



LIQUID URINE CONTROL FOR MICROSCOPIC ASSAY CATALOG NUMBER 210307

Lot Numbers : 183338 Level-1
183339 Level-2

183337 BI - LEVEL KIT
Exp. Date : Jun 05

PRINCIPLE

The usefulness of Quality Control materials for monitoring the accuracy and precision of clinical testing is well documented.

KENLOR LIQUID URINE CONTROL FOR MICROSCOPIC ASSAY.

KENLOR LIQUID URINE CONTROL FOR MICROSCOPIC ASSAY is stable for two years at refrigerated temperature of 2^o-8^o C. The control should be used like a patient sample to assist in the assessment of the listed analytical procedures.

PROCEDURE

To use, remove control from refrigerator and invert several times (do not shake) to assure complete mixing of the contents. Remove bottle cap and pour 12 ml into a clean, dry conical centrifuge tube. Centrifuge the tube for 5 minutes at 2000 RPM. Remove control from the centrifuge and pour off and discard all but 0.5 ml of the supernatant. Resuspend the sediment in the remaining 0.5 ml of supernatant by touching the bottom of the tube to a vortex machine or by flicking the bottom of the tube with your finger. Transfer a drop of the resuspended sediment to a clean dry microscope slide and cover with a cover slip. Count and record the average number of cells found in 10 high power field.

ASSIGNMENT OF VALUES

The values assigned to each constituent is derived from assay of multiple vials that are representative of the lot. These values should be used only as a guidelines by the laboratory until it has established its own precision and accuracy parameters.

LIMITATION OF THE PROCEDURE

The listed value and ranges were obtained using instruments, reagents and procedures available at the time of analysis. Any changes in the reagents, methods or instrument methodology by the manufacturer may result in different values. Consult manufacturer's instructions for the procedures for further information. Laboratories employing methods other than those listed should establish their own mean values and ranges and determine if there is any interaction and/or interference from the system.

SPECIFIC PERFORMANCE CHARACTERISTICS

The values listed detail the characteristics of the Kenlor Liquid Urine Control for Microscopic Assay and outlines the reliability and usefulness of the product in clinical quality control.

PRODUCT STABILITY

The product is stable up to expiration date printed on the label if kept at 2⁰-8⁰ C and used as directed.

This product is warranted to perform as described in its labeling and in the product literature. Kenlor Industries, Inc. disclaims any implied warranty or merchantability or fitness for any other purpose, and in no event shall be liable for any consequential damages arising out of the aforesaid expressed warranty.

ASSIGNED VALUES

LIQUID MICROSCOPIC CONTROL LEVEL-1

Lot Number : 183338	Exp. Date : Jun 05
pH METER	5.0 – 7.0
pH (Multistix 10 SG)	5.0- 7.0
SPECIFIC GRAVITY (Multistix 10 SG)	1.015 ≥1.030
pH (Chemstrip 10 SG)	5.0-7.0
SPECIFIC GRAVITY (Chemstrip 10 SG)	1.015 ≥ 1.030
SPECIFIC GRAVITY (Urinometer&and T.S. Meter [@]) :	1.010 -1.025

MICROSCOPIC

Constituent	Method	Value Range
Red Cells	hpf [‡]	0—10
White Cells	hpf	0—5
Crystals	hpf	0 — present
Casts	lpf [#]	absent

ASSIGNED VALUES

LIQUID MICROSCOPIC CONTROL LEVEL-2

Lot No. : 183339

Exp. Date : Jun 05

pH (pH METER) 6.5-8.5
pH (Multistix 10 SG) 7.0-9.0
SPECIFIC GRAVITY (Multistix 10 SG) 1.005-1.025

pH (Chemstrip 10 SG) 7.0-9.0
SPECIFIC GRAVITY (Chemstrip 10 SG) 1.010 -1.025

SPECIFIC GRAVITY (Urinometer&and T.S. Meter@) : 1.005 - 1.020

MICROSCOPIC

Constituent	Method	Value Range
Red Cells	hpf [‡]	5 — 80
White Cells	hpf	1 — 20
Crystals	hpf	Present
Casts	lpf [#]	Absent

N.A. : NOT AVAILABLE

* : MULTISTIX, CLINITEK 100, 200, 200+ , CLINITEST, ICTOTEST AND ACETEST ARE REGISTERED PRODUCTS OF AMES CORPORATION

** : CHEMSTRIP IS A REGISTERED PRODUCT OF BOEHRINGER MANNHEIM CORPORATION.

@ : Cambridge Instruments, Inc. Buffalo, NY

& : Profex Co.

‡ : High power field

: Low power field

STORE AT 2-8° C.

WASTE DISPOSAL METHOD : The above product contains 0.05% **sodium azide** as preservative. Best disposal method for biological material containing sodium azide is to wash it down sewer with large excess of water . Disposal should be made in accordance with existing disposal practices. Observe all Federal, State and Local laws.

BIOHAZARD

CAUTION : Human source material used in the preparation has been found non-reactive for HBsAg when tested by RIA , and also negative for HIV-1 antibody when tested by ELISA. However, no known test method can assure that a product derived from human source does not contain hepatitis or HIV-1 viruses.

**WARNING : HANDLE AS IF CAPABLE OF TRANSMITTING HEPATITIS
FOR IN VITRO DIAGNOSTIC USE ONLY, NOT FOR INTERNAL USE BY HUMANS OR ANIMALS.**

**KENLOR INDUSTRIES INC.
1560 E.EDINGER STE A 1
SANTA ANA CA 92705
800-899-9371, FAX 714-647-0593
website: KENLOR.COM**

A183337 - 210307