

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

A. 510(k) Number:

k103387

B. Purpose for Submission:

New device

C. Measurand:

Quality control materials for urinalysis for Ascorbic acid, Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes analytes.

D. Type of Test:

Not Applicable

E. Applicant:

Acon Laboratories, Inc.

F. Proprietary and Established Names:

Mission[®] Liquid Urine Control
Mission[®] Liquid Diptube Urine Control
Mission[®] Dry Strip Urine Control

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1660, Quality Control Material

2. Classification:

Class I, reserved

3. Product code:

JJW – Urinalysis Controls

4. Panel:

Clinical Chemistry (75)

H. Intended Use:1. Intended use(s):

See indications for use below.

2. Indications(s) for use:

The Mission[®] Liquid Urine Control, Mission[®] Liquid Diptube Urine Control and the Mission[®] Dry Strip Urine Control are assayed urine controls intended for use in validating the precision of visual and analyzer reading of urinalysis for one or more of the following analytes: Ascorbic acid, Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes. It is intended for professional in vitro diagnostic use only.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

The Mission[®] Liquid Urine Control, Mission[®] Liquid Diptube Urine Control, and the Mission[®] Dry Strip Urine Control are for use with the Mission[®] Urinalysis Reagent Strips and Mission U120 Urine Analyzer.

I. Device Description:

The Mission[®] Liquid Urine Control and Mission[®] Liquid Diptube Urine Control are prepared from simulated human urine with purified chemicals, constituents of animal origin, preservatives and stabilizers. The controls are available in two levels, ready to use liquid format packaged in dropper bottles under the brand name Mission[®] Liquid Urine Control and in diptube containers under the brand name Mission[®] Liquid Diptube Urine Control. The results of the Mission[®] Liquid Urine Control and Mission[®] Liquid Diptube Urine Control are compared to the lot-specific expected values listed in the package insert to ensure the consistent performance of Mission[®] Urinalysis Reagent Strips and Mission[®] Urine Analyzers.

The Mission[®] Dry Strip Urine Controls are firm plastic strips onto which reagent areas are affixed. The negative level strips have five reagent areas containing one or more synthetic ingredients. When placed in a measured quantity of distilled or deionized water, the ingredients dissolve out of the reagent areas to produce a Level 1 Control Solution. The Level 2 strips have six reagent areas affixed. The ingredients on the positive level strips dissolve out to produce a Level 2 Control Solution. The results of the Mission[®] Dry Strip Urine Control are compared to the lot-specific expected values listed in the package insert to

ensure the consistent performance of Mission[®] Urinalysis Reagent Strips and Mission[®] Urine Analyzers.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bio-Rad[™], Liquichek Urinalysis Control
Siemens Healthcare Diagnostics, Chek-Stix[®] Control Strips for Urinalysis

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

k070848 (Bio-Rad Liquichek Urinalysis Control)
k931467 (Chek-Stix Control Strips for Urinalysis)

3. Comparison with predicate:

Reagent Similarities and Differences		
Feature	Candidate Device: Mission Liquid Urine Control; Mission Liquid Diptube Urine Control (k103387)	Predicate Device: Bio- Rad[™] Liquichek Urinalysis Control (k070848)
Intended/Indications for Use	For use as an assayed quality control urine to monitor the precision of urinalysis test procedures for the analytes listed in the package insert.	Same
Levels	2	Same
Form	Liquid	Same
Analytes	Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes, and Ascorbic Acid	Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes, Creatinine, Microalbumin, Microscopic (RBC, WBC, Crystals), Osmolality, Pregnancy (hCG), Protein-to-Creatine Ratio
Storage	2 to 8°C	Same
Matrix	Liquid Matrix Solution	Human Urine
Open Vial	24 months at 2-8°C 30 Days at 15-30°C	30 months at 2-8°C 30 Days at 18-25°C
Packaging Configuration	Dropper, diptube	Dropper
Shelf Life	24 months at 2-8°C	30 months at 2-8°C

Reagent Similarities and Differences		
Feature	Candidate Device: Mission Dry Strip Urine Control (k103387)	Predicate Device: Siemens Healthcare Diagnostics Chek-Stix Control Strips for Urinalysis (k931467)
Intended/Indications for Use	For use as an assayed quality control urine to monitor the precision of urinalysis test procedures for the analytes listed in the package insert.	Same
Levels	2	Same
Form	Dry Strip	Same
Analytes	Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes, and Ascorbic Acid	Same
Maximum Tests Per Unit	12	Same
Incubation Time	30 minutes	Same
Storage	2-30°C	15-30°C
Open Vial	3 months at 2-30°C	18 months at 15-30°C
Shelf Life	24 months at 2-30°C	18 months at 15-30°C
Stability after Reconstitution	8 hours for all parameters	8 hours for all parameters except 3 hours for bilirubin

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

- FDA Guidance for Industry and FDA Staff, Assayed and Unassayed Quality Control Materials.

