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

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

k142391

**B. Purpose for Submission:**

New device

**C. Measurand:**

Urine Creatinine and Albumin

**D. Type of Test:**

Semi-quantitative colorimetric reagent strip test

**E. Applicant:**

Acon Laboratories, Inc.

**F. Proprietary and Established Names:**

Mission U120 Ultra Urine Analyzer

Mission Urinalysis Reagent Strips (Microalbumin/Creatinine)

Mission Liquid Urine Controls and Mission Liquid Diptube Urine Controls

**G. Regulatory Information:**

| Product Code | Classification | Regulation Section | Panel |
|---|---|---|---|
| KQO | I | 21 CFR §862.2900<br>Automated urinalysis system | Chemistry (75) |
| JIR | I | 21 CFR §862.1645<br>Urinary protein or albumin (nonquantitative) test system | Chemistry (75) |
| JFY | II | 21 CFR §862.1225<br>Creatinine test system | Chemistry (75) |
| JJW | I | 21 CFR §862.1660<br>Quality Control Material (assayed and unassayed) | Chemistry (75) |

## H. Intended Use:

1. Intended use(s):

   Refer to Indications for Use below.

2. Indication(s) for use:

   The Mission U120 Ultra Urine Analyzer is a urinalysis instrument intended for in vitro diagnostic use. It is intended for professional use only at point-of-care locations. The Mission U120 Ultra Urine Analyzer is intended to read Mission Urinalysis Reagent strips (Microalbumin/Creatinine) for the semi quantitative measurement of Albumin and Creatinine. These measurements are used to assist diagnosis for kidney function.

   The Mission Liquid Urine Controls and Mission Liquid Diptube Urine Controls are assayed urine controls, intended for use in validating the precision of analyzer reading of urinalysis for the Creatinine and Albumin analytes.

3. Special conditions for use statement(s):

   For prescription use only.

4. Special instrument requirements:

   Mission U120 Ultra Urine Analyzer

## I. Device Description:

The Mission U120 Ultra Urine Analyzer is a reflectance photometer that analyzes the intensity and color of light reflected from the reagent areas of a urinalysis reagent strip. Mission U120 Ultra Urine Analyzer also features data management and report generation capabilities.

Mission urinalysis strips (Microalbumin and Creatinine) are plastic strips that contain two reagent pads to test for small amounts of albumin in urine (microalbuminuria), creatinine in urine, and also to determine the albumin-to-creatinine ratio in urine. The strip results are read on the analyzer.

## J. Substantial Equivalence Information:

1. Predicate device name(s):
   Instrument: Clinitek Status Analyzer
   Assay: Clinitek Microalbumin 2 Reagent Strips read on Clinitek Status Analyzer
   Controls: Biorad Liquicheck Urinalysis Control

2. Predicate 510(k) number(s):
   k031947, k972706, k070848, respectively

3. Comparison with predicate:

| Similarities and Differences | | |
|---|---|---|
| Item | Mission Urinalysis Reagent Strips (Microalbumin/ Creatinine) (New Device) | Clinitek Clinitek Microalbumin 2 Reagent Strips K972706 (Predicate Device) |
| Intended Use | Intended to read urinalysis Reagent strips (Microalbumin/Creatinine) for the semi quantitative measurement of Albumin and Creatinine. These measurements are used to assist diagnosis for kidney function. | Same |
| Assay Methodology | Dye binding assay | Same |
| Test Principle | Light is reflected at specific wavelengths from the test pad read area. Reported results depend upon the degree of color change and intensity in the pad which is directly related to the concentration of the analyte in the urine. | Same |
| Measuring Range | 10-150 mg/L Albumin<br>10-300 mg/dL Creatinine | Same |
| Controls | 2 levels provided | Commercially available controls |
| Sample Type | Urine | Same |
| Format | Strips | Same |

| Similarities and Differences | | |
|---|---|---|
| Item | Mission U120 Ultra Urine Analyzer (New Device) | Clinitek Status Analyzer k031947 (Predicate Device) |
| Intended Use | Intended to read Urinalysis Reagent strips for the semi quantitative measurement of Albumin and Creatinine. These measurements are used to assist diagnosis for kidney function. | Same |
| Analytes | Albumin and creatinine in urine | Glucose, bilirubin, ketone, specific gravity, occult blood, pH, protein, urobilinogen, nitrite leukocytes, albumin and creatinine in urine |

