KOVA INTERNATIONAL

KOVA® Liqua-Trol™ with Microscopics

Urinalysis Controls IVD

INTENDED USE

KOVA Liqua-Trol with Microscopics 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 physiochemical and chemical determinations and for microscopic sediment analyses of human urine. Liqua-Trol is designed for, but not limited to use with the KOVA® System for Standardized 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, 3] 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. Medical microscopy developed in parallel with the development of chemical tests. The identification of cells and crystals in urine sediments is most important. Staining techniques were developed to assist the examiner with the identification of formed elements and artifacts found in urine sediment.[2]

DESCRIPTION

KOVA Liqua-Trol with Microscopics contains measured amounts of chemicals, stabilized human red cells and organic particles to simulate leukocytes. Liqua-Trol serves as a control for physical, chemical and microscopic tests routinely performed in urinalysis. Liqua-Trol Level II (normal level with hCG) contains <0.1% sodium azide.

STABILITY AND STORAGE

KOVA Liqua-Trol with microscopics 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 with Microscopics is available in two different levels, providing the laboratory a means of controlling reproducibility and accuracy over a range of clinically significant values.

MATERIALS PROVIDED

1. KOVA Liqua-Trol with Microscopics Level II (normal with hcg) control or KOVA Liqua-Trol with Microscopics Level I (abnormal) control.
2. Value sheet for physical, chemical and microscopic constituents.
3. Daily control sheet.
4. Directions for use.

Product Number	Description KOVA Liqua-Trol with Microscopics	Packaging
87122	KOVA Liqua-Trol Level II (normal with hCG)	2 x 120ml
87176	KOVA Liqua-Trol Level I (abnormal)	2 x 120ml
87123	KOVA Liqua-Trol Level II (normal with hCG)	4 x 120ml
87177	KOVA Liqua-Trol Level I (abnormal)	4 x 120ml
37036	KOVA Liqua-Trol Level I (abnormal) KOVA Liqua-Trol Level II (normal with hCG)	2 x 120ml

SPECIMEN COLLECTION

1. For the best chemical and microscopic results, analyze a clean, fresh, first morning urine specimen.
2. Due to the increased concentration of urine constituents, the first morning specimen is most useful. Constituents such as casts may be better observed under a microscope in the concentrated, first morning specimen.
3. A random specimen (collected from an ambulatory patient who has eaten two to three hours earlier) is more suitable for the detection of reducing sugars.
4. Disposable plastic specimen cups or disposable plastic containers with lids are suitable for sample collection. KOVA Cups are provided in the KO-LEC-PAC® for this purpose.
5. Following collection, process the urine specimen as soon as possible. Processing within four hours is imperative to avoid deterioration of the sediment or a change in the chemical and physical composition. If this is not possible, refrigerate the specimen between 2° and 8°C.[3] Do not freeze.

DIRECTIONS FOR USE

A. STANDARDIZED CHEMICAL TESTS

1. Remove the Liqua-Trol from the refrigerator. Gently swirl the control to resuspend any sediment and dispense an aliquot of no less than 7ml. Label the tube appropriately for identification.
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. Promptly recap the bottle and return it to the refrigerator.
3. Allow the Liqua-Trol aliquot to reach room temperature (20-25°C) prior to testing. Perform the chemical test as for a patient specimen.
4. Dip and read the urine reagent strips and perform additional chemical tests in accordance with the manufacturer's instructions for timing and interpretation. Avoid excessive dipping into one aliquot, allowing no more than ten dips of a single manufacturer's strip into a 12ml aliquot. Recommended aliquot size of no less than 7 mL.

B. STANDARDIZED PHYSICAL TESTS

1. Remove the Liqua-Trol from the refrigerator. Gently swirl the contents to resuspend any sediment and dispense an aliquot. Label the tube for identification.
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. Promptly recap the bottle and return it to the refrigerator.
3. Allow the Liqua-Trol aliquot to reach room temperature prior to testing. Perform the physical tests as for a patient specimen.
4. Appearance: Record the color and turbidity.
5. Specific Gravity: Measure and record specific gravity with a temperature compensated refractometer, hydrometer or urinometer.
6. Osmolality: Measure and record the osmolality by using a freezing point depression osmometer.

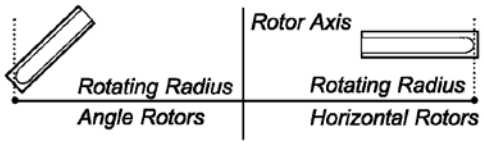
7. Record the Liqua-Trol section results on the daily control chart provided. To assess the reliability of each test procedure, compare the results to the expected ranges.

C. STANDARDIZED CENTRIFUGATION AND MICROSCOPIC EXAMINATION

1. Transfer a thoroughly mixed aliquot of Liqua-Trol or urine specimen to a KOVA Tube, filling it to the 12ml graduation.
2. Centrifuge the tubes (each containing 12ml of urine specimen or Liqua-Trol) at a relative centrifugal force (rcf) of 400 for five minutes; approximately 1500 revolutions per minute (rpm) with a 6-inch radius rotor. Formula used:

$$rcf = 28.38\,(R)\left(\frac{N}{1000}\right)^2 \qquad R = \text{radius of rotor in inches} \qquad N = \text{revolutions per minute}$$

The rotating radius is the distance measured from the rotor axis to the tip of the liquid inside the tubes at the greatest horizontal distance from the rotor axis.



3. Remove the tubes from the centrifuge being careful not to disturb or dislodge the sediment.
4. Insert a KOVA Petter into the tube. Push the petter to the bottom of the tube until it seats firmly (at the 1ml graduation).
5. Decant and discard 11ml from the tube while the petter is locked in position in the tube. This will retain 1ml of urine sediment at the bottom of the tube. With the use of the KOVA Decanting Rack, 10 tubes can be decanted simultaneously. To release the tubes, squeeze the top of the rack while pulling the tube straight up.
6. Withdraw the petter from the tube.
7. Add one drop of KOVA Stain[4] to the 1ml of urine sediment.
8. Using the petter, gently resuspend the sediment and stain until a homogeneous mixture is obtained.
9. Withdraw a small sample of the urine sediment stain mixture by squeezing the bulb of the petter.
10. Transfer the sediment mixture to a KOVA Slide by placing one drop in the corner of the well. The chamber will fill by capillary action.
11. Remove any excess specimen remaining on the open recessed area by touching the open edge with absorbent material.
12. Place the slide on a microscopic stage under the objective lens.
13. Scan the slide chamber under low power magnification (10X eyepiece/10X objective) to enumerate casts. Enumerate all other formed elements under high power magnification (10X eyepiece/40X objective).[5] Do not reuse KOVA products.

EXPECTED RANGE

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

MATERIALS NOT PROVIDED

Materials not provided include routine laboratory equipment, KOVA Cups, KOVA Tubes, KOVA Caps, KOVA Petters, KOVA Slides and KOVA Stain.

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 manufacturer's 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.
- Immerse the pads in KOVA Liqua-Trol with Microscopics (dip following the strip manufacturer's instructions), 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 Kova Customer Service, call (855) 217-6399.

BIBLIOGRAPHY

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2. Weller, J.M., and Greene, J.A., Jr.: Examination of the Urine. New York, Meredith Publishing Co., 1966.
3. Haber, M.H.: A Primer of Microscopic Urinalysis. Hycor Biomedical, 1991.
4. Sternheimer, R., and Malbin, B.: Clinical Recognