March 16, 2022

Healgen Scientific, LLC
℅ Joe Shia
Director
LSI International Inc.
504 East Diamond Ave. Suite I
Gaithersburg, Maryland 20877

Re: K212623
Trade/Device Name: Healgen Strep A Rapid Test Strip (Throat Swab)
Regulation Number: 21 CFR 866.3740
Regulation Name: Streptococcus Spp. Serological Reagents
Regulatory Class: Class I
Product Code: GTY
Dated: August 16, 2021
Received: August 18, 2021

Dear Joe Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ribhi Shawar, Ph.D. (ABMM)
Chief
General Bacteriology and Antimicrobial
Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212623

Device Name
Strep A Rapid Test Strip (Throat Swab)

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

K212623

1. Date: March 7, 2022

2. Submitter: HEALGEN SCIENTIFIC LLC
5213 Maple St
Bellaire, TX77401

3. Contact person: Joe Shia
LSI International Inc.
504 East Diamond Ave.
Gaithersburg, MD 20877
Telephone: 240-505-7880
Email:shiajl@yahoo.com

4. Device Name: Healgen Strep A Rapid Test Strip (Throat Swab)
Class: **Class I**

Product Code	**CFR #**	**Panel**
GTY	866.3740 streptococcus spp serological reagents	Microbiology

5. Predicate Devices:
K133343
Wondfo Strep A Rapid Test
Guangzhou Wondfo Biotech Co., Ltd.

6. Intended Use/Indications 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.

7. Device Description

Healgen Strep A Rapid Test Strip (Throat Swab) is a qualitative, lateral flow immunoassay for the detection of Strep A antigen directly from a throat swab sample.
In this test, antibody specific to Strep A carbohydrate antigen is coated on the test line region of the test. During testing, the extracted throat swab specimen reacts with an antibody to Strep A that is coated onto particles. The mixture migrates up the membrane to react with the antibody to Strep A on the membrane and

generate a color line in the test line region. The presence of this color line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

8. Substantial Equivalence Information

A summary comparison of features of the Healgen Strep A Rapid Test Strip (Throat Swab) and the predicate device is provided in Table 1.

Similarities		
Item	**Device**	**Predicate (k133343)**
Intended Use	For the qualitative detection of group A streptococcal antigen directly from throat swabs.	Same
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
Differences		
Item	**Device**	**Predicate (k133343)**
Test format	Strip	Cassette
Analytical sensitivity	7.2×10^3 CFU/mL	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

9. Test Principle

Group A *Streptococcus* 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.

10. Performance Characteristics

1. Analytical Performance

a. Precision/Reproducibility

A test panel consists of a true negative sample (diluent only), a low negative sample ($3.6x10^3$ CFU/mL), a moderate positive sample (1.8×10^4 CFU /mL) and a LoD sample (7.2×10^3 CFU/mL) were tested. Three lots

of the device are used. The study is performed at two runs per day in 5 different days at three different sites. Six professional operators who don't know the sample number code participated in the study (two operators at each site). Each operator tests two runs per day at each concentration with three lots of Healgen Strep A Rapid Test Strip (Throat Swab). A total of 30 determinations by each operator at each concentration are made. The obtained results are shown in the following table.

Results / Samples	Positive Agreement % (Positive/Total tested)			Overall Positive Detection
	Site A	Site B	Site C	
True negative sample (Diluent only)	0%(0/60)	0%(0/60)	0%(0/60)	0%(0/180)
Moderate positive sample, 1.8×10^4 CFU/mL	100%(60/60)	100%(60/60)	100%(60/60)	100%(180/180)
LoD sample, 7.2×10^3 CFU/mL	98.3%(59/60)	93.3%(56/60)	95.0%(57/60)	95.6%(172/180)
Low negative sample, 3.6×10^3 CFU/mL	48.3%(29/60)	43.3%(26/60)	41.7%(25/60)	44.4%(80/180)

It's concluded that there are no significant differences of the test results obtained between different users, different sites and different lots in different days. The obtained results are reproducible in good precision.

b. Linearity

Not applicable

c. Stability

Stable at 4-30℃ for 24 months based on real time stability determination at both 4°C and 30°C.

d. LoD

The limit of detection (LoD) for the Healgen Strep A Rapid Test Strip was established using limiting dilutions of *Streptococcus pyogenes* and tested by spiking with 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 contrived dilution sample was pipetted onto negative throat swab clinical matrix for testing. Each dilution was tested by seven operators with three lots of Healgen Strep A Rapid Test Strip (Throat Swab), for a total of 21 results for each dilution. The test results are shown in the following table.

