

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

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

k111221

**B. Purpose for Submission:**

New urine analyzer using test strips cleared in k070929

**C. Measurand:**

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

**D. Type of Test:**

Qualitative and semi-quantitative

**E. Applicant:**

ACON Laboratories, Inc.

**F. Proprietary and Established Names:**

Mission U500 Urine Analyzer, Mission Urinalysis Reagent Strips with a combination of one to eleven test pads per strip. The names of the test strips are included in section I, Device Description.

**G. Regulatory Information:**

1. Regulation section:

| <b>Classification Name</b>                                          | <b>Product Code</b> | <b>Device Class</b> | <b>Regulation Number</b> |
|---------------------------------------------------------------------|---------------------|---------------------|--------------------------|
| Occult blood test                                                   | 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                    | NGJ | I | 21 CFR §862.1510 |
| Leukocyte peroxidase test                                 | 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 |
| Specific Gravity                                          | JRE | I | 21 CFR §862.2800 |
| Automated Urinalysis System                               | KQO | I | 21 CFR §862.2900 |

4. Panel:

(75) Clinical Chemistry, (81) Hematology

**H. Intended Use:**

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Mission<sup>®</sup> U500 Urine Analyzer is intended for use in conjunction with the Mission<sup>®</sup> Urinalysis Reagent Strips for the semi-quantitative detection of the following analytes in urine: Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Leukocytes and Ascorbic Acid as well as the qualitative detection of Nitrite. The instrument is intended for prescription, in vitro diagnostic use only. The Mission Urinalysis Reagent Strips are available in different test configurations and the measurement can be used in general evaluation of health, and aids in the diagnosis and monitoring of metabolic or systemic diseases that affect kidney function, endocrine disorders and diseases or disorders of the urinary tract.

3. Special conditions for use statement(s):

Prescription use

4. Special instrument requirements:

Mission U500 Urine Analyzer (U211-101)

**I. Device Description:**

The Mission<sup>®</sup> U500 Urine Analyzer is a semi-automated reflectance photometer that

analyzes the intensity and color of light reflected from the reagent areas of a urinalysis reagent strip. The analyzer throughput is 500 tests per hour and the measuring cycle is 7 seconds per test. The analyzer stores up to 2,000 patient records and prints the results in Conventional, SI, or arbitrary units using an integrated internal or external thermal printer. The Mission U500 is able to recall and display measurements from memory on the LCD display. It also has a serial interface (RS232) for connection to a computer or barcode reader (model U211-111), and a parallel interface for connection to an external printer. The Mission U500 uses the following compatible formats of the Mission Urinalysis Reagent Test Strips which the operator selects from a touch screen menu:

| Product Name                           | No. Parameters | Strip Code on Analyzer | Analytes                                                                                                              |
|----------------------------------------|----------------|------------------------|-----------------------------------------------------------------------------------------------------------------------|
| Mission® Urine Analysis Strip U031-111 | 11             | 11A                    | Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose and Ascorbic Acid |
|                                        |                | 10U                    | Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin and Glucose                |
| Mission® Urine Analysis Strip U031-101 | 10             | 10A                    | Ascorbic Acid, Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite                |
|                                        |                | 9U                     | Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin and Glucose                            |
| Mission® Urine Analysis Strip U031-091 | 9              | 8U                     | Glucose, Bilirubin, Ketone, Blood, pH, Protein, Urobilinogen, Nitrite                                                 |
|                                        |                | 8N                     | Leukocytes, Nitrite, Protein, pH, Blood, Specific Gravity, Ketone and Glucose                                         |
| Mission® Urine Analysis Strip U031-081 | 8              | 8S                     | Glucose, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes                                      |
|                                        |                | 7N                     | Glucose, Ketone, Blood, pH, Protein, Nitrite, Leukocytes                                                              |
| Mission® Urine Analysis Strip U031-071 | 7              | 6NE                    | Glucose, Blood, pH, Protein, Nitrite, Leukocytes                                                                      |
|                                        |                | 6NU                    | Bilirubin, Specific Gravity, Blood, Protein, Urobilinogen, Nitrite                                                    |
| Mission® Urine Analysis Strip U031-061 | 6              | 5BE                    | Glucose, Ketone, Blood, pH, Protein                                                                                   |
|                                        |                | 5NE                    | Glucose, Blood, Protein, Nitrite, Leukocytes                                                                          |
|                                        |                | 5SE                    | Glucose, Specific Gravity, Blood, pH, Protein                                                                         |
|                                        |                | 5UE                    | Bilirubin, Blood, Urobilinogen, Nitrite, Leukocytes                                                                   |
| Mission® Urine Analysis Strip U031-051 | 5              | 4SE                    | Glucose, Specific Gravity, pH, Protein                                                                                |
|                                        |                | 4BE                    | Glucose, Blood, pH, Protein                                                                                           |
|                                        |                | 4KE                    | Glucose, Ketone, pH, Protein                                                                                          |
|                                        |                | 4GE                    | Glucose, Blood, Protein, Leukocytes                                                                                   |
|                                        |                | 4NE                    | Blood, Protein, Nitrite, Leukocytes                                                                                   |
|                                        |                | 4PE                    | Glucose, Protein, Nitrite, Leukocytes                                                                                 |
| Mission® Urine Analysis Strip U031-031 | 3              | 3PE                    | Glucose, Blood, Protein                                                                                               |
|                                        |                | 3KE                    | Glucose, Ketone, Protein                                                                                              |
|                                        |                | 3GE                    | Glucose, Ketone, pH                                                                                                   |
|                                        |                | 3NE                    | Blood, Nitrite, Leukocytes                                                                                            |
|                                        |                | 2GE                    | Glucose, Protein                                                                                                      |
|                                        |                | 2KE                    | Glucose, Ketone                                                                                                       |
| Mission® Urine Analysis Strip U031-021 | 2              | 2NE                    | Nitrite, Leukocytes                                                                                                   |
|                                        |                | 2BE                    | Blood, Leukocytes                                                                                                     |
|                                        |                | 2UE                    | Bilirubin, Urobilinogen                                                                                               |
|                                        |                | 2SE                    | Specific Gravity, pH                                                                                                  |
|                                        |                | 1BE                    | Blood                                                                                                                 |
|                                        |                | 1PE                    | pH                                                                                                                    |
| Mission® Urine Analysis Strip U031-011 | 1              | 1GE                    | Glucose                                                                                                               |
|                                        |                | 1KE                    | Ketone                                                                                                                |
|                                        |                | 1RE                    | Protein                                                                                                               |
|                                        |                |                        |                                                                                                                       |

The Mission U500 reports the semi-quantitative or qualitative ranges listed below for each test parameter on the reagent strips.

The ranges for pH, protein, and urobilinogen differ between the Mission U500 and the visually read test strips. The analyzer can distinguish pH of 5.5 and 8.5 whereas the visual reading cannot. The sponsor provided data showing that the device can read 5.5 and 8.5 below in sections M.1.b and M.1.d. In addition, the analyzer does not read protein above 300 mg/dL, glucose above 1000 mg/dL, or urobilinogen above 8 mg/dL. These differences have been included in the labeling.

