SEMIQUANTITATIVE (DIPSTICK) LIQUID CONTROL

CATALOG NUMBERS: 210303, 210304 AND 210306

Lot Numbers : 006933 DIPSTICK NEGATIVE 006936 DIPSTICK KIT
006934 DIPSTICK POSITIVE Exp. Date : Dec/10

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.

www.kenlor.com
Ph: 800-899-9371, 714-647-0770
Fax 714-647-0593

ASSIGNED VALUES:

LIQUID URINE CONTROL DIPSTICK NEGATIVE (Level 1)

LOT No.: 006933 **EXP. DATE: Dec /10**

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.: 006934 **EXP. DATE: Dec /10**

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

Semi Quantitative Dipstick Liquid Urine Control

Catalog Numbers	**210303, 210304 & 210306**		
Level 1 Lot #	**006933**	**Exp. Date**	**Dec-10**
Level 2 Lot #	**006934**	**Exp. Date**	**Dec-10**

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Fax 714-647-0593

All Multi Stix Dipstick					
	Clinitek 100 200, 200+, 50 Status, Atlas	Clinitek 100 200, 200+, 50 Status, Atlas		Visual	Visual
Lot #	**006933**	**006934**		**006933**	**006934**
pH	5.5 – 8.0	6.0-9.0		5.5 – 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 -> 80 mg/dl		Negative	TR - > 80 mg/dl
UROBILINOGEN	0.2 EU/dl	1-4 EU/dl		0.2 EU/dl	1-4 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 Constituent	**006933** Clinitek (Bayer)			**006934** 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 Urisys 1100	MINI UA Urisys 1100		Visual	Visual
Lot #	**006933**	**006934**		**006933**	**006934**
pH	5.5 – 8.0	6.0-9.0		5.5 – 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	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 Constituent	**006933** Chemstrip Micral (Roche)			**006934** Chemstrip Micral (Roche)	
Albumin	Negative			50 - ≥ 100 mg/l	
Creatinine	NA			NA	
A:C	NA			Abnormal - High	

N.A. : NOT AVAILABLE

* : MULTISTIX, CLINITEK 100, 200, 200+ , CLINITEST, ARE REGISTERED PRODUCTS OF BAYER CORPORATION

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

www.kenlor.com
Ph: 800-899-9371, 714-647-0770
Fax 714-647-0593

§ : 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^{o}-8^{o} 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.

A006936-210306 G

www.kenlor.com
Ph: 800-899-9371, 714-647-0770
Fax 714-647-0593

LIQUID URINE CONTROL
FOR DIPSTICK AND MICROSCOPIC ASSAY
CATALOG NUMBERS 220301, 220302, 220305, 220306, 220307, 220308, 220310

Lot Numbers : 280838 Level-1 280830 BI - LEVEL KIT
337829 Level-2 Exp. Date : Sep /10

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 months 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^{o}-8^{o} 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 : 280838 Exp. Date : Sep /10

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*		CHEMSTRIP	
	VISUAL	CLINITEK 50,100, 200, AND 200+ Status, Atlas	VISUAL 10 WITH SG++	MINI UA 10 MD Urisys 1100,2400 Criterion
pH	5 –8	5 – 8	5 – 8	5 – 8
SPECIFIC GRAVITY	1.010 – 1.030	1.010 – 1.030	1.010–1.030	1.010 – 1.030
BILIRUBIN	NEG	NEG	NEG	NEG
GLUCOSE	NEG	NEG	NEG	NEG
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