Table: Determining Limit of Detection (LoD) for Healgen Strep A Rapid Test in clinicalmatrix

Dilutions	Number of bacteria loaded* (5 µL per swab)	Positive/Tested	% Detection
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.

Table: 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.

e. Interference

The potentially interfering substances of blood, mucus, saliva, and medications used to relieve a sore throat, such as over-the-counter cough drops, lozenges, cough syrups, throat sprays, mouth wash etc. were tested with Healgen Strep A Rapid Test Strip (Throat Swab). Each potentially interfering substance was diluted and splitted into two aliquots. One aliquot was spiked with *S. pyogenes* to a final concentration of 1.44 x 10^4 CFU/ml. The second aliquot contained no bacteria. These aliquot samples were tested by three batches of Healgen Strep A Rapid Test Strip (Throat Swab). Three laboratory assistants with relevant experience performed the test. The obtained results are shown in the following table.

Interfering Substance	**Concentration Tested**	**1.44×10^4 CFU/mL *S. pyogenes* Positive specimen（2×LOD）**			***S. pyogenes* Negative Specimen**		
		Lot1	**Lot2**	**Lot3**	**Lot1**	**Lot2**	**Lot3**
Blood (human)	20% (vol/vol)	+	+	+	-	-	-
Mucin	1mg/mL	+	+	+	-	-	-
OTC Mouthwashes							
Listerine Antiseptic Cool Mint	20%(vol/vol)	+	+	+	-	-	-
Crest Pro-Health Clean Mint	20%(vol/vol)	+	+	+	-	-	-
Crest Pro Health	20%(vol/vol)	+	+	+	-	-	-

Multi Protection Clean Mint							
Colgate Total Pro-Shield，Spearmint	20%(vol/vol)	+	+	+	-	-	-
OTC Lozenges							
Sucrets Sore Throat & Cough Lozenges, Honey Lemon,	5mg/mL	+	+	+	-	-	-
Sucrets Sore Throat Lozenges Cherry	5mg/mL	+	+	+	-	-	-
Halls Mentho-Lyptus Drops Cherry	5mg/mL	+	+	+	-	-	-
Halls Cough Suppressant Cherry Triple Soothing Action	5mg/mL	+	+	+	-	-	-
Cepacol Extra Strength Sore Throat & Cough Drop Lozenges, Cherry	5mg/mL	+	+	+	-	-	-
OTC Throat Sprays							
Cepacol Dual Relief	20%(vol/vol)	+	+	+	-	-	-
Chloraseptic Max	20%(vol/vol)	+	+	+	-	-	-
OTC Cough Syrups							
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)	+	+	+	-	-	-
Active Ingredients							
Acetaminophen (Tylenol)	5mg/mL	+	+	+	-	-	-
Brompheniramine Maleate	5mg/mL	+	+	+	-	-	-
Chlorpheniramine Maleate	5mg/mL	+	+	+	-	-	-
Dextromethorphan HBr	5mg/mL	+	+	+	-	-	-
Diphenhydramine HCI	5mg/mL	+	+	+	-	-	-
Doxylamine Succinate	5mg/mL	+	+	+	-	-	-
Guaifenesin(Guaiacol Glyceryl)	5mg/mL	+	+	+	-	-	-
Ibuprofen (Advil)	5mg/mL	+	+	+	-	-	-
Phenylephrine HCI	5mg/mL	+	+	+	-	-	-

Neither false positive nor false negative results are shown in the Healgen Strep A Rapid Test Strip (Throat Swab) at the concentrations listed.

f. Analytical Specificity

Analytical specificity (cross-reactivity) of Healgen Strep A Rapid Test Strip (Throat Swab) was carried out for organisms likely to be found in the respiratory tract. It was tested by three lots of Healgen Strep A Rapid Test Strip (Throat Swab). Three professional users performed the test. The obtained results are summarized in the following table.