| <b>Parameter Name<br/>(Abbreviation on<br/>Display)</b> | <b>Qualitative</b>                                    | <b>Conventional<br/>Semi-<br/>quantitative</b>                  | <b>SI Semi-<br/>quantitative</b>                                |
|---------------------------------------------------------|-------------------------------------------------------|-----------------------------------------------------------------|-----------------------------------------------------------------|
| Leukocytes<br>(LEU)                                     | -<br>±<br>1+<br>2+<br>3+                              | Neg<br>15 Leu/μL<br>70 Leu/μL<br>125 Leu/μL<br>500 Leu/μL       | Neg<br>15 Leu/μL<br>70 Leu/μL<br>125 Leu/μL<br>500 Leu/μL       |
| Nitrite<br>(NIT)                                        | -<br>+                                                | N/A                                                             | N/A                                                             |
| Urobilinogen<br>(URO)                                   | -<br>±<br>1+<br>2+<br>3+                              | 0.2 mg/dL<br>1 mg/dL<br>2 mg/dL<br>4 mg/dL<br>8 mg/dL           | 3.5 μmol/L<br>17 μmol/L<br>35 μmol/L<br>70 μmol/L<br>140 μmol/L |
| Protein<br>(PRO)                                        | -<br>±<br>1+<br>2+<br>3+                              | Neg<br>15 mg/dL<br>30 mg/dL<br>100 mg/dL<br>300 mg/dL           | Neg<br>0.15 g/L<br>0.3 g/L<br>1.0 g/L<br>3.0 g/L                |
| pH                                                      | 5.0<br><br>6.0<br>6.5<br>7.0<br>7.5<br>8.0<br><br>9.0 | 5.0<br><br>5.5<br>6.0<br>6.5<br>7.0<br>7.5<br>8.0<br>8.5<br>9.0 | 5.0<br><br>5.5<br>6.0<br>6.5<br>7.0<br>7.5<br>8.0<br>8.5<br>9.0 |
| Blood<br>(BLO)                                          | -<br>±<br>1+<br>2+<br>3+                              | Neg<br>10 Ery/μL<br>25 Ery/μL<br>80 Ery/μL<br>200 Ery/μL        | Neg<br>10 Ery/μL<br>25 Ery/μL<br>80 Ery/μL<br>200 Ery/μL        |
| Specific Gravity<br>(SG)                                | 1.000<br>1.005                                        | 1.000<br>1.005                                                  | 1.000<br>1.005                                                  |

|                        |                                           |                                                          |                                                             |
|------------------------|-------------------------------------------|----------------------------------------------------------|-------------------------------------------------------------|
|                        | 1.010<br>1.015<br>1.020<br>1.025<br>1.030 | 1.010<br>1.015<br>1.020<br>1.025<br>1.030                | 1.010<br>1.015<br>1.020<br>1.025<br>1.030                   |
| Ketone<br>(KET)        | -<br>±<br>1+<br>2+<br>3+                  | Neg<br>5 mg/dL<br>15 mg/dL<br>40 mg/dL<br>80 mg/dL       | Neg<br>0.5 mmol/L<br>1.5 mmol/L<br>4.0 mmol/L<br>8.0 mmol/L |
| Bilirubin<br>(BIL)     | -<br>1+<br>2+<br>3+                       | Neg<br>1 mg/dL<br>2 mg/dL<br>4 mg/dL                     | Neg<br>17 µmol/L<br>35 µmol/L<br>70 µmol/L                  |
| Glucose<br>(GLU)       | -<br>±<br>1+<br>2+<br>3+                  | Neg<br>100 mg/dL<br>250 mg/dL<br>500 mg/dL<br>1000 mg/dL | Neg<br>5 mmol/L<br>15 mmol/L<br>30 mmol/L<br>60 mmol/L      |
| Ascorbic Acid<br>(ASC) | -<br>1+<br>2+<br>3+                       | Neg<br>10 mg/dL<br>20 mg/dL<br>40 mg/dL                  | Neg<br>0.56 mmol/L<br>1.14 mmol/L<br>2.28 mmol/L            |

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

ACON U120 Urine Analyzer

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

k070929

3. Comparison with predicate:

| <b>Similarities</b> |                                             |                                                                                                                                            |
|---------------------|---------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| Item                | Device: <b>Mission® U500 Urine Analyzer</b> | Predicate: <b>Acon U120 Urine Analyzer (k070929)</b>                                                                                       |
| Intended Use        | Same                                        | For the detection of the following analytes in urine: Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, |

| <b>Similarities</b>                  |                                             |                                                                                                                       |
|--------------------------------------|---------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| <b>Item</b>                          | <b>Device: Mission® U500 Urine Analyzer</b> | <b>Predicate: Acon U120 Urine Analyzer (k070929)</b>                                                                  |
|                                      |                                             | Urobilinogen, Leukocytes, Ascorbic Acid and Nitrite . For Prescription, In Vitro Diagnostic Use Only                  |
| Specimen                             | Same                                        | Urine                                                                                                                 |
| Methodology                          | Same                                        | Reflectance Photometer                                                                                                |
| Test strip analytes that can be read | Same                                        | pH, blood, glucose, protein, ketone, urobilinogen, bilirubin, specific gravity, nitrite, ascorbic acid and leukocytes |
| Strip Incubation Time                | Same                                        | 1 minute                                                                                                              |
| Detection                            | Same                                        | Photosensitive diode                                                                                                  |
| PC Port                              | Same                                        | Standard RS232C Port                                                                                                  |
| Analyzer Operating Conditions        | Same                                        | 0-40°C (32-104°F); ≤85% Relative Humidity                                                                             |
| Wavelength                           | Same                                        | 525nm and 635nm (nominal)                                                                                             |
| Calibration                          | Same                                        | Automatic                                                                                                             |
| Strip Incubation Time                | Same                                        | 1 minute                                                                                                              |
| Strip Operating Conditions           | Same                                        | 15-30°C (59-86°F); ≤85% Relative Humidity                                                                             |
| Capabilities                         | Same                                        | Internal printer (included)<br>External Printer Port<br>Connector Barcode Reader (optional)                           |
| Available Languages on Screen        | Same                                        | English (default), Spanish, and French                                                                                |
| Power Source                         | Same                                        | 100-240 VAC, 50-60 Hz,                                                                                                |
| Line Leakage Current                 | Same                                        | <3.5 mA (single fault)                                                                                                |

| <b>Differences</b> |                                                       |                                                                         |
|--------------------|-------------------------------------------------------|-------------------------------------------------------------------------|
| <b>Item</b>        | <b>Device: Mission® U500 Urine Analyzer</b>           | <b>Predicate: Acon U120 Urine Analyzer (k070929)</b>                    |
| Memory             | 2,000 results                                         | Last 500 results                                                        |
| Throughput         | 500 tests/hour                                        | Single Test Mode: 40 tests/hour,<br>Continuous Test Mode: 120 test/hour |
| Dimensions         | 35.5(L) x 27.4 (W) x 19.5(H) cm<br>14" x 10.8" x 7.7" | 27.1 (L) x 26.5(W) x 14.8 (H) cm                                        |
| Weight             | 4.0 kg (8.82 lbs)                                     | 2.6 kg (5.73 lbs)                                                       |
| Display Dimensions | 11.5 (W) x 9.0 (H) cm (4.5" x 3.5")                   | 10.6(W) x 2.8 (H) cm                                                    |

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

- EN 61010-1:2001 - Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements
- EN 61326-1:2006 Class A - Electrical equipment for measurement, control and laboratory use - EMC requirements. General requirements
- EN ISO 14971:2007 - Medical devices - Application of Risk management to medical devices

**L. Test Principle:**

The Mission U500 contains a Central Control Unit and Photoelectric Scanning Unit. When the urine test strip is recognized by a sensor, the strip feed motor transports the strip to a platform where it is adjusted for testing. Test strips are analyzed in the Photoelectric Scanning Unit by reflectance photometry at 525 nm and 635 nm. The signal is amplified and converted by an A/D converter. From there, the signal is sent to the Central Control Unit. The Central Control Unit functions include sending, receiving, storing and processing signals, and coordinating operation of every component of the analyzer.

The user operates the device via a touch screen which is used for all operations and for displaying test results.

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

1. Analytical performance:

a. *Precision/Reproducibility:*

Within run precision studies were performed by the sponsor using 2 commercially available urine controls at negative and positive ranges, and an ascorbic acid standard. The study was performed with three lots of urine test strips on three analyzers. Testing was performed in 10 replicates for each control level, for each lot, and on each analyzer for 10 days (n=300 per device). Within run and total precision for each device was 100% exact agreement. The results are summarized below:

| Analyte          | Control Level 1 | Analyzer A Results (n) | Analyzer B Results (n) | Analyzer C Results (n) | % Agreement |
|------------------|-----------------|------------------------|------------------------|------------------------|-------------|
| Glucose          | Neg             | Neg (300)              | Neg (300)              | Neg (300)              | 100%        |
| Bilirubin        | Neg             | Neg (300)              | Neg (300)              | Neg (300)              | 100%        |
| Ketone           | Neg             | Neg (300)              | Neg (300)              | Neg (300)              | 100%        |
| Specific Gravity | 1.010 - 1.020   | 1.010 (300)            | 1.010 (300)            | 1.010 (300)            | 100%        |
| Blood            | Neg             | Neg (300)              | Neg (300)              | Neg (300)              | 100%        |
| pH               | 6.0 – 7.0       | 6.0 (300)              | 6.0 (300)              | 6.0 (300)              | 100%        |
| Protein          | Neg             | Neg (300)              | Neg (300)              | Neg (300)              | 100%        |
| Urobilinogen     | 0.2 – 1.0       | 0.2 (300)              | 0.2 (300)              | 0.2 (300)              | 100%        |
| Nitrite          | Neg             | Neg (300)              | Neg (300)              | Neg (300)              | 100%        |

