Clarity Liquid Urine Control Set (25ml)

Urinalysis Controls (CLA-UHCRL25)

For use with Clarity Platinum Analyzer and Clarity Platinum Urine Reagent Strips only
For use with Clarity Microalbumin/Creatinine Visual Read Urinalysis Reagent Strips (CLA-MAC)

Lot Numbers: K307357 LEVEL1/NEGATIVE
K307343 LEVEL 2/POSITIVE

KIT LOT:K307346 **Exp. Date:05/2027**

INTENDED USE

The Clarity Liquid Urine Control is a ready-to-use, liquid product intended for use in the clinical laboratory as a control for qualitative and semi-quantitative procedures used in routine urinalysis. Assay values are provided for the specific systems listed. The product is intended for use as a control material for physiochemical and chemical methods in routine urinalysis.

For in vitro diagnostic use.

HISTORY

The examination of urine for diagnostic purposes is thought to represent the oldest of laboratory procedures used in clinical medicine today. The examination of urine may be considered from two general points: the diagnosis and management of renal or urinary tract disease and the detection of metabolic or systemic diseases not directly related to the kidney.[1,2] Physical tests for specific gravity, pH, osmolality, and color observation for the most part measure renal function. Among the most important metabolites or systemic conditions readily detected by chemical means are proteinuria, glycosuria, ketonuria, and the presence of the pigment's urobilinogen, bilirubin, hemoglobin, and the porphyrins. Many of the chemical tests have been simplified by the introduction of simple techniques in which reagent stripsand tablets are used.

DESCRIPTION

The Clarity Liquid Urine Control contains measured amounts of chemicals and serves as a control for physical and chemical tests routinely performed in urinalysis. Both level of controls contains <0.1% Sodium Azide.

STABILITY AND STORAGE

The Clarity Liquid Urine Control should be kept at 2-8°C when not in use. When stored at 2-8°C, the control is stable for 22 months from the date of manufacture or until the expiration date, whichever comes first. The control can be used for chemical analysis when stored at room temperature (20-25°C) for up to 30 days. After opening, the controls will remain stable until the expiration date stated on the label when stored at 2-8°C between uses. Label the bottle with the date it was originally brought to room temperature to ensure proper performance. **Do not freeze.**

PRECAUTIONS

All human sourced material used in this product was tested for the presence of the antibody specific to the human immunodeficiency virus (HIV - 1/2), as well as for the hepatitis B surface antigen (HBsAg) and hepatitis C (HCV) and found to be negative.

Because no test method can offer complete assurance that HIV, HBsAg, HCV or other infectious agents are absent, it is recommended that human serum-based products be handled with the same precautions used for patient specimens.

AVAILABILITY

The Clarity Liquid Urine Control is available in two different reference ranges (Level 1 Negative and Level 2 Positive) providing the laboratory a means of monitoring reproducibility and accuracy over a range of clinically significant values.

MATERIALS PROVIDED

1. Clarity Liquid Urine Control- Level1 /Negative	1 x 25mL
2. Clarity Liquid Urine Control- Level2 /Positive	1 x 25mL
3. Directions for use	

DIRECTIONS FOR USE WITH REAGENT STRIPS

1. ***Allow the Clarity Liquid Urine Control to reach room temperature (20- 25°C) prior to testing.***
2. Verify that the lot number on the value sheet enclosed in the package matches the lot number on the bottle of Clarity Liquid Urine Control.
3. Gently swirl the control bottle to ensure the product has been mixed thoroughly, remove the vial cap, and apply one drop of the Clarity Liquid Urine Control directly on each pad of the reagent strip using a spraying technique. Hold the reagent strip horizontally to ensure adequate pad saturation, then remove excess control by tilting the reagent strip on its edge on a paper towel. Each pad should be thoroughly moistened.
4. If the Clarity Platinum Urine Analyzer being used has the software version **V1.0.230126.1,** scan the linear barcode. If the Clarity Platinum Urine Analyzer being used has the software version **V1.0.230228.0,** you must scan the QR code. (To view your software version, select ***Settings*** from the home screen, and select ***System Information.***)
5. Read the Clarity Platinum Urine reagent strips using the Clarity Platinum Urine Analyzer.
6. Read the Clarity Microalbumin/Creatinine visual read urinalysis reagent strips visually, according to the read times specified on the canister color chart on the side of the bottle.
7. Promptly recap the bottle and return the Clarity Liquid Urine Controls to refrigerated storage. Control may also be stored at room temperature (see stability and storage).

EXPECTED RANGE

The expected ranges have been established from interlaboratory data using a representative lot of manufacturers' reagent strips or reagent tablets. Each laboratory should establish its own precision and accuracy parameters.

LIMITATIONS

Any future changes in test methods may result in different values from the indicated range. Detailed information on the limitations of each test method is included in the limitations section of the manufacturers' package insert.

TROUBLESHOOTING

If discrepancies arise from the expected ranges on the lot specific insert, we recommend the following:

- Refer to the manufacturer's directions for reagent strips and alternative tests.
- Ensure that the reagent strips have not become discolored by exposure to air.
- Apply Clarity Liquid Urine Control uniformly to the reagent strip and blot the strip horizontally on a paper towel to prevent run-off/bleeding of the reagents from pad to pad.
- If the values remain beyond the expected range, try a different container of strips and, if possible, a different lot number of strips.
- If the discrepancy is in an instrument-generated value, clean the instrument and check its calibration. If the discrepancy is still observed, check the parameter visually (applicable for Clarity Microalbumin/Creatinine Visual Read urinalysis reagent strips only).

To reach Clarity Diagnostics Technical Support Call (877) 485-7877

BIBLIOGRAPHY

1. Henry, J.B. (Ed.): Clinical Diagnosis and Management by Laboratory Methods. 18th Edition, W.B. Saunders Co., Philadelphia, 1991.
2. Haber, M.H.: A Primer of Microscopic Urinalysis. Hycor Biomedical Inc., 1991.

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K307343 LEVEL 2/POSITIVE

Value Assignment of Clarity Liquid Urine Controls

Clarity CLA-10P Parameters	Clarity Urinalysis Quality Control Solutions For use with Clarity Platinum Analyzer and Clarity Platinum Urine Reagent Strips only	
	Level 1/Negative Lot: K307357	Level 2/Positive Lot:K307343
LEU	Negative	Trace to Large
NIT	Negative	Positive
URO	0.2 – 1.0 EU/dL	2.0 – >=8.0 EU/dL
PRO	Negative	30 – >=300 mg/dL
pH	5.0 – 7.0	7.0 – 8.5
BLD	Negative	Small to Large
SG	1.005 – 1.025	1.010 – 1.030
KET	Negative	Trace – >=80 mg/dL
BIL	Negative	Small to Large
GLU	Negative	250 – 1000 mg/dL

Clarity CLA-MAC Parameters	Clarity Urinalysis Quality Control Solutions For use with Clarity Microalbumin/Creatinine Visual Read Urinalysis Reagent Strips (CLA-MAC)	
	Level 1/Negative Lot: K307357	Level 2/Positive Lot:K307343
MALB	10 - 30 mg/L	80 - 150 mg/L
CRE	1.0 - 3.0 g/L	2.0 - 3.0 g/L

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Made in the USA

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