L. Test Principle:

Not Applicable

M. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

Not Applicable

b. *Linearity/assay reportable range:*

Not Applicable

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

Traceability:

None was provided.

Stability:

Accelerated stability studies were performed by placing three lots of Level 1 and 2 dropper and diptube urine controls packaged in dropper and diptube configuration at 37°C for 20 days to simulate a 24-month shelf life at 2-8°C. The urine controls were read visually and tested on the Mission U120 Urine analyzer using three replicates. The results indicated that they were within the acceptance criteria ranges for Level 1 and Level 2. Real time stability studies to confirm the 24 month shelf-life are ongoing at 2-8°C.

Accelerated open stability studies were performed using three lots of dropper and diptube urine controls at 37°C and at room temperature (15-30°C) for 20 days. The controls were tested on the Mission Urinalysis Reagent Strips and read visually and tested on the Mission U120 Urine analyzer. The results indicated that the Level 1 and Level 2 controls were within the acceptance criteria. Real time studies are ongoing to support the 24 month storage time at 2-8°C.

The accelerated stability study for the Mission Dry Strip Urine Controls was performed by placing three lots of Level 1 and Level 2 urine controls at 45°C for 80 days and 37°C for 200 days. They were then tested on the Mission Urinalysis Reagent Strips and read visually and tested on the Mission U120 Urine Analyzer. All controls were within the established acceptance criteria and the shelf life was determined to be 24 months at 2-30°C. Real time stability studies are ongoing to support the 24 month storage time at 2-30°C.

Real time open stability studies were performed using three lots of Level 1 and Level 2 Dry Strip Urine Control at 30°C for three months. Strips were tested on the Mission Urinalysis Reagent Strips and read visually and tested on the Mission U120 Urine Analyzer. All controls were within the established acceptance criteria. Real time stability studies are ongoing to support the 24 month storage time at 2-30°C.

Stability after reconstitution for the Dry Strip Controls was done by reconstituting three lots of Level 1 and Level 2 controls according to the package insert. The strips were initially tested, and then placed at 2-8°C, 25°C, and 37°C for 2, 4, 6, 8, and 9 hours. The solutions were allowed to equilibrate to room temperature and then retested on the Mission Urinalysis Reagent Strips and read visually and tested on the Mission U120 Urine Analyzer. All controls were within the established acceptance criteria. Stability after reconstitution for the Dry Strip Controls was set to be 8 hours at 2-37°C.

Value Assignment

Control value assignment for the Mission Liquid Urine Control, Mission Liquid Diptube Urine Control and Mission Dry Strip was done by testing Level 1 and Level 2 using the Mission Urinalysis Reagent Strips read visually and tested on the Mission U120 Urine analyzer. Three lots of strips and three analyzers were tested for three consecutive days by three operators. All results for level 1 were negative and all results for level 2 showed positive results.

Matrix Effects

The sponsor performed spiking studies to evaluate matrix effects of the Mission Liquid Urine Control, Mission Liquid Diptube Urine Control and Mission Dry Strip urine controls compared to human urine. Matrix 1, Matrix 2, and negative human urine were spiked with zero, low and high level concentrations of analyte and measured in triplicate using three lots of Mission Urinalysis Reagent Strip and tested on the Mission U120 Urine Analyzer. The following analytes were studied for matrix effects: leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, blood, and ascorbic acid. All results showed that Matrix 1 and 2 of the Mission Liquid Urine Control, Mission Liquid Diptube Urine Control, and the Mission Dry Strip Urine Control met acceptance criteria and perform similarly to negative human urine pools when spiked with various analytes across the measurement range of the Mission Urinalysis Reagent Strips.

Temperature and humidity studies found that the Mission Liquid Urine Control, Mission Liquid Diptube Urine Control and Mission Dry Strip Urine Control can provide expected results when tested between 2-55°C and up to a 24 hour exposure to humidity conditions ranging from 5-95% relative humidity. Additionally, lighting studies showed that Mission Liquid Urine Control, Mission Liquid Diptube Urine Control and Mission Dry Strip Urine Control can provide expected results when tested under white light (fluorescent), yellow light (sodium vapor) and no light for Levels 1 and 2.

d. Detection limit:

Not applicable

e. Analytical specificity:

Not Applicable

f. Assay cut-off:

Not Applicable

2. Comparison studies:*a. Method comparison with predicate device:*

Not Applicable

b. Matrix comparison:

Not applicable.

3. Clinical studies:

a. Clinical Sensitivity:

Not Applicable

b. Clinical specificity:

Not Applicable

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

Not Applicable

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range

Specific ranges for each analyte/methodology are listed in the package insert.

N. Proposed Labeling:

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

O. Conclusion:

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