|               |     |           |           |           |      |
|---------------|-----|-----------|-----------|-----------|------|
| Leukocytes    | Neg | Neg (300) | Neg (300) | Neg (300) | 100% |
| Ascorbic Acid | Neg | Neg (300) | Neg (300) | Neg (300) | 100% |

| Analyte       | Conc. (mg/dL) | Analyzer A Results (n) | Analyzer B Results (n) | Analyzer C Results (n) | % Agreement |
|---------------|---------------|------------------------|------------------------|------------------------|-------------|
| Ascorbic Acid | 20            | 20 (300)               | 20 (300)               | 20 (300)               | 100%        |

| Analyte          | Control Level 2 | Analyzer A Results (n) | Analyzer B Results (n) | Analyzer C Results (n) | % Agreement |
|------------------|-----------------|------------------------|------------------------|------------------------|-------------|
| Glucose          | 250 - 2000      | 500 (300)              | 500 (300)              | 500 (300)              | 100%        |
| Bilirubin        | Mod. - Large    | Large (300)            | Large (300)            | Large (300)            | 100%        |
| Ketone           | 5 - 40          | 15 (300)               | 15 (300)               | 15 (300)               | 100%        |
| Specific Gravity | 1.015 – 1.025   | 1.020 (300)            | 1.020 (300)            | 1.020 (300)            | 100%        |
| Blood            | Mod. - Large    | Large (300)            | Large (300)            | Large (300)            | 100%        |
| pH               | 6.5 – 7.5       | 7.0 (300)              | 7.0 (300)              | 7.0 (300)              | 100%        |
| Protein          | 30 -300         | 300 (300)              | 300 (300)              | 300 (300)              | 100%        |
| Urobilinogen     | 4.0 - 8.0       | 8.0 (300)              | 8.0 (300)              | 8.0 (300)              | 100%        |
| Nitrite          | Positive        | Pos (300)              | Pos (300)              | Pos (300)              | 100%        |
| Leukocytes       | 70 – 500        | 500 (300)              | 500 (300)              | 500 (300)              | 100%        |

Precision studies were also performed by the two intended users at three point-of-care sites using 3 levels of contrived samples on 3 Mission U500 with 3 lots of test strips. Each operator tested contrived samples at three levels: negative, low positive and high positive using the Mission U500 and the ACON U120. Ascorbic acid was prepared in negative urine and spiked to the target concentrations. The contrived samples consisted of a set of coded samples with 3 target values for each analyte at negative, low positive (with the expected result “+/- to +”), and high positive (with the expected result “2+ to 3+”), or 3 target values at low, middle and high for specific gravity. For pH, all contrived solutions were prepared without pH adjustment, with pH range from 5.5 to 7. Results with pH from 2 solutions were analyzed with pH 5.5 and 7. Testing was conducted twice a day for 20 days. Total of 40 replicates for each level of the solution were performed by each operator (n=240). Precision was evaluated as follows for each color block:

Agreement% of same block compared to Expected Result = (number of testing results from Mission® U500 at the same block / number of expected results at the same block) x 100%.

| Sample   | Negative                |                                | Low Positive            |                                | High positive           |                                |
|----------|-------------------------|--------------------------------|-------------------------|--------------------------------|-------------------------|--------------------------------|
|          | % Agreement within same | % Agreement within +/- 1 block | % Agreement within same | % Agreement within +/- 1 block | % Agreement within same | % Agreement within +/- 1 block |
| Analytes |                         |                                |                         |                                |                         |                                |

|                  | block              |                   | block               |                     | block               |                   |
|------------------|--------------------|-------------------|---------------------|---------------------|---------------------|-------------------|
| Leukocyte        | 240/240<br>(100%)  | 240/240<br>(100%) | 240/240<br>(100%)   | 240/240<br>(100%)   | 240/240<br>(100%)   | 240/240<br>(100%) |
| Nitrite          | 240/240<br>(100%)  | 240/240<br>(100%) | 240/240<br>(100%)   | 240/240<br>(100%)   | 240/240<br>(100%)   | 240/240<br>(100%) |
| Urobilinogen     | 240/240<br>(100%)  | 240/240<br>(100%) | 217/240<br>(90.42%) | 240/240<br>(100%)   | 240/240<br>(100%)   | 240/240<br>(100%) |
| Protein          | 240/240<br>(100%)  | 240/240<br>(100%) | 236/240<br>(98.33%) | 240/240<br>(100%)   | 235/240<br>(97.92%) | 240/240<br>(100%) |
| pH               | N/A                | N/A               | 225/240<br>(93.75%) | 240/240<br>(100%)   | 231/240<br>(96.25%) | 240/240<br>(100%) |
| Blood            | 240/240<br>(100%)  | 240/240<br>(100%) | 207/240<br>(86.25%) | 240/240<br>(100%)   | 240/240<br>(100%)   | 240/240<br>(100%) |
| Specific gravity | 223/240<br>(92.9%) | 240/240<br>(100%) | 199/240<br>(82.92%) | 240/240<br>(100%)   | 178/240<br>(74.17%) | 240/240<br>(100%) |
| Ketone           | 240/240<br>(100%)  | 240/240<br>(100%) | 236/240<br>(98.33%) | 240/240<br>(100%)   | 232/240<br>(96.67%) | 240/240<br>(100%) |
| Bilirubin        | 240/240<br>(100%)  | 240/240<br>(100%) | 239/240<br>(99.58%) | 239/240<br>(99.58%) | 239/240<br>(99.58%) | 240/240<br>(100%) |
| Glucose          | 240/240<br>(100%)  | 240/240<br>(100%) | 240/240<br>(100%)   | 240/240<br>(100%)   | 240/240<br>(100%)   | 240/240<br>(100%) |
| Ascorbic acid    | 240/240<br>(100%)  | 240/240<br>(100%) | 233/240<br>(97.08%) | 240/240<br>(100%)   | 236/240<br>(98.33%) | 240/240<br>(100%) |

*b. Linearity/assay reportable range:*

The sponsor validated the reportable range for each color block by using negative urine samples spiked with commercially available reagents to the specific concentrations corresponding to the color chart for each of the 11 analytes on the Mission Urinalysis Reagent Strips. The negative urine samples and the spiked positive samples (except ascorbic acid, pH and specific gravity) were confirmed by Bayer Multistix 10 SG Reagent Strips and the Bayer Clinitek U500 Urine Analyzer. The concentration of ascorbic acid was confirmed with the predicate, the ACON U120 Urine Analyzer.

Each sample was tested with three lots of Mission Urinalysis Reagent Strips and 3 Mission® U500 Urine Analyzers. Each sample was tested in 5 replicates with each lot of urine test strips and analyzer for three consecutive days following the product insert. A total of 135 strips were used for each concentration tested (3 Analyzers x 3 days x 5 strips x 3 lot strips = 135 strips). Sensitivity was calculated as the number of exact color block on the Mission U500 / the total number of samples tested at the same expected value X 100%. Sensitivity was also calculated for within ± 1 color block using the same formula above, except tabulating the number of samples within 1 color block. All results matched 100% between the new device and the expected results across the measuring range for each test pad. The measuring range for each assay is listed below in semi-quantitative and qualitative units. pH was confirmed by

pH meter and specific gravity was confirmed by refractometry.