MICROSCOPIC

Constituent	Method	Value Range
Red Cells	hpf‡	0 - 12
White Cells	hpf	0—3

Crystals	hpf	0 - Present
Casts	hpf	absent

LIQUID URINE CONTROL DIPSTICK AND MICROSCOPIC ASSAY LEVEL-2

Lot No. : 337829 Exp. Date : Nov /10

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*		CHEMSTRIP **	
	VISUAL	CLINITEK 50,100,200 AND 200+ Status, Atlas	VISUAL 10 WITH SG	MINI UA 10 MD Urisys 1100, 2400 Criterion
pH	6.0-9.0	6.0 – 9.0	6.0-9.0	6.0 – 9.0
SPECIFIC GRAVITY	1.005-1.025	1.005-1.025	1.005-1.025	1.005 – 1.025
BILIRUBIN	SMALL TO MOD	SMALL TO LRG	+ TO +++	1 – 6 mg/dl
GLUCOSE	100 - 1000 mg/dl	100–1000 mg/dl	100–1000 mg/dl	100-- 1000 mg/dl
KETONES	5 -> 80 mg/dl	5–>80 mg/dl	+ TO +++	50 – 150 mg/dl
UROBILINOGEN	1– 4 EU/dl	1–4 EU/dl	1-8mg/dl	1 ≥ 8 mg/dl
PROTEINS	30 – 300 mg/dl	30 – 300 mg/dl	TR-500mg/dl	TR–500mg/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	TR to ++	50 – 500 Leu/µl

MICROSCOPIC

Constituent	Method	Value Range
Red Cells	hpf‡	19 - 245
White Cells	hpf	0 - 22
Crystals	hpf	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.

KENLOR INDUSTRIES INC.
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A280830-220305 X

LIQUID URINE CONTROL
FOR MICROSCOPIC ASSAY
CATALOG NUMBER 210307, 210308, 210309

Lot Numbers : 280838 Level-1
280839 Level-2

280837 BI - LEVEL KIT
Exp. Date : Oct 10

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 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 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 : 277738 Exp. Date : Oct 10

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—9
White Cells	hpf	0—3
Crystals	hpf	0 — present
Casts	lpf#	absent

ASSIGNED VALUES

LIQUID MICROSCOPIC CONTROL LEVEL-2

Lot No. : 281739 Exp. Date : Oct 10

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‡	12 — 225
White Cells	hpf	0 — 19
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^{o} 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.
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714-647-0770, FAX 714 - 647 - 0770
WWW.KENLOR.COM

A 280837 - 210307

KENLOR
LIQUID URINE MICROALBUMIN CONTROL
FOR CLINITEK STRIP
CATALOG NUMBERS 170804

Lot Numbers : 332831 LEVEL 1 Bi – Level Kit 332833
332832 LEVEL 2 Exp. Date : Dec 10

PRINCIPLE

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

KENLOR LIQUID URINE CONTROL FOR MICROALBUMIN ASSAY

KENLOR LIQUID URINE CONTROL for Microalbumin assay is liquid, stable for 2 years at a refrigerated temperature of 2º-8º C. The control is designed specifically to be used in assays for microalbuminin urine. 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 :

For dipstick use , remove cap insert dipstick, remove the dipstick after the time recommended by the manufacturer of the dipstick. Follow the procedure for testing as described the manufacturer of the dipstick. **If the vial will be used within 30 days you may recap the control and leave it at ambient room temperature (15º-25º C)**. If the bottle will be used beyond 30 days, store the bottle at 2º-8º 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 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 MICROALBUMIN 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 2º-8º C. and used as directed. Once opened the product is stable or 60 days or 30 test per vial.

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 CLINITEK MICROALBUMIN
LEVEL 1

LOT No. : 332831 **EXP. DATE : Dec 10**

PHYSICAL CHARACTERISTICS :

PROPERTY	OBSERVATION OR VALUE RANGE	METHOD
APPEARANCE	CLEAR	VISUAL
COLOR	YELLOW	VISUAL
pH	7 - 8	pH METER

REAGENT STRIP RESULTS :

CONSTITUENT	CLINITEK 100
Albumin	**10 – 30 mg/l**
Creatinine	**10 - 50 mg/dl**
A:C	**< 30 mg/g Normal**

LIQUID URINE CONTROL FOR CLINITEK MICROALBUMIN LEVEL 2

LOT No. 332832 **EXP. DATE : Dec 10**

PHYSICAL CHARACTERISTICS :

PROPERTY	OBSERVATION OR VALUE RANGE	METHOD
APPEARANCE	CLEAR	VISUAL
COLOR	YELLOW-AMBER	VISUAL
pH	7.0-8.0	pH METER

REAGENT STRIP RESULTS :

CONSTITUENT	CLINITEK 100*
ALBUMIN	**100 – 200 mg/l**
CREATININE	**50 - 100 mg/dl**

A: C $\geq$ 300 mg/g Abnormal - High Abnormal

* CLINITEK : IS A REGISTERED PRODUCT OF BAYER CORPORATION.

STORE AT 2^{o}-8^{o} 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 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.

