

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

**A. 510(k) Number:**

k111999

**B. Purpose for Submission:**

New device

**C. Measurand:**

Urine leukocytes, nitrite, urobilinogen, protein, pH, blood, specific gravity, ascorbic acid, ketone, bilirubin and glucose

**D. Type of Test:**

Qualitative and semi-quantitative urinalysis

**E. Applicant:**

Healgen Scientific LLC

**F. Proprietary and Established Names:**

Healgen Series Reagent Strips and Analyzers for Urinalysis

**G. Regulatory Information:**

1. Regulation section, classification, and product code:

<b>Classification Name</b>	<b>Product Code</b>	<b>Device Class</b>	<b>Regulation Number</b>
Blood occult, colorimetric, in urine	JIO	II	21 CFR 864.6550
Urinary glucose (non-quantitative) test system	JIL	II	21 CFR 862.1340
Urinary urobilinogen (non-quantitative) test system	CDM	I	21 CFR 862.1785
Urinary bilirubin and its conjugates (non-quantitative) test system	JJB	I	21 CFR 862.1115
Ketones (non-quantitative) test system	JIN	I	21 CFR 862.1435
Urinary protein or albumin (non-quantitative) test system	JIR	I	21 CFR 862.1645
Nitrite (non-quantitative) test system	JMT	I	21 CFR 862.1510
Test, Urine Leukocyte	LJX	I	21 CFR 864.7675

Urinary pH (non-quantitative) test system	CEN	I	21 CFR 862.1550
Ascorbic acid test system	JMA	I	21 CFR 862.1095
Refractometer for clinical use (specific gravity)	JRE	I	21 CFR 862.2800
Automated urinalysis system	KQO	I	21 CFR 862.2900

2. Panel:

Clinical Chemistry, 75  
Hematology, 82

**H. Intended Use:**

1. Intended use(s):

Refer to indications for use below.

2. Indication(s) for use:

The Healgen Series Urine Reagent Strips and Urine Analyzers are in-vitro test systems intended for qualitative and semi-quantitative analysis of Urobilinogen, Bilirubin, Ketone, Blood, Protein, Nitrite, Leucocytes, Glucose, Specific gravity, pH and Ascorbic Acid in urine. The test systems consist of the Healgen Series Reagent Strips (Healgen 10 and Healgen 11) and the Healgen 500 or Healgen 800 Urine Analyzers. The Healgen 10 and 11 strips can be read visually and instrumentally with the Healgen 500 and 800 Analyzers. The Healgen 4 reagent strip can be read visually only. The Healgen Series Urine Reagent Strips and Urine Analyzers are intended for use to detect conditions indicating possible diabetes, metabolic abnormalities, liver diseases, kidney function, and urinary tract infections. Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed.

The Healgen 500 and 800 Urine Analyzers use reflectance photometry to quantitate analyte values from urine samples when using the Healgen 10 and 11 reagent test strips.

The system is intended for prescription, in vitro diagnostic use only.

3. Special conditions for use statement(s):

For *in vitro* diagnostic use only

For prescription use

4. Special instrument requirements:

Healgen 500 or 800 urine analyzer (if reading instrumentally) for Healgen 11 and Healgen 10 reagent strips only.

**I. Device Description:**

Healgen Series Reagent strips for Urinalysis and urine analyzers are in vitro diagnostic test devices that use reagents for qualitative and semi-quantitative urinalysis. The device is composed of several color pads aligned on a strip. Each pad is employed for testing one assay item by visually or instrumentally reading the color change of the pad and comparing with the corresponding blocks on a color chart.

Healgen Series Reagent Strip provides tests for Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Ascorbic Acid, and Leukocytes in Urine and described in the table below.

Reagent Strip	Test Analytes	Visual Read	Instrumentally Read
Healgen 11	Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Ascorbic Acid, Leukocytes	Yes	Yes
Healgen 10	Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes	Yes	Yes
Healgen 4	Ketone, Protein, Glucose, pH	Yes	No

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

URISTK H Series Reagent Strips and Dirui H-50, H-100, H-500 Urine Analyzers for urinalysis.

2. Predicate 510(k) number(s):

k040703

3. Comparison with predicate:

Comparison Table		
Item	New Device (k111999)	Predicate (k040703)
Intended Use	The Urine Reagent Strips and Urine Analyzers are in-vitro test systems intended for qualitative and semi-quantitative analysis of Urobilinogen, Bilirubin, Ketone, Blood, Protein, Nitrite, Leucocytes, Glucose, Specific gravity, pH and Ascorbic Acid in urine.	Same
Specimen	Fresh Urine	Same
Test Principles	Established clinical chemistry methods	Same
Test Analytes	Urobilinogen, Bilirubin, Ketone, Blood, Protein, Nitrite, Leucocytes, Glucose, Specific gravity, pH, Ascorbic Acid	Same
Strip Incubation	Immerse the reagent area of the strip	Same

Comparison Table		
Item	New Device (k111999)	Predicate (k040703)
Time	in the urine specimen, take it up quickly and immediately.	
Detection Method	Reflectance Photometry or Visual	Same
PC Port	Standard RS 232C	Same
Analyzer Operating Conditions	0 to 40 degrees C; RH < 85%	Same
Wavelength	420nm, 525nm, 560nm, 610nm, 660nm, 950nm	Same
Calibration	Using a Calibration Strip	Same
Strip Operation	Semi-automatic	Same
Power Source	AC 220V ( $\pm 15\%$ ); 50 to 60Hz	Same
Line Leakage Current	<0.5 milliamperes in normal condition; <3.5 milliamperes in single fault condition	Same
Memory	1000 test results	Same
Throughput	Healgen 500: 120 test/hour Healgen 800: 500 test/hour	Dirui-50: 60 test/hour Dirui-100: 120 test/hour Dirui-500: 500 test/hour
Dimensions	355mm×300mm×145mm	324mm×327mm×185mm
Weight	4 kg	About 5 kg
Display Dimensions	Healgen 500 240mm*64mm Healgen 800 240mm*128mm	Dirui-50: 240mm*64mm Dirui-100: 240mm*64mm Dirui-500: 240mm*128mm

#### K. Standard/Guidance Document Referenced:

CLSI EP12-A2 – User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline.

CLSI EP9-A2 – Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.

ISO 2859-1:1999 - Sampling Procedures for Inspection by Attributes-Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.

#### L. Test Principle:

Urobilinogen - This test is based on the Ehrlich reaction in which p-diethylamino benzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium to produce a pink-red color.

Bilirubin - The direct bilirubin and dichlorobenzene diazonium produce fuchsia azo dyes in a strongly acid medium.

Ketone - The acetoacetate and sodium nitroprusside cause a reaction in the alkaline medium, which produces a violet color.

Blood - Hemoglobin acts as a peroxidase. It can cause peroxidase to release neo-ecotypes oxide [O]. [O] oxidizes the indicator and causes the color change.

Protein - The test is based on the protein-error-of-indicators principle. An ion in the specific pH indicator attracted by cation on the protein molecule makes the indicator further ionized, which changes its color.

Nitrite - Nitrite in the urine and aromatic amino sulphanilamide are diazotized to form a diazonium compound. The diazonium compound reacting with tetrahydro benzo(h) quinolin 3-phenol causes the color change.

Leukocytes - Granulocyte leukocytes in urine contain esterase that catalyzes the hydrolysis of the pyrrole amino acid ester to liberate 3-hydroxy-5-pheny pyrrole. This pyrrole reacting with diazonium forms a purple color.

