Mission®

Liquid Urine Control
Expected Values

Mission® Urinalysis Reagent Strips Visual Reading

Analyte	Level 1 (Lot#17110079)			Level 2 (Lot#17100429)			Level 1 (14C and 13CE) (Lot#17110079)			Level 2 (14C and 13CE) (Lot#17100429)		
	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary
Leukocytes (LEU)	Negative	Negative	–	15-500 Leu/µL	15-500 Leu/µL	+/- – 3+	Negative	Negative	–	15-500 Leu/µL	15-500 Leu/µL	+/- – 3+
Nitrite (NIT)	Negative	Negative	–	Positive	Positive	+	Negative	Negative	–	Positive	Positive	+
Urobilinogen (URO)	0.2 – 1mg/dL	3.5 – 17µmol/L	– - ±	2 – 12 mg/dL	35 – 200µmol/L	1+ – 4+	0.2 – 1 mg/dL	3.5– 17µmol/L	– - ±	2 – 12 mg/dL	35 – 200µmol/L	1+ – 4+
Protein (PRO)	Negative	Negative	–	30 – 2000mg/dL	0.3 – 20.0g/L	1+ – 4+	Negative	Negative	–	30 – 2000mg/dL	0.3 – 20.0g/L	1+ – 4+
pH	5.0 – 7.0	5.0 – 7.0	5.0 – 7.0	6.5 – 9.0	6.5 – 9.0	6.5 – 9.0	5.0 – 7.0	5.0 – 7.0	5.0 – 7.0	6.5 – 9.0	6.5 – 9.0	6.5 – 9.0
Blood (BLO)	Negative	Negative	–	25 – 200 Ery/µL	25 – 200 Ery/µL	1+ – 3+	Negative	Negative	–	25 – 200 Ery/µL	25 – 200 Ery/µL	1+ – 3+
Specific Gravity (SG)	1.015 – 1.030	1.015 – 1.030	1.015–1.030	1.005 – 1.025	1.005 – 1.025	1.005 – 1.025	1.015-1.030	1.015 – 1.030	1.015–1.030	1.005-1.025	1.005 – 1.025	1.005 – 1.025
Ketone (KET)	Negative	Negative	–	5 – 160mg/dL	0.5-16.0mmol/L	± – 4+	Negative	Negative	–	5-160mg/dL	0.5-16.0mmol/L	± – 4+
Bilirubin (BIL)	Negative	Negative	–	1 – 4 mg/dL	17 – 70µmol/L	1+ – 3+	Negative	Negative	–	1 – 6 mg/dL	17 – 100µmol/L	1+ – 3+
Glucose (GLU)	Negative	Negative	–	100-1000mg/dL	5 – 60mmol/L	± – 3+	Negative	Negative	–	100-1000mg/dL	5 – 60mmol/L	1+ – 4+
Ascorbic Acid (ASC)	Negative	Negative	–	Negative	Negative	–	Negative	Negative	–	Negative	Negative	–
Microalbumin (ALB)	10 – 30mg/L	10 – 30mg/L	10 – 30mg/L	80 – 150mg/L	80 – 150mg/L	80 – 150mg/L	10 – 30mg/L	10 – 30mg/L	10 – 30mg/L	80 – 150mg/L	80 – 150mg/L	80 – 150mg/L
Creatinine (CRE)	10 –100mg/dL	0.9-8.8mmol/L	10 -100mg/dL	100 –300mg/dL	8.8-26.5mmol/L	100 –300mg/dL	10 –100mg/dL	0.9-8.8mmol/L	10 -100mg/dL	100-300mg/dL	8.8-26.5mmol/L	100 –300mg/dL
Albumin-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal	NA	NA	NA	NA	NA	NA
Protein-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal
Calcium (CA)	4 – 10mg/dL	1.0-2.5mmol/L	4 – 10mg/dL	20 – 40mg/dL	5.0-10mmol/L	20 – 40mg/dL	4 – 10mg/dL	1.0-2.5mmol/L	4 – 10mg/dL	20 – 40mg/dL	5.0-10mmol/L	20 – 40mg/dL

Mission® Urinalysis Reagent Strips Analyzer Reading with *Mission*® U120/U500/U120 Ultra*

