



SEMIQUANTITATIVE (DIPSTICK) LIQUID CONTROL CATALOG NUMBERS 210303, 210304 AND 210306

Lot Numbers : 225333 DIPSTICK NEGATIVE
230334 DIPSTICK POSITIVE

230336 DIPSTICK KIT
Exp. Date : Jul/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 SEMIQUANTITATIVE (DIPSTICK) ASSAY

KENLOR LIQUID URINE CONTROL for semiquantitative (Dipstick) assay is liquid, stable for 2 years at a refrigerated temperature of 2°-8° 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°-25° C).** If the bottle will be used beyond 30 days, store the bottle at 2°-8° 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.

ASSIGNED VALUES :

LIQUID URINE CONTROL DIPSTICK NEGATIVE

LOT No. : 225333

EXP. DATE : Jul/05

PHYSICAL CHARACTERISTICS :

PROPERTY	OBSERVATION OR VALUE RANGE	METHOD
APPEARANCE	CLEAR	VISUAL
COLOR	YELLOW	VISUAL
SPECIFIC GRAVITY	1.010 -1.030	REFRACTOMETER@
pH	5.0 – 7.0	pH METER

ALTERNATIVE TESTS

HCG

QuPID PLUS Pregnancy Test

NEGATIVE

REAGENT STRIP RESULTS :

CONSTITUENT	MULTISTIX SG 10*		CHEMSTRIP	
	VISUAL	CLINITEK 100*, 200,200+ CLINITEK 50*	VISUAL 10 WITH SG++	MINI UA 10 -M UA
pH	5 – 7	5 – 7	5 – 7	5 – 7
SPECIFIC GRAVITY	1.015 – 1.030	1.015 – 1.030	1.015–1.030	1.010 – 1.030
BILIRUBIN	NEG	NEG	NEG	NEG
GLUCOSE	NEG	NEG	NORMAL	NORMAL
KETONES	NEG	NEG	NEG	NEG
UROBILINOGEN	NORMAL	0.2 EU/dl	NORMAL	NORMAL
PROTEINS	NEG	NEG	NEG	NEG
NITRITE	NEG	NEG	NEG	NEG
BLOOD	NEG	NEG	§	§
HEMOGLOBIN	N.A.	N.A.	NEG	NEG
LEUKOCYTES	NEG	NEG	NEG	NEG

LIQUID URINE CONTROL DIPSTICK POSITIVE

LOT No. : 230334

EXP. DATE : JUL /05

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

REAGENT STRIP RESULTS :

CONSTITUENT	MULTISTIX SG 10*		CHEMSTRIP **	
	VISUAL	CLINITEK 50,100,200 AND 200+	VISUAL 10 WITH SG	MINI UA 10 M - UA
pH	6.0-8.5	6.0 – 8.5	6.0-8.5	6.0 – 8.5
SPECIFIC GRAVITY	1.005-1.020	1.005-1.025	1.005-1.025	1.005 – 1.025
BILIRUBIN	SMALL TO LARGE	SMALL TO LARGE	+ TO +++	1-6 mg/dl
GLUCOSE	TR - > 500 mg/dl	TR->≥500 mg/dl	100- >500 mg/dl	100 – ≥250 mg/dl
KETONES	TR->80 mg/dl	TR->80 mg/dl	+ to +++	50 – 150 mg/dl
UROBILINOGEN	1-4 EU/dl	1-4 EU/dl	1-12 mg/dl	1 – >8 mg/dl
PROTEINS	30 – ≥ 300 mg/dl	30 – ≥ 300 mg/dl	30 - 500 mg/dl	30 – 500 mg/dl
NITRITE	POSITIVE	POSITIVE	POSITIVE	POSITIVE
BLOOD	SMALL-LARGE	SMALL-LARGE	§	§
HEMOGLOBIN	N.A.	N.A.	About 50-250	50 – 250 Ery/μl
LEUKOCYTES	TRACE-MOD	TRACE-MOD	+ to +++	75 – 500 Leu/μl

N.A. : NOT AVAILABLE

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

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

§ : 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

QuPID PLUS is a product of Stanbio Corporation San Antonio TX USA

STORE AT 2°-8° 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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