Glucose - The glucose oxidized by glucose oxidase catalyzes the formation of glucuronic acid and peroxide hydrogen. Peroxide hydrogen releases neo-ecotypes oxide [O] under the function of peroxidase. [O] oxidizes iodide potassium, which causes the color change.

Specific Gravity - Electrolyte (M+X-) in the form of salt in urine reacts with poly methyl vinyl ether and maleic acid (-COOH), which is a weak acid ionic exchanger. The reaction produces hydrogenous ionogen, which reacts with a pH indicator that causes the color change.

pH - This test is based on a double indicator principle that gives a broad range of colors covering the entire urinary pH range.

Ascorbic Acid - Ascorbic acid, with 1,2-dihydroxy alkenes, under the alkaline condition, deoxidizes the blue 2,6-dichloroindophenolate into colorless N- (p-phenol)- 2,6-dichloro-p-amine phenol.

Healgen series Urine Analyzer adopts the principle of reflectance photometry to test the quantity of biochemical component according to the color change caused by getting the urinalysis strips react with the biochemical components in urine. The instrument uses four kinds of monochromatic light (wavelengths: 420, 525, 560, 610, 660, and 950 nm) to scan the reagent areas one after another, and the scanning system converts the optical signal to electric signal. After treatment, the reflection rate of the reagent area can be calculated according to the strength of the electric signal. The amount of the biochemical component in the urine sample can be calculated according to the reflective rate.

## **M. Performance Characteristics (if/when applicable):**

### 1. Analytical performance:

#### *a. Precision/Reproducibility:*

The cut-off evaluation for all three formats (Healgen 4, 10, and 11) strips was evaluated using 20 replicates from each of 3 levels of urine controls (N=60). Control levels 1 and 2 represented the low and high samples. Level 3 controls was spiked sample with analyte concentration adjusted to around the cutoff value. The samples were blinded. Within-run precision was evaluated by testing 20 replicates on each of the three levels of urine controls using strips from each of 3 lots of strips. Within-day prevision was evaluated by testing three levels of urine controls in duplicate, one a day, for 10 days using strips from 3 lots. Both reading methods (qualitative or semi-quantitative) were evaluated. Instrumental readings were performed on the Healgen 500 and Healgen 800. Testing was completed at three different point-of-care (POC) sites by six technicians at the POC sites. The technicians were provided with no other

instructions other than the instrument manual and the test strip labeling. The results from the precision evaluation are summarized below:

Analyte Levels Tested

Analyte	Level 1	Level 2	Level 3
Urobilinogen	0.2 - 1.0 mg/dL	4.0 - 8.0 mg/dL	1.0 - 2.0 mg/dL
Bilirubin	Negative	3.0 – 6.0 mg/dL (2+ - 3+)	1.0 - 2.0 mg/dL (1+)
Ketone	Negative	5.0 - 40 mg/dL (± - 2+)	2.0 - 10 mg/dL (±)
Blood	Negative	80 - 200 Cells /µL (2+ - 3+)	20 - 50Cells /µL (1+)
Protein	Negative	30 - 300 mg/dL (1+ - 3+)	10 - 80 mg/dL (± - 1+)
Nitrite	Negative	Positive	Positive
Leukocytes	Negative	70 - 500 Cells /µL (1+ - 3+)	20 - 120 Cells /µL (1+ - 2+)
Ascorbic Acid	0	50 - 100 mg/dL	12 - 25 mg/dL
Glucose	Negative	270 - 1100 mg/dL (1+ - 3+)	60 - 300 mg/dL (± - 1+)
Specific Gravity	1.005 - 1.015	1.015 - 1.025	1.005 - 1.010
pH	5.0 - 6.5	7.0 - 8.5	5.5 - 6.5

Within-Run Study

Healgen 11 - Agreement of Visual Reading

Analyte	Exact match			Match within ±1 color block		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Urobilinogen	60/60 (100%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Bilirubin	60/60 (100%)	58/60 (96.7%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Ketone	60/60 (100%)	58/60 (96.7%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Blood	60/60 (100%)	57/60 (95%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Protein	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Nitrite	60/60 (100%)	58/60 (96.7%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Leukocytes	60/60 (100%)	58/60 (96.7%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Glucose	60/60 (100%)	59/60 (98.3%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Ascorbic Acid	60/60 (100%)	59/60 (98.3%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Specific Gravity	58/60 (96.7%)	59/60 (98.3%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
pH	60/60 (100%)	57/60 (95%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)

Healgen 11-Agreement of Reading by Healgen 500

Analyte	Exact match			Match within $\pm 1$ color block		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Urobilinogen	60/60 (100%)	60/60 (100%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Bilirubin	60/60 (100%)	58/60 (96.7%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Ketone	60/60 (100%)	58/60 (96.7%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Blood	60/60 (100%)	58/60 (96.7%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Protein	60/60 (100%)	59/60 (98.3%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Nitrite	60/60 (100%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Leukocytes	60/60 (100%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Glucose	60/60 (100%)	59/60 (98.3%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Ascorbic Acid	60/60 (100%)	59/60 (98.3%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Specific Gravity	60/60 (100%)	59/60 (98.3%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
pH	59/60 (98.3%)	59/60 (98.3%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)

Healgen 11 - Agreement of reading by Healgen 800

Analyte	Exact match			Match within $\pm 1$ color block		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Urobilinogen	60/60 (100%)	58/60 (96.7%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Bilirubin	60/60 (100%)	59/60 (98.3%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Ketone	60/60 (100%)	57/60 (95%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Blood	60/60 (100%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Protein	60/60 (100%)	58/60 (96.7%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)

Nitrite	60/60 (100%)	58/60 (96.7%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Leukocytes	60/60 (100%)	59/60 (98.3%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Glucose	60/60 (100%)	58/60 (96.7%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Ascorbic Acid	60/60 (100%)	58/60 (96.7%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Specific Gravity	60/60 (100%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
pH	60/60 (100%)	59/60 (98.3%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)

### Healgen 10 - Agreement of visual reading

Analyte	Exact match			Match within $\pm 1$ color block		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Urobilinogen	60/60 (100%)	60/60 (100%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Bilirubin	60/60 (100%)	59/60 (98.3%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Ketone	60/60 (100%)	58/60 (96.7%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Blood	60/60 (100%)	59/60 (98.3%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Protein	60/60 (100%)	57/60 (95%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Nitrite	60/60 (100%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Leukocytes	60/60 (100%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Glucose	60/60 (100%)	60/60 (100%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Specific Gravity	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
pH	59/60 (98.3%)	58/60 (96.7%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)

Healgen 10-Agreement of Reading by Healgen 500

Analyte	Exact match			Match within $\pm 1$ color block		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Urobilinogen	60/60 (100%)	58/60 (96.7%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Bilirubin	60/60 (100%)	59/60 (98.3%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Ketone	60/60 (100%)	59/60 (98.3%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Blood	60/60 (100%)	59/60 (98.3%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Protein	60/60 (100%)	59/60 (98.3%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Nitrite	60/60 (100%)	58/60 (96.7%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Leukocyte	60/60 (100%)	58/60 (96.7%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Glucose	60/60 (100%)	58/60 (96.7%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Specific Gravity	60/60 (100%)	57/60 (95%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
pH	60/60 (100%)	58/60 (96.7%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)

