/mL	0/9	3/3
Enterococcus faecalis	2.3×10^8 CFU/mL	0/9	3/3
Enterococcus faecium	4.4×10^8 CFU/mL	0/9	3/3
Escherichia coli	1.1×10^8 CFU/mL	0/9	3/3
Fusobacterium necrophorum	7.3×10^8 CFU/mL	0/9	3/3
Haemophilus parahaemolyticus	1.3×10^8 CFU/mL	0/9	3/3
Haemophilus parainfluenzae	1.6×10^8 CFU/mL	0/9	3/3
Haemophilus influenzae	4.5×10^8 CFU/mL	0/9	3/3
Klebsiella pneumoniae	3.1×10^8 CFU/mL	0/9	3/3
Legionella pneumophila	1×10^4 bacteria/mL	0/9	3/3
Lactobacillus sp. (Lactobacillus casei)	6.5×10^8 CFU/mL	0/9	3/3

Test Microorganisms	Concentrations	Test Result (Positive/Tested)	
		Absence of *S. pyogenes*	Presence of *S. pyogenes*
Moraxella lacunata	1.95×10^8 CFU/mL	0/9	3/3
Moraxella catarrhalis	4.8×10^8 CFU/mL	0/9	3/3
Mycobacterium tuberculosis	1×10^3 bacteria/mL	0/9	3/3
Mycobacterium tuberculosis (avirulent strain)	2.3×10^8 CFU/mL	0/9	3/3
Neisseria gonorrhoeae	3.8×10^8 CFU/mL	0/9	3/3
Neisseria lactamica	1.19×10^8 CFU/mL	0/9	3/3
Neisseria meningitides	7.5×10^8 CFU/mL	0/9	3/3
Neisseria mucosa	3.25×10^8 CFU/mL	0/9	3/3
Neisseria sicca	8.5×10^8 CFU/mL	0/9	3/3
Neisseria subflava	3.27×10^8 CFU/mL	0/9	3/3
Proteus vulgaris	2.9×10^8 CFU/mL	0/9	3/3
Pseudomonas aeruginosa	5.1×10^8 CFU/mL	0/9	3/3
Serratia marcescens	2.1×10^8 CFU/mL	0/9	3/3
Staphylococcus aureus	3.2×10^8 CFU/mL	0/9	3/3
Staphylococcus epidermidis	2.1×10^8 CFU/mL	0/9	3/3
Staphylococcus marcescens	1.5×10^8 CFU/mL	0/9	3/3
Staphylococcus haemolyticus	1.58×10^8 CFU/mL	0/9	3/3
Streptococcus agalactiae (Group B)	7.9×10^7 CFU/mL	0/9	3/3
Streptococcus dysgalactiae (Group C)	1.43×10^5CFU/mL	0/9	3/3
Streptococcus sp. Strain H60R (Group F)	1×10^6 CFU/mL	0/9	3/3
Streptococcus anginosus (Group G)	4.2×10^7 CFU/mL	0/9	3/3
Streptococcus sp. (bovis II) Group D	5.6×10^8 CFU/mL	0/9	3/3
Streptococcus pneumoniae	4.2×10^6 CFU/mL	0/9	3/3
Streptococcus salivarius	8.7×10^8 CFU/mL	0/9	3/3
Streptococcus mitis	5.9×10^8 CFU/mL	0/9	3/3
Streptococcus mutans	4.7×10^8 CFU/mL	0/9	3/3
Streptococcus oralis	6.4×10^8 CFU/mL	0/9	3/3
Streptococcus sanguis	1.5×10^8 CFU/mL	0/9	3/3
Yersinia enterocolitica	2.0×10^8 CFU/mL	0/9	3/3
Adenovirus Type I	3.09×10^8 $TCID_{50}$/mL	0/9	3/3
Adenovirus Type II	3.9×10^7 $TCID_{50}$/mL	0/9	3/3

Test Microorganisms	Concentrations	Test Result (Positive/Tested)	
		Absence of *S. pyogenes*	Presence of *S. pyogenes*
Adenovirus 3	1.5×10^8 TCID50/mL	0/9	3/3
Adenovirus 7	2.8×10^6 $TCID_{50}$/mL	0/9	3/3
Cytomegalovirus	$1.6\times10^5$$TCID_{50}$/mL	0/9	3/3
Enterovirus (VR-28 Human Coxsackievirus)	1.6×10^8 $TCID_{50}$/mL	0/9	3/3
Epstein Barr Virus	7.85×10^7 copies/mL	0/9	3/3
HSV Type 1 MacIntyre strain	1.6×10^5 $TCID_{50}$/mL	0/9	3/3
Human coronavirus OC43	1.7×10^5 $TCID_{50}$/mL	0/9	3/3
Human metapneumovirus (HMPV-27 A2)	3.55×10^5 $TCID_{50}$/mL	0/9	3/3
Human parainfluenza Type 1	$1.6\times10^5$$TCID_{50}$/mL	0/9	3/3
Human parainfluenza Type 2	$1.6\times10^5$$TCID_{50}$/mL	0/9	3/3
Human parainfluenza Type 3	$1.6\times10^5$$TCID_{50}$/mL	0/9	3/3
Human rhinovirus 26	5×10^6 $TCID_{50}$/mL	0/9	3/3
Measles Virus	8.9×10^5 $TCID_{50}$/mL	0/9	3/3
Mumps Virus	1.38×10^7 $TCID_{50}$/mL	0/9	3/3
Respiratory syncytial virus Type A	5.5×10^7 PFU/mL	0/9	3/3
Respiratory syncytial virus Type B	2.8×10^5 $TCID_{50}$/mL	0/9	3/3

No cross reactivity or microbial interference were found for the above organisms at the concentrations tested and the results are acceptable.

B. Interfering Substances:

To evaluate the potential for interference of Healgen Strep A Rapid Test performance, potentially interfering substances were evaluated in samples spiked with *S. pyogenes* ATCC 19615. Each sample was tested using three lots of Healgen Strep A Rapid Test Strip. The list of interfering substances and tested concentrations are provided in Table 3.

Table 3. Interfering substances evaluated for the performance of Healgen Strep A Rapid Test

Interfering Substances	
Blood (human)	20% (vol/vol)
Mucin	1 mg/mL
Listerine Antiseptic	20% (vol/vol)
Cool Mint	20% (vol/vol)

Interfering Substances	Concentration Tested
Crest Pro-Health Clean Mint	20% (vol/vol)
Crest Pro Health Multi Protection Clean Mint	20% (vol/vol)
Colgate Total Pro-Shield，	20% (vol/vol)
Spearmint	20% (vol/vol)
Sucrets Sore Throat & Cough Lozenges, Honey Lemon,	5 mg/mL
Sucrets Sore Throat Lozenges Cherry	5 mg/mL
Halls Mentho-Lyptus Drops Cherry	5 mg/mL
Halls Cough Suppressant Cherry Triple Soothing Action	5 mg/mL
Cepacol Extra Strength Sore Throat & Cough Drop Lozenges, Cherry	5 mg/mL
Cepacol Dual Relief	20% (vol/vol)
Chloraseptic Max	20% (vol/vol)
Tylenol Cough and Sore Throat	10% (vol/vol)
Basic Care Tussin DM, Cough Suppressant & Expectorant	10% (vol/vol)
Robitussin (Guaifenesin Syrup)	10% (vol/vol)
Robitussin Nighttime Cough	10% (vol/vol)
Children's Dimetapp Cold & Flu	10% (vol/vol)
Children's Dimetapp Cold & Cough	10% (vol/vol)
Acetaminophen (Tylenol)	5 mg/mL
Brompheniramine Maleate	5 mg/mL
Chlorpheniramine Maleate	5 mg/mL
Dextromethorphan HBr	5 mg/mL
Diphenhydramine HCI	5 mg/mL
Doxylamine Succinate	5 mg/mL
Guaifenesin (Guaiacol Glyceryl)	5 mg/mL
Ibuprofen (Advil)	5 mg/mL
Phenylephrine HCI	5 mg/mL

