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## SENTRY URINE DIPSTICK CONTROL

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### **INTENDED USE**

The Thermo Scientific SENTRY Urine Dipstick Control is intended to confirm the performance of MultiStix®, Chemstrip®, DiaScreen®, and other urinalysis reagent strips for quality control purposes. It is also intended to be used to verify the performance of various hCG test kits.

### **PRODUCT DESCRIPTION**

The Thermo Scientific SENTRY Urine Dipstick Controls are supplied in two levels, 2 x 25 mL each level per box. They are ready to use liquid controls that DO NOT require any dilution or reconstitution. The two Sentry controls are prepared with human and animal proteins and with various chemical additives. These chemicals interact with the dipstick reactant pads to produce specific color changes that mimic actual normal and/or abnormal urine samples. Level 1 is an Abnormal control, and Level 2 is a Normal control with hCG and microalbumin. Preservatives have been added to inhibit microbial growth.

### **WARNINGS & PRECAUTIONS**

#### FOR IN VITRO DIAGNOSTIC USE ONLY

**POTENTIALLY BIOHAZARDOUS MATERIAL** Contains human sourced materials. All human sourced materials used in the manufacture of this product have been tested and found non-reactive for Hepatitis B Surface Antigen, Hepatitis C, and HIV 1&2 antibody when tested by FDA accepted methods. Because no test method can provide complete assurance that HBsAg, HIV, or other infectious agents are absent, it is recommended that samples be handled according to the Centers for Disease Control's Bio-Safety Level 2 recommendations.

**DISPOSE OF PROPERLY.** Sodium Azide may form metal azides in plumbing and pose a threat of explosion. Flush with excess water upon disposal.

### **STORAGE & STABILITY**

The Sentry Urine Dipstick Control Kit should be stored at 2-8°C when not in use. **DO NOT FREEZE.** When stored at 2-8°C the controls are stable until the expiration date printed on the label. When stored at Room Temperature the controls are stable for 12 months. Discard the controls if there is any evidence of turbidity, or microbial contamination.

### **PROCEDURE FOR DIPSTICK TESTING**

1. Allow controls to come to room temperature. Mix gently by inversion to assure homogeneity of the contents. Avoid Foaming.
2. Remove cap and invert bottle. While holding dipstick, gently squeeze the sides of the bottle, and touch the tip of the bottle to the dipstick. Draw across all of the reagent pads, thoroughly saturating each pad. Turn dipstick on its side and drain excess control onto an absorbent material. Do not aspirate excess control back into the bottle.
3. Read the urine dipsticks, visually or with an instrumental reader in accordance with the dipstick manufacturers' instructions.
4. Wipe off dropper tips and recap controls. Store at 2-8°C when not in use to enjoy the full shelf-life of the product.

### **PROCEDURE FOR hCG TESTING**

Note: The SENTRY Controls are supplied in dropper tip bottles for the convenience of easily dispensing the control onto the urine dipsticks. Most manufacturers of hCG kits require a specific sample size to be used with their kits in order to obtain proper results. It is important to ensure that the proper amount of sample is used in order to obtain the correct results.

1. Allow controls to come to room temperature.
2. Treat the controls as patient samples in accordance with the hCG kit manufacturer's instructions.
3. Immediately recap the controls and store at 2-8°C when not in use to enjoy the full shelf-life of the product.

### **EXPECTED VALUES**

For visual readings, the controls are expected to give readings within the visual assay ranges provided with this kit. For instrument readings, the controls are expected to give readings within the instrument assay ranges provided with this kit.

The Level 1 Abnormal Control is intended to provide a negative test result for hCG and a positive test result for microalbumin. Some hCG lateral flow test kits may not exhibit background clearing with the Abnormal Control but should continue to yield a negative hCG test result.

The Level 2 Normal control is intended to give positive test results for hCG and microalbumin.

### **LIMITATIONS**

Any future changes made by the manufacturer of a test method may give different values from the indicated range. Detailed information on the limitations of each test method is included in the limitations section of the manufacturer's package insert.

The Level 1 Abnormal control may exhibit significant background color when used on some hCG lateral flow test kits but should continue to yield a negative hCG test result.

### **MULTISTIX USERS**

Colors produced by the bilirubin reaction on the MultiStix reagent strips with the Urine Dipstick Control may not be characteristic of those shown on the manufacturer's label when reading the dipsticks visually. The bilirubin reactions are consistent, intensify with the increase in the bilirubin concentration and give correct instrument readings but may not provide an exact color match to those shown on the label.

### **DIASCREEN USERS**

Colors produced by the bilirubin reaction on the DiaScreen reagent strips with the Abnormal Urine Dipstick Control may not be characteristic of those shown on the manufacturer's label when reading the dipsticks visually. Detailed information on the limitation of each test method is included in the limitations section of the manufacturer's package insert.

To place an order or to receive technical assistance, please call Thermo Fisher Scientific at: (401) 438-0386 or (800) 556-7575.

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