Healgen 10 - Agreement of reading by Healgen 800

Analyte	Exact match			Match within $\pm 1$ color block		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Urobilinogen	60/60 (100%)	58/60 (96.7%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Bilirubin	60/60 (100%)	57/60 (95%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Ketone	60/60 (100%)	60/60 (100%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Blood	60/60 (100%)	57/60 (95%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Protein	60/60 (100%)	58/60 (96.7%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Nitrite	60/60 (100%)	60/60 (100%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Leukocytes	60/60 (100%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)

Glucose	60/60 (100%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Specific Gravity	60/60 (100%)	60/60 (100%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
pH	60/60 (100%)	58/60 (96.7%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)

#### Healgen 4-Agreement of Visual Reading

Analyte	Exact match			Match within $\pm 1$ color block		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Ketone	60/60 (100%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Protein	60/60 (100%)	59/60 (98.3%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Glucose	60/60 (100%)	57/60 (95%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
pH	60/60 (100%)	58/60 (96.7%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)

#### Within- Day Study

#### Healgen 11 - Agreement of Visual Reading

Analyte	Exact match			Match within $\pm 1$ color block		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Urobilinogen	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Bilirubin	60/60 (100%)	58/60 (96.7%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Ketone	60/60 (100%)	59/60 (98.3%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Blood	60/60 (100%)	58/60 (96.7%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Protein	60/60 (100%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Nitrite	60/60 (100%)	57/60 (95%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Leukocytes	60/60 (100%)	59/60 (98.3%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Glucose	60/60 (100%)	60/60 (100%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Ascorbic Acid	60/60 (100%)	57/60 (95%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)

Specific Gravity	59/60 (98.3%)	58/60 (96.7%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
pH	60/60 (100%)	58/60 (96.7%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)

**Healgen 11 - Agreement of reading by Healgen 500**

Analyte	Exact match			Match within $\pm 1$ color block		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Urobilinogen	60/60 (100%)	59/60 (98.3%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Bilirubin	60/60 (100%)	58/60 (96.7%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Ketone	60/60 (100%)	60/60 (100%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Blood	60/60 (100%)	58/60 (96.7%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Protein	60/60 (100%)	59/60 (98.3%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Nitrite	60/60 (100%)	59/60 (98.3%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Leukocytes	60/60 (100%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Glucose	60/60 (100%)	58/60 (96.7%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Ascorbic Acid	60/60 (100%)	59/60 (98.3%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Specific Gravity	60/60 (100%)	59/60 (98.3%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
pH	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)

**Healgen 11 - Agreement of reading by Healgen 800**

Analyte	Exact match			Match within $\pm 1$ color block		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Urobilinogen	60/60 (100%)	58/60 (96.7%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Bilirubin	60/60 (100%)	58/60 (96.7%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Ketone	60/60 (100%)	59/60 (98.3%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)

Blood	60/60 (100%)	59/60 (98.3%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Protein	60/60 (100%)	57/60 (95%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Nitrite	60/60 (100%)	59/60 (98.3%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Leukocytes	60/60 (100%)	58/60 (96.7%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Glucose	60/60 (100%)	59/60 (98.3%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Ascorbic Acid	58/60 (96.7%)	59/60 (98.3%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Specific Gravity	60/60 (100%)	58/60 (96.7%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
pH	60/60 (100%)	59/60 (98.3%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)

Healgen 10 - Agreement of visual reading

Analyte	Exact match			Match within $\pm 1$ color block		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Urobilinogen	60/60 (100%)	58/60 (96.7%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Bilirubin	60/60 (100%)	57/60 (95%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Ketone	60/60 (100%)	60/60 (100%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Blood	60/60 (100%)	57/60 (95%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Protein	60/60 (100%)	58/60 (96.7%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Nitrite	60/60 (100%)	60/60 (100%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Leukocytes	60/60 (100%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Glucose	60/60 (100%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Specific Gravity	60/60 (100%)	60/60 (100%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
pH	60/60 (100%)	58/60 (96.7%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)

Healgen 10 - Agreement of reading by Healgen 500

Analyte	Exact match			Match within $\pm 1$ color block		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Urobilinogen	60/60 (100%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Bilirubin	60/60 (100%)	57/60 (95%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Ketone	60/60 (100%)	59/60 (98.3%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Blood	60/60 (100%)	60/60 (100%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Protein	60/60 (100%)	57/60 (95%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Nitrite	60/60 (100%)	58/60 (96.7%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Leukocytes	60/60 (100%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Glucose	60/60 (100%)	58/60 (96.7%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Specific Gravity	60/60 (100%)	60/60 (100%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
pH	60/60 (100%)	58/60 (96.7%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)

Healgen 10 - Agreement of reading by Healgen 800

Analyte	Exact match			Match within $\pm 1$ color block		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Urobilinogen	60/60 (100%)	60/60 (100%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Bilirubin	60/60 (100%)	59/60 (98.3%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Ketone	60/60 (100%)	58/60 (96.7%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Blood	60/60 (100%)	59/60 (98.3%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Protein	60/60 (100%)	59/60 (98.3%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Nitrite	60/60 (100%)	57/60 (95%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)

Leukocyte	60/60 (100%)	58/60 (96.7%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Glucose	60/60 (100%)	57/60 (95%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Specific Gravity	59/60 (98.3%)	59/60 (98.3%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
pH	60/60 (100%)	59/60 (98.3%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)

Healgen 4 - Agreement of visual reading

Analyte	Exact match			Match within $\pm 1$ color block		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Ketone	60/60 (100%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Protein	60/60 (100%)	59/60 (98.3%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
Glucose	60/60 (100%)	59/60 (98.3%)	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	60/60 (100%)
pH	60/60 (100%)	58/60 (96.7%)	58/60 (96.7%)	60/60 (100%)	60/60 (100%)	60/60 (100%)

b. Linearity/assay reportable range:

Linearity for the device was evaluated by visual reading and instrumental reading on the Healgen 500 and 800 by repeated testing of urine specimen containing known concentration of analytes. Negative samples and samples with pH or specific gravity at different levels were obtained by testing clinical samples with the predicate device. Those samples confirmed to be negative or expected were selected for the study. Positive samples were obtained by adding known amounts of analytes to negative control and confirming the expected value using the predicate device. Samples with specified values of pH or specific gravity were obtained by titration. Blind and random testing of samples was completed by two experimenters. Ten replicates for each strip from 3 manufacturing lots (n = 30) were tested with each sample. The percentages of exact match and  $\pm 1$  color block match of reported result to expected result were calculated and recorded as shown below:

Analyte	Levels	Exact Match			$\pm 1$ Color Block Match		
		Visual Read	Healgen 500 Read	Healgen 800 Read	Visual Read	Healgen 500 Read	Healgen 800 Read
Leukocytes (cells / $\mu$ L)	Negative	30	30	30			
	15	29	27	29	30	30	30
	70	29	27	29	30	30	30
	125	29	27	28	30	30	30
	500	30	30	29	30	30	30
Nitrite	Negative	30	30	30			