The reportable ranges for protein, glucose, urobilinogen, and ketone are lower by one color block for the Mission U500 than for the visual read reportable ranges for the Mission Urinalysis Reagent Strips. In addition, the reportable range for pH includes 5.5 and 8.5 which are not included for visual reading of the test strips.

| Analyte          | Semi-Quantitative Detection Range of Mission® U500 Urine Analyzer | Corresponding Qualitative Detection Range of Mission® U500 Urine Analyzer |
|------------------|-------------------------------------------------------------------|---------------------------------------------------------------------------|
| Glucose          | 0, 100, 250, 500, 1000 mg/dL                                      | Not applicable—semi-quantitative only                                     |
| Bilirubin        | 0, 1, 2, 4 mg/dL                                                  | Neg, +, ++, +++                                                           |
| Ketone           | 0, 5, 15, 40, 80 mg/dL                                            | Neg, ±, +, ++, +++                                                        |
| Blood            | 0, 10, 25, 80, 200 Ery/µL                                         | Neg, ±, +, ++, +++                                                        |
| Protein          | 0, 15, 30, 100, 300 mg/dL                                         | Neg, ±, +, ++, +++                                                        |
| Urobilinogen     | 0.2, 1, 2, 4, 8 mg/dL                                             | Not applicable—semi-quantitative only                                     |
| Nitrite          | Not applicable-qualitative only                                   | Negative, Positive                                                        |
| Leukocyte        | 0, 15, 70, 125, 500 Leu/µL                                        | Neg, ±, +, ++, +++                                                        |
| Ascorbic Acid    | 0, 10, 20, 40 mg/dL                                               | Neg, +, ++, +++                                                           |
| pH               | 5, 5.5, 6, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0                           | Not applicable—semi-quantitative only                                     |
| Specific Gravity | 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030                   | Not applicable—semi-quantitative only                                     |

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

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.

Temperature and humidity operating conditions were evaluated for the test strips and the analyzer at temperatures ranging from -2°C to 45°C for the analyzer and 15°C to 30°C for the test strips and relative humidity from 10% to 90%. Extreme temperatures and humidity conditions combinations were tested as follows:

| Analyzer temp/RH | Test Strip temp/RH |
|------------------|--------------------|
| -2°C/10%         | 15°C/10%           |
| -2°C/10%         | 15°C/90%           |
| -2°C/90%         | 15°C/10%           |
| -2°C/90%         | 15°C/90%           |
| 45°C/10%         | 30°C/10%           |
| 45°C/10%         | 30°C/90%           |
| 45°C/90%         | 30°C/10%           |
| 45°C/90%         | 30°C/90%           |

Protocol and acceptance criteria were provided and found to be acceptable. The results supported the sponsor's claimed operating temperature for the Mission U500 analyzer of -2° C to 45° C (28.4° F to 113° F) with relative humidity ranging from 10-90% and test strip operating conditions of 15-30° C (59° F to 86° F) and relative humidity range from 10% to 90%.

Stability studies for the Mission Urinalysis Reagent Strips were conducted in k061559.

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.
- Test the strips monthly that are stored for more than 30 days.
- Run QC tests to ensure reagent storage integrity; train new users; confirm test performance; and when patients' clinical conditions or symptoms do not match the results obtained on the test strips.

*d. Detection limit:*

Expected cutoffs for each color block were determined by adding the expected values of the color block and the immediate lower color block and dividing by 2. The analytical sensitivity for each color block was determined by using commercially available materials and preparing standard solutions in negative human urine at the expected cutoff concentration for each color block. Aliquots of each sample were then diluted to 110% and 90% of the cutoff. The analytical sensitivity for each color block for each analyte is defined by the sponsor as the lowest concentration at which over 55% of the test results are positive. If less than 55% positive results are achieved at 110% or 90% cutoff, then samples were diluted until > 55% sensitivity were obtained. Further dilutions were made for ascorbic acid, glucose, bilirubin, ketone, blood, protein, urobilinogen, and leukocytes. See the tables below.

| <b>Target Ascorbic Acid Concentration per color block</b> | <b>Cutoff concentration</b> | <b>% Sensitivity</b> |
|-----------------------------------------------------------|-----------------------------|----------------------|
| <b>10</b>                                                 | 8 mg/dL*                    | 79.26                |
| <b>20</b>                                                 | 16.5 mg/dL                  | 71.1                 |
| <b>40</b>                                                 | 33 mg/dL                    | 59.26                |

\*160% cutoff

| <b>Target Glucose Concentration per color block</b> | <b>Cutoff concentration</b> | <b>% Sensitivity</b> |
|-----------------------------------------------------|-----------------------------|----------------------|
| <b>100 mg/dL</b>                                    | 80 mg/dL*                   | 68.15                |
| <b>250 mg/dL</b>                                    | 192.5 mg/dL                 | 57.78                |
| <b>500 mg/dL</b>                                    | 412.5 mg/dL                 | 69.63                |

|                   |           |       |
|-------------------|-----------|-------|
| <b>1000 mg/dL</b> | 825 mg/dL | 60.74 |
|-------------------|-----------|-------|

\*160% cutoff

| <b>Target Bilirubin Concentration per color block</b> | <b>Cutoff concentration</b> | <b>% Sensitivity</b> |
|-------------------------------------------------------|-----------------------------|----------------------|
| <b>1 mg/dL</b>                                        | 0.8 mg/dL*                  | 82.96                |
| <b>2 mg/dL</b>                                        | 1.65 mg/dL                  | 77.78                |
| <b>4 mg/dL</b>                                        | 3.3 mg/dL                   | 79.26                |

\*160% cutoff

| <b>Target Ketone Concentration per color block</b> | <b>Cutoff concentration</b> | <b>% Sensitivity</b> |
|----------------------------------------------------|-----------------------------|----------------------|
| <b>5 mg/dL</b>                                     | 4 mg/dL*                    | 82.22                |
| <b>15 mg/dL</b>                                    | 11 mg/dL                    | 72.59                |
| <b>40 mg/dL</b>                                    | 30.25 mg/dL                 | 65.19                |
| <b>80 mg/dL</b>                                    | 66 mg/dL                    | 64.44                |

\*160% cutoff

| <b>Target Blood Concentration per color block</b> | <b>Cutoff concentration</b> | <b>% Sensitivity</b> |
|---------------------------------------------------|-----------------------------|----------------------|
| <b>5-10 Ery/micL</b>                              | 5 Ery/micL*                 | 57.04                |
| <b>25 Ery/micL</b>                                | 19.25 Ery/micL              | 67.41                |
| <b>80 Ery/micL</b>                                | 57.75 Ery/micL              | 62.96                |
| <b>200 Ery/micL</b>                               | 154 Ery/micL                | 82.96                |

\*100% of cutoff

| <b>Target Protein Concentration per color block</b> | <b>Cutoff concentration</b> | <b>% Sensitivity</b> |
|-----------------------------------------------------|-----------------------------|----------------------|
| <b>15 mg/dL</b>                                     | 12 mg/dL*                   | 85.93                |
| <b>30 mg/dL</b>                                     | 24.75 mg/dL                 | 66.67                |
| <b>100 mg/dL</b>                                    | 77 mg/dL                    | 69.93                |
| <b>300 mg/dL</b>                                    | 220 mg/dL                   | 83.70                |

\*160% cutoff

| <b>Target Urobilinogen Concentration per color block</b> | <b>Cutoff concentration</b> | <b>% Sensitivity</b> |
|----------------------------------------------------------|-----------------------------|----------------------|
| <b>0.2</b>                                               | 0.2                         | 100                  |
| <b>1</b>                                                 | 0.8 mg/dL*                  | 68.89                |
| <b>2</b>                                                 | 1.65 mg/dL                  | 58.52                |
| <b>4</b>                                                 | 3.3 mg/dL                   | 59.26                |
| <b>8</b>                                                 | 6.6 mg/dL                   | 55.56                |

\*133% cutoff

| <b>Target Nitrite Concentration per color block</b> | <b>Cutoff concentration</b> | <b>% Sensitivity</b> |
|-----------------------------------------------------|-----------------------------|----------------------|
| <b>Pos</b>                                          | 0.05 mg/dL                  | 60                   |

| <b>Target Leukocyte Concentration per color block</b> | <b>Cutoff concentration</b> | <b>% Sensitivity</b> |
|-------------------------------------------------------|-----------------------------|----------------------|
| <b>15 Leu/micL</b>                                    | 12 Leu/micL*                | 71.1                 |

|                     |                 |       |
|---------------------|-----------------|-------|
| <b>70 Leu/micL</b>  | 46.75 Leu/micL  | 65.93 |
| <b>125 Leu/micL</b> | 107.25 Leu/micL | 59.26 |
| <b>500 Leu/micL</b> | 343.75 Leu/micL | 76.30 |

