CLARITY

SEMIQUANTITATIVE (DIPSTICK) LIQUID CONTROL
Product code: CD-UCTL30

Lot Numbers: **240704032-2 DIPSTICK NEGATIVE / LEVEL1** **UCL4070024 DIPSTICK KIT**
240718025-2 DIPSTICK POSITIVE / LEVEL 2 **Exp. Date : 03/07/2026**

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

Clarity LIQUID URINE CONTROL FOR SEMIQUANTITATIVE (DIPSTICK) ASSAY
The Clarity LIQUID URINE CONTROL for semi quantitative (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:

For use with Clarity Urinalysis Strips and Clarity Urine Analyzers Only:

Bring controls to room temperature.
To Ensure reproducible results invert the control bottle 3 times before each 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 of first opening you may recap the control and leave it at ambient room temperature (15-25°C/59-77°F). If the bottle will be used beyond 30 days, store the bottle at 2-8°C (35.6-46.4°F) and can be used till the labeled expiration date. The Clarity LIQUID CONTROL is specially designed and packaged to be stable in liquid state till the labeled date of expiration, if refrigerated after each use.** The Clarity 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 guidelines by the laboratory until it has established its own precision and accuracy parameters. THE Clarity 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 CLARITY 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 2-8°C. & used as directed. This product is warranted to perform as described in its labeling and in the product literature. Clarity Diagnostics LLC. 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.

Semi Quantitative Dipstick Liquid Urine Control
Catalog Numbers: CD-UCTL30
Level 1 Lot # 240704032-2 **Exp. Date 03/07/2026**
Level 2 Lot # 240718025-2 **Exp. Date 17/07/2026**

ALL CLARITY UROCHECK / CLARIFY DIPSTICKS

	Clarity Urocheck 120 Urine Analyzer Clarity Urocheck 120C Urine Analyzer Clarify U122 Urine Analyzer		Visual	Visual
Lot #	240704032-2	240718025-2	240704032-2	240718025-2
GLUCOSE	Negative	100-1000mg/dl	Negative	100-1000mg/dl
BILIRUBIN	Negative	1-4mg/dl	Negative	1-4mg/dl
KETONES	Negative	5-80mg/dl	Negative	5-160mg/dl
SPECIFIC GRAVITY	1.015-1.030	1.005-1.025	1.015-1.030	1.005-1.025
BLOOD	Negative	25-200Ery/ul	Negative	25-200Ery/ul
pH	5.0-7.0	6.5-9.0	5.0-7.0	6.5-9.0
PROTEIN	Negative	30-300mg/dl	Negative	30-2000mg/dl
UROBILINOGEN	0.2-1mg/dl	2-8mg/dl	0.2-1mg/dl	2-12mg/dl
NITRITE	Negative	Positive	Negative	Positive
LEUKOCYTES	Negative	15-500Leu/ul	Negative	15-500Leu/ul
Creatinine	10-100 mg/dl	100-300 mg/dl	/	/
Albumin	10-30 mg/l	80-150 mg/l	/	/

* **The Clarity Urocheck 120 Analyzer QC set-up screen recognizes only arbitrary values**
**** The Albumin and Creatinine parameters are 510(k) cleared and CLIA waived for analyzer reading on the Clarity Urocheck 120C only**

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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