	Positive 1	27	29	27	30	30	30
	Positive 2	30	30	29	30	30	30
Urobilinogen (mg / dL)	0.2	30	30	30	30	30	30
	1	29	28	30	30	30	30
	2	29	30	27	30	30	30
	4	27	28	28	30	30	30
	8	29	30	30	30	30	30
Protein (mg / dL)	Negative	30	30	30			
	10	27	28	29	30	30	30
	30	28	27	27	30	30	30
	100	30	29	29	30	30	30
	300	29	27	27	30	30	30
	2000	30	30	29	30	30	30
pH	5.0	29	30	30	30	30	30
	6.0	28	27	27	30	29	30
	6.5	27	30	29	30	30	30
	7.0	28	30	28	30	30	30
	7.5	29	30	26	30	30	30
	8.0	28	28	29	30	30	30
	8.5	30	29	30	30	30	30
Blood (cells / $\mu$ L)	Negative	30	30	30			
	10 (NH)*	30	N/A	N/A	30	30	30
	10	29	27	27	30	30	30
	25	27	30	27	30	30	30
	80	26	29	26	30	30	30
	200	29	30	29	30	30	30
Specific Gravity	1.000	30	30	30	30	30	30
	1.005	29	30	28	30	30	30
	1.010	27	29	28	30	30	30
	1.015	26	27	30	30	30	30
	1.020	28	29	30	30	30	30
	1.025	29	30	28	30	30	30
	1.030	30	30	30	30	30	30
Ascorbic Acid (mg / dL)	0	30	30	30			
	10	29	29	29	30	30	30
	25	28	29	27	29	30	30
	50	29	28	27	30	30	30
	100	30	30	29	30	30	30
Ketone (mg / dL)	Negative	30	30	30			
	5	29	30	28	30	30	30
	15	29	28	27	30	30	30
	40	27	29	28	30	30	30
	80	27	30	29	30	30	30
	160	29	29	30	30	30	30
Bilirubin (mg / dL)	Negative	30	30	30			
	1	30	29	27	30	30	30
	3	29	28	28	30	30	30
	6	30	30	30	30	30	30
Glucose (mg / dL)	Negative	30	30	30			
	90	28	29	29	30	30	30
	270	29	28	29	30	30	30
	550	27	28	27	30	30	30
	1100	27	29	30	30	30	30

	2000	30	29	30	30	30	30
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\*NH, Non-hemolyzed

The reportable ranges of Healgen strips for each analyte are listed in the table below.

Analyte	Unit	Lab Assay Range	Reportable Range
Urobilinogen	(mg / dL)	0.01 - 18.75	0.2 – 8
Bilirubin	(mg / dL)	0 - 18.8	Negative – 6
Ketone	(mg / dL)	0.2 – 350	Negative - 160
Blood	cells / $\mu$ L	0 – 350	Negative - 200
Protein	(mg / dL)	0.3 - 5000	Negative - 2000
Nitrite	(mg / dL)	5.0 - 2000	Negative - Positive
Leukocytes	cells / $\mu$ L	0 – 800	Negative - 500
Glucose	(mg / dL)	0 - 5500	Negative - 2000
Specific Gravity		1.000 - 1.040	1.000 - 1.030
pH		0 - 14.0	5.0 - 8.5
Ascorbic Acid	(mg / dL)	1 - 230	Negative - 100

The specified reportable values of all the analytes are labeled above the corresponding blocks of the color charts on the strips inner labeling as shown below:

Analyte	Unit	Levels (color Blocks)						
		Negative	Positive					
Leukocytes	cells / $\mu$ L	Negative	15	70	125	500		
Nitrite		Negative	Positive 1	Positive 2				
Urobilinogen	(mg / dL)	0.2	1	2	4	8		
Protein	(mg / dL)	Negative	10	30	100	300	2000	
pH		5	6	6.5	7	7.5	8	8.5
Blood	cells / $\mu$ L	Negative	10(NH)	10	25	80	200	
Specific Gravity		1	1.005	1.01	1.015	1.02	1.025	1.03
Ascorbic Acid	(mg / dL)	0	10	25	50	100		
Ketone	(mg / dL)	Negative	5	14	40	80	160	
Bilirubin	(mg / dL)	Negative	1	3	6			
Glucose	(mg / dL)	Negative	90	270	550	1100	2000	

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The stability of the Healgen strips for urinalysis was evaluated using Healgen 11. This strip format has all 11 analytes that the strip series can test. Test results were read by the Healgen 500. Real-time stability data support the following manufacturer claim: “The strips can be stored in room temperature and closed package to 18

months from the manufacture date. If exposed to air with temperature of 15-30°C and relative humidity of 65-85%, the strips can be stored at least 12 hours.”

The manufacturer claims that the temperature of working environment for the Healgen 500 and 800 analyzers is 18-30°C with an optimum temperature range of 20-25°C and a relative humidity should be less than 80%.

No urinalysis controls are provided with the device. The sponsor recommends using commercially available positive and negative controls. Labeling also recommends the following:

- That two levels of commercially available controls are analyzed following laboratory policies and local, state and federal guidelines.
- Test commercially available positive and negative quality controls with each new lot, each new shipment of strips, and when a new bottle of reagent strips is opened.
- Water should not be used as a negative control.

*d. Detection limit:*

The cut-off evaluation was conducted using 20 replicates for each type of strip and each reading method. Negative and positive samples at different levels were confirmed by testing clinical samples with the predicate device. Positive samples were prepared by adding known amounts of analyte to negative samples. The cut-off for each analyte is defined as the value at which 50% of the test results are positive. The cut-off values for each strip format on all reading modes are shown in the tables below.

Visual results of Healgen 11

Analyte	Cut-off (at least 50% Positive results)
Urobilinogen (mg / dL)	2.5
Bilirubin (mg / dL)	0.80
Ketone (mg / dL)	0.60
Blood (cells / µl)	6
Protein (mg / dL)	7
Nitrite (µg / dL)	48
Leukocytes (cells / µl)	10
Glucose (mg / dL)	75
Ascorbic Acid (mg / dL)	7.5
pH	5.6
Specific Gravity	1.003

Results of Healgen 11 by Healgen 500

Target values of Leukocytes (cells / µL)	Cutoff concentration (cells / µL)	% Sensitivity
15	10	55

70	55	100
125	105	100
500	350	100
<b>Target values of Nitrite (µg / dL)</b>	<b>Cutoff concentration (µg / dL)</b>	<b>% Sensitivity</b>
Positive	50	55
<b>Target values of Urobilinogen (mg / dL)</b>	<b>Cutoff concentration (mg / dL)</b>	<b>% Sensitivity</b>
1	0.7	60
2	1.6	100
4	3.4	100
8	6.2	100
<b>Target values of Protein (mg / dL)</b>	<b>Cutoff concentration (mg / dL)</b>	<b>% Sensitivity</b>
10	7.2	55
30	18	100
100	55	100
300	190	100
2000	550	100
<b>Target values of pH</b>	<b>Cutoff</b>	<b>% Sensitivity</b>
6	5.6	55
6.5	6.2	100
7	6.7	100
7.5	7.3	100
8	7.8	100
8.5	8.2	100
<b>Target values of Blood (cells / µL)</b>	<b>Cutoff concentration (cells / µL)</b>	<b>% Sensitivity</b>
10	6.5	50
25	18	100
80	48	100
200	135	100
<b>Target values of Specific Gravity</b>	<b>Cutoff</b>	<b>% Sensitivity</b>
1.005	1.003	60
1.01	1.008	100
1.015	1.013	100
1.02	1.018	100
1.025	1.023	100
1.03	1.028	100
<b>Target values of Ascorbic Acid (mg / dL)</b>	<b>Cutoff concentration (mg / dL)</b>	<b>% Sensitivity</b>
10	6.5	60
25	18	100
50	35	100
100	75	100
<b>Target values of Ketone (mg / dL)</b>	<b>Cutoff concentration (mg / dL)</b>	<b>% Sensitivity</b>
5	3.5	50
14	9.5	100
40	26	100
80	60	100
160	125	100
<b>Target values of Bilirubin (mg / dL)</b>	<b>Cutoff concentration (mg / dL)</b>	<b>% Sensitivity</b>
1	0.7	55