Each of listed interfering substances at the given concentrations when spiked with 2 × LoD of *S. pyogenes* ATCC 19615 tested 100% positive for Strep A using Healgen Strep A Rapid Test. As a control, the listed interfering substances at the given concentrations tested for Strep A results into no detection using Healgen Strep A Rapid Test. No interference with any of the interfering substances tested were found at the tested concentrations and the results are acceptable.

3. Assay Reportable Range:

   Not applicable

4. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   A. Quality Control:

   The Healgen Strep A Rapid Test incorporates three controls:

- Internal Positive Control: A color line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. If a color band is not visible in the control region (C), the test is invalid.

- External Positive Control: The external positive control is provided with the Healgen Strep A Rapid Test. It contains non-viable Group A *Streptococcus* in 0.05% Proclin 300.

- External Negative Control: The external negative control is provided with the Healgen Strep A Rapid Test. It contains non-viable *Streptococcus* Group C in 0.05% Proclin 300.

The instructions for use (package insert) recommends that a positive and negative external control be tested at least once within each test kit and by each operator performing testing within a kit. This will verify that the reagents and test strips are working properly, and the operator is able to correctly perform the test procedure.

B. Evaluation of Control Performance:

During the Clinical Study to evaluate performance of the Healgen Strep A Rapid Test, each operator tested five positive and five negative controls. All these control samples were blinded and randomized. All controls gave the expected results as shown in Table 4.

Table 4. Evaluation of Control Performance of Healgen Strep A Rapid Test.

Sites	Operators	Test Results (Positive/Tested)	
		Negative Control	Positive Control
Site 1	Operator 1	0/5	5/5
	Operator 2	0/5	5/5
	Operator 3	0/5	5/5
	Operator 4	0/5	5/5
Site 2	Operator 1	0/5	5/5
	Operator 2	0/5	5/5
Site 3	Operator 1	0/5	5/5
	Operator 2	0/5	5/5
	Operator 3	0/5	5/5

The performance when testing the positive and negative control was acceptable.

C. Specimen Storage Stability:
The instructions for use (package insert) for the Healgen Strep A Rapid Test states that swab specimens may be stored in a clean, dry plastic tube for up to 48 hours at room temperature or 72 hours at 2-8°C. To evaluate sample storage, negative clinical matrix swab spiked with *S. pyogenes* at 2× LoD and 4 × LoD were placed in a clean plastic tube and capped tightly. These swab samples were divided into two groups: one stored at refrigerated (2-8ºC) and other at room temperature (15-30ºC). The results for these samples are in Table 5.

Table 5. Specimen Storage Stability for Healgen Strep A Rapid Test.

Storage Temperature	Results (Positive/Tested) in time points									
	0 hr		8 hr		24 hr		48 hr		72 hr	
	2 × LoD	4 × LoD	2 × LoD	4 × LoD	2 × LoD	4 × LoD	2 × LoD	4 × LoD	2 × LoD	4 × LoD
Refrigerated (2-8ºC)	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20
Room Temperature (15-30ºC)	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	NA	NA

Healgen Strep A Rapid Test demonstrates that the swab samples can be stored at refrigerated condition (2-8ºC) for 72 hours or at room temperature (15-30 ℃) for 48 hours. Specimen Storage Stability is acceptable.