| Similarities and Differences | | |
|---|---|---|
| Item | Mission U120 Ultra Urine Analyzer (New Device) | Clinitek Status Analyzer k031947 (Predicate Device) |
| Detection | The Mission U120 Ultra Urine Analyzer utilizes a CMOS image sensor to measure the intensity of light. The frequency of the light is determined by the LED light source. | The Clinitek Status Analyzer utilizes a CCD (charge coupled device) to measure the intensity of light. The frequency of the light is determined by the LED light source. |
| Strip Read Time | 1 min | Same |

| Similarities and Differences | | |
|---|---|---|
| Item | Mission Liquid Urine Controls and Mission Liquid Diptube Urine Controls (New Device) | Biorad Liquicheck Urinalysis Controls k070848 (Predicate Device) |
| Intended Use | Assayed urine controls, intended for use in validating the precision of analyzer reading of urinalysis for the Creatinine and Albumin analytes. | Same |
| Form | Liquid | Same |
| Matrix | Buffered solution | Urine |
| Storage | 2 to 8℃ | Same |
| Open Vial | 30 days at 15-30° C) | 30days at 2- 25℃ |

**K. Standard/Guidance Document Referenced (if applicable):**

CLSI EP07-A2: Interference Testing in Clinical Chemistry

ISO 14971:2007 - Medical devices - Application of Risk management to medical devices

**L. Test Principle:**

The Mission U120 Ultra Urine Analyzer is a reflectance photometer that analyzes the intensity and color of light reflected from the reagent areas of a urinalysis reagent strip. Using a light emitting diode (LED) as the light source and a CMOS image sensor as a light sensor, the optical system reads the color change in the urine test strips after a sample is applied.

The albumin test is based on affinity binding of albumin to a sulfonephthalein dye at a constant pH. The development of pale green to aqua blue indicates the presence of albumin.

The creatinine test is based on the peroxidase-like activity of a copper creatinine complex that catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-

tetramethylbenzidine. The resulting color ranges from orange through green to blue.

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

1. Analytical performance:

*a. Precision/Reproducibility:*

To evaluate between-run precision, 3 levels of albumin and creatinine in contrived urine samples were tested at 3 external sites with three lots of strips on the Mission U120 Ultra urine analyzer. Testing was performed by three operators at each site typically found at these settings on blind labeled samples, with each operator performing the test for 6-7 days. Each sample was assayed for 20 days with 2 runs per day. For within-run precision, 3 levels of albumin and creatinine were run for 1 day with 20 replicates per sample. Results for each of the 3 POC sites are summarized:

POC Site 1:

| Analyte | Concentration | Result (Exact Match/Total) | | |
|---|---|---|---|---|
| | | Operator 1 | Operator 2 | Operator 3 |
| Albumin | 10mg/L | 14/14 | 14/14 | 12/12 |
| | 30 mg/L | 14/14 | 13/14 | 12/12 |
| | 150 mg/L | 14/14 | 14/14 | 12/12 |
| Creatinine | 10 mg/dL | 14/14 | 14/14 | 12/12 |
| | 50 mg/dL | 14/14 | 14/14 | 12/12 |
| | 300 mg/dL | 14/14 | 14/14 | 12/12 |

POC Site 2:

| Analyte | Concentration | Result (Exact Match/Total) | | |
|---|---|---|---|---|
| | | Operator 1 | Operator 2 | Operator 3 |
| Albumin | 10mg/L | 14/14 | 14/14 | 12/12 |
| | 30 mg/L | 14/14 | 14/14 | 12/12 |
| | 150 mg/L | 14/14 | 14/14 | 12/12 |
| Creatinine | 10 mg/dL | 14/14 | 14/14 | 12/12 |
| | 50 mg/dL | 14/14 | 14/14 | 12/12 |
| | 300 mg/dL | 14/14 | 14/14 | 12/12 |

POC Site 3:

| Analyte | Concentration | Result (Exact Match/Total) | | |
|---|---|---|---|---|
| | | Operator 1 | Operator 2 | Operator 3 |
| Albumin | 10mg/L | 14/14 | 14/14 | 12/12 |
| | 30 mg/L | 14/14 | 14/14 | 12/12 |
| | 150 mg/L | 14/14 | 13/14 | 12/12 |
| Creatinine | 10 mg/dL | 13/14 | 14/14 | 12/12 |
| | 50 mg/dL | 14/14 | 14/14 | 12/12 |
| | 300 mg/dL | 14/14 | 14/14 | 12/12 |