3	2.2	100
6	4.5	100
<b>Target values of Glucose (mg / dL)</b>	<b>Cutoff concentration (mg / dL)</b>	<b>% Sensitivity</b>
90	65	50
270	205	100
550	420	100
1100	850	100
2000	1450	100

#### Results of Healgen 11 by Healgen 800

<b>Target values of Leukocytes (cells / <math>\mu</math>L)</b>	<b>Cutoff concentration (cells / <math>\mu</math>L)</b>	<b>% Sensitivity</b>
15	10	55
70	55	100
125	105	100
500	350	100
<b>Target values of Nitrite (<math>\mu</math>g / dL)</b>	<b>Cutoff concentration (<math>\mu</math>g / dL)</b>	<b>% Sensitivity</b>
Positive	50	55
<b>Target values of Urobilinogen (mg / dL)</b>	<b>Cutoff concentration (mg / dL)</b>	<b>% Sensitivity</b>
1	0.7	60
2	1.6	100
4	3.4	100
8	6.2	100
<b>Target values of Protein (mg / dL)</b>	<b>Cutoff concentration (mg / dL)</b>	<b>% Sensitivity</b>
10	7.2	55
30	18	100
100	55	100
300	190	100
2000	550	100
<b>Target values of pH</b>	<b>Cutoff</b>	<b>% Sensitivity</b>
6	5.6	55
6.5	6.2	100
7	6.7	100
7.5	7.3	100
8	7.8	100
8.5	8.2	100
<b>Target values of Blood (cells / <math>\mu</math>L)</b>	<b>Cutoff concentration (cells / <math>\mu</math>L)</b>	<b>% Sensitivity</b>
10	6.5	50
25	18	100
80	48	100
200	135	100
<b>Target values of Specific Gravity</b>	<b>Cutoff</b>	<b>% Sensitivity</b>
1.005	1.003	50
1.01	1.008	100
1.015	1.013	100
1.02	1.018	100
1.025	1.023	100
1.03	1.028	100
<b>Target values of Ascorbic</b>	<b>Cutoff concentration</b>	<b>% Sensitivity</b>

<b>Acid (mg / dL)</b>	<b>(mg / dL)</b>	
10	6.5	60
25	18	100
50	35	100
100	75	100
<b>Target values of Ketone (mg / dL)</b>	<b>Cutoff concentration (mg / dL)</b>	<b>% Sensitivity</b>
5	3.5	50
14	9.5	100
40	26	100
80	60	100
160	125	100
<b>Target values of Bilirubin (mg / dL)</b>	<b>Cutoff concentration (mg / dL)</b>	<b>% Sensitivity</b>
1	0.7	55
3	2.2	100
6	4.5	100
<b>Target values of Glucose (mg / dL)</b>	<b>Cutoff concentration (mg / dL)</b>	<b>% Sensitivity</b>
90	65	50
270	205	100
550	420	100
1100	850	100
2000	1450	100

#### Visual results of Healgen 10

<b>Analyte</b>	<b>Cut-off (at least 50% Positive results)</b>
Urobilinogen (mg / dL)	2.5
Bilirubin (mg / dL)	0.80
Ketone (mg / dL)	0.60
Blood (cells / $\mu$ l)	6
Protein (mg / dL)	7
Nitrite ( $\mu$ g / dL)	48
Leukocytes (cells / $\mu$ l)	10
Glucose (mg / dL)	75
pH	5.6
Specific Gravity	1.003

#### Results of Healgen 10 by Healgen 500

<b>Target values of Leukocytes (cells / <math>\mu</math>L)</b>	<b>Cutoff concentration (cells / <math>\mu</math>L)</b>	<b>% Sensitivity</b>
15	10	55
70	55	100
125	105	100
500	350	100
<b>Target values of Nitrite (<math>\mu</math>g / dL)</b>	<b>Cutoff concentration (<math>\mu</math>g / dL)</b>	<b>% Sensitivity</b>
Positive	50	55

<b>Target values of Urobilinogen (mg / dL)</b>	<b>Cutoff concentration (mg / dL)</b>	<b>% Sensitivity</b>
1	0.7	60
2	1.6	100
4	3.4	100
8	6.2	100
<b>Target values of Protein (mg / dL)</b>	<b>Cutoff concentration (mg / dL)</b>	<b>% Sensitivity</b>
10	7.2	55
30	18	100
100	55	100
300	190	100
2000	550	100
<b>Target values of pH</b>	<b>Cutoff</b>	<b>% Sensitivity</b>
6	5.6	50
6.5	6.2	100
7	6.7	100
7.5	7.3	100
8	7.8	100
8.5	8.2	100
<b>Target values of Blood (cells / <math>\mu</math>L)</b>	<b>Cutoff concentration (cells / <math>\mu</math>L)</b>	<b>% Sensitivity</b>
10	6.5	50
25	18	100
80	48	100
200	135	100
<b>Target values of Specific Gravity</b>	<b>Cutoff</b>	<b>% Sensitivity</b>
1.005	1.003	50
1.01	1.008	100
1.015	1.013	100
1.02	1.018	100
1.025	1.023	100
1.03	1.028	100
<b>Target values of Ketone (mg / dL)</b>	<b>Cutoff concentration (mg / dL)</b>	<b>% Sensitivity</b>
5	3.5	50
14	9.5	100
40	26	100
80	60	100
160	125	100
<b>Target values of Bilirubin (mg / dL)</b>	<b>Cutoff concentration (mg / dL)</b>	<b>% Sensitivity</b>
1	0.7	55
3	2.2	100
6	4.5	100
<b>Target values of Glucose (mg / dL)</b>	<b>Cutoff concentration (mg / dL)</b>	<b>% Sensitivity</b>
90	65	50
270	205	100
550	420	100
1100	850	100
2000	1450	100

Results of Healgen 10 by Healgen 800

<b>Target values of Leukocytes (cells / <math>\mu</math>L)</b>	<b>Cutoff concentration (cells / <math>\mu</math>L)</b>	<b>% Sensitivity</b>
15	10	55
70	55	100
125	105	100
500	350	100
<b>Target values of Nitrite (<math>\mu</math>g / dL)</b>	<b>Cutoff concentration (<math>\mu</math>g / dL)</b>	<b>% Sensitivity</b>
Positive	50	55
<b>Target values of Urobilinogen (mg / dL)</b>	<b>Cutoff concentration (mg / dL)</b>	<b>% Sensitivity</b>
1	0.7	60
2	1.6	100
4	3.4	100
8	6.2	100
<b>Target values of Protein (mg / dL)</b>	<b>Cutoff concentration (mg / dL)</b>	<b>% Sensitivity</b>
10	7.2	55
30	18	100
100	55	100
300	190	100
2000	550	100
<b>Target values of pH</b>	<b>Cutoff</b>	<b>% Sensitivity</b>
6	5.6	50
6.5	6.2	100
7	6.7	100
7.5	7.3	100
8	7.8	100
8.5	8.2	100
<b>Target values of Blood (cells / <math>\mu</math>L)</b>	<b>Cutoff concentration (cells / <math>\mu</math>L)</b>	<b>% Sensitivity</b>
10	6.5	60
25	18	100
80	48	100
200	135	100
<b>Target values of Specific Gravity</b>	<b>Cutoff</b>	<b>% Sensitivity</b>
1.005	1.003	55
1.01	1.008	100
1.015	1.013	100
1.02	1.018	100
1.025	1.023	100
1.03	1.028	100
<b>Target values of Ketone (mg / dL)</b>	<b>Cutoff concentration (mg / dL)</b>	<b>% Sensitivity</b>
5	3.5	50
14	9.5	100
40	26	100
80	60	100
160	125	100
<b>Target values of Bilirubin (mg / dL)</b>	<b>Cutoff concentration (mg / dL)</b>	<b>% Sensitivity</b>
1	0.7	55
3	2.2	100
6	4.5	100
<b>Target values of Glucose</b>	<b>Cutoff concentration</b>	<b>% Sensitivity</b>

(mg / dL)	(mg / dL)	
90	65	50
270	205	100
550	420	100
1100	850	100
2000	1450	100

e. *Analytical specificity:*

To evaluate interferences, known amounts of potential interfering substances were added to urine samples and tested using the Healgen 11 strip format. Five test strips from each of 3 lots were evaluated, in replicates of 15, for each interference test using the 3 reading modes (visual, Healgen 500, and Healgen 800). Analyte levels (positive, negative) were confirmed with the predicate method. Two levels of each analyte and 3 levels of interfering substance per analyte were evaluated in the study. Interference is defined by the sponsor as: a) For negative or lower level samples, with the presence of one potential interfering substance in a certain concentration, and no change of other conditions in the test system, if the reported results are  $\geq 2$  color blocks different from the expected results (any positive result for nitrite), it is interference. And if  $\pm 1$  color block match with the expected values (only negative for nitrite), it is non-interference. B) For positive or higher level samples, with the presence of one potential interfering substance in a certain concentration, and no change of other conditions in the test system, if the reported results  $\geq 2$  color blocks different from the expected results (only negative for nitrite), it is an interference. And if  $\pm 1$  color block match with the expected values (not negative for nitrite), it is non-interference.

Concentrations of the potentially interfering substances that will not have influence on the test results are shown below:

Potential Interfering Substance	Concentration Not Affecting Test
Albumin	800 mg/dL
Ascorbic Acid	50 mg/dL
Hemoglobin	50 mg/dL
Citric Acid	50 mg/dL
Bilirubin	3.0 mg/dL
Creatine	8 mg/dL
Acetoacetate Acid	1 mmol/L
Ammonium Chloride	189 mg/dL
Calcium Chloride	50 mg/dL
Creatinine	800 mg/dL
Glucose	2000 mg/dL
Glycine	1000 mg/dL
KCL	550 mg/dL
NaCl	2800 mg/dL
Oxalic Acid	70 mg/dL
Sodium Acetate	1200 mg/dL
Sodium Bicarbonate	1500 mg/dL
Sodium Nitrate	0.26 mg/dL
Sodium Nitrite	0.3 mg/dL
Sodium Phosphate	16 mg/dL
Urobilinogen	3.0 mg/dL
Urea	3000 mg/dL

Riboflavin	100 mg/L
Theophylline	100 mg/L
Phenolphthalein	1200 mg/L
pH	9.0
Specific gravity	1.030
Glutathione	200 mg/dL
Hypochlorite	10 mg/L
Chlorine	1 mg/dL
Peroxide	1 mg/L
Atropine	300 mg/L
Fructose	5000 mg/dL
Lactose	5000 mg/dL
Leucocytes	800 cells/ $\mu$ L
Ketone	200 mg/dL
Blood	300 cells/ $\mu$ L
Mesna	50 mg/dL

The following limitations were observed and added to the strips instructions for use:

A high glucose concentration ( $\geq 2000$  mg/dL) or a high specific gravity in urine may reduce the sensitivity of the test of leukocytes.

A high concentration of ascorbic acid ( $\geq 50$  mg/dL) may cause a false negative result of bilirubin, blood, nitrite, and glucose.

Presence of oxidants (hypochlorite  $\geq 50$  mg/L, chlorine  $\geq 5$  mg/dL, and peroxide  $\geq 5$  mg/L) will reduce the sensitivity of ascorbic acid in urine and lead to false positive results of blood in urine.

f. *Assay cut-off:*

Not applicable

## 2. Comparison studies:

### a. *Method comparison with predicate device:*

Comparison studies were performed at three different POC sites between the Healgen strips and the predicate method by visual and instrument readings. Urine samples were collected as indicated in the instructions for use and tested by 5 persons in each POC site (15 persons in total). The operators were blinded by masking the urine sample receptacles before being sent to them. Number of patient samples tested for each analyte was 100 (i.e. 33-34 patient samples tested at each of the 3 sites). The patient samples were collected so that at least 40 to 50% of the samples were positive across the measuring range of each analyte, and at least 10% of the samples were around the cutoff of each analyte. Results of the comparison study for the combined sites are shown in the table below.

#### Visual Read, Combined Sites 1- 3 (n=100)

Leukocytes (cells / $\mu$ L)		Predicate Device				
		Negative	15	70	125	500
Proposed	Negative	40	1	0	0	0

Device	15	1	16	1	0	0
	70	0	1	16	0	0
	125	0	2	1	9	0
	500	0	0	1	1	10
Total		41	20	19	10	10
% exact match		97.6	80	84.2	90	100
% ±1 color block			90	94.7	100	100

Nitrite (µg / dL)		Predicate Device		
		Negative	Positive 1	Positive 2
Proposed Device	Negative	57	1	0
	Positive 1	0	26	1
	Positive 2	0	0	15
Total		57	27	16
% exact match		100	96.3	93.6
% ±1 color block			100	100

Urobilinogen (mg/dL)		Predicate Device				
		0.2	1	2	4	8
Proposed Device	0.2	46	0	0	0	0
	1	1	16	1	1	0
	2	0	1	10	2	0
	4	0	1	1	9	1
	8	0	0	0	0	10
Total		47	18	12	12	11
% exact match		97.9	88.9	83.3	75	90.9
% ±1 color block		100	94.4	100	91.7	100

Protein (mg/dL)		Predicate Device					
		NEG	10	30	100	300	2000
Proposed Device	NEG	42	0	0	0	0	0
	10	0	11	2	1	0	0
	30	0	1	11	1	0	0
	100	0	0	0	11	1	0
	300	0	0	0	0	11	0
	2000	0	0	0	0	0	8
Total		42	12	13	13	12	8
% exact match		100	91.7	84.6	84.6	91.7	100
% ±1 color block			100	100	92.3	100	100

pH		Predicate Device						
		5	6	6.5	7	7.5	8	8.5
Proposed Device	5	7	0	0	0	0	0	0
	6	0	14	0	0	0	0	0
	6.5	0	1	11	0	1	0	0
	7	0	0	1	11	2	0	0
	7.5	0	0	0	1	20	1	0
	8	0	0	0	0	1	22	0
	8.5	0	0	0	0	0	0	7
Total		7	15	12	12	24	23	7
% exact match		100	93.3	91.7	91.7	83.3	95.7	100
% ±1 color block		100	100	100	100	95.8	100	100