KENLOR IDUSTRIES INC.,
SANTA ANA , CA , 92705 USA
1-800-899-9371

A 332833- 170804

Addendum to the Product Insert:

UC Micro Albumin for Clinitek is produce from other UC already made for other kit.

UC Micro level – 1 for Roche designated product identification code 21 is also UC Micro level – 1 for Clinitek .

UC Quant Level 2, designated product code 02 is also UC Micro level –2 for Clinitek.

LIQUID URINE CONTROL
CAT. No. 210301; 210302 and 210305

Level-1 Lot No. : 312831 **Urine Control Kit** : 312835
Level-2 Lot No. : 312832 Exp. Date : Oct 10

INTENED USE:

As an external control for urine assays in Clinical Laboratories, Hospital Laboratories, etc. The controls gives values at two levels for quantitative assays. The usefulness of Quality Control materials for monitoring the accuracy and precision of clinical testing is well documented.

PRODUCT DESCRIPTION AND CONTENTS:

Ready to use stabilized, Liquid Urine Control at two Levels. The Control is made of synthetic aqueous base matrix supplemented with chemical and biological ingredients and analogs of urine constituents. Assay values are provided for popular methodologies for assays on Total Protein, Glucose, Sodium, Potassium, Chloride, Magnesium, Phosphorus, Creatinine, Urea, Uric acid and Amylase. The controls contain 0.05% Sodium azide as preservative. The source materials for different constituents are as follows

Total Protein : fractions of human whole blood, human plasma and serum;
Amylase : Amylases from bacterial and fungal origin;
Sodium, Potassium, Chloride, Magnesium, glucose, phosphate, urea, uric acid, creatine : chemicals.

KENLOR LIQUID URINE CONTROL is designed specifically to provide assayed values of the listed components. The control should be used like a patient sample to assist in the assessment of the listed analytical procedures. It is packaged as 6 X 10 ml bottles of individual Level or 3 X 10 ml bottles of each Level in a Kit form.

PROCEDURE:

The LIQUID URINE CONTROL should be used in the same manner as patient samples and routinely used for day to day quality control of the assay systems. To use, remove the cap and squeeze gently the required amount of control as needed for assay. Do not remove the dropper tips to retrieve material. After using, close the cap and store the remaining control at refrigerated temperature (2^{o}-8^{o}C).

ASSIGNMENT OF VALUES:

The mean value assigned to each method is derived from assay of 3 vials that are representative of the lot. The suggested target ranges represent 2 X Standard Deviation (S.D.) of the assayed values for quantitative assays. These values should be used only as a guideline by the laboratory until it has established its own precision and accuracy parameters. The listed values are method dependent and different laboratories may observe variations as a result of differences in technique, 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 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. **These controls are NOT designed to be used as calibrators for the machines.**

SPECIFIC PERFORMANCE CHARACTERISTICS:
The values listed detail the characteristics of the KENLOR LIQUID TOTAL URINE CONTROL and outlines the reliability and usefulness of the product in clinical quality control.

PRODUCT STABILITY:
The product is stable up to one year if kept at 2° - 8° C. After opening and initial use, the product is stable for one month (30 days). Once opened, the product should be stored at 2° - 8° C. If any visual signs of deterioration such as excessive cloudiness and/or microbial growth is observed, please discard the vial. It is normal to observe some sedimentation at the bottom of the tube when stored for a long time.

SUMMARY OF DATA: Stability of components of Urine Control were studied by measuring the individual components at a regular interval of time. The controls were kept at 2° - 8° C for the shelf life study. The mean of the assigned value is derived from assay of 24 vials that are representative of the lot. Suggested target ranges for quantitative values represent 2 X Standard Deviation (S.D.) of the assayed values. The stability data were obtained from the mean value of three vials analyzed at the regular interval of time. Studies on closed vial stability was conducted over a period of one year at 2° - 8° C indicates that all the components assayed remains within the assigned range for the duration and condition of the study. Based on this study a stability of one year is assigned for closed vials at refrigerated temperatures (2° - 8° C). Opened vials when used as directed and stored at 2°- 8° C are stable upto one month (thirty days).

