SEMIQUANTITATIVE (DIPSTICK) LIQUID CONTROL
Product code: DTG-UHCTLS / DTG-UHCONTROL

PLEASE NOTE: For use with Siemens Urinalysis Strips and Analyzers, Roche Urinalysis Strips and Analyzers, and HCG tests ONLY. NOT FOR USE with Clarity Urinalysis Strips and Analyzers. Please order new controls for Clarity brand strips and analyzers, CD-UCTL30.

Lot Numbers: **277733 DIPSTICK NEGATIVE / LEVEL1** **277736 DIPSTICK KIT**
277734 DIPSTICK POSITIVE / LEVEL 2 **Exp. Date: 10/2019**

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 Urinalysis Strips:

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 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.

For use with Clarity Pregnancy Test Device:

Bring controls to room temperature.
- The control with the Blue Cap is the Negative Urine HCG control and the control with the Red Cap is the Positive Urine HCG control.
- Allow the Clarity HCG test device and controls to warm to room temperature before testing.
- Add 3 drops of the Negative control to the sample well of the test cassette, Repeat the same procedure for the Positive control.
- The results should be read at 5 minutes, do not interpret results after 10 minutes.
- The Negative control should only produce the control line; whereas the Positive control should produce both the test line and the control line. Even if a very faint colored line appears in the test region, it should be considered as a positive result.
- For further information, please refer to the Clarity HCG test cassettes package insert.

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.

ALL MULTI STIX DIPSTICK				
	Clinitek 100 200, 200+, 50 Status, Atlas	**Clinitek 100 200, 200+, 50 Status, Atlas**	**Visual**	**Visual**
Lot #	**277733**	**277734**	**277733**	**277734**
GLUCOSE	Negative	TR - ≥500mg/dl	Negative	TR - ≥500mg/dl
BILIRUBIN	Negative	Small to Large	Negative	Small to Large
KETONES	Negative	TR-> 80mg/dl	Negative	TR-> 80mg/dl
SPECIFIC GRAVITY	1.015 – 1.030	1.005 – 1.025	1.015 – 1.030	1.005 – 1.025
BLOOD	Negative	Small to Large	Negative	Small-Large
pH	5.0 – 8.0	6.0 – 9.0	5.0-8.0	6.0-9.0
PROTEIN	Negative	30 - ≥ 300mg/dl	Negative	30-≥ 300mg/dl
UROBILINOGEN	0.2EU/dl	1-4 EU/dl	0.2EU/dl	1-4 EU/dl
NITRITE	Negative	Positive	Negative	Positive
LEUKOCYTES	Negative	Trace- MOD	Negative	Trace- MOD

Micro albumin	**277733**	**277734**
Constituent	Clinitek (Bayer)	Clinitek (Bayer)
Albumin	10 – 30 mg/l	100 - 200 mg/l
Creatinine	10 – 50 mg/dl	50 - 100 mg/dl
A:C	< 30 mg/g	≥ 300 mg/g

ALL CHEMSTRIP DIPSTICK

	MINI UA Urisys 1100	MINI UA Urisys 1100	Visual	Visual
Lot #	**277733**	**277734**	**277733**	**277734**
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	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/µl	Negative	About 50-250 Ery/µl
LEUKOCYTES	Negative	75-500 Leu/µl	Negative	TR to ++

Micro albumin	**277733**	**277734**
Constituent	Chemstrip Micral (Roche)	Chemstrip Micral (Roche)
Albumin	Negative	50 - ≥ 100 mg/l
Creatinine	NA	NA
A:C	NA	Abnormal - High

ALTERNATIVE TESTS - HCG

HCG	**277733**	**277734**
Constituent	**Clarity / Other Pregnancy Tests**	**Clarity / Other Pregnancy Tests**
Result	**Negative**	**Positive**

*: MULTISTIX, CLINITEK 50,100, 200, 200+, Atlas & CLINITEST, ARE REGISTERED PRODUCTS OF BAYER CORPORATION

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

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

For HCG, the positive and Negative results were obtained by testing each lot number of the controls with multiple lot numbers of different HCG test kits with sensitivity of ≥ 20 MIU/ml.

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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