

# Liquid Urine Control

For use with MFR # 121-011.

## INSTRUCTIONS FOR USE

### INTENDED USE

The McKesson CONSULT<sup>®</sup> Liquid Urine Controls are assayed urine controls, intended for use in validating the precision of analyzer reading of urinalysis for the Creatinine and Albumin analytes. It is intended for professional *in vitro* diagnostic use only, Rx only.

### SUMMARY AND EXPLANATION

The McKesson CONSULT<sup>®</sup> 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 the McKesson CONSULT<sup>®</sup> Urinalysis Reagent Strips, and the McKesson CONSULT<sup>®</sup> 121-120 Urine Analyzer.

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

### MATERIALS

#### Materials Provided:

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

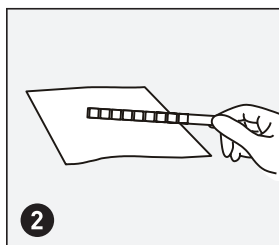
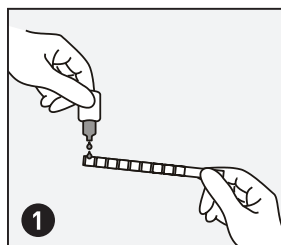
#### Materials Required But Not Provided:

- Strips
- Timer

### DIRECTIONS FOR USE

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

- 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.
- 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.
- Results are read using the McKesson CONSULT<sup>®</sup> 121-120 Urine Analyzer. Refer to the Instruction Manual for details.
- Clean the dropper tip, and immediately replace the cap tightly.



### LIMITATIONS

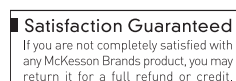
The McKesson CONSULT<sup>®</sup> Liquid Urine Controls can only be used with the McKesson CONSULT<sup>®</sup> Urinalysis Reagent Strips, and the CONSULT<sup>®</sup> 121-120 Urine Analyzer. Ensure reproducible results by inverting the urine control bottle 3 times before each use. Use the results provided as reference only. It is recommended that each laboratory establish its own parameters of precision.

### EXPECTED VALUES

Expected values were obtained from replicate analysis using three lots of the McKesson CONSULT<sup>®</sup> Urinalysis Reagent Strips, and the McKesson CONSULT<sup>®</sup> 121-120 Urine Analyzer for three consecutive days, performed by three operators, to obtain 81 total results. Different laboratory methods, instruments and reagents can create variations between laboratories and variations overtime.

ANALYTE	LEVEL 1	LEVEL 2
Creatinine (CRE)	10 mg/dL ~ 100 mg/dL	100 mg/dL ~ 300 mg/dL
Albumin (ALB)	10 mg/L ~ 30 mg/L	80 mg/L ~ 150 mg/L

Questions? Call 1-800-777-4908



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