ASSIGNED VALUES:

QUANTITATIVE ASSAYS:

Constituent Method of Analysis	Level-1	Level-2	Unit
Total Protein			
Dimension	15.8 ± 7.2	63.4 ± 11.8	mg/dl
Pyrogallol Red (Kenlor)	16.1 ± 8.1	64.1 ± 11.9	mg/dl
Glucose			
Hitachi 747	20 ± 7	83 ± 13	mg/dl
CX7	20 ± 8	80 ± 12	mg/dl
Sodium			
Hitachi 747	55 ± 14	169 ± 22	meq/l
CX7	56 ± 18	169 ± 21	meq/l

Constituent Method of Analysis	Level-1	Level-2	Unit
Potassium			
Hitachi 747	13 ± 6	57 ± 7	meq/L
CX7	18 ± 6	55 ± 7	meq/L

Chloride			
Hitachi 747	72 ± 11	214 ± 15	meq/L
CX7	72 ± 11	208 ± 19	meq/L
Calcium			
Hitachi 747	7.1 ± 3.6	3.3 ± 1.9	mg/dl
CX7	6.7 ± 4.1	3.2 ± 2.2	mg/dl
Magnesium			
Hitachi 747	8.2 ± 3.9	3.3 ± 1.9	mg/dl
CX7	8.7 ± 3.8	3.2 ± 2.1	mg/dl
Phosphorus			
Hitachi 747	6.8 ± 3.1	19.2 ± 6.4	mg/dl
CX7	6.7 ± 3.2	21.2 ± 6.3	mg/dl
Amylase			
Hitachi 747	205 ± 57	747 ± 67	U/L
Uric Acid			
Hitachi 747	4.2 ± 2.5	10.7 ± 4.8	mg/dl
CX7	4.3 ± 2.5	11.1 ± 3.6	mg/dl
Creatinine			
Hitachi 747	22 ± 7	73 ± 14	mg/dl
CX7	20 ± 5	68 ± 14	mg/dl
Urea/BUN			
Hitachi 747	81 ± 13	318 ± 47	mg/dl
CX7	82 ± 12	336 ± 46	mg/dl
Specific Gravity			
R J optical T.S. meter	1.001 – 1.007	1.005 – 1.015	
Osmolality	164 - 188	505 - 565	MOSM/KG

Store at 2 - 8^{o}C

CX7 : Trademark of Beckman Company

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 INFECTIONS
FOR IN VIRTO DIAGNOSTIC USE ONLY
NOT FOR INTERNAL USE BY HUMANS OR ANIMALS

MANUFACTURED BY : KENLOR INDUSTRIES, INC. SANTA ANA, CA 92705, USA

A312835 - 210305

LIQUID HUMAN SPINAL FLUID CONTROL
CAT. NO. 190601; 190602 AND 190605

Level-1 Lot No.: 042811 042815 BI-LEVEL KIT
Level-2 Lot No.: 042812 Exp. Date: Feb / 10

INTENDED USE:

As an external control for spinal fluid assays in Clinical Laboratories, Hospital Laboratories, etc. Assay values are provided for popular methodologies for assays on Protein, Glucose, Sodium, Potassium, Chloride, Lactic Acid, LDH, Albumin and Ig.G. Assay values for Electrophoretic separation are also provided. The usefulness of Quality Control materials for monitoring the accuracy and precision of clinical testing is well documented.

PRODUCT DESCRIPTION AND CONTENTS:

Ready to use stabilized, Liquid Human Spinal Fluid Control at two Levels representing Normal and Abnormal Controls. The product is prepared in a matrix of human plasma and serum fractions. The controls contain 0.1% Sodium azide and EDTA as preservatives.

KENLOR LIQUID HUMAN SPINAL FLUID CONTROL is designed specifically to provide assayed values of the listed components. The control should be used like a patient sample to assist in the assessment of the listed analytical procedures. It is packaged as 6 X 3 ml of individual Level or 3 X 3 ml of each Level in a Kit form.

PROCEDURE:

The **LIQUID HUMAN SPINAL FLUID CONTROL** should be used in the same manner as patient samples and routinely used for day to day quality control of the assay systems. To use, remove the cap and squeeze gently the required amount of control as needed for assay. Do not remove the dropper tips to retrieve material. After using, close the cap and store the remaining control at refrigerated temperature (2°-8°). The stable **LIQUID CONTROL** eliminates errors arising from lyophilization, pipeting errors and discrepancies due to uneven lyophilization or improper mixing.