\*160% cutoff

| <b>Target pH Concentration per color block</b> | <b>Cutoff concentration</b> | <b>% Sensitivity</b> |
|------------------------------------------------|-----------------------------|----------------------|
| <b>5.0</b>                                     | 5.0                         | 100                  |
| <b>5.5</b>                                     | 5.5                         | 100                  |
| <b>6.0</b>                                     | 6.0                         | 100                  |
| <b>6.5</b>                                     | 6.5                         | 100                  |
| <b>7.0</b>                                     | 7.0                         | 100                  |
| <b>7.5</b>                                     | 7.5                         | 100                  |
| <b>8.0</b>                                     | 8.0                         | 91.85                |
| <b>8.5</b>                                     | 8.5                         | 92.59                |
| <b>9.0</b>                                     | 9.0                         | 86.67                |

| <b>Target Specific Gravity Concentration per color block</b> | <b>Cutoff concentration</b> | <b>% Sensitivity</b> |
|--------------------------------------------------------------|-----------------------------|----------------------|
| <b>1.000</b>                                                 | 1.000                       | 100                  |
| <b>1.005</b>                                                 | 1.005                       | 97.04                |
| <b>1.010</b>                                                 | 1.010                       | 100                  |
| <b>1.015</b>                                                 | 1.015                       | 100                  |
| <b>1.020</b>                                                 | 1.020                       | 99.26                |
| <b>1.025</b>                                                 | 1.025                       | 100                  |
| <b>1.030</b>                                                 | 1.030                       | 100                  |

The lowest concentrations detected for pH is 5.0 and specific gravity is 1.000. To determine the minimum concentrations for pH and specific gravity where the tests change from the minimum concentration (5 and 1.000) to the next higher concentrations, the sponsor spiked urine with commercially available reagents to obtain concentrations of 5, 5.2, 5.4, 5.5, 5.6, 5.8, and 6 for pH, and 1.002, 1.004, 1.005 for specific gravity. The solutions for pH and specific gravity were confirmed using a pH meter and a refractometer, respectively. The minimum sensitivity was defined as the concentration where >55% of the results are positive for the next higher color block. The minimum sensitivity for pH 5.5 is 5.4 (87.4% positive) and minimum sensitivity for specific gravity 1.005 is 1.004 (96.3% positive).

*e. Analytical specificity:*

3 negative human urine pools were obtained. Two pools were spiked with test strip analytes (pH, glucose, etc.) at 2 concentrations; one that yielded positive for the first color block and the second at a 2+ or 3+ concentration. The concentration of each analyte was confirmed with the Bayer Clinitek 500 urine analyzer. The negative and two positive urine samples were then spiked with two different concentrations of potential interferents and the results compared to samples without the interferent(s).

Interference was defined as any result other than 100% concurrence with the non-spiked control samples. The following substances were evaluated for interference: lithium, ammonium chloride, albumin, ascorbic acid, bilirubin, calcium chloride, citric acid, creatine, creatinine, fructose, galactose, glucose, glycine, hemoglobin, lactose, KCl, NaCl, oxalic acid, phenolphthalein, riboflavin, sodium bicarbonate, sodium nitrate, sodium 2-mercaptoethane sulfonate (Mesna), sodium nitrite, sodium phosphate, theophylline, and urea. The interferents and affected tests are summarized below:

| Interference Substances       | Level II Conc. Tested (Mg/dl) | Effect of Interference Substances at the lowest concentration to the Testing Results |                             |                                                    |                            |                             |                            |                            |                                           |                           |
|-------------------------------|-------------------------------|--------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------------|----------------------------|-----------------------------|----------------------------|----------------------------|-------------------------------------------|---------------------------|
|                               |                               | Leu                                                                                  | Nit                         | Uro                                                | Pro                        | Blo                         | Ket                        | Bil                        | Glu                                       | ASC                       |
| Acetoacetic Acid              | 250                           | no                                                                                   | no                          | no                                                 | no                         | no                          | no                         | no                         | False negative at 120 mg/dl               | no                        |
| Albumin                       | 5,000                         | no                                                                                   | no                          | no                                                 | no                         | no                          | no                         | no                         | no                                        | no                        |
| Ammonium Chloride             | 500                           | no                                                                                   | no                          | no                                                 | no                         | no                          | no                         | no                         | no                                        | no                        |
| Ascorbic Acid                 | 200                           | no                                                                                   | False negative at 30 mg/dl  | no                                                 | no                         | False negative at 35 mg/dl  | no                         | False negative at 30 mg/dl | False negative at 25mg/dl                 | no                        |
| Bilirubin                     | 170                           | False Positive at 130mg/dl                                                           | False Positive at 65mg/dl   | False increase on 1 <sup>st</sup> block at 65mg/dl | No                         | No                          | False Positive at 130mg/dl | N/A                        | False Positive at 170mg/dl                | No                        |
| Calcium Chloride              | 275                           | no                                                                                   | no                          | no                                                 | no                         | no                          | no                         | no                         | no                                        | no                        |
| Citric Acid                   | 75                            | no                                                                                   | no                          | no                                                 | no                         | no                          | no                         | no                         | no                                        | no                        |
| Creatine                      | 10                            | no                                                                                   | no                          | no                                                 | no                         | no                          | no                         | no                         | no                                        | no                        |
| Creatinine                    | 600                           | no                                                                                   | no                          | no                                                 | no                         | no                          | no                         | no                         | no                                        | no                        |
| Fructose                      | 100                           | no                                                                                   | no                          | no                                                 | no                         | no                          | no                         | no                         | no                                        | no                        |
| Galactose                     | 80                            | no                                                                                   | no                          | no                                                 | no                         | no                          | no                         | no                         | no                                        | no                        |
| Glucose                       | 5000                          | False negative at 4000mg/dl                                                          | no                          | no                                                 | no                         | no                          | no                         | no                         | no                                        | no                        |
| Glycine                       | 450                           | no                                                                                   | no                          | no                                                 | no                         | no                          | no                         | no                         | no                                        | no                        |
| Hemoglobin                    | 1000                          | False Positive at 200mg/dl                                                           | False Positive at 200mg/dl  | False Positive at 800mg/dl                         | False Positive at 200mg/dl | N/A                         | False Positive at 800mg/dl | False Positive at 800mg/dl | False increase on "+/-" block at 800mg/dl | no                        |
| Lactose                       | 10                            | no                                                                                   | no                          | no                                                 | no                         | no                          | no                         | no                         | no                                        | no                        |
| KCl                           | 1500                          | no                                                                                   | no                          | no                                                 | no                         | no                          | no                         | no                         | no                                        | no                        |
| NaCl                          | 5500                          | no                                                                                   | no                          | no                                                 | no                         | no                          | no                         | no                         | no                                        | no                        |
| Oxalic acid                   | 70                            | no                                                                                   | no                          | no                                                 | no                         | no                          | no                         | no                         | no                                        | no                        |
| Phenolphthalein               | 1200                          | no                                                                                   | no                          | no                                                 | no                         | no                          | no                         | no                         | no                                        | no                        |
| Riboflavin                    | 10                            | False negative at 10mg/dl                                                            | False negative at 10mg/dl   | no                                                 | no                         | False negative at 5mg/dl    | no                         | no                         | no                                        | no                        |
| Sodium bicarbonate            | 1500                          | no                                                                                   | False negative at 1000mg/dl | no                                                 | no                         | False negative at 1500mg/dl | no                         | no                         | no                                        | no                        |
| Sodium nitrate                | 10                            | no                                                                                   | no                          | no                                                 | no                         | no                          | no                         | no                         | no                                        | no                        |
| Sodium nitrite                | 10                            | no                                                                                   | no                          | no                                                 | no                         | no                          | no                         | no                         | no                                        | no                        |
| Sodium phosphate              | 500                           | no                                                                                   | no                          | no                                                 | no                         | no                          | no                         | no                         | no                                        | no                        |
| Theophylline                  | 100                           | no                                                                                   | no                          | no                                                 | no                         | no                          | no                         | no                         | no                                        | no                        |
| Urea                          | 4000                          | no                                                                                   | no                          | no                                                 | no                         | no                          | no                         | no                         | no                                        | no                        |
| Sodium mercaptoethane (Mesna) | 530                           | no                                                                                   | no                          | no                                                 | no                         | False negative at 250mg/dl  | False positive at 10mg/dl  | False negative at 250mg/dl | False negative at 250mg/dl                | False positive at 10mg/dl |

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

307 urine samples were collected from 3 physician office laboratory (POL) sites from patients with Type 1, Type 2, or gestational diabetes, experiencing urinary tract infection (UTI) symptoms, with liver disease, with kidney disease, other disease, and patients who were undergoing routine physical examinations. Samples were coded and 3 operators at each site (N=9) tested the samples on the new device and the predicate. Three analyzers and three test strip lots were used during the study. The combined results from the three sites are summarized below. Both the semi-quantitative and qualitative values are given.