The combined precision data for the POC sites is summarized below:

| Analyte | Conc | | Total Agreement within same block | Total Agreement within ± 1 block |
|---|---|---|---|---|
| Albumin | 10 mg/L | Within-run | 60/60<br>100% | 60/60<br>100% |
| | | Between run | 120/120<br>100% | 120/120<br>100% |
| | 30 mg/L | Within-run | 60/60<br>100% | 60/60<br>100% |
| | | Between run | 119/120<br>99.2% | 120/120<br>100% |
| | 150 mg/L | Within-run | 60/60<br>100% | 60/60<br>100% |
| | | Between run | 119/120<br>99.2% | 120/120<br>100% |
| Creatinine | 10 mg/dL | Within-run | 60/60<br>100% | 60/60<br>100% |
| | | Between run | 119/120<br>99.2% | 120/120<br>100% |
| | 50 mg/dL | Within-run | 60/60<br>100% | 60/60<br>100% |
| | | Between run | 120/120<br>100% | 120/120<br>100% |
| | 300 mg/dL | Within-run | 60/60<br>100% | 60/60<br>100% |
| | | Between run | 120/120<br>100% | 120/120<br>100% |

*b. Linearity/assay reportable range:*

This assay reports color block outputs of 10mg/L, 30 mg/L, 80 mg/L, 150 mg/L for albumin, and 10 mg/dL, 50 mg/dL, 100 mg/dL, 200 mg/dL, 300 mg/dL for creatinine.

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

Traceability and Value Assignment: The control solutions were prepared in house by adding a commercially available stock of albumin and creatinine in buffered solutions. The controls are traceable to internal standards. The values for the internal standards for creatinine are assigned through an internal procedure. The target values are:
Control Level 1: Albumin 10-30 mg/L; Creatinine 10-100 mg/dL
Control Level 2: Albumin 80-150 mg/L; Creatinine 100-300 mg/dL

Calibration: The Mission U500 performs a "self-test" and calibration each time it is turned on. Each time a test is run the analyzer re-calibrates using a white plastic

calibration bar located at the bottom of the analyzer optical system. Reflectance measurements from the bar must match the factory set calibration.

Shelf life stability and open vial protocols for the controls were reviewed and found acceptable. The sponsor claims that the controls are stable for 24 months when stored at 2°C to 8°C in closed package, opened package for 30 days at 15ºC to 30ºC

Shelf-life and open-vial stability protocols and acceptance criteria were reviewed and found to be adequate for Mission Urinalysis Reagent Strips (Microalbumin/ Creatinine). The stability studies support the following manufacturer's claim: The strip can be stored at 2ºC to 8ºC in closed package to 24 months, opened package for 30 days at 15ºC to 30ºC.

*d. Detection limit:*

The sensitivity of the assay was evaluated at each color block of albumin (10, 30, 80, 150 mg/L) and creatinine (10, 50, 100, 200, 300 mg/dL). Urine samples were spiked or diluted to known concentrations for each analyte with a minimum of 4 levels across the measuring range of each color block. Each sample was tested by three operators with 3 lots of strips for 3 days generating 81 datapoints for each level. The cutoff for each block is defined as the lowest concentration at which >50% of the results are positive for each color block.

The cut-off values for each color block of albumin and creatinine are summarized below:

| Analyte | Color Block | Cut-off Concentration | % Positive results |
|---|---|---|---|
| Albumin | 10 mg/L | 0 mg/L | 100% |
| | 30 mg/L | 20 mg/L | 72.8% |
| | 80 mg/L | 55 mg/L | 67.9% |
| | 150 mg/L | 125 mg/L | 65.4% |
| Creatinine | 10 mg/dL | 0 mg/dL | 100% |
| | 50 mg/dL | 30 mg/dL | 60.5% |
| | 100 mg/dL | 75 mg/dL | 54.3% |
| | 200 mg/dL | 150 mg/dL | 56.8% |
| | 300 mg/dL | 250 mg/dL | 54.3% |