Organisms	Concentration Tested	Test results								
		Lot1#			Lot2#			Lot3#		
		Operator A	Operator B	Operator C	Operator A	Operator B	Operator C	Operator A	Operator B	Operator C
Arcanobacterium haemolyticum	2.6×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Bordetella pertussis	7.5×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Candida albicans	9.5×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Corynebacterium diphtheria	5.37×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Enterococcus faecalis	2.3×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Enterococcus faecium	4.4×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Enterovirus (VR-28 Human Coxsackievirus)	1.6×10^8 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-
Escherichia coli	1.1×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Fusobacterium necrophorum	7.3×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Haemophilus parahaemolyticus	1.3×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Haemophilus influenzae	4.5×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Haemophilus parainfluenzae	1.6×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Human metapneumovirus (HMPV-27 A2)	3.55×10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-
Human coronavirus OC43	1.7×10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-
Klebsiella pneumoniae	3.1×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Legionella pneumophila	1×10^4 bacteria/mL	-	-	-	-	-	-	-	-	-

Lactobacillus sp. (Lactobacillus casei)	6.5×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Mycobacterium tuberculosis	1×10^3 bacteria/mL	-	-	-	-	-	-	-	-	-
Moraxella lacunata	1.95×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Moraxella (Branhamella) catarrhalis	4.8×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Mycobacterium tuberculosis (avirulent strain)	2.3×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Neisseria gonorrhoeae	3.8×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Neisseria lactamica	1.19×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Neisseria meningitides	7.5×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Neisseria mucosa	3.25×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Neisseria sicca	8.5×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Neisseria subflava	3.27×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Proteus vulgaris	2.9×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Pseudomonas aeruginosa	5.1×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Serratia marcescens	2.1×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Staphylococcus aureus	3.2×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Staphylococcus epidermidis	2.1×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Staphylococcus marcescens	1.5×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Staphylococcus haemolyticus	1.58×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Streptococcus agalactiae (Group B)	7.9×10^7 CFU/mL	-	-	-	-	-	-	-	-	-
Streptococcus dysgalactiae (Group C)	1.43×10^5CFU/mL	-	-	-	-	-	-	-	-	-
Streptococcus sp. (bovis II) Group D	5.6×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Streptococcus sp. Strain	1×10^6 CFU/mL	-	-	-	-	-	-	-	-	-

H60R (Group F)										
Streptococcus anginosus (Group G)	4.2×10^7 CFU/mL	-	-	-	-	-	-	-	-	-
Streptococcus pneumoniae	4.2×10^6 CFU/mL	-	-	-	-	-	-	-	-	-
Streptococcus salivarius	8.7×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Streptococcus mitis	5.9×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Streptococcus mutans	4.7×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Streptococcus oralis	6.4×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Streptococcus sanguis	1.5×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Yersinia enterocolitica	2.0×10^8 CFU/mL	-	-	-	-	-	-	-	-	-
Adenovirus Type I	3.09×10^8 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-
Adenovirus Type II	3.9×10^7 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-
Adenovirus 3	1.5×10^8 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-
Adenovirus 7	2.8×10^6 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-
Cytomegalovirus	1.6×10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-
Epstein Barr Virus	7.85×10^7 copies/mL	-	-	-	-	-	-	-	-	-
HSV Type 1 MacIntyre strain	1.6×10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-
Human parainfluenza Type 1	1.6×10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-
Human parainfluenza Type 2	1.6×10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-
Human parainfluenza Type 3	1.6×10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-
Human rhinovirus 26	5×10^6 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-
Measles Virus	8.9×10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-
Mumps virus	1.38×10^7 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-
Respiratory syncytial virus Type A	5.5×10^7 PFU/mL	-	-	-	-	-	-	-	-	-
Respiratory syncytial virus Type B	2.8×10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-

No cross reactivity was found for the above organisms at the concentrations tested.

2. Comparison Studies

   NA

3. Clinical Studies

   A total of 368 subjects were tested from patients exhibiting symptoms of pharyngitis by both the Healgen Strep A Rapid Test Strip (Throat Swab) and the culture studies. Of the 368 total subjects, 162 were found to be negative (-) by culture and 206 were found to be positive (+) by culture. These test results are summarized in the following tables.

ALL AGES			
Strep A Rapid Test Strip (Throat Swab)	Culture Result		Total
	+	-	
+	200	1	201
-	6	161	167
Total	206	162	368

Age	Sensitivity	Sensitivity(95%CI)	Specificity	Specificity(95%CI)
0 ~ 5	97.4% (74/76)	90.4% - 99.8%	98.1% (52/53)	89.1% - 100.0%
5+ ~ 21	96.7% (119/123)	91.7% - 99.0%	100% (88/88)	95.0% - 100.0%
21+	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%

There were no statistical differences in the Healgen Strep A Rapid Test Strip (Throat Swab) performance between the age groups. The overall Clinical Sensitivity is 97%. The overall clinical specificity is 99%.

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, LoD, interference, specificity and clinical study of the device, it's concluded that Healgen Strep A Rapid Test Strip (Throat Swab) is substantially equivalent to the predicate.