Analyte	Level 1 (Lot#17110079)			Level 2 (Lot#17100429)			Level 1 (14C and 13CE) (Lot#17110079)			Level 2 (14C and 13CE) (Lot#17100429)		
	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary
Leukocytes (LEU)	Negative	Negative	–	15-500 Leu/µL	15-500 Leu/µL	+/- – 3+	Negative	Negative	–	15-500 Leu/µL	15-500 Leu/µL	+/- – 3+
Nitrite (NIT)	Negative	Negative	–	Positive	Positive	+	Negative	Negative	–	Positive	Positive	+
Urobilinogen (URO)	0.2 – 1mg/dL	3.5 – 17µmol/L	– - ±	2 – 8 mg/dL	35 – 140µmol/L	1+ – 3+	0.2 – 1 mg/dL	3.5– 17µmol/L	– - ±	2 – 8 mg/dL	35 – 140µmol/L	1+ – 3+
Protein (PRO)	Negative	Negative	–	30 – 300mg/dL	0.3 – 3.0g/L	1+ – 3+	Negative	Negative	–	30 – 300mg/dL	0.3 – 3.0g/L	1+ – 3+
pH	5.0 – 7.0	5.0 – 7.0	5.0 – 7.0	6.5 – 9.0	6.5 – 9.0	6.5 – 9.0	5.0 – 7.0	5.0 – 7.0	5.0 – 7.0	6.5 – 9.0	6.5 – 9.0	6.5 – 9.0
Blood (BLO)	Negative	Negative	–	25 – 200 Ery/µL	25 – 200 Ery/µL	1+ – 3+	Negative	Negative	–	25 – 200 Ery/µL	25 – 200 Ery/µL	1+ – 3+
Specific Gravity (SG)	1.015 – 1.030	1.015 – 1.030	1.015–1.030	1.005 – 1.025	1.005 – 1.025	1.005 – 1.025	1.015-1.030	1.015 – 1.030	1.015–1.030	1.005-1.025	1.005 – 1.025	1.005 – 1.025
Ketone (KET)	Negative	Negative	–	5 – 80mg/dL	0.5-8.0mmol/L	± – 3+	Negative	Negative	–	5-80mg/dL	0.5-8.0mmol/L	± – 3+
Bilirubin (BIL)	Negative	Negative	–	1 – 4 mg/dL	17 – 70µmol/L	1+ – 3+	Negative	Negative	–	1 – 6 mg/dL	17 – 100µmol/L	1+ – 3+
Glucose (GLU)	Negative	Negative	–	100-1000mg/dL	5 – 60mmol/L	± – 3+	Negative	Negative	–	100-1000mg/dL	5 – 60mmol/L	1+ – 4+
Ascorbic Acid (ASC)	Negative	Negative	–	Negative	Negative	–	Negative	Negative	–	Negative	Negative	–
Microalbumin (ALB)	10 – 30mg/L	10 – 30mg/L	10 – 30mg/L	80-150mg/L	80 – 150mg/L	80 – 150mg/L	10-30mg/L	10 – 30mg/L	10 – 30mg/L	80 – 150mg/L	80 – 150mg/L	80 – 150mg/L
Creatinine (CRE)	10 –100mg/dL	0.9-8.8mmol/L	10 -100mg/dL	100 –300mg/dL	8.8-26.5mmol/L	100 –300mg/dL	10 –100mg/dL	0.9-8.8mmol/L	10 -100mg/dL	100-300mg/dL	8.8-26.5mmol/L	100 –300mg/dL
Albumin-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal	NA	NA	NA	NA	NA	NA
Protein-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal
Calcium (CA)	4 – 10mg/dL	1.0-2.5mmol/L	4 – 10mg/dL	20 – 40mg/dL	5.0-10mmol/L	20 – 40mg/dL	4 – 10mg/dL	1.0-2.5mmol/L	4 – 10mg/dL	20 – 40mg/dL	5.0-10mmol/L	20 – 40mg/dL