Blood (cells / $\mu$ L)		Predicate Device					
		NEG	10(NH)	10	25	80	200
Proposed Device	NEG	40	N/A	0	0	0	0
	10(NH)	N/A	10	N/A	N/A	N/A	N/A
	10	0	N/A	15	0	1	0
	25	0	N/A	2	10	1	0
	80	0	N/A	0	2	10	0
	200	0	N/A	0	0	0	9
Total		40	10	17	12	12	9
% exact match		100	100	88.2	83.3	83.3	100
% $\pm$ 1 color block			100	100	100	100	100

Ascorbic Acid (mg/dL)		Predicate Device				
		0	10	25	50	100
Proposed Device	0	13	0	0	0	0
	10	0	22	0	0	0
	25	0	2	21	0	0
	50	0	1	2	26	1
	100	0	0	1	2	9
Total		13	25	24	28	10
% exact match		100	88	87.5	92.8	90
% $\pm$ 1 color block			96	95.8	100	100

Specific Gravity		Predicate Device						
		1	1.005	1.01	1.015	1.02	1.025	1.03
Proposed Device	1	9	0	0	0	0	0	0
	1.005	0	16	1	0	0	0	0
	1.01	0	1	18	1	1	0	0
	1.015	0	0	1	14	1	0	0
	1.02	0	0	0	2	11	1	0
	1.025	0	0	0	1	1	14	0
	1.03	0	0	0	0	0	0	7
Total		9	17	20	18	14	15	7
% exact match		100	94.1	90	77.8	78.6	93.3	100
% $\pm$ 1 color block		100	100	100	94.4	92.8	100	100

Ketone (mg/dL)		Predicate Device					
		NEG	5	14	40	80	160
Proposed Device	NEG	46	0	0	0	0	0
	5	0	11	0	0	0	0
	14	0	0	14	0	0	0
	40	0	0	1	10	1	0
	80	0	0	0	1	9	0
	160	0	0	0	0	0	7
Total		46	11	15	11	10	7
% exact match		100	100	93.3	90.9	90	100
% $\pm$ 1 color block			100	100	100	100	100

Bilirubin (mg/dL)		Predicate Device			
		NEG	1	3	6
Proposed Device	NEG	44	0	0	0
	1	0	23	0	0

	3	0	2	20	0
	6	0	0	1	10
Total		44	25	21	10
% exact match		100	92	95.2	100
% ±1 color block			100	100	100

Glucose (mg/dL)		Predicate Device					
		NEG	90	270	550	1100	2000
Proposed Device	NEG	40	0	0	0	0	0
	90	0	12	0	0	0	0
	270	0	0	10	1	0	0
	550	0	0	1	10	0	0
	1100	0	0	1	1	12	0
	2000	0	0	0	0	0	12
Total		40	12	12	12	12	12
% exact match		100	100	83.3	83.3	100	100
% ±1 color block			100	91.7	100	100	100

### Healgen 500 Read, Combined Sites 1- 3 (n=100)

Leukocytes (cells / $\mu$ L)		Predicate Device				
		Negative	15	70	125	500
Proposed Device	NEG	39	0	0	0	0
	15	2	18	1	0	0
	70	0	1	17	0	0
	125	0	1	1	9	0
	500	0	0	0	1	10
Total		41	20	19	10	10
% exact match		95.1	90	89.5	90	100
% ±1 color block			95	100	100	100

Nitrite ( $\mu$ g / dL)		Predicate Device	
		Negative	Positive
Proposed Device	NEG	57	1
	positive	0	42
Total		57	43
% exact match		100	97.7

Urobilinogen (mg/dL)		Predicate Device				
		0.2	1	2	4	8
Proposed Device	0.2	47	0	0	0	0
	1	0	16	0	0	0
	2	0	1	10	2	0
	4	0	0	1	10	0
	8	0	0	1	0	11
Total		47	17	12	12	11
% exact match		100	94.4	83.3	83.3	100
% ±1 color block		100	100	91.7	100	100

Protein (mg/dL)		Predicate Device					
		NEG	10	30	100	300	2000
Proposed Device	NEG	42	0	0	0	0	0
	10	0	12	0	0	0	0

	30	0	0	11	1	0	0
	100	0	0	1	11	0	0
	300	0	0	1	1	11	0
	2000	0	0	0	0	0	8
Total		42	12	13	13	12	8
% exact match		100	100	84.6	84.6	100	100
% ±1 color block			100	92.3	100	100	100

pH		Predicate Device						
		5	6	6.5	7	7.5	8	8.5
Proposed Device	5	7	1	0	0	0	0	0
	6	0	13	0	0	0	0	0
	6.5	0	1	12	1	1	0	0
	7	0	0	0	11	2	0	0
	7.5	0	0	0	0	21	2	0
	8	0	0	0	0	0	21	0
	8.5	0	0	0	0	0	0	7
Total		7	15	12	12	24	23	7
% exact match		100	86.7	100	91.7	87.5	91.3	100
% ±1 color block			100	100	100	95.8	100	100

Blood (cells / $\mu$ L)		Predicate Device				
		NEG	10	25	80	200
Proposed Device	NEG	40	0	0	0	0
	10	0	25	1	1	0
	25	0	1	10	1	0
	80	0	1	1	10	0
	200	0	0	0	0	9
Total		40	27	12	12	9
% exact match		100	92.6	83.3	83.3	100
% ±1 color block			96.3	100	91.7	100

Ascorbic Acid (mg/dL)		Predicate Device				
		0	10	25	50	100
Proposed Device	0	13	0	0	0	0
	10	0	24	0	0	0
	25	0	1	22	1	0
	50	0	0	1	26	0
	100	0	0	1	1	10
Total		13	25	24	28	10
% exact match		100	92	91.6	92.8	100
% ±1 color block			100	95.8	100	100

Specific Gravity		Predicate Device						
		1	1.005	1.01	1.015	1.02	1.025	1.03
Proposed Device	1	9	0	0	0	0	0	0
	1.005	0	17	0	0	0	0	0
	1.01	0	0	17	0	0	0	0
	1.015	0	0	2	14	1	0	0
	1.02	0	0	1	2	12	0	0
	1.025	0	0	0	2	1	15	0
	1.03	0	0	0	0	0	0	7
Total		9	17	20	18	14	15	7

% exact match	100	100	85	77.8	85.7	100	100
% ±1 color block	100	100	95	88.9	100	100	100

Ketone (mg/dL)		Predicate Device					
		NEG	5	14	40	80	160
Proposed Device	NEG	46	0	0	0	0	0
	5	0	10	0	0	0	0
	14	0	1	12	0	0	0
	40	0	0	2	10	0	0
	80	0	0	1	1	10	0
160		0	0	0	0	0	7
Total		46	11	15	11	10	7
% exact match		100	90.9	80	90.9	100	100
% ±1 color block			100	93.3	100	100	100

Bilirubin (mg/dL)		Predicate Device			
		NEG	1	3	6
Proposed Device	NEG	44	0	0	0
	1	0	22	0	0
	3	0	2	19	0
	6	0	1	2	10
Total		44	25	21	10
% exact match		100	88	90.5	100
% ±1 color block			96	100	100

Glucose (mg/dL)		Predicate Device					
		NEG	90	270	550	1100	2000
Proposed Device	NEG	40	0	0	0	0	0
	90	0	12	0	0	0	0
	270	0	0	11	0	0	0
	550	0	0	1	10	0	0
	1100	0	0	0	2	12	0
	2000	0	0	0	0	0	12
Total		40	12	12	12	12	12
% exact match		100	100	91.7	83.3	100	100
% ±1 color block			100	100	100	100	100