5. Detection of Limit:

The limit of detection (LoD) for the Healgen Strep A Rapid Test Strip was established by testing limiting dilutions of *Streptococcus pyogenes* spiked onto a negative throat swab (clinical matrix). A concentrated stock (3.6×10^7 CFU/mL) of inactivated *S. pyogenes* ATCC 19615 was serially diluted in saline solution. 5 µL of each dilution was pipetted onto a negative throat swab for testing by seven operators with three lots of Healgen Strep A Rapid Test Strip, for a total of 21 results for each dilution. The test results are shown in Table 6.

Table 6. Determining Limit of Detection (LoD) for Healgen Strep A Rapid Test in clinical matrix

Dilutions	Number of bacteria loaded*		
1.8×10^5 CFU/mL	900	21/21	100%
7.2×10^4 CFU/mL	360	20/21	95.2%
3.6×10^4 CFU/mL	180	12/21	57.6%
1.8×10^4 CFU/mL	90	1/21	4.8%
4.5×10^3 CFU/mL	23	0/21	0%

*Calculated values based on dilution and volume of sample loaded on the swab per test.

The LoD was determined to be 7.2×10^4 CFU/mL when 5 µL of sample was pipetted onto a negative clinical matrix (equivalent to 360 bacteria on the swab).

The LoD for the Healgen Strep A Rapid Test Strip was also examined by using limiting dilutions of *S. pyogenes* ATCC 19615 in saline and pipetting 50 µL of each dilution with equivalent bacterial amounts as those used with the clinical matrix onto a swab. The study results are shown in Table 7.

Table 7. Determining Detection of Limit (LoD) for Healgen Strep A Rapid Test in Saline Solution.

Dilutions	Number of bacteria loaded* (50 µL per swab)	Positive/Tested	% Detection
1.8×10^4 CFU/mL	900	21/21	100%
7.2×10^3 CFU/mL	360	20/21	95.2%
3.6×10^3 CFU/mL	180	11/21	47.6%
1.8×10^3 CFU/mL	90	1/21	4.8%
4.5×10^3 CFU/mL	23	0/21	0%

*Calculated values based on dilution and volume of sample loaded on the swab per test.

The LoD was determined to be 7.2×10^3 CFU/mL when 50 µL of sample was pipetted onto a swab (equivalent to 360 bacteria on the swab) which is consistent with the LoD established using negative throat swab clinical matrix.

Inclusivity:
Two strains of *S. pyogenes* ATCC 19615 and ATCC 49399 were tested at the level of 2 × LoD with 30 replicates in three lots of test kits (see Matrix Comparisons/Equivalency). Both the strains result into 100% detection to indicate the coverage of phenotypic diversity.

6. Assay Cut-Off:
   Not Applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Not applicable

2. Matrix Comparison:

A Matrix Equivalency Study was performed to evaluate the equivalency between saline solution and natural clinical throat matrix. A collection of 360 swabs from healthy subjects were screened for GAS using the Healgen Strep A Rapid Test Strip to produce a negative clinical matrix. *Streptococcus pyogenes* ATCC 19615 and ATCC 49399 were serially diluted in saline solution to achieve final LoD levels of 5×, 2×, 0.5× and negative. 5 µL of each sample was added to negative clinical matrix swabs or swabs without clinical matrix (saline solution). Three lots of the devices with 10 replicates were tested for target levels 5×, 0.5× and negative LoD samples producing 30 test results whereas 30 replicates were tested for the target level 2× LoD sample generating 90 test results. The results are summarized in Table 8.

Table 8. Determining matrix equivalency for Healgen Strep A Rapid Test.

LoD Level	ATCC 19615				ATCC 49399			
	Saline solution		Clinical matrix		Saline solution		Clinical matrix	
	Positive /Tested	% Detection	Positive /Tested	% Detection	Positive /Tested	% Detection	Positive /Tested	% Detection
5 ×	30/30	100%	30/30	100%	30/30	100%	30/30	100%
2 ×	90/90	100%	90/90	100%	90/90	100%	90/90	100%
0.5 ×	13/30	43.3%	14/30	46.7%	10/30	33.3%	11/30	36.7%
Negative	0/30	0%	0/30	0%	0/30	0%	0/30	0%

Healgen demonstrates the matrix equivalency between saline solution and natural clinical matrix. The matrix equivalency study is acceptable.