ASSIGNMENT OF VALUES:

The mean value assigned to each method is derived from assay of 36 vials that are representative of the lot. The suggested target ranges represent 2 X Standard Deviation (S.D.) of the assayed values. These values should be used only as a guideline by the laboratory until it has established its own precision and accuracy parameters. The listed values are method dependent and different laboratories may observe variations as a result of differences in technique, 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.

LIMITATIONS 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. These controls are **NOT** designed to be used as calibrators for the machines.

SPECIFIC PERFORMANCE CHARACTERISTICS

The values listed detail the characteristics of the **KENLOR LIQUID HUMAN SPINAL FLUID CONTROL** and outlines the reliability and usefulness of the product in clinical quality control.

PRODUCT STABILITY:

The product is stable up to two years if kept at 2°- 8°C. The opened vials are stable for one month if used as directed. If any visual signs of deterioration such as cloudiness and/or precipitation is observed, please disregard the vial.

SUMMARY OF DATA: Stability of components of Spinal Fluid Controls was studied by measuring the individual components at a regular interval of time. The controls were kept at 37°C for the accelerated stability study and at 2°- 8°C for the shelf life study. The mean of the assigned value is derived from assay of 36 vials that are representative of the lot. The suggested target ranges represent 2 X Standard Deviation (S.D.) of the assayed values. The experimental values are the mean of the three vials analyzed at the time period. Studies on open and closed vial stability was conducted over a period of eight weeks at 37°C and continuous study at 2°- 8°C indicates that all the components assayed remains within the assigned range for the duration and condition of the study.

ASSIGNED VALUES:

Constituent	Method of Analysis	Level-1 Lot # 042811	Level-2 Lot # 042812	Unit
Total Protein	l			
	Coomassie Blue (Kenlor)	32 ±11	71 ± 13	mg/dl
	Pyrogallol Red (Kenlor)	34 ± 10	76 ± 14	mg/dl
	Hitachi	35 ± 12	78 ± 14	mg/dl

Glucose	Dimension	52± 11	108 ± 17	mg/dl
	Hitachi	56 ± 12	120 ± 15	mg/dl
Sodium	Hitachi 911	153 ± 14	181 ± 23	MEQ/L
	Dimension	152 ± 15	184 ± 21	MEQ/L
Potassium	Hitachi 911	3.2 ± 1.2	6.1 ± 1.3	MEQ/L
	Dimension	3.1 ± 1.2	6.2 ± 1.5	MEQ/L
Chloride	Hitachi 911	145 ± 16	184 ± 17	MEQ/L
	Dimension	141 ± 17	181 ± 16	MEQ/L
Lactic Acid	Dimension	2.0 ± 1.1	7.0 ± 2.9	mmol/L
	Cobas Bio	16 ± 8	60 ± 14	mg/dl
LDH	Dimension	14 ± 11	30 ± 14	IU/L
Albumin	Electrophoresis	18 ± 6	42 ± 8	mg/dl
	Immunodiagnostic	22 ± 7	49 ± 9	mg/dl
IgG	Nephelometric	3.9 ± 2	9.4 ± 3	mg/dl
	Immunodiagnostic	5.8 ± 2	16.2 ± 4	mg/dl

Constituent	Method of Analysis	Level-1 Lot # 042811	Level-2 Lot # 042812	Unit
*****ELECTROPHORESIS*****				
Total Protein		32 ± 10	74 ± 13	mg/dl
Prealbumin		0.8 ± 0.5	0.7 ± 0.5	%Total Protein
Albumin		58 ± 9	61 ± 7	"
Alpha 1 Globulin		5.3 ± 3.4	5.7 ± 4.9	"
Alpha 2 Globulin		12.2 ± 5.8	12.1 ± 5.7	"
Beta Globulin		9.4 ± 3.5	9.5 ± 4.5	"
Gamma Globulin		13.1 ± 4.2	12.8 ± 4.5	"

Dimension: Trademarks of DuPont Company
Hitachi: Trademark of Hitachi Co.
Cobas Bio: Trademark of Roche

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.

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 ELISIA. 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 INFECTIONS
FOR IN VITRO DIAGNOSTIC USE ONLY
NOT FOR INTERNAL USE BY HUMANS OR ANIMALS

MANUFACTURED BY KENLOR INDUSTRIES, INC. SANTA ANA, CA 92705, USA

A042815-190605 R1

KENLOR
Liquid H.Pylori Human IgG Antibody Serum Control
(Unassayed)

CATALOG NUMBER 150302

KIT CONTENT: H. Pylori stabilized Liquid IgG Antibody Serum Control.