#### Healgen 800 Read, Combined Sites 1- 3 (n=100)

Leukocytes (cells / µL)		Predicate Device				
		Negative	15	70	125	500
Proposed Device	NEG	40	0	0	0	0
	15	1	19	1	0	0
	70	0	1	17	0	0
	125	0	0	0	10	0
	500	0	0	1	0	10
Total		41	20	19	10	10
% exact match		97.6	95	89.5	100	100
% ±1 color block			100	94.7	100	100

Nitrite (µg / dL)		Predicate Device	
		Negative	Positive
Proposed	NEG	57	0

Device	positive	0	43
Total		57	43
% exact match		100	100
% ±1 color block			100

Urobilinogen (mg/dL)		Predicate Device				
		0.2	1	2	4	8
Proposed Device	0.2	47	0	0	0	0
	1	0	15	1	1	0
	2	0	2	10	1	0
	4	0	0	1	10	0
	8	0	0	0	0	11
Total		47	17	12	12	11
% exact match		100	88.2	83.3	83.3	100
% ±1 color block		100	100	100	91.7	100

Protein (mg/dL)		Predicate Device					
		NEG	10	30	100	300	2000
Proposed Device	NEG	42	0	0	0	0	0
	10	0	11	1	0	0	0
	30	0	1	12	1	0	0
	100	0	0	0	12	0	0
	300	0	0	0	0	12	0
	2000	0	0	0	0	0	8
Total		42	12	13	13	12	8
% exact match		100	91.7	92.3	92.3	100	100
% ±1 color block			100	100	100	100	100

pH		Predicate Device						
		5	6	6.5	7	7.5	8	8.5
Proposed Device	5	7	0	0	0	0	0	0
	6	0	15	0	0	0	0	0
	6.5	0	0	11	1	0	0	0
	7	0	0	1	10	1	0	0
	7.5	0	0	0	1	22	0	0
	8	0	0	0	0	1	21	0
	8.5	0	0	0	0	0	2	7
Total		7	15	12	12	24	23	7
% exact match		100	100	91.7	83.3	91.7	91.3	100
% ±1 color block		100	100	100	100	100	100	100

Blood (cells / $\mu$ L)		Predicate Device				
		NEG	10	25	80	200
Proposed Device	NEG	40	0	0	0	0
	10	0	25	0	0	0
	25	0	1	10	0	0
	80	0	0	2	10	0
	200	0	0	0	2	9
Total		40	27	12	12	9
% exact match		100	96.3	83.3	83.3	100
% ±1 color block			100	100	100	100

Ascorbic Acid (mg/dL)		Predicate Device				
		0	10	25	50	100
Proposed Device	0	13	0	0	0	0
	10	0	22	1	1	0
	25	0	3	21	2	0
	50	0	0	1	24	0
	100	0	0	1	1	10
Total		13	25	24	28	10
% exact match		100	88	87.5	85.7	100
% ±1 color block			100	95.8	96.4	100

Specific Gravity		Predicate Device						
		1	1.005	1.01	1.015	1.02	1.025	1.03
Proposed Device	1	9	0	0	0	0	0	0
	1.005	0	16	0	0	0	0	0
	1.01	0	1	19	1	0	0	0
	1.015	0	0	1	15	2	0	0
	1.02	0	0	0	1	12	1	0
	1.025	0	0	0	1	0	14	0
	1.03	0	0	0	0	0	0	7
Total		9	17	20	18	14	15	7
% exact match		100	94.1	95	83.3	85.7	93.3	100
% ±1 color block			100	100	94.4	100	100	100

Ketone (mg/dL)		Predicate Device					
		NEG	5	14	40	80	160
Proposed Device	NEG	46	0	0	0	0	0
	5	0	10	0	0	0	0
	14	0	1	13	0	0	0
	40	0	0	1	9	0	0
	80	0	0	1	2	10	0
	160	0	0	0	0	0	7
Total		46	11	15	11	10	7
% exact match		100	90.9	86.7	81.81	100	100
% ±1 color block			100	93.3	100	100	100

Bilirubin (mg/dL)		Predicate Device			
		NEG	1	3	6
Proposed Device	NEG	44	0	0	0
	1	0	24	1	0
	3	0	1	18	0
	6	0	0	2	10
Total		44	25	21	10
% exact match		100	96	85.7	100
% ±1 color block			100	100	100

Glucose (mg/dL)		Predicate Device					
		NEG	90	270	550	1100	2000
Proposed Device	NEG	40	0	0	0	0	0
	90	0	11	0	0	0	0
	270	0	1	11	0	0	0
	550	0	0	1	11	0	0
	1100	0	0	0	1	11	0

	2000	0	0	0	0	1	12
Total		40	12	12	12	12	12
% exact match		100	91.7	91.7	91.7	91.7	100
% $\pm 1$ color block			100	100	100	100	100

Note:

- 1) Possible visual results of nitrite are 3(negative, positive 1 and 2), while possible instrumental results are 2 (negative and positive);
- 2) Instrumental reading does not include the result of non-hemolyzed blood.

*b. Matrix comparison:*

Not applicable

3. Clinical studies:

*a. Clinical Sensitivity:*

Not applicable

*b. Clinical specificity:*

Not applicable

*c. Other clinical supportive data (when a. and b. are not applicable):*

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Expected values are included in the strips instructions for use and as shown in the table below:

Analyte	Expected Values
Urobilinogen	0.2-1 mg/dL
Bilirubin	Negative
Ketone	Negative
Blood	Negative
Protein	Negative or $\pm$
Nitrite	Negative
Leukocytes	Negative
Glucose	Negative
Ascorbic Acid	0-100 mg/dL
Specific Gravity	1.000-1.030
pH	5.0-8.0

References:

- 1) "European Urinalysis Guidelines", the Scandinavian Journal of Clinical & Laboratory Investigation, Scand J Clin Lab Invest-Vol. 60-Supplement 231.2000.
- 2) "Compendium – Urinalysis with Test Strips" Roche Diagnostic, Combur® Reagent Strips.

**N. Instrument Name:**

Healgen 500 and 800 urine analyzers for Healgen 11 and Healgen 10 reagent strips only.

**O. System Descriptions:**

1. Modes of Operation:

Semi-automatic reading of Healgen 11 and Healgen 10 reagent strips on Healgen 500 and Healgen 800 urine analyzers. The Healgen 4 reagent strip is for manual/visual reading only. Each reagent strip is single use and must be replaced with a new strip for additional readings. The labeling and user guide specify that the strips are for single use.

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?:

Yes  X  or No \_\_\_\_\_

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?:

Yes \_\_\_\_\_ or No  X

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes  X  or No \_\_\_\_\_

3. Specimen Identification:

There is no sample identification function with this device. Samples are applied directly to the reagent strip as they are collected.

4. Specimen Sampling and Handling:

Healgen 500/800 urine analyzers are intended to be used with urine samples which can be applied directly to the reagent strip. Healgen 500 and Healgen 800 has a throughout of 120 tests per hour and 500 tests per hour, respectively.

5. Calibration:

The Healgen 500/800 urine analyzers use a check strip for a recommended once or twice a week calibration.

6. Quality Control:

Quality control monitoring is recommended (testing of known positive and negative controls) when a new bottle of reagent strips is first opened (at least every 12 hours). Use of water as a negative control is not recommended.

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:**

Not applicable

**Q. Proposed Labeling:**

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

**R. Conclusion:**

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