A fourth site (n=167) was added in order to increase the number of positive samples for urobilinogen, bilirubin, nitrite, ketone, and glucose. Samples were analyzed by 3 users at that site and the patient population was similar to POL sites. Results are summarized separately below. Both the semi-quantitative and qualitative values are given.

**1) Combined sites 1-3 (n=307):**

|                  |          | Leukocyte cells/micL | Predicate device |        |        |        |     |
|------------------|----------|----------------------|------------------|--------|--------|--------|-----|
|                  |          |                      | 0                | 15     | 70     | 125    | 500 |
| Proposed device  | 0 (-)    | 205                  |                  |        |        |        |     |
|                  | 15 (±)   |                      | 40               |        |        |        |     |
|                  | 70 (1+)  |                      | 10               | 11     | 3      |        |     |
|                  | 125 (2+) |                      |                  | 1      | 21     | 1      |     |
|                  | 500 (3+) |                      |                  |        | 3      | 12     |     |
| Total            |          | 205                  | 50               | 12     | 27     | 13     |     |
| % exact match    |          | 100%                 | 80%              | 91.67% | 77.78% | 92.31% |     |
| % ±1 color block |          | 100%                 | 100%             | 100%   | 100%   | 100%   |     |

|                  |              | Nitrite | Predicate device |          |
|------------------|--------------|---------|------------------|----------|
|                  |              |         | Negative         | Positive |
| Proposed device  | Negative (-) | 293     |                  |          |
|                  | Positive (+) |         | 14               |          |
| Total            |              | 293     | 14               |          |
| % exact match    |              | 100%    | 100%             |          |
| % ±1 color block |              | 100%    | 100%             |          |

|                 |     | Urobilinogen mg/dL | Predicate device |   |   |   |   |
|-----------------|-----|--------------------|------------------|---|---|---|---|
|                 |     |                    | 0.2              | 1 | 2 | 4 | 8 |
| Proposed device | 0.2 | 293                |                  |   |   |   |   |
|                 | 1   | 1                  | 10               |   |   |   |   |
|                 | 2   |                    |                  |   |   |   |   |

|                         |          |        |      |      |      |    |
|-------------------------|----------|--------|------|------|------|----|
|                         | <b>4</b> |        |      | 1    | 1    |    |
|                         | <b>8</b> |        |      |      | 1    |    |
| <b>Total</b>            |          | 294    | 10   | 1    | 2    | 0  |
| <b>% exact match</b>    |          | 99.66% | 100% | 0    | 50%  | NA |
| <b>% ±1 color block</b> |          | 99.66% | 100% | 100% | 100% | NA |

|                         |          | Protein<br>mg/dL | Predicate device |        |      |     |      |
|-------------------------|----------|------------------|------------------|--------|------|-----|------|
|                         |          |                  | 0                | 15     | 30   | 100 | 300  |
| Proposed<br>device      | 0 (-)    | 216              |                  |        |      |     |      |
|                         | 15 (±)   | 1                | 46               | 2      |      |     |      |
|                         | 30 (1+)  |                  | 2                | 25     |      |     |      |
|                         | 100 (2+) |                  |                  | 1      | 8    |     |      |
|                         | 300 (3+) |                  |                  |        |      |     | 6    |
| <b>Total</b>            |          | 217              | 48               | 28     | 8    |     | 6    |
| <b>% exact match</b>    |          | 99.54%           | 95.83%           | 89.29% | 100% |     | 100% |
| <b>% ±1 color block</b> |          | 99.54%           | 100%             | 100%   | 100% |     | 100% |

|                         |          | Blood<br>cells/micL | Predicate device |        |        |    |        |
|-------------------------|----------|---------------------|------------------|--------|--------|----|--------|
|                         |          |                     | 0                | 10     | 25     | 80 | 200    |
| Proposed<br>device      | 0 (-)    | 186                 |                  |        |        |    |        |
|                         | 10 (±)   |                     | 33               | 5      |        |    |        |
|                         | 25 (1+)  |                     | 5                | 34     | 1      |    |        |
|                         | 80 (2+)  |                     |                  | 3      | 9      | 3  |        |
|                         | 200 (3+) |                     |                  |        |        | 3  | 25     |
| <b>Total</b>            |          | 186                 | 38               | 42     | 13     |    | 28     |
| <b>% exact match</b>    |          | 100%                | 86.84%           | 80.95% | 69.23% |    | 89.29% |
| <b>% ±1 color block</b> |          | 100%                | 100%             | 100%   | 100%   |    | 100%   |

|                         |         | Ketone<br>mg/dL | Predicate device |      |      |    |    |
|-------------------------|---------|-----------------|------------------|------|------|----|----|
|                         |         |                 | 0                | 5    | 15   | 40 | 80 |
| Proposed<br>device      | 0 (-)   | 277             | 1                |      |      |    |    |
|                         | 5 (±)   | 2               | 17               |      |      |    |    |
|                         | 15 (1+) |                 |                  | 9    |      |    |    |
|                         | 40 (2+) |                 |                  |      | 1    |    |    |
|                         | 80 (3+) |                 |                  |      |      |    |    |
| <b>Total</b>            |         | 279             | 18               | 9    | 1    |    | 0  |
| <b>% exact match</b>    |         | 99.28%          | 94.44%           | 100% | 100% |    | NA |
| <b>% ±1 color block</b> |         | 99.28%          | 94.44%           | 100% | 100% |    | NA |

|                    |        | Bilirubin<br>mg/dL | Predicate device |      |    |   |
|--------------------|--------|--------------------|------------------|------|----|---|
|                    |        |                    | 0                | 1    | 2  | 4 |
| Proposed<br>device | 0 (-)  | 296                |                  |      |    |   |
|                    | 1 (1+) |                    | 7                | 1    |    |   |
|                    | 2 (2+) |                    |                  | 3    |    |   |
|                    | 4 (+3) |                    |                  |      |    |   |
| Total              |        | 296                | 7                | 4    | 0  |   |
| % exact match      |        | 100%               | 100%             | 75%  | NA |   |
| % ±1 color block   |        | 100%               | 100%             | 100% | NA |   |

|                    |           | Glucose<br>mg/dL | Predicate device |      |      |        |      |
|--------------------|-----------|------------------|------------------|------|------|--------|------|
|                    |           |                  | 0                | 100  | 250  | 500    | 1000 |
| Proposed<br>device | 0 (-)     | 278              | 1                |      |      |        |      |
|                    | 100 (±)   |                  | 11               | 1    |      |        |      |
|                    | 250 (1+)  |                  |                  | 1    |      |        |      |
|                    | 500 (2+)  |                  |                  |      | 2    | 1      |      |
|                    | 1000 (3+) |                  |                  |      |      | 12     |      |
| Total              |           | 278              | 12               | 2    | 2    | 13     |      |
| % exact match      |           | 100%             | 91.67%           | 50%  | 100% | 92.31% |      |
| % ±1 color block   |           | 100%             | 91.67%           | 100% | 100% | 100%   |      |

|                    |         | Ascorbic Acid<br>mg/dL | Predicate device |        |      |    |
|--------------------|---------|------------------------|------------------|--------|------|----|
|                    |         |                        | 0                | 10     | 20   | 40 |
| Proposed<br>device | 0 (-)   | 212                    |                  |        |      |    |
|                    | 10 (1+) |                        | 43               | 7      |      |    |
|                    | 20 (2+) |                        |                  | 6      |      |    |
|                    | 40 (3+) |                        |                  | 1      | 38   |    |
| Total              |         | 212                    | 43               | 14     | 38   |    |
| % exact match      |         | 100%                   | 100%             | 42.86% | 100% |    |
| % ±1 color block   |         | 100%                   | 100%             | 100%   | 100% |    |

