

### Intended Use

Mission's Urobilinogen Linearity Standards are intended for verification of linearity (analytical measuring range) for Urobilinogen assays run on Mission CA200\* and Beckman AU680 analyzers in accordance with the instrument manufacturer's directions.

For Research Use Only. Site validation required for Lab Developed Test (LDT), 510K approval pending.

### Summary and Explanation

The use of linearity standards is an established procedure for verifying full reportable range of performance for chemistry analyzer systems.

### Composition

Mission Urobilinogen Linearity Standards are formulated with synthetic urobilinogen and additives to preserve the integrity of the product. The formulation is then lyophilized to improve stability.

### User Precautions

1. Not to be used internally. Normal precautions exercised in handling laboratory reagents should be followed.
2. Do not mix or use standards from one kit with those from a different lot number.
3. Do not use standards past the expiration date stated on each vial label.

### Instructions For Use

1. Store unopened vials at  $-20\pm 10^{\circ}\text{C}$ .
2. Bring each vial to room temperature.
3. Carefully remove aluminum crimp ring and septum.
4. Add 1.0 mL deionized water to each vial.
5. Cap and gently invert multiple times.
6. After 10 minutes, invert several more times and transfer solution from vial to sample cup and place in analyzer.
7. Discard after use. Reconstituted solution is not stable beyond 5 hours at  $2-8^{\circ}\text{C}$ .

### Storage And Stability

The Mission Urobilinogen Linearity Standards should be stored between  $-20\pm 10^{\circ}\text{C}$ . The lyophilized product is stable through the expiration date stated on the vial labels.

### Limitations

Erroneous results may occur from prolonged exposure of open vial to ambient air and/or technical errors associated with instrumentation or reagents.

### Linearity Standard Values

Standard 1: Refer to vial label, mg/dL

Standard 2: Refer to vial label, mg/dL

Standard 3: Refer to vial label, mg/dL

Standard 4: Refer to vial label, mg/dL

Standard 5: Refer to vial label, mg/dL

\* Also known as Zybio EXC200 Analyzer