3 x 1 ml of Level - 1 (Negative) Lot Number 348821	BI-Level Kit : 348825
3 x 1 ml of Level - 2 (Positive) Lot Number 348822	Exp. Date: Dec 11

INTENDED USE:
The Kenlor Liquid H.pylori IgG antibody serum controls are intended for use as unassayed precision control reagents. These controls are to be used with in vitro immunoassay procedures for the qualitative determination of H. pylori IgG antibody in human serum assays. The controls are designed for routine use to provide a means of estimating precision and monitoring system performance. The controls are not intended to replace reagent controls furnished with the commercial kit used.

SUMMARY AND EXPLANATION:
The usefulness of Quality Control materials for monitoring the accuracy and precision of clinical testing is well documented. The Kenlor Liquid H. pylori Serum Control is designed specifically to be used in qualitative analysis of H. pylori IgG antibody assay in serum. The control should be used like a patient sample to assist in the assessment of the analytical procedures and routinely used for the day to day quality control of the assay system. Kenlor Liquid H.pylori IgG serum for antibody assay is liquid, stable for two years at a refrigerated temperature of 2º-8º C.

REAGENTS:
The Kenlor H. pylori IgG antibody negative control serum is prepared by mixing appropriate amount of H. pylori negative human serum with other serum until desired concentration of H. pylori IgG antibodies are obtained. The Kenlor H. pylori IgG antibody positive control serum is prepared by mixing appropriate amount of H.pylori positive human serum with other serum until desire concentration of H. pylori IgG antibodies are obtained. All sera were preserved with a mixture of 0.1% EDTA, 0.05% Benzamide and 0.1% Sodium azide as preservatives. The volume of H. pylori negative and H. pylori positive human sera to be used in the preparation was determined by analysis of H. pylori IgG antibodies concentration in these sera by EIA with available commercial kit. Follow the manufacturer's recommended protocol in assaying Kenlor Liquid H.pylori IgG antibody control.

WARNINGS AND PRECAUTIONS:

* FOR IN VITRO DIAGNOSTIC USE ONLY
* **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.

* If particulate matter is observed in the product, discard the product.
* **WASTE DISPOSAL METHOD:** The above product contains 0.1% **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.
* HANDLE AS IF CAPABLE OF TRANSMITTING HEPATITIS
* NOT FOR INTERNAL USE BY HUMANS OR ANIMALS.

STORAGE AND STABILITY

STORE AT 2º-8º C.

The product is stable up to the expiration date printed on the label if kept at 2º-8º C. and 6month at room temp. Once opened it is stable for 60 days.

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.

PROCEDURE:

The Kenlor Liquid H. pylori IgG antibody Serum Control should be used like a patient sample to assist in the assessment of the analytical procedures and routinely used for the day to day quality control of the assay system. Carefully follow the test procedures of the manufacturer of the test kit including bringing the controls to room temperature if so indicated, for the analysis of the Kenlor Liquid H. pylori IgG antibody serum controls. The LIQUID CONTROL is specially designed and packaged to be stable in liquid state for two years. Once open, the Controls stable for 60 days. The stable LIQUID CONTROL eliminates errors arising from lyophilization, pipeting errors and discrepancies due to uneven lyophilization or improper mixing.

QUALITY CONTROL

SPECIFIC PERFORMANCE CHARACTERISTICS:

KENLOR LIQUID H. PYLORI IgG ANTIBODY SERUM CONTROL is formulated to give consistent result for use in clinical quality control. It is recommended that each laboratory validate the use of each lot of reagents with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF THE RESULTS:

Once a laboratory has established the range of values for the Liquid H.pylori IgG antibody controls it can use those values for routine day to day quality control of clinical test. However, the 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.

LIMITATION OF THE PROCEDURE:

The Kenlor H. pylori human IgG antibody Serum Controls are not intended to be used as calibrators and should not be used for calibration of the assays. The controls should be used only when testing serum specimens following protocol of the test kit manufacturer. Performance characteristic of the controls were determined for H.pylori human IgG antibody only. Control should be used only in test involving serum; it is not intended for use in test of plasma or other body fluid.

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