



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

I Background Information:

A 510(k) Number

K251800

B Applicant

Healgen Scientific LLC

C Proprietary and Established Names

Healgen® URS Test Strips

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LJX	Class I, meets the limitations of exemptions in 21 CFR 862.9 (c)(9)	21 CFR 864.7675 - Leukocyte Peroxidase Test	HE - Hematology
JMT	Class I, meets the limitations of exemptions in 21 CFR 862.9 (c)(9)	21 CFR 862.1510 - Nitrite (nonquantitative) test system	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Modified Device

B Measurand:

Urine leukocytes and nitrite

C Type of Test:

Qualitative and semi-quantitative urinalysis

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Healgen® URS Test Strips are for the qualitative detection of leukocytes (white blood cells) and nitrite in urine as an aid in the screening of a urinary tract infection (UTI). It is intended for over-the-counter home use only.

C Special Conditions for Use Statement(s):

OTC - Over the Counter

D Special Instrument Requirements:

Not applicable

IV Device/System Characteristics:

A Device Description:

Same as described in K231045. The device was modified to add dipping as a testing method.

B Principle of Operation:

Same as described in K231045.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Healgen URS Test Strips

B Predicate 510(k) Number(s):

K231045

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K251800</u>	<u>K231045</u>
Device Trade Name	Healgen® URS Test Strips	Healgen URS Test Strips
General Device Characteristic Similarities		
Intended Use/Indications For Use	For the qualitative detection of leukocytes and nitrite in urine.	Same
Sample Type	Human Urine	Same
Analytes	Nitrite, Leukocyte	Same
Nitrite test methodology	By conversion of nitrate to nitrite using the action of p-arsanilic acid to form a diazonium compound in an acid medium. This compound then couples with 1, 2, 3, 4-tetrahydrobenzo(<i>h</i>)quinoline to produce a pink color.	Same
Leukocyte test methodology	By hydrolysis of an indoxyl ester derivative through the action of leukocyte esterase. The liberated indoxyl ester reacts with a diazonium salt to produce a colored compound (pink to purple).	Same
Conditions for use	Over-the-counter	Same
Read time	2 minutes	Same
General Device Characteristic Differences		
Testing Format	Dipping	Midstream

VI Standards/Guidance Documents Referenced:

None were referenced.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

The precision study for the Healgen URS Test Strips was performed at three testing sites with one operator at each site. The evaluation included three runs per day for five days. Three lots of the reagent were used with each level of control samples in each run. A total of forty-five results (3x3x5) on each concentration were obtained. All sample concentrations were masked. The results are listed in the tables below.

Analyte	Concentration	Expected Value	N	% Agreement with Expected results
Leukocyte	0 cells/ μ L	Negative	45	100
	15 cells/ μ L	Trace (15)	45	100
	70 cells/ μ L	Small (70)	45	100
	125 cells/ μ L	Moderate (125)	45	100
	500 cells/ μ L	Large (500)	45	100
Nitrite	0 mg/dL	Negative	45	100
	0.08 mg/dL	Positive	45	100
	0.1 mg/dL	Positive	45	100

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

Potentially interfering substances were added to negative urine or urine with different analyte concentrations. These samples were tested with three lots of the Healgen URS Test Strips by three different operators. The following substances showed no interference with the tests at the specified concentrations.

Substances	Testing Concentration (mg/dL)
Albumin	1000 mg/dL
Ascorbic Acid	100 mg/dL
Hemoglobin	100 mg/dL
Citric Acid	50 mg/dL
Bilirubin	10 mg/dL
Ciprofloxacin	1 mg/dL
Creatine	8 mg/dL
Acetoacetate Acid	1 mmol/L
Ammonium Chloride	400 mg/dL
Calcium Chloride	50 mg/dL
Creatinine	800 mg/dL
Galactose	80 mg/dL

Substances	Testing Concentration (mg/dL)
Glucose	500 mg/dL
Glycine	1000 mg/dL
KCL	1500 mg/dL
NaCl	2800 mg/dL
Oxalic Acid	70 mg/dL
Sodium Acetate	1200 mg/dL
Sodium Bicarbonate	1500 mg/dL
Sodium Nitrate	10 mg/dL
Sodium Nitrite*	10 mg/dL
Sodium Phosphate	1000 mg/dL
Sulfamethoxazole	40 mg/dL
Urobilinogen	3.0 mg/dL
Urea	4000 mg/dL
Riboflavin	50 mg/dL
Theophylline	100 mg/dL
Phenolphthalein	120 mg/dL
Phenazopyridine	30 mg/dL
Glutathione	200 mg/dL
Hypochlorite	1 mg/dL
Hydrochloric Acid	1 mg/dL
Peroxide	0.1mg/dL
Atropine	30 mg/dL
Fructose	5000 mg/dL
Lactose	5000 mg/dL
Ketone	200 mg/dL
Mesna	50 mg/dL

* This interference is tested for Leukocyte results only.