Results for each level tested at each color block is shown below:

| | Conc. Tested | Percentage Agreement at Each Color Block | | | |
|---|---|---|---|---|---|
| Albumin | | 10 mg/L | 30 mg/L | 80 mg/L | 150 mg/L |
| | 300 mg/L | 0% | 0% | 0% | 100% |
| | 225 mg/L | 0% | 0% | 0% | 100% |
| | 150 mg/L | 0% | 0% | 0% | 100% |
| | 137.5 | 0% | 0% | 17.3% | 82.7% |

| | | | | | |
|---|---|---|---|---|---|
| | mg/L | | | | |
| | 125 mg/L | 0% | 0% | 34.6% | 65.4% |
| | 103.5 mg/L | 0% | 0% | 56.8% | 43.2% |
| | 80 mg/L | 0% | 0% | 100% | 0% |
| | 60.5 mg/L | 0% | 13.6% | 86.4% | 0% |
| | 55 mg/L | 0% | 32.1% | 67.9% | 0% |
| | 49.5 mg/L | 0% | 55.6% | 44.4% | 0% |
| | 30 mg/L | 0% | 100% | 0% | 0% |
| | 22 mg/L | 13.6% | 86.4% | 0% | 0% |
| | 20 mg/L | 27.2% | 72.8% | 0% | 0% |
| | 18 mg/L | 51.9% | 48.1% | 0% | 0% |
| | 10 mg/L | 100% | 0% | 0% | 0% |
| | 7.5 mg/L | 100% | 0% | 0% | 0% |
| | 5 mg/L | 100% | 0% | 0% | 0% |
| | 2.5 mg/L | 100% | 0% | 0% | 0% |

| | Conc. Tested | Percentage Agreement at Each Color Block | | | | |
|---|---|---|---|---|---|---|
| | | 10 mg/dL | 50 mg/dL | 100 mg/dL | 200 mg/dL | 300 mg/dL |
| Creatinine | 600 mg/dL | 0% | 0% | 0% | 0% | 100% |
| | 450 mg/dL | 0% | 0% | 0% | 0% | 100% |
| | 300 mg/dL | 0% | 0% | 0% | 0% | 100% |
| | 275 mg/dL | 0% | 0% | 0% | 7.4% | 92.6% |
| | 250 mg/dL | 0% | 0% | 0% | 45.7% | 54.3% |
| | 225 mg/dL | 0% | 0% | 0% | 69.1% | 30.9% |

| | | | | | | |
|---|---|---|---|---|---|---|
| | 200 mg/dL | 0% | 0% | 0% | 100% | 0% |
| | 165 mg/dL | 0% | 0% | 25.9% | 74.1% | 0% |
| | 150 mg/dL | 0% | 0% | 43.2% | 56.8% | 0% |
| | 135 mg/dL | 0% | 0% | 56.8% | 43.2% | 0% |
| | 100 mg/dL | 0% | 0% | 100% | 0% | 0% |
| | 82.5 mg/dL | 0% | 22.2% | 77.8% | 0% | 0% |
| | 75 mg/dL | 0% | 45.7% | 54.3% | 0% | 0% |
| | 67.5 mg/dL | 0% | 56.8% | 43.2% | 0% | 0% |
| | 50 mg/dL | 0% | 100% | 0% | 0% | 0% |
| | 33 mg/dL | 25.9% | 74.1% | 0% | 0% | 0% |
| | 30 mg/dL | 39.5% | 60.5% | 0% | 0% | 0% |
| | 27.5 mg/dL | 53.1% | 46.9% | 0% | 0% | 0% |
| | 10 mg/dL | 100% | 0% | 0% | 0% | 0% |
| | 7.5 mg/dL | 100% | 0% | 0% | 0% | 0% |
| | 5 mg/dL | 100% | 0% | 0% | 0% | 0% |
| | 2.5 mg/dL | 100% | 0% | 0% | 0% | 0% |

e. *Analytical specificity:*

Interference studies were performed to evaluate the effects of potential interferents commonly found in urine on the performance of Mission Urinalysis Reagent strips, following CLSI EP7-A2. Testing was done with contrived urine samples at 3 levels of albumin (10, 30, 150 mg/L) and creatinine (10, 100, 300 mg/dL) and at least two levels of the listed compounds with 3 lots of strips. Interference was defined as a change in output of ≥±1 color blocks between spiked and unspiked control sample.

The table below summarized the data:

| Interferent | Conc. Tested | Interference on the Testing Result | | | | | |
|---|---|---|---|---|---|---|---|
| | | Result of Albumin | | | Result of Creatinine | | |
| | | 10 mg/L | 30 mg/L | 150 mg/L | 10 mg/d | 100 mg/d | 300 mg/d |
| Ammonium Chloride | 100 mg/dL | -- | -- | -- | -- | -- | -- |
| Ascorbic acid | 200 mg/dL | -- | -- | -- | -- | -- | -- |
| Bilirubin | 170 mg/dL | -- | -- | -- | -- | -- | -- |
| Calcium chloride | 275 mg/dL | -- | -- | -- | -- | -- | -- |
| Citric acid | 75 mg/dL | -- | -- | -- | -- | -- | -- |
| Creatine | 10 mg/dL | -- | -- | -- | -- | -- | -- |
| Creatinine | 600 mg/dL | -- | -- | -- | -- | -- | -- |
| Fructose | 100 mg/dL | -- | -- | -- | -- | -- | -- |
| Galactose | 80 mg/dL | -- | -- | -- | -- | -- | -- |
| Glucose | 5000 mg/dL | -- | -- | -- | -- | -- | -- |
| Glycine | 450 mg/dL | -- | -- | -- | -- | -- | -- |
| Hemoglobin | 10 mg/dL | +1 | +2 | -- | +1 | +1 | -- |
| Lactose | 10 mg/dL | -- | -- | -- | -- | -- | -- |
| Lithium acetoacetate | 250 mg/dL | -- | -- | -- | -- | -- | -- |
| Oxalic acid | 70 mg/dL | -- | -- | -- | -- | -- | -- |
| Potassium chloride | 1500 mg/dL | -- | -1 | -2 | -- | -- | -- |
| Riboflavin | 10 mg/dL | -- | -- | -- | -- | -- | -- |
| Sodium acetate | 2.25 mg/dL | -- | -- | -- | -- | -- | -- |
| Sodium bicarbonate | 1500 mg/dL | +2 | +2 | -- | -- | -- | -- |
| Sodium chloride | 5500 mg/dL | -- | -- | -- | -- | -- | -- |
| Sodium nitrate | 10 mg/dL | -- | -- | -- | -- | -- | -- |
| Sodium nitrite | 10 mg/dL | -- | -- | -- | -- | -- | -- |
| Sodium phosphate | 500 mg/dL | -- | -- | -- | -- | -- | -- |
| Theophylline | 100 mg/dL | -- | -- | -- | -- | -- | -- |
| Urea | 400 mg/dL | -- | -- | -- | -- | -- | -- |
| Uric acid | 150 mg/dL | -- | -- | -- | -- | -- | -- |
| Blood | 0.05% | +2 | +2 | -- | +3 | +2 | -- |
| Leucocyte | 2500 leu/μL | -- | -- | -- | -- | -- | -- |
| Human IgG | 25 mg/dL | +1 | +2 | -- | -- | -- | -- |

*-- indicates that the no interference was observed at these interferent and analyte levels.

The following table shows the substances which did interfere with albumin and/or creatinine results. Results are expressed as the lowest concentration of interfering substance that exhibited interference and the resulting change in results:

| Analyte | Decreased Results | Increased results |
|---|---|---|
| Albumin | Potassium chloride (1500 mg/dL) | Hemoglobin (10 mg/dL), sodium bicarbonate (10 mg/dL), Blood (0.05%), Human IgG (25 mg/dL) |
| Creatinine | None | Hemoglobin (10 mg/dL), Blood (0.05%) |

The sponsor states the following in the labeling regarding potentially interfering substances:

The Urinalysis Reagent Strips (Urine) may be affected by substances that cause abnormal urine color such as drugs containing azo dyes (e.g. Pyridium, Azo Gantrisin, Azo Gantanol), nitrofurantoin (Microdantin, Furadantin), and riboflavin. Urine specimen contaminated with soaps, detergents, antiseptics, or skin cleansers may also affect test results.

For albumin, a pH ≥10.0 or a specific gravity of 1.000 will affect albumin test results. Whereas, a specific gravity ≥1.035 will generate falsely elevated results for creatinine.

*Specific Gravity and pH studies:*
5 fresh urine samples were pooled and separated into 9 aliquots. The specific gravity of the aliquots was adjusted with purified water and sodium chloride to 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030, 1.035 and 1.040 respectively. The adjusted samples were spiked or diluted to achieve the desired albumin (10, 80, and 150 mg/L) and creatinine (10, 100, 300 mg/dL) concentrations. For albumin, urine specific gravity range of 1.010 to 1.035 does not affect the results of the albumin test, but specific gravity at 1.000 will generate false low result on albumin test. For creatinine, specific gravity from 1.000 to 1.030 will not affect the results; however specific gravity higher than or equal to 1.035 will generate false high results of creatinine test.

5 fresh urine samples were pooled and separated into 7 aliquots. The pH of the aliquots was adjusted to a range of 4.00 to 10.00 in 1 pH unit increments and were spiked or diluted with albumin and creatinine respectively. Samples were tested using three lots of each format of the devices, and results showed that urine pH range of 4.00 to 9.00 does not affect the results of the albumin test but samples at pH 10.0 would generate false high results. Urine sample pH from 4 to 10 did not affect the creatinine test results.