|                    |     | pH | Predicate device |     |     |     |     |     |     |     |
|--------------------|-----|----|------------------|-----|-----|-----|-----|-----|-----|-----|
|                    |     |    | 5.0              | 5.5 | 6.0 | 6.5 | 7.0 | 7.5 | 8.0 | 8.5 |
| Proposed<br>device | 5.0 | 7  | 2                |     |     |     |     |     |     |     |
|                    | 5.5 | 17 | 34               | 11  |     |     |     |     |     |     |
|                    | 6.0 | 4  | 26               | 63  | 1   |     |     |     |     |     |
|                    | 6.5 |    |                  | 35  | 43  | 5   |     |     |     |     |

|                         |            |       |       |       |      |       |       |      |      |   |
|-------------------------|------------|-------|-------|-------|------|-------|-------|------|------|---|
|                         | <b>7.0</b> |       |       | 2     | 6    | 26    | 2     |      |      |   |
|                         | <b>7.5</b> |       |       |       |      | 3     | 13    | 4    |      |   |
|                         | <b>8.0</b> |       |       |       |      |       |       | 1    | 1    |   |
|                         | <b>8.5</b> |       |       |       |      |       |       |      | 1    |   |
|                         | <b>9.0</b> |       |       |       |      |       |       |      |      |   |
| <b>Total</b>            |            | 28    | 62    | 111   | 50   | 34    | 15    | 5    | 2    | 0 |
| <b>% exact match</b>    |            | 25%   | 54.8% | 56.8% | 86%  | 76.5% | 86.7% | 20%  | 50%  |   |
| <b>% ±1 color block</b> |            | 85.7% | 100%  | 100%  | 100% | 100%  | 100%  | 100% | 100% |   |

|                         |              | Specific gravity | Predicate device |       |       |       |       |       |       |  |
|-------------------------|--------------|------------------|------------------|-------|-------|-------|-------|-------|-------|--|
|                         |              |                  | 1.000            | 1.005 | 1.010 | 1.015 | 1.020 | 1.025 | 1.030 |  |
| <b>Proposed device</b>  | <b>1.000</b> |                  |                  |       |       |       |       |       |       |  |
|                         | <b>1.005</b> | 3                | 15               | 2     | 1     |       |       |       |       |  |
|                         | <b>1.010</b> |                  | 1                | 21    | 12    |       |       |       |       |  |
|                         | <b>1.015</b> |                  | 1                | 8     | 72    | 22    |       |       | 1     |  |
|                         | <b>1.020</b> |                  |                  |       | 11    | 21    | 7     |       |       |  |
|                         | <b>1.025</b> |                  |                  |       |       | 15    | 31    | 11    |       |  |
|                         | <b>1.030</b> |                  |                  |       |       |       |       |       | 46    |  |
| <b>Total</b>            |              | 3                | 17               | 31    | 96    | 58    | 44    | 58    |       |  |
| <b>% exact match</b>    |              | 0%               | 88.2%            | 67.7% | 75%   | 36.2% | 70.5% | 79.3% |       |  |
| <b>% ±1 color block</b> |              | 100%             | 100%             | 100%  | 98.9% | 100%  | 100%  | 98.3% |       |  |

2) Site 4 (n=167):

|                         |                 | Leukocyte cells/micL | Predicate device |     |     |     |     |
|-------------------------|-----------------|----------------------|------------------|-----|-----|-----|-----|
|                         |                 |                      | 0                | 15  | 70  | 125 | 500 |
| <b>Proposed device</b>  | <b>0 (-)</b>    | 149                  |                  |     |     |     |     |
|                         | <b>15 (±)</b>   |                      | 10               |     |     |     |     |
|                         | <b>70 (1+)</b>  |                      |                  | 2   |     |     |     |
|                         | <b>125 (2+)</b> |                      |                  |     | 1   |     |     |
|                         | <b>500 (3+)</b> |                      |                  |     |     | 1   | 4   |
| <b>Total</b>            |                 | 149                  |                  |     |     |     |     |
| <b>% exact match</b>    |                 | 100                  | 100              | 100 | 50  | 100 |     |
| <b>% ±1 color block</b> |                 | 100                  | 100              | 100 | 100 | 100 |     |

|                 |                     | Nitrite | Predicate device |          |
|-----------------|---------------------|---------|------------------|----------|
|                 |                     |         | Negative         | Positive |
| <b>Proposed</b> | <b>Negative (-)</b> | 119     |                  |          |

|                         |                     |     |     |
|-------------------------|---------------------|-----|-----|
| <b>device</b>           | <b>Positive (+)</b> |     | 48  |
| <b>Total</b>            |                     | 119 | 48  |
| <b>% exact match</b>    |                     | 100 | 100 |
| <b>% ±1 color block</b> |                     | 100 | 100 |

| <b>Urobilinogen<br/>mg/dL</b> |            | <b>Predicate device</b> |          |          |          |          |
|-------------------------------|------------|-------------------------|----------|----------|----------|----------|
|                               |            | <b>0.2</b>              | <b>1</b> | <b>2</b> | <b>4</b> | <b>8</b> |
| <b>Proposed<br/>device</b>    | <b>0.2</b> | 123                     | 1        |          |          |          |
|                               | <b>1</b>   |                         | 18       | 1        |          |          |
|                               | <b>2</b>   |                         |          | 14       |          |          |
|                               | <b>4</b>   |                         |          |          | 5        |          |
|                               | <b>8</b>   |                         |          |          |          | 5        |
| <b>Total</b>                  |            | 123                     | 19       | 15       | 5        | 5        |
| <b>% exact match</b>          |            | 100                     | 97.4     | 93.33    | 100      | 100      |
| <b>% ±1 color block</b>       |            | 100                     | 100      | 100      | 100      | 100      |

| <b>Protein<br/>mg/dL</b>   |                 | <b>Predicate device</b> |           |           |            |            |
|----------------------------|-----------------|-------------------------|-----------|-----------|------------|------------|
|                            |                 | <b>0</b>                | <b>15</b> | <b>30</b> | <b>100</b> | <b>300</b> |
| <b>Proposed<br/>device</b> | <b>0 (-)</b>    | 156                     |           |           |            |            |
|                            | <b>15 (±)</b>   | 1                       | 7         |           |            |            |
|                            | <b>30 (1+)</b>  |                         | 1         | 2         |            |            |
|                            | <b>100 (2+)</b> |                         |           |           | 0          |            |
|                            | <b>300 (3+)</b> |                         |           |           |            | 0          |
| <b>Total</b>               |                 | 157                     | 8         | 2         | 0          | 0          |
| <b>% exact match</b>       |                 | 99.36                   | 87.5      | 100       | NA         | NA         |
| <b>% ±1 color block</b>    |                 | 100                     | 100       | 100       | NA         | NA         |

| <b>Blood<br/>cells/micL</b> |                 | <b>Predicate device</b> |           |           |           |            |
|-----------------------------|-----------------|-------------------------|-----------|-----------|-----------|------------|
|                             |                 | <b>0</b>                | <b>10</b> | <b>25</b> | <b>80</b> | <b>200</b> |
| <b>Proposed<br/>device</b>  | <b>0 (-)</b>    | 145                     |           |           |           |            |
|                             | <b>10 (±)</b>   |                         | 9         |           |           |            |
|                             | <b>25 (1+)</b>  |                         | 1         | 1         | 1         |            |
|                             | <b>80 (2+)</b>  |                         |           | 1         | 1         |            |
|                             | <b>200 (3+)</b> |                         |           |           | 2         | 6          |
| <b>Total</b>                |                 | 145                     | 10        | 2         | 4         | 6          |
| <b>% exact match</b>        |                 | 100                     | 90        | 50        | 25        | 100        |
| <b>% ±1 color block</b>     |                 | 100                     | 100       | 100       | 100       | 100        |

|                         |         | Ketone<br>mg/dL | Predicate device |       |      |      |    |
|-------------------------|---------|-----------------|------------------|-------|------|------|----|
|                         |         |                 | 0                | 5     | 15   | 40   | 80 |
| Proposed<br>device      | 0 (-)   | 141             |                  |       |      |      |    |
|                         | 5 (±)   |                 | 4                |       |      |      |    |
|                         | 15 (1+) |                 | 3                | 8     | 2    |      |    |
|                         | 40 (2+) |                 |                  | 1     | 2    | 1    |    |
|                         | 80 (3+) |                 |                  |       |      | 5    |    |
| <b>Total</b>            |         | 141             | 7                | 9     | 4    | 6    |    |
| <b>%exact match</b>     |         | 100             | 57.14            | 88.89 | 50.0 | 83.3 |    |
| <b>% ±1 color block</b> |         | 100             | 100              | 100   | 100  | 100  |    |

