KOVA® Liqua-Trol™

Urinalysis Controls

INTENDED USE

KOVA Liqua-Trol 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 pigments 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

KOVA Liqua-Trol contains measured amounts of chemicals and serves as a control for physical and chemical tests routinely performed in urinalysis. Liqua-Trol Level II (normal with hCG) contains <0.1% sodium azide.

STABILITY AND STORAGE

KOVA Liqua-Trol is stable until the expiration date stated on the label, when stored between 2° and 8°C. Do not freeze. Liqua-Trol can be stored at room temperature (20-25°C) for up to 30 days. Controls used at room temperature are for reagent strip and hCG testing only. Label the bottle with the date it was originally brought to room temperature to ensure proper performance.

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

KOVA Liqua-Trol is available in two distinct levels (level II and level I) providing the laboratory a means of monitoring reproducibility and accuracy over a range of clinically significant values.

MATERIALS PROVIDED

KOVA Liqua-Trol, Level II (normal with hCG) Control	3 x 15ml
KOVA Liqua-Trol, Level I (abnormal) Control	3 x 15ml
Value sheet for physiochemical and chemical methods	
Daily control sheet	
Directions for use	

DIRECTIONS FOR USE WITH REAGENT STRIPS

1. Remove the control from the refrigerator and allow it to reach room temperature (20-25°C) prior to testing.
2. Verify that the lot number given on the value sheet enclosed in the package matches the lot number of the bottle of Liqua-Trol.
3. Gently swirl the control to assure good mixing, open the vial cap and apply Liqua-Trol 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 urine reagent strips in accordance with the manufacturer's instructions as to timing and interpretation.
5. Record the results on the daily control chart provided.
6. Promptly recap the bottle and return the Liqua-Trol to refrigerated storage. Liqua-Trol 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 KOVA Liqua-Trol 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.
- If a discrepancy arises in the specific gravity reading on the reagent strips, use the refractometer to check the KOVA control. There is a range provided for the refractometer.
- To reach Hycor Technical Services, call (800) 382-2527.

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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