

INTENDED USE

The Liquid Urine Control is an assayed urine control 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, Leukocytes, Creatinine, Albumin and Albumin-to-Creatinine Ratio.

SUMMARY AND EXPLANATION

The Liquid Urine Control is available in two levels and is ready to use for monitoring routine urinalysis within the clinical range. The results should be compared to the expected values listed to ensure the consistent performance of *Mission®* Urinalysis Reagent Strips, U120 Urine Analyzers, U120 Ultra Urine Analyzers and U500 Urine Analyzers.

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.
- Quality control materials should be used in accordance with local, state and/or federal regulations or accreditation requirements.

REAGENTS

Depending on the component reactivity, the exact percent composition varies for each lot.

Level 1 Control Solution: Phosphate buffer, urea, sodium chloride, proclin

Level 2 Control Solution: Protease, sodium nitrite, N(1-Naphthyl) ethylenediamine dihydrochloride, 2,4-dimethylpyrrole-3-carboxy acid, bovine serum albumin, bovine hemoglobin, D-Glucose, sodium chloride, methyl acetoacetate sodium, proclin

STORAGE AND STABILITY

- Store and ship at 2-8°C (36-46°F). Do not freeze.
- Unopened 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

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

Materials Provided

- Package Insert

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:

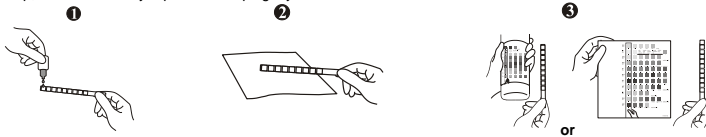
- Do not touch the tip of the urine control bottle to the reagent areas on the urinalysis reagent strip to avoid contamination.
- Dispense the remaining hanging drop of urine control before turning the urine control bottle upright.

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®* U120 Urine Analyzers, *Mission®* U120 Ultra Urine Analyzers or *Mission®* U500 Urine Analyzers. Refer to the Instruction Manual for details.

4. Clean the dropper tip, and immediately replace the cap tightly.



LIMITATIONS

The *Mission®* Liquid Urine Control can only be used with *Mission®* Urinalysis Reagent Strips, U120 Urine Analyzers, U120 Ultra Urine Analyzers and U500 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. Use the results provided as reference only. It is recommended that each laboratory establish its own parameters of precision.

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 using three lots of *Mission®* Urinalysis Reagent Strips, three *Mission®* U120 Urine Analyzers, *Mission®* U120 Ultra Urine Analyzers and *Mission®* U500 Urine Analyzers for three consecutive days, performed by three operators, to obtain 81 total results. Expected values for the Level 1 control solution were assigned as negative for all parameters, except for Specific Gravity and pH which have a ± 2 color block range. For the Level 2 control solution, expected values were assigned by providing a ± 2 color block range, except Ascorbic Acid which is negative. 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.

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.

510(k) Cleared



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