Audit® Micro*DROP*™ Urine Dipstick Control

Cat. No. **K065M-4**
Contents 4 x 25mL (Multi-Level)

Lot No. Level 1 – 06168
Level 2 – 06169

Expires 03/21/2011

For In Vitro Diagnostic Use Only.

©Audit® MicroControls™, Inc., Las Vegas, NV 89102

INTENDED USE

Audit® Micro*DROP*™ Urine Dipstick Control is a bi-level reference control which may contain human source materials fortified to target levels with compounds that produce the desired reaction when tested by the methods indicated. It is intended to simulate human patient urine samples for the purpose of monitoring the precision of the Multistix®, Chemstrip®, and vChem™ urinalysis reagent strips, the iChem™ 100 and Clintek Status® urine chemistry analyzers, as well as for confirmatory tests such as Acetest® and Clinitest®.

SUMMARY AND PRINCIPLE

Good laboratory practices require that stable reference materials be used to verify the accuracy and precision of testing methods and techniques. Audit® Micro*DROP*™ Urine Dipstick Control may be used as one would use human urine to obtain the stated urine dipstick values.

WARNINGS AND PRECAUTIONS

Because this product may contain human urine, it should be handled as though capable of transmitting infectious diseases. Components used in the preparation of this material were tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV and nonreactive for HBSAg. Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples be handled at the Centers for Disease Control's Biosafety Level 2.

Audit® Micro*DROP*™ Urine Dipstick Control is intended solely for in vitro diagnostic use for the purpose described on the labeling. Audit® MicroControls™, Inc. shall not be liable for any unclaimed damages arising from any other usage.

STORAGE AND STABILITY

When used to monitor the precision of urinalysis reagent strips, Audit® Micro*DROP*™ Urine Dipstick Control is stored at 2-8℃ and will remain stable in the dropper bottle at 2-8℃ until the expiration date. After opening, the contents should be used according to the manufacturer's instructions and are stable at room temperature for 30 days. If you choose not to keep the product at room temperature then immediately return the dropper bottle to 2-8℃. Leaving the bottle uncapped, or prolonging its time at room temperature, will void this stability claim. Make sure the contents of the bottle are well mixed before use.

PROCEDURE

Follow the manufacturer's instructions provided for urinalysis reagent strips. Verify that the lot number on the bottle matches the assay sheet. To avoid evaporation, do not leave the bottle uncapped. Q.C. requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements. Controls should be run:

1. daily, in conjunction with patient samples.
2. as recommended by the manufacturer.
3. as required by the relevant regulatory agency.

Materials provided

- Audit® Micro*DROP*™ Urine Dipstick Control, Bi-Level, 4 x 25mL

EXPECTED VALUES

The expected ranges for visual readings for each level, based on interlaboratory data established by comparing the dipstick reaction that occurs with the controls to the color comparison chart with multiple lots of each manufacturers' dipsticks or reagent tablets, is provided below.

INSTRUCTIONS FOR USE

1. The Audit® Micro*DROP*™ Urine Dipstick Control should be stored at 2-8℃. Do not shake. Do not mix mechanically.

2. Remove the controls from the refrigerator and allow to come to room temperature (20-25℃) at least 15 minutes, depending on the remaining volume. Mix gently by inversion to assure complete mixing of the contents.

3. Remove cap and invert bottle. While holding the dipstick, gently squeeze the dropper bottle, and touch the tip of the bottle to the dipstick, thoroughly saturating each pad. Turn dipstick on its side to drain excess control material onto an absorbent material.

2. Read the urine dipstick in accordance with the manufacturer's instruction manual.

3. After sampling, wipe off dropper tip, replace cap and return to 2-8℃ when not in use.

LIMITATIONS OF THE PROCEDURE

Some analytes may take longer to develop than the indicated times. Bilirubin and urobilinogen may not show characteristic colors on some strips. Make sure that the vial is brought to room temperature before testing. If the liquid in the vial becomes frozen, discard and use another vial, as the results will not be valid.

ORDERING INFORMATION

Multistix®,Acetest®, Clinitest® and Status® are registered trademarks of Siemens Healthcare Diagnostics. Chemstrip® is a registered trademark of Roche Diagnostics. iChem™ is a registered trademark of IRIS International, Inc.

Product Number	Product Description	Product Packaging
K065M-4	Audit® Micro*DROP*™ Urine Dipstick Control	4x25mL

Siemens Multistix® Urinalysis Reagent Strips

	Level 1 (Lot # 06168)	***Level 2 (Lot #06169)***
Glucose	Negative	100 – 2000 mg/dL
Bilirubin	Negative	Small (+) – Large (+++)
Ketones	Negative	5 (tr) - ≥180 (Large)
Specific Gravity	1.010 - ≥1.030	1.000 – 1.015
Blood	Negative	Small (+) – Large (+++)
PH	5 – 6.5	7.5 - ≥8.5
Protein	Negative	30 (+) - ≥300 (+++) mg/dL
Urobilinogen	0.2 mg/dL	1 – 8 mg/dL
Nitrite	Negative	Positive
Leukocytes	Negative	Trace – Large (+++)

Iris vChem™ 10 SG Urinalysis Reagent Strips

	Level 1 (Lot # 06168)	***Level 2 (Lot #06169)***
Urobilinogen	Negative	1 - ≥8 mg/dL
Glucose	Negative	50 - ≥1000 mg/dL
Ketones	Negative	Small (+) – Large (+++)
Bilirubin	Negative	Small (+) – Large (+++)
Protein	Negative	30 - ≥500 mg/dL
Nitrite	Negative	Positive
Leukocytes	Negative	25 – 500 Leuk/uL
Blood	Negative	Small (+) – Large (+++)
PH	5 – 6.5	7 - 9
Specific Gravity	1.010 – 1.035	1.000 – 1.015

Roche Chemstrip® Urinalysis Reagent Strips

	Level 1 (Lot # 06168)	***Level 2 (Lot # 06169)***
pH	5 – 6.5	7 - 9
Leukocytes	Negative	Trace – (++)
Nitrite	Negative	Positive
Protein	Negative	30 (+) - ≥500 (+++)
Glucose	Negative	50 - ≥1000 mg/dL
Ketones	Negative	Small (+) – Large (+++)
Urobilinogen	Negative	1 – 12 mg/dL
Bilirubin	Negative	Small (+) – Large (+++)
Blood	Negative	50 (+) - ≥250 (+++) Ery/uL
Specific Gravity	1.010 – 1.030	1.000 – 1.015

	Level 1 (Lot # 06168)	***Level 2 (Lot #06169)***
Acetest	Negative	Positive
Clinitest	Negative	¼ - 1%
Total Protein (sulfosalicylic acid)	Negative	Positive

Clinitek Status® Analyzer

	Level 1 (Lot # 06168)	***Level 2 (Lot #06169)***
pH	5.5 – 6.5	8 – 9
Leukocytes	Negative	Trace – Large (+++)
Nitrite	Negative	Positive
Protein	Negative	250 – 350 mg/dL
Glucose	Negative	250 – 500 mg/dL
Ketones	Negative	≥160 mg/mL
Blood	Negative	Small (+) – Large (+++)
Specific Gravity	1.020 - ≥1.030	1.010 – 1.020
Bilirubin	Negative	Small (+) – Large (+++)
Urobilinogen	0.2 mg/dL	1 – 8 mg/dL

Siemens Uristix®

	Level 1 (Lot # 06168)	***Level 2 (Lot #06169)***
Glucose	Negative	100 – 2000 mg/dL
Protein	Negative	30 - ≥300 mg/dL

	Level 1 (Lot # 06168)	***Level 2 (Lot # 06169)***
hCG	Negative	Positive

Multistix®,Acetest®, Clinitest® and Status® are registered trademarks of Siemens Healthcare Diagnostics. Chemstrip® is a registered trademark of Roche Diagnostics. iChem™ is a registered trademark of IRIS International, Inc.