Mission® *Expert* Urinalysis Reagent Strips Visual Reading

Analyte	Level 1 (Lot#17110079)			Level 2 (Lot#17100429)		
	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary
Ascorbic Acid (ASC)	Negative	Negative	–	Negative	Negative	–
Blood (ERY, Hb)	Negative	Negative	–	Ca.25 – Ca.250 Ery/µl	Ca.25 – Ca.250 Ery/µl	2+ – 4+
Bilirubin (BIL)	Negative	Negative	–	1– 6 mg/dL	17 – 100µmol/L	1+ – 3+
Urobilinogen (URO)	0.2 mg/dL	3.5 µmol/L	–	4 – 12 mg/dL	70 – 200 µmol/L	2+ – 4+
Ketone Bodies (KET)	Negative	Negative	–	10 – 150 mg/dL	1.0 – 15.0 mmol/L	1+ – 3+
Glucose (GLU)	Negative	Negative	–	100 – 1000 mg/dL	5.5 – 56 mmol/L	2+ – 4+
Protein (PRO)	Negative	Negative	–	30 – 500 mg/dL	0.3 – 5.0 g/L	1+ – 3+
Nitrite (NIT)	Negative	Negative	–	Positive	Positive	+
Leukocytes (LEU)	Negative	Negative	–	ca. 10-25 – ca. 500 Leu/µl	ca. 10-25 – ca. 500 Leu/µl	1+ – 3+
pH	5.0 – 7.0	5.0 – 7.0	5.0 – 7.0	7.0 – 9.0	7.0 – 9.0	7.0 – 9.0
Specific Gravity (SG)	1.015 – 1.030	1.015 – 1.030	1.015 – 1.030	1.005 – 1.025	1.005 – 1.025	1.005 – 1.025
Microalbumin (ALB)	10 – 30 mg/L	10 – 30mg/L	10 – 30 mg/L	80 – 150 mg/L	80 – 150 mg/L	80 – 150 mg/L
Creatinine (CRE)	10 – 100 mg/dL	0.9 – 8.8 mmol/L	10 – 100 mg/dL	100 – 300 mg/dL	8.8 – 26.5 mmol/L	100 – 300 mg/dL
Albumin-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal
Protein-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal

Mission® *Expert* Urinalysis Reagent Strips Analyzer Reading with *Mission*® *Expert* U120/U500*

Analyte	Level 1 (Lot#17110079)			Level 2 (Lot#17100429)		
	Conventional	SI	Arbitrary	Conventional	SI	Arbitrary
Ascorbic Acid (ASC)	Negative	Negative	–	Negative	Negative	–
Blood (ERY, Hb)	Negative	Negative	–	25 – 250 Ery/µl	25 – 250 Ery/µl	2+ – 5+
Bilirubin (BIL)	Negative	Negative	–	1– 6 mg/dL	17 – 100 µmol/L	1+ – 3+
Urobilinogen (URO)	0.2 mg/dL	3.5 µmol/L	–	4 – 12 mg/dL	70 – 200 µmol/L	2+ – 4+
Ketone Bodies (KET)	Negative	Negative	–	15 – 150 mg/dL	1.5 – 15.0 mmol/L	2+ – 4+
Glucose (GLU)	Negative	Negative	–	100 – 1000 mg/dL	5.5 – 56 mmol/L	2+ – 4+
Protein (PRO)	Negative	Negative	–	25 – 500 mg/dL	0.25 – 5.0 g/L	1+ – 4+
Nitrite (NIT)	Negative	Negative	–	Positive	Positive	+
Leukocytes (LEU)	Negative	Negative	–	25 – 500 Leu/µl	25 – 500 Leu/µl	1+ – 3+
pH	5.0 – 7.0	5.0 – 7.0	5.0 – 7.0	6.5 – 9.0	6.5 – 9.0	6.5 – 9.0
Specific Gravity (SG)	1.015 – 1.030	1.015 – 1.030	1.015 – 1.030	1.005 – 1.025	1.005 – 1.025	1.005 – 1.025
Microalbumin (ALB)	10 – 30 mg/L	10 – 30 mg/L	10 – 30 mg/L	80 – 150 mg/L	80 – 150 mg/L	80 – 150mg/L
Creatinine (CRE)	10 – 100 mg/dL	0.9 – 8.8 mmol/L	10 – 100 mg/dL	100 – 300 mg/dL	8.8 – 26.5 mmol/L	100 – 300mg/dL
Albumin-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal
Protein-to-Creatinine Ratio	Normal	Normal	Normal	Abnormal	Abnormal	Abnormal

*The U120 QC set-up screen recognizes only arbitrary values

(LCD0187-05)

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Date: 2019.03.13 12:10:47 EET
Reason: MoldSign Signature
Location: Moldova

Mission®

Liquid Urine Control

Package Insert

REF U021-011	English

For validating visual and analyzer reading of urinalysis.
For in vitro diagnostic use only.

INTENDED USE

The Liquid Urine Control is intended for use in validating the visual and analyzer reading of urinalysis. The results should be compared to the expected results listed below to ensure the consistent performance of *Mission®* and *Mission® Expert* Urinalysis Reagent Strips and Urine Analyzers. The Liquid Urine Control is available in two levels and is ready to use for monitoring routine urinalysis.