|                         |        | Bilirubin<br>mg/dL | Predicate device |     |     |   |
|-------------------------|--------|--------------------|------------------|-----|-----|---|
|                         |        |                    | 0                | 1   | 2   | 4 |
| Proposed<br>device      | 0 (-)  | 129                |                  |     |     |   |
|                         | 1 (1+) |                    | 7                |     |     |   |
|                         | 2 (2+) |                    |                  | 11  | 1   |   |
|                         | 4 (+3) |                    |                  |     | 19  |   |
| <b>Total</b>            |        | 129                | 7                | 11  | 20  |   |
| <b>% exact match</b>    |        | 100                | 100              | 100 | 95  |   |
| <b>% ±1 color block</b> |        | 100                | 100              | 100 | 100 |   |

|                         |           | Glucose<br>mg/dL | Predicate device |       |     |     |      |
|-------------------------|-----------|------------------|------------------|-------|-----|-----|------|
|                         |           |                  | 0                | 100   | 250 | 500 | 1000 |
| Proposed<br>device      | 0 (-)     | 135              |                  |       |     |     |      |
|                         | 100 (±)   |                  | 15               | 3     |     |     |      |
|                         | 250 (1+)  |                  | 2                | 4     |     |     |      |
|                         | 500 (2+)  |                  |                  |       | 4   | 2   |      |
|                         | 1000 (3+) |                  |                  |       |     | 2   |      |
| <b>Total</b>            |           | 135              | 17               | 7     | 4   | 4   |      |
| <b>% exact match</b>    |           | 100              | 88.24            | 57.14 | 100 | 50  |      |
| <b>% ±1 color block</b> |           | 100              | 100              | 100   | 100 | 100 |      |

|                    |         | Ascorbic Acid<br>mg/dL | Predicate device |    |    |    |
|--------------------|---------|------------------------|------------------|----|----|----|
|                    |         |                        | 0                | 10 | 20 | 40 |
| Proposed<br>device | 0 (-)   | 160                    |                  |    |    |    |
|                    | 10 (1+) |                        | 1                |    |    |    |
|                    | 20 (2+) |                        |                  | 0  |    |    |
|                    | 40 (3+) |                        |                  |    | 6  |    |

|                         |     |     |    |     |
|-------------------------|-----|-----|----|-----|
| <b>Total</b>            | 100 | 100 | NA | 100 |
| <b>% exact match</b>    |     |     | NA |     |
| <b>% ±1 color block</b> | 100 | 100 | NA | 100 |

|                         |            | pH   | Predicate device |       |      |      |     |     |     |       |
|-------------------------|------------|------|------------------|-------|------|------|-----|-----|-----|-------|
|                         |            |      | 5.0              | 5.5   | 6.0  | 6.5  | 7.0 | 7.5 | 8.0 | 8.5   |
| <b>Proposed device</b>  | <b>5.0</b> | 25   |                  |       |      |      |     |     |     |       |
|                         | <b>5.5</b> | 5    | 6                |       |      |      |     |     |     |       |
|                         | <b>6.0</b> |      | 1                | 6     |      |      |     |     |     |       |
|                         | <b>6.5</b> |      |                  | 26    |      |      |     |     |     |       |
|                         | <b>7.0</b> |      |                  | 11    | 16   | 15   |     |     |     |       |
|                         | <b>7.5</b> |      |                  |       | 4    | 23   |     |     |     |       |
|                         | <b>8.0</b> |      |                  |       |      | 2    | 14  | 1   |     |       |
|                         | <b>8.5</b> |      |                  |       |      |      |     | 1   | 5   | 2     |
|                         | <b>9.0</b> |      |                  |       |      |      |     |     |     | 4     |
| <b>Total</b>            |            | 30   | 7                | 43    | 20   | 40   | 14  | 2   | 5   | 6     |
| <b>% exact match</b>    |            | 83.3 | 85.71            | 60.47 | 80.0 | 57.5 | 100 | 50  | 100 | 66.67 |
| <b>% ±1 color block</b> |            | 100  | 100              | 100   | 100  | 100  | 100 | 100 | 100 | 100   |

|                         |              | Specific gravity | Predicate device |       |       |       |       |       |
|-------------------------|--------------|------------------|------------------|-------|-------|-------|-------|-------|
|                         |              |                  | 1.000            | 1.005 | 1.010 | 1.015 | 1.020 | 1.025 |
| <b>Proposed device</b>  | <b>1.000</b> |                  |                  |       |       |       |       |       |
|                         | <b>1.005</b> |                  | 1                | 1     |       |       |       |       |
|                         | <b>1.010</b> |                  | 2                | 23    | 14    |       |       |       |
|                         | <b>1.015</b> |                  |                  | 8     | 49    | 9     |       |       |
|                         | <b>1.020</b> |                  |                  |       | 2     | 26    | 5     |       |
|                         | <b>1.025</b> |                  |                  |       |       | 1     | 13    | 4     |
|                         | <b>1.030</b> |                  |                  |       |       |       | 2     | 7     |
| <b>Total</b>            |              | 0                | 3                | 43    | 65    | 36    | 20    | 11    |
| <b>% exact match</b>    |              | NA               | 33.33            | 71.88 | 75.38 | 72.22 | 65    | 63.64 |
| <b>% ±1 color block</b> |              | NA               | 100              | 100   | 100   | 100   | 100   | 100   |

*b. Matrix comparison:*

Not applicable. This device is for urine testing only.

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:

|                   |             |               |               |
|-------------------|-------------|---------------|---------------|
| Ascorbic Acid:    | 2-10 mg/dL  | pH:           | 4.5-8         |
| Glucose:          | Negative    | Protein:      | Negative      |
| Bilirubin:        | Negative    | Urobilinogen: | 0.2-1.0 mg/dL |
| Ketone:           | Negative    | Nitrite:      | Negative      |
| Specific Gravity: | 1.003-1.035 | Leukocyte:    | Negative      |
| Blood:            | Negative    |               |               |

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3. Williamson DH. *Physiological Ketoses, or Why Ketone Bodies?* Postgrad. Med. J. (June Suppl.): 372-375, 1971.
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5. Fraser J, et al. *Studies with a Simplified Nitroprusside Test for Ketone Bodies in Urine, Serum, Plasma and Milk*. Clin. Chem. Acta II: 372-378, 1965.
6. Henry JB, et al. *Clinical Diagnosis and Management by Laboratory Methods, 20<sup>th</sup> Ed. Philadelphia*. Saunders. 371-372, 375, 379, 382, 385, 2001.
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**N. Instrument Name:**

Mission® U500 Urine Analyzer

**O. System Descriptions:**

1. Modes of Operation:

There is a routine sample and STAT sample mode. In addition, a system administrator can set up the instrument to lock out operators if QC fails.

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. Either unique sample identification numbers or assigned sequential specimen identification numbers up to 9999 sample IDs can be used prior to analyzing the samples. Samples will need to be analyzed in the same order as the identification numbers were entered. In addition, the Mission U500 Urine Analyzer automatically assigns a sequence number to each sample that is run.

4. Specimen Sampling and Handling:

A test strip containing sample is placed on the strip platform where its presence is sensed by a LED. The test strip is then transported into the reading area of the analyzer and a new strip can then be placed on the platform. A new test strip can be added to the test platform every 7 seconds. Results for the first test strip are available after one minute. Used strips are automatically deposited into a waste tray. The U500 Urine Analyzer prompts the operator to empty the tray when it is full. The device also stores up to 2000 patient results which can be recalled by the operator using the specimen identification number. The analyzer also has a STAT mode.

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 vial of reagent strips contains a code which includes the lot number and expiration date of the strips. This code is entered into the U500 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. The device expects that 2 levels of the quality control are analyzed. When two quality control levels pass, the instrument can be used for patient testing. If the quality control does not pass, the operator is locked out of the device. The analyzer, however, can only be run in the STAT mode and all testing results will be marked as not having passed QC testing. QC frequency can be programmed so that the operator is prompted to run controls every 8 hours, daily, weekly

or monthly, depending on the device usage.

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

None

**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.