C Clinical Studies:

1. Clinical Sensitivity and Specificity:
   The performance of the Healgen Strep A Rapid Test Strip was evaluated at Point of Care (POC) in Physicians' offices located at three different geographical sites. Two throat swabs were collected from a total of 368 patients exhibiting symptoms of pharyngitis. One swab was used for the Healgen Strep A Rapid Test Strip and tested on site right after sample collection. The other swab was transported to a reference laboratory for culture confirmation. The combined performance of the Healgen Strep A Rapid Test compared to culture results is summarized in Table 9A. The performance stratified by each site is shown in Tables 9-B-D.

   Table 9A. Clinical performance of Healgen Strep A Rapid Test.

		Culture Results		Total
		Positive	Negative	
Healgen Strep A Rapid Test	Positive	200	1	201
	Negative	6	161	167
Total		206	162	368

   Sensitivity: 97.1% (200/206) with 95% CI = 93.7% - 98.8%

   Specificity: 99.4% (161/162) with 95% CI = 96.2% - 100.0%

   Table 9B. Site 1: Clinical Performance:

Site 1		Culture Results		Total
		Positive	Negative	
	Positive	48	0	48

Healgen Strep A Rapid Test	Negative	3	51	54
Total		51	51	102

Sensitivity: 94.1% (48/51) with 95% CI = 83.5% - 98.6%

Specificity: 100% (51/51) with 95% CI = 91.6% - 100.0%

Table 9C. Site 2: Clinical Performance:

Site 2		Culture Results		Total
		Positive	Negative	
Healgen Strep A Rapid Test	Positive	26	0	26
	Negative	1	39	40
Total		27	39	66

Sensitivity: 96.3% (26/27) with 95% CI = 80.2% - 100.0%

Specificity: 100% (39/39) with 95% CI = 89.3% - 100.0%

Table 9D. Site 3: Clinical Performance:

Site 3		Culture Results		Total
		Positive	Negative	
Healgen Strep A Rapid Test	Positive	126	1	127
	Negative	2	71	73
Total		128	72	200

Sensitivity: 98.4% (126/128) with 95% CI = 94.1% - 99.9%

Specificity: 98.6% (71/72) with 95% CI = 91.8% - 100.0%

Healgen Strep A Rapid Test demonstrated the ability to detect Strep A antigen as compared to the culture conducted at three different point of care testing sites with overall Sensitivity 97.1% and Specificity 99.4%. The clinical results are acceptable.

2. Clinical Specificity:

   See Section 1A.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

The clinical study analysis included results from 368 throat swab specimens collected from three point of care sites in the U.S. between February to May of 2017 to 2019. The prevalence of *S. pyogenes* for this period in this clinical study was 55.9% (206/368) as determined by culture and the positivity was 54.6% (201/368) as determined by the Healgen Strep A Rapid Test. No specific reasons could be identified based on the study protocols that could explain the high prevalence observed in this study. However, the higher-than-expected prevalence was possibly due to prior determination to conduct the study during a peak of *S. pyogenes* infection season covering Feb-May each given calendar year.

The clinical outcome stratified by age of the participants are shown in Table 10.

Table 10. Clinical outcomes stratified by age.

Age (in years)				
0 to 5	97.4% (74/76)	90.4% - 99.8%	98.1% (52/53)	89.1% - 100.0%
5 to 21	96.7% (119/123)	91.7% - 99.0%	100% (88/88)	95.0% - 100.0%
21 & older	100% (7/7)	59.6% - 100.0%	100% (21/21)	81.8% - 100.0%
All	97.1% (200/206)	93.7% - 98.8%	99.4% (161/162)	96.2% - 100.0%

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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