PRECAUTIONS

- For *in vitro* diagnostic use only. Do not use after the expiration date.
- All materials should be considered potentially hazardous and handled in the same manner as an infectious agent.
- Discard if there is excessive turbidity or evidence of microbial contamination.
- The used materials should be discarded according to local regulations after testing.
- This product is not intended for use as a standard.
- The use of quality control materials is an important part of good laboratory practices. Quality control materials are an objective method of assessing techniques or practices in use.

REAGENTS

The product is a liquid stable control prepared from simulated human urine with added chemicals, constituents of animal origin, preservatives and stabilizers. The control does not include human resource materials. Various pure chemicals are used to adjust each analyte level.

STORAGE AND STABILITY

- Store and ship at 2-8°C (36-46°F). Do not freeze.
- Controls are stable until the expiration date printed on the bottle label when stored at 2-8°C (36-46°F).
- All analytes are stable for 30 days at 15-30°C (59-86°F) or until the expiration date at 2-8°C (36-46°F) once opened and stored with the cap on tightly.

MATERIALS

Materials Provided

- Liquid Urine Control Level 1 and/or Level 2
- Package Insert
- Strips

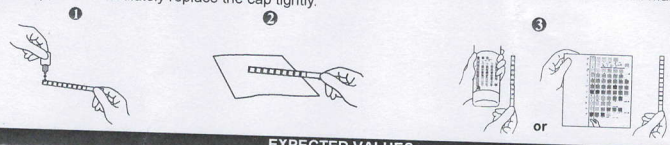
Materials Required But Not Provided

- Timer

DIRECTIONS FOR USE

Allow all test materials to reach room temperature (15-30°C or 59-86°F) prior to testing.

1. Invert the urine control bottle 3 times to ensure reproducible results, then remove the cap. While holding the urinalysis reagent strip, invert the urine control bottle and gently squeeze the urine control bottle to dispense the urine control. Ensure each reagent area on urinalysis reagent strip is completely saturated with urine control. See illustration 1 below.
   Note:
   - Do not touch the tip of the urine control bottle to the reagent areas on the urinalysis reagent strip to avoid contamination.
   - Dispense the remaining hanging drop of urine control before turning the urine control bottle upright. Dispose of the hanging drop of urine control to avoid contaminating the unused control with reagents from the urinalysis reagent strip.
2. Hold the strip in a horizontal position and bring the edge of the strip into contact with an absorbent material (e.g. a paper towel) to avoid mixing chemicals from adjacent reagent areas and/or soiling hands with the urine control. See illustration 2 below.
3. Compare the reagent areas to the corresponding color blocks on the color chart at the specified times. Hold the strip close to the color blocks and match carefully. See illustration 3 below.
   Note:
   - Results may be read up to 2 minutes after the specified times.
   - Results may also be read using the *Mission®* and *Mission® Expert* Urine Analyzers. Refer to the Instruction Manual for details.
4. Clean the dropper tip, and immediately replace the cap tightly.



EXPECTED VALUES

The expected values listed on the following page should only be used for the specific lots printed. Expected values were obtained from replicate analysis. The urine control and urinalysis reagent strip lots can create slight differences in expected results. Different laboratory methods, instruments and reagents can create variations between laboratories and variations over time. Use the results provided as reference only. It is recommended that each laboratory establish its own parameters of precision.
Note: The color reactions of Urobilinogen and Bilirubin reagent areas on the urinalysis reagent strips may produce colors that are atypical when visually compared to the color blocks on the color chart.

LIMITATIONS

The *Mission®* Liquid Urine Control can only be used with *Mission®* and *Mission® Expert* Urinalysis Reagent Strips and Urine Analyzers. Ensure reproducible results by inverting the urine control bottle 3 times before each use. Interpretation of visual results depends on several factors: the variability of color perception, the presence or absence of inhibitory factors, and the lighting conditions when the strip is read. Each color block on the color chart does not correspond to a specific concentration, but it does correspond to a range of analyte concentrations.

Index of Symbols

	Consult instructions for use	Σ	Tests per kit		Manufacturer
IVD	For *in vitro* diagnostic use only		Use by	EC REP	Authorized Representative
2°C 8°C	Store between 2-8°C	LOT	Lot Number	REF	Catalog #

***ACON* Laboratories, Inc.**
10125 Mesa Rim Road,
San Diego, CA 92121, USA

CE

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Number: 1150529004
Effective date: 2013-02-16