



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: K305869 LEVEL1/NEGATIVE
K306060 LEVEL 2/POSITIVE

KIT LOT: K306072

Exp. Date: 01/2024

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 probably represents 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 strips and 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 source 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 levels (Negative and 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. Perform the chemical test as for a patient specimen.
2. Verify that the lot number given on the value sheet enclosed in the package matches the lot number of the bottle of Clarity Liquid Urine Control.
3. Gently swirl the control to assure good mixing, open the vial cap and apply Clarity Liquid Urine Control directly onto the reagent strips with a spraying technique. Hold the reagent strip horizontally, ensure good pad saturation and remove excess control by tilting the reagent strip on its edge on a paper towel. Each pad should be thoroughly moistened.
4. Read the Clarity Platinum Urine reagent strips using the Clarity Platinum Urine Analyzer.
5. Read the Clarity Microalbumin/Creatinine Visual Read urinalysis reagent strips visually per read times mentioned on the canister color chart.
6. Promptly recap the bottle and return the Clarity Liquid Urine Controls to refrigerated storage. Control may be left 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 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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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	Level 2/Positive
	Lot: K305869	Lot: K306037
LEU	Negative	Small 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 – 6.5	7.0 – 8.5
BLD	Negative	Moderate to Large
SG	1.005 – 1.015	1.010 – 1.025
KET	Negative	40 – 80 mg/dL
BIL	Negative	Moderate 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: K305869	Level 2/Positive Lot: K306037
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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