*Humidity studies:*

Testing was done with contrived urine samples at 3 levels of albumin (10, 30, 150 mg/L) and creatinine (10, 50, 300 mg/dL). 50 strips were placed in relative humidity of <20%, 30-50%, 60-70%, and 85% environments at 15º C and 45° C, and stored in

these conditions for 0.5hr, 1hr, 2hr, 4hr, 8hr, 16hr, and 24hr. 5 replicates were tested for each level. The strips were stable up to 50% humidity for over 24hrs, at humidity conditions above 60%, the strip was stable for 1 hr.

*Timing Flex Study:*

The effect of different dipping times and strip wetting times on strip test results were assessed. Results of the timing flex studies demonstrated that the dipping time or strip wetting time had no interfering effect on the color development.

*Sample Carryover Studies:*

To assess the interference from sample carried over from one pad to the adjacent pad, pooled urine samples with adjusted levels of albumin (10, 30, 150 mg/L) and creatinine (10, 50, 300 mg/dL) were tested. The strip was dipped into a urine sample, and then upon removal, held vertically to allow the sample to move from the albumin pad to the creatinine pad. The same process was repeated for the creatinine pad. 5 replicates were tested for each level. The results indicated that sample carryover from adjacent pads do not interfere with the results.

*f. Assay cut-off:*

See detection limits above.

2. Comparison studies:

*a. Method comparison with predicate device:*

At least 120 native samples were tested at each of 3 point-of-care settings by three operators per site. Urine specimens were randomly collected from patients. Additionally, 18 contrived samples (12-13%) were generated to cover the measuring range. Each specimen was tested by ACON U120 Ultra Urine Analyzers with one ACON Urinalysis Microalbumin/ Creatinine Reagent strip and by Clinitek Status Analyzer with Clinitek Microalbumin 2 reagent strip in duplicates. The results are presented in the tables below:

| Albumin (Site 1, n= 153) | | Predicate Device | | | |
|---|---|---|---|---|---|
| | | 10 mg/L | 30 mg/L | 80 mg/L | 150 mg/L |
| Mission Urinalysis Reagent Strips | 10 mg/L | 30 | 1 | 0 | 0 |
| | 30 mg/L | 2 | 14 | 4 | 0 |
| | 80 mg/L | 0 | 3 | 27 | 6 |
| | 150 mg/L | 0 | 0 | 4 | 62 |
| Total | | 32 | 18 | 35 | 68 |
| Exact Agreement | | 93.8% | 77.8% | 77.1% | 91.2% |
| Agreement within ± 1 block | | 100% | 100% | 100% | 100% |

| Albumin (Site 2, n= 138) | | Predicate Device | | | |
|---|---|---|---|---|---|
| | | 10 mg/L | 30 mg/L | 80 mg/L | 150 mg/L |
| Mission Urinalysis Reagent Strips | 10 mg/L | 36 | 4 | 0 | 0 |
| | 30 mg/L | 3 | 40 | 3 | 0 |
| | 80 mg/L | 0 | 5 | 25 | 2 |
| | 150 mg/L | 0 | 0 | 3 | 17 |
| Total | | 39 | 49 | 31 | 19 |
| Exact Agreement | | 92.3% | 81.6% | 80.6% | 89.5% |
| Agreement within ± 1 block | | 100% | 100% | 100% | 100% |

| Albumin (Site 3, n= 138) | | Predicate Device | | | |
|---|---|---|---|---|---|
| | | 10 mg/L | 30 mg/L | 80 mg/L | 150 mg/L |
| Mission Urinalysis Reagent Strips | 10 mg/L | 60 | 2 | 0 | 0 |
| | 30 mg/L | 5 | 31 | 4 | 0 |
| | 80 mg/L | 0 | 5 | 14 | 2 |
| | 150 mg/L | 0 | 0 | 0 | 15 |
| Total | | 65 | 38 | 18 | 17 |
| Exact Agreement | | 92.3% | 81.6% | 77.8% | 88.2% |
| Agreement within ± 1 block | | 100% | 100% | 100% | 100% |