High glucose levels (≥ 1000 mg/dL) or high Vitamin C (≥ 150 mg/dL) may decrease leukocyte readings. High Vitamin C (≥ 150 mg/dL) may cause a false negative nitrite reading.

To investigate the effect of urine specific gravity and urine pH, urine samples, with 1.005 to 1.035 specific gravity or urine samples with pH 5 to 8.5 were tested at different analytes concentrations. The test results show that there is no effect of both pH and specific gravity on leukocyte, nitrite and blood tests.

Sample Carryover

A sample carryover study was performed. Three (3) lots of test strips were used for testing. The study was performed by dipping the test strip into the sample and holding the test strip vertically upward or downward for 10 seconds to allow the sample flow from one pad to the other pad (e.g., run-over for the leukocyte pad to the nitrite pad with a sample with a high concentration of leukocyte and runover for the nitrite to the leukocyte pad with a sample with a high concentration of nitrite). Testing was also repeated in the other direction. The study demonstrated that carryover (run-over) does not impact the test results.

4. Assay Reportable Range:

The sponsor provided the following measurement ranges in the labeling:

Analyte	Measurement range
Leukocytes	qualitative: Negative, Trace, +, ++, +++ semi-quantitative: Negative, 15, 70, 125, 500 (cells/ μ L)
Nitrite	qualitative: Negative, Positive

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

Traceability

The nitrite test is traceable to NIST SRM di-Sodium oxalate 8040a, and the leukocyte pad is traceable to a commercially available solution.

Stability

The sponsor provided information to support that the device is stable for 24 months when stored at 2-30°C based on real-time stability studies. The package insert recommends that users store the strips at 15-30°C (59-86°F).

The sponsor instructs the user to use the test strip immediately after the pouch is opened, based on the results of an open-pouch stability study that demonstrated an open-pouch stability of 2 hours.

6. Detection Limit:

See Assay Cut-off section below.

7. Assay Cut-Off:

A sensitivity study was performed to evaluate the lower limits of detection for each analyte on the Healgen URS Test Strips. Urine samples were spiked to known concentrations of each analyte. These samples were then diluted to the lowest positive concentrations that are indicated on the color chart. Each sample was tested in duplicate with three reagent lots by five different operators for a total of 30 measurements per sample.

The sponsor defined the limit of detection (LOD) as the concentration of analyte that produces positive Healgen URS Test Strips results $\geq 50\%$ of the time. The results support the claim that the sensitivity of the leukocyte test is 15 cells/ μ L and the sensitivity of the nitrite test is 0.05 mg/dL.

The sponsor also provided studies to support the recommended dipping time (1-2 seconds) and the recommended reading time (2 minutes).

B Comparison Studies:

1. Method Comparison with Predicate Device:

Lay-user Study

Three sites were selected to perform the lay-user studies. 234 lay users with UTI symptoms were recruited to test their own urine sample using the Healgen URS Test Strips. Laypersons performed one test with the Healgen URS Test Strips according to the product insert and then collected a sample of their urine for comparison testing by healthcare professionals using the comparator device. The results obtained by the lay users compared to the results obtained by the healthcare professionals are summarized below.

Comparison Results between Lay-user using Subject Device and Health Professionals using comparator device

Leukocytes

Lay User \ HCP	500 (3+)	125 (2+)	70 (1+)	15 (±)	Negative	Total
500 (3+)	13	0	0	0	0	13
125 (2+)	1	42	1	0	0	44
70 (1+)	0	2	54	2	0	58
15(±)	0	0	2	32	2	36
Negative	0	0	0	0	83	83
Total	14	44	57	34	85	234
% Agreement (Exact Match)	92.9	95.5	94.7	94.1	97.6	
% Agreement (+/- Color Block)	100	100	100	100	100	

Nitrite

Lay User \ HCP	Positive	Negative	Overall
Positive	100	0	100
Negative	0	134	134
Total	100	134	234
% Agreement (Exact Match)	100	100	
% Agreement (+/- Color Block)	100	100	

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on the package insert and the score revealed a reading grade level of less than 8.

2. Matrix Comparison:

Not Applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not Applicable.

2. Clinical Specificity:

Not Applicable.

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

Not Applicable.

D Clinical Cut-Off:

Not Applicable.

E Expected Values/Reference Range:

The following information is provided in the labeling:

TEST STRIP RESULTS		RECOMMENDATIONS
Leukocytes (LEU)	Nitrite (NIT)	
Negative	Negative	No sign of UTI detected. However, if you still have symptoms, consult your physician; there are some cases of UTI that the test may not detect.
Trace	Negative	Results suggest additional testing is required. Test again the following day with a new strip. If you have symptoms or if you get another trace leukocyte result, consult your physician.
Negative or Trace	Positive	Results suggest a sign of a UTI. Consult your physician immediately.
Positive +, ++, +++	Positive	Results suggest a sign of a UTI. Consult your physician immediately.
Positive +, ++, +++	Negative	Results suggest a sign of a UTI. Repeat the test next time you urinate using a new test strip. Make sure to wash the genital area first. If LEU is still positive, consult your physician.

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.