LIQUID URINE CONTROL
FOR DIPSTICK AND MICROSCOPIC ASSAY

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

KENLOR LIQUID URINE CONTROL FOR DIPSTICK AND MICROSCOPIC ASSAY.

KENLOR LIQUID URINE CONTROL FOR DIPSTICK AND MICROSCOPIC ASSAY is stable for two years at refrigerated temperature of 2^{o}-8^{o} C, and four weeks at room temperature (18 –25 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. For 115 ml bottle and 20 ml product, transfer 12 ml to a centrifuge tube for microscopic analysis. To check dipsticks, keep the control at room temperature for 10 - 15 minutes to let it warm and then completely immerse a dipstick into the tube, remove, blot excess fluid and check according to the manufacturer's instructions. For microscopic analysis, centrifuge the tube for 5 minutes at 2000 RPM. Remove control from the centrifuge and pour off or aspirate 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 fields. The standard procedure specifies 12 ml of sample to conduct the test. However smaller or larger volumes can be used as the sample volume. If the amount used is significantly less than the standard volume, crystals may not appear in every field when analysing Level-2.

If the final volume is kept the same (0.5 ml), then the values should be adjusted as follows :

Corrected values = Volume used/12 ml X values in the insert.

EXAMPLE : If the sample is 6 ml instead of 12 ml, then the given value of 12 RBC per hpf should be changed to 6 ml/12 ml X 12 = 6 RBC per hpf.

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 Dipstick and Microscopic Assay and outlines the reliability and usefulness of the product in clinical quality control.

STORE AT 2-8^{o} C.

PRODUCT STABILITY

The product is stable up to expiration date printed on the label if kept at 2°-8° C and used as directed. After opening and initial use, the product is stable for two weeks or 15 immersions whichever occurs first. When stored at room temperature after opening the product is stable for two weeks or 10 immersions whichever occurs first. Discard the control if turbid or any evidence of microbial contamination is present, however, it is normal to observe some sedimentation at the bottom of the tube when stored for a long time.

This product is warranted to perform as described in its labeling and in the product literature. Kenlor Industries, Inc. disclaims any implied warranty, 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 URINE CONTROL FOR DIPSTICK AND MICROSCOPIC ASSAY
LEVEL-1

Lot Number : 338128 Exp. Date :Dec/23

PHYSICAL CHARACTERISTICS :

PROPERTY	OBSERVATION OR VALUE RANGE	METHOD
APPEARANCE	CLEAR	VISUAL
COLOR	YELLOW	VISUAL
SPECIFIC GRAVITY	1.010 - 1.030	REFRACTOMETER@
SPECIFIC GRAVITY	1.010 - 1.030	URINOMETER
pH	5-7	pH METER

ALTERNATIVE TESTS

HCG : QuPID PREGNANCY (STANBIO) NEGATIVE

REAGENT STRIP RESULTS :

CONSTITUENT	MULTISTIX SG 10*		**
	VISUAL	CLINITEK 50,100, 200, AND 200+ 500 Status, Atlas	
pH	5 –8	5 – 8	
SPECIFIC GRAVITY	1.010 – 1.030	1.010 – 1.030	
BILIRUBIN	NEG	NEG	
GLUCOSE	NEG	NEG	
KETONES	NEG	NEG	
UROBILINOGEN	NORMAL	0.2 EU/dl	
PROTEINS	NEG	NEG	
NITRITE	NEG	NEG	
BLOOD	NEG- TR	NEG-TR	
HEMOGLOBIN	N.A.	N.A.	
LEUKOCYTES	NEG	NEG	

MICROSCOPIC

Constituent	Method	Value Range

Red Cells	hpf‡	1 - 12
White Cells	hpf	0 - 4
Crystals	hpf	0 - Present
Casts	hpf	absent

LIQUID URINE CONTROL DIPSTICK AND MICROSCOPIC ASSAY LEVEL-2

Lot No. : 102129 Exp. Date :Apr/23

PHYSICAL CHARACTERISTICS :

PROPERTY	OBSERVATION OR VALUE RANGE	METHOD
APPEARANCE	CLEAR	VISUAL
COLOR	YELLOW	VISUAL
SPECIFIC GRAVITY	1.005 - 1.025	REFRACTOMETER@
SPECIFIC GRAVITY	1.005 - 1.025	URINOMETER
pH	6.5 – 8.5	pH METER

ALTERNATIVE TESTS

CONSTITUENT/METHOD	RESULTS
HCG : QuPID PLUS PREGNANCY (STANBIO)	Positive

REAGENT STRIP RESULTS :

CONSTITUENT	MULTISTIX SG 10*	**
	VISUAL	CLINITEK 50,100,200 AND 200+ 500 Status, Atlas
pH	6.0-9.0	6.0 – 9.0
SPECIFIC GRAVITY	1.005-1.025	1.005-1.025
BILIRUBIN	SMALL TO MOD	SMALL TO LRG
GLUCOSE	100 - 1000 mg/dl	100–1000 mg/dl
KETONES	5 - 160 mg/dl	5–160 mg/dl
UROBILINOGEN	1– 4 EU/dl	1–4 EU/dl
PROTEINS	30 – 300 mg/dl	30 – 300 mg/dl
NITRITE	POSITIVE	POSITIVE
BLOOD	SMALL–LARGE	SMALL–LARGE
HEMOGLOBIN	N.A.	N.A.
LEUKOCYTES	TRACE–MOD	TRACE–MOD

Urisys has been recalled by the manufacturer.

MICROSCOPIC

Constituent	Method	Value Range
Red Cells	hpf‡	22- 198
White Cells	hpf	0 - 17

Crystals	hpf	0 - Present
Casts	hpf	Absent

N.A. : NOT AVAILABLE

* : MULTISTIX, CLINITEK 50,100, 200, 200+ , CLINITEST, ICTOTEST AND ACETEST ARE REGISTERED PRODUCTS OF BAYERS CORPORATION

** : CHEMSTRIP IS A REGISTERED PRODUCT OF ROCHE CORPORATION.

¶ : Read the color of Ketones as directed on the manufacturer's label. Reading color after recommended time period may result in lower value.

§ : On Chemstrip SG-10, the reagent area will read either as Hemoglobin or whole blood. The control gives reading as hemoglobin only.

@ : Cambridge Instruments, Inc. Buffalo, NY

‡ : High power field

: Low power field

QuPID PLUS is a product of Stanbio Corp San Antonio TX USA.

WASTE DISPOSAL METHOD : The above product contains **sodium azide** as preservative. Best disposal method for biological material containing sodium azide is to wash it down the 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.

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