| Creatinine (Site 1, n= 153) | | Predicate Device | | | | |
|---|---|---|---|---|---|---|
| | | 10 mg/dL | 50 mg/dL | 100 mg/dL | 200 mg/dL | 300 mg/dL |
| Mission Urinalysis Reagent Strips | 10 mg/dL | 8 | 1 | 0 | 0 | 0 |
| | 50 mg/dL | 1 | 32 | 6 | 0 | 0 |
| | 100 mg/dL | 0 | 4 | 32 | 3 | 0 |
| | 200 mg/dL | 0 | 0 | 5 | 31 | 1 |
| | 300 mg/dL | 0 | 0 | 0 | 6 | 23 |
| Total | | 9 | 37 | 43 | 40 | 24 |
| Exact Agreement | | 88.9% | 86.5% | 74.4% | 77.5% | 95.8% |

| | | | | | | |
|---|---|---|---|---|---|---|
| Agreement within ± 1 block | | 100% | 100% | 100% | 100% | 100% |

| Creatinine (Site 2, n= 138) | | Predicate Device | | | | |
|---|---|---|---|---|---|---|
| | | 10 mg/dL | 50 mg/dL | 100 mg/dL | 200 mg/dL | 300 mg/dL |
| Mission Urinalysis Reagent Strips | 10 mg/dL | 10 | 0 | 0 | 0 | 0 |
| | 50 mg/dL | 2 | 30 | 2 | 0 | 0 |
| | 100 mg/dL | 0 | 4 | 22 | 3 | 0 |
| | 200 mg/dL | 0 | 0 | 4 | 41 | 2 |
| | 300 mg/dL | 0 | 0 | 0 | 2 | 16 |
| Total | | 12 | 34 | 28 | 46 | 18 |
| Exact Agreement | | 83.3% | 88.2% | 78.6% | 89.1% | 88.9% |
| Agreement within ± 1 block | | 100% | 100% | 100% | 100% | 100% |

| Creatinine (Site 3, n= 138) | | Predicate Device | | | | |
|---|---|---|---|---|---|---|
| | | 10 mg/dL | 50 mg/dL | 100 mg/dL | 200 mg/dL | 300 mg/dL |
| Mission Urinalysis Reagent Strips | 10 mg/dL | 14 | 3 | 0 | 0 | 0 |
| | 50 mg/dL | 2 | 23 | 2 | 0 | 0 |
| | 100 mg/dL | 0 | 4 | 29 | 1 | 0 |
| | 200 mg/dL | 0 | 0 | 2 | 23 | 1 |
| | 300 mg/dL | 0 | 0 | 0 | 3 | 31 |
| Total | | 16 | 30 | 33 | 27 | 32 |
| Exact Agreement | | 87.5% | 76.7% | 87.9% | 85.2% | 96.9% |
| Agreement within ± 1 block | | 100% | 100% | 100% | 100% | 100% |

For all three sites combined:

| Creatinine | | Predicate Device | | | | |
|---|---|---|---|---|---|---|
| | | 10 mg/dL | 50 mg/dL | 100 mg/dL | 200 mg/dL | 300 mg/dL |
| Mission | 10 mg/dL | 32 | 4 | 0 | 0 | 0 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Urinalysis Reagent Strips | 50 mg/dL | 5 | 85 | 10 | 0 | 0 |
| | 100 mg/dL | 1 | 12 | 83 | 7 | 0 |
| | 200 mg/dL | 0 | 0 | 11 | 95 | 4 |
| | 300 mg/dL | 0 | 0 | 0 | 11 | 70 |
| Total | | 37 | 101 | 104 | 113 | 74 |
| Exact Agreement | | 86.5% | 84.1% | 79.8% | 84.7% | 94.5% |
| Agreement within ± 1 block | | 100% | 100% | 100% | 100% | 100% |

| Albumin | | Predicate Device | | | |
|---|---|---|---|---|---|
| | | 10 mg/L | 30 mg/L | 80 mg/L | 150 mg/L |
| Mission Urinalysis Reagent Strips | 10 mg/L | 126 | 7 | 0 | 0 |
| | 30 mg/L | 10 | 85 | 11 | 0 |
| | 80 mg/L | 0 | 13 | 66 | 10 |
| | 150 mg/L | 0 | 0 | 11 | 94 |
| Total | | 136 | 105 | 84 | 104 |
| Exact Agreement | | 91.5% | 80.0% | 80.9% | 88.6% |
| Agreement within ± 1 block | | 100% | 100% | 100% | 100% |

Albumin: creatinine ratio for all three sites combined

| A:C | | Predicate Device | | | |
|---|---|---|---|---|---|
| | | <30 | 30-300 | >300 | Total |
| Mission Urinalysis Reagent Strips | <30 | 186 | 16 | 0 | 202 |
| | 30-300 | 10 | 131 | 9 | 150 |
| | >300 | 0 | 5 | 72 | 77 |
| | Total | 196 | 152 | 81 | 429 |
| Agreement at same block | | 94.89% | 86.18% | 88.9% | |
| Agreement within ±1 block | | 100% | 100% | 100% | |
| Positive Agreement | | 94.89% | 89.47% | 100% | |
| Negative Agreement | | 5.11% | 13.8% | 11.1% | |
| Agreement within same | | | 90.67% | | |

| | | |
|---|---|---|
| block | | |
| Agreement within ±1 block | | 100% |

The agreement of A:C ratios of positives and negatives at cutoff of <30 mg/g were 94.89% and 5.11%, respectively. Of the 217 A:C predicate positive results, 7.37% (16/217) were Mission Strip negative. Of the 196 assay A:C ratio predicate negative results, 5.11% (10/196) were positive. In summary, the overall exact agreement between Mission Urinalysis Strips (Microalbumin/Creatinine) and Clinitek Microalbumin 2 Reagents strips for positive albumin results is 90.67%, and the overall agreement for ±1 block is 100%.

*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. Clinical studies are not typically submitted for this device type.

5. Expected values/Reference range:

The expected values are included in the labeling and are taken from literature references.

Normally, albumin is present in urine at concentrations < 20 mg/L[1]. Results of 20-200 mg/L may indicate microalbuminuria. It is associated with early-stage kidney disease when a small amount of Albumin, also called Microalbumin is consistently present in urine. Clinical albuminuria is indicated by results of >200 mg/L. These levels can be predictive of albumin excretion rates of 30-300 mg/24hours and >300 mg/24hours, respectively[2-3]. Exercise, acute illness and fever, and urinary tract infections may temporarily elevate urinary albumin excretions. Creatinine concentrations of 10-300 mg/dL are normally present in urine.

Albumin is normally present in urine at concentrations of <30 mg albumin/g creatinine. Microalbuminuria is indicated at a ratio result of 30-300 mg/g (Abnormal) and clinical albuminuria at a ratio of >300 mg/g (High Abnormal)[4].

1. Burtis, C.A. and Ashwood, E.R.: Tietz Textbook of Clinical Chemistry, 3rd ed.

Philadelphia: Saunders; 1999; pp. 483-484.
2. Mangili, R. et al.: Prevalence of Hypertension and Microalbuminuria in Adult Type 1 (Insulin-Dependent) Diabetic patients Without Renal Failure in Italy-Validation of Screening Techniques to Detect Microalbuminuria. Acta Diabetol. 29: 156-166; 1992.
3. American Diabetes Association, Clinical Practice Recommendations, Diabetes Care, Vol. 31, Suppl. 1, January 2008
4. Position Statement: Diabetic Nephropathy. Diabetes Care 20: S24-S27; 1997.

**N. Instrument Name:**

Mission U120 Ultra Urine Analyzer

**O. System Descriptions:**

1. Modes of Operation:

   Semi-automatic reading of Mission Urinalysis Microalbumin/Creatinine Reagent strip on Mission U120 Ultra Urine Analyzer. 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 ____X____ or No _____

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:

   An external bar code reader, or manual entry of sample numbers are used for sample identification. Mission U120 Ultra Urine Analyzer can be interfaced with a laboratory information system for data management via serial port or USB port.

4. Specimen Sampling and Handling:

   Mission U120 Ultra Urine Analyzer can only accept one test strip at a time. Test strips are dipped in urine, and read on the analyzer. The analyzer also stores up to 2000 patient results which can be recalled by the operator using the Records Review Function.

5. Calibration:

   The instrument performs a "self-test" and calibration each time it is turned on. Each time

a test is run the analyzer re-calibrates using a white plastic calibration bar located at the bottom of the analyzer optical system.

6. Quality Control:

   Each canister of strips contains a code that includes information such as brand, type of strip, strips per canister, expiration date. This code is entered into the U120 Ultra Urine analyzer either manually or by a barcode reader prior to testing. An error code is generated if this is not done.

   The instrument includes a quality control function (QC), and a lock out function. When the QC function is enabled, the instrument will ask for control testing during the system initialization prior to the routine testing run.

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

Mission U120 Ultra Urine Analyzer demonstrates compliance to EMC requirements including general requirements for laboratory use by meeting EN 61326-1 as well as requirements for in vitro diagnostic medical equipment by meeting EN 61326-2-6.

**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.