SEMIQUANTITATIVE (DIPSTICK) LIQUID CONTROL

PRINCIPLE

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

KENLOR LIQUID URINE CONTROL FOR SEMIQUANTITATIVE (DIPSTICK) ASSAY
KENLOR LIQUID URINE CONTROL for semiquantitative (Dipstick) assay is liquid, stable for 2 years at a refrigerated temperature of 2^{o}-8^{o} C. The control is designed specifically to react with commercial dipsticks to register listed responses on the color pads. The control should be used like a patient sample to assist in the assessment of the listed analytical procedures and routinely used for the day to day quality control of the assay system.

PROCEDURE: Bring controls to room temperature.
To use, remove dropper tip cap, invert and apply control material directly onto the dipstick by gently squeezing the bottle. Remove excess control by tilting the dipstick on its edge on a paper towel. **If the bottle will be used within 30 days you may recap the control and leave it at ambient room temperature (15^{o}-25^{o} C)**. If the bottle will be used beyond 30 days, store the bottle at 2^{o}-8^{o} C. The LIQUID CONTROL is specially designed and packaged to be stable in liquid state for two years. The stable LIQUID CONTROL eliminates errors arising from lyophilization, pipeting errors and discrepancies due to uneven lyophilization or improper mixing.

ASSIGNMENT OF VALUES:
The value 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. THE KENLOR LIQUID URINE CONTROL FOR SEMIQUANTITATIVE (DIPSTICK) ASSAY contains certain chemical analogs of the constituents which simulates the color reaction on the dipstick pads. The listed values are method dependent and different laboratories may observe variations as a result of differences in techniques, the instrument and/or reagent variation, method modifications and other systemic and random errors. These differences may result in the values to fall outside the suggested ranges.

LIMITATION OF THE PROCEDURE :
The listed value and ranges were obtained using instruments, reagents and procedures available at the time of analysis. Any change 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 SEMIQUANTITATIVE (DIPSTICK) ASSAY, and outlines the reliability and usefulness of the product in clinical quality control.

PRODUCT STABILITY:
The product is stable up to the expiration date printed on the label if kept at 2^{o}-8^{o} 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, 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.

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Ph: 800-899-9371, 714-647-0770
Fax 714-647-0593

ASSIGNED VALUES:

LIQUID URINE CONTROL DIPSTICK NEGATIVE (Level 1)

LOT No.: 339133 **EXP. DATE: NOV23**

PHYSICAL CHARACTERISTICS :

PROPERTY	**OBSERVATION OR VALUE RANGE**	**METHOD**
APPEARANCE	CLEAR	VISUAL
COLOR	YELLOW	VISUAL
SPECIFIC GRAVITY	1.010 -1.030	REFRACTOMETER
pH	5.0 – 7.5	pH METER

ALTERNATIVE TESTS

HCG

QuPID PLUS Pregnancy Test NEGATIVE

LIQUID URINE CONTROL DIPSTICK POSITIVE (Level 2)

LOT No.: 339134 **EXP. DATE: NOV23**

PHYSICAL CHARACTERISTICS :

PROPERTY	**OBSERVATION OR VALUE RANGE**	**METHOD**
APPEARANCE	CLEAR	VISUAL
COLOR	YELLOW	VISUAL
SPECIFIC GRAVITY	1.005 -1.020	REFRACTOMETER
pH	6.0-8.5	pH METER

ALTERNATIVE TESTS

HCG

QuPID PLUS Pregnancy test POSITIVE

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Level 1 Lot #	**339133**	**Exp. Date**	**NOV23**
Level 2 Lot #	**339134**	**Exp. Date**	**NOV23**

All Multi Stix Dipstick

	Clinitek 100 50 200, 200+, 500 Status, Status +,Atlas	Clinitek 100 50 200, 200+, 500 Status, Status +, Atlas		Visual	Visual
Lot #	**339133**	**339134**		**339133**	**339134**
pH	5.0 – 8.0	6.0-9.0		5.0 – 8.0	6.0-9.0
SPECIFIC GRAVITY	1.015 – 1.030	1.005-1.025		1.015 ≥ 1.030	1.005-1.025
BILIRUBIN	Negative	Small to Large		Negative	Small to Large
GLUCOSE	Negative	TR - ≥ 500 mg/dl		Negative	TR - > 500 mg/dl
KETONES	Negative	TR -160 mg/dl		Negative	TR - 160 mg/dl
UROBILINOGEN	0.2 EU/dl	1- 12 EU/dl		0.2 EU/dl	1- 12 EU/dl
PROTEINS	Negative	30 - ≥ 300 mg/dl		Negative	30 - ≥ 300 mg/dl
NITRITE	Negative	Positive		Negative	Positive
BLOOD	Negative	Small - Large		Negative	Small - Large
HEMOGLOBIN	N.A.	N.A.		N.A.	N.A.
LEUKOCYTES	Negative	Trace-MOD		Negative	Trace-MOD

Microalbumin	339133	339134
Constituent	Clinitek (Bayer)	Clinitek (Bayer)
Albumin	10 – 30 mg/l	100 – 200 mg/l
Creatinine	10 – 50 mg/l	50 – 100 mg/l
A:C	< 30 mg/g	≥ 300 mg/g

All Chemstrip Dipstick

	MINI UA, Criterion Urisys 1100,1800,2400	MINI UA,Criterion Urisys 1100.1800,2400		Visual	Visual
Lot #	**339133**	**339134**		**339133**	**339134**
pH	5.0 – 8.0	6.0-9.0		5.0 – 8.0	6.0-9.0
SPECIFIC GRAVITY	1.005 – 1.030	1.005-1.025		1.005 – 1.030	1.005-1.025
BILIRUBIN	Negative	1-6 mg/dl		Negative	+To+++
GLUCOSE	NORMAL	100- ≥ 250 mg/dl		NORMAL	100->500 mg/dl
KETONES	Negative	50-150 mg/dl		Negative	+To+++
UROBILINOGEN	NORMAL	1->8 mg dl		NORMAL	1-12 mg/dl
PROTEINS	Negative	30-500 mg/dl		Negative	30-500 mg/dl
NITRITE	Negative	Positive		Negative	Positive
BLOOD	Negative	§		Negative	§
HEMOGLOBIN	Negative	50-250 Ery/ml		Negative	About 50-250
LEUKOCYTES	Negative	75-500 Leu/ul		Negative	TR to ++

Microalbumin	339133	339134
Constituent	Chemstrip Micral (Roche)	Chemstrip Micral (Roche)
Albumin	Negative	50 - ≥ 100 mg/l
Creatinine	NA	NA
A:C	NA	Abnormal - High

N.A. : NOT AVAILABLE

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* : MULTISTIX, CLINITEK 100, 200, 200+ , CLINITEST, ARE REGISTERED PRODUCTS OF BAYER CORPORATION
** : CHEMSTRIP IS A REGISTERED PRODUCT OF ROCHE CORPORATION.
§ : On all Chemstrip dipstick, the reagent area will read either as Hemoglobin or whole blood. The control gives reading as hemoglobin only.
@ : Cambridge Instruments, Inc. Buffalo, NY
QuPID PLUS is a product of Stanbio Corporation San Antonio TX USA

STORE AT 2^{0}-8^{0} C.

WASTE DISPOSAL METHOD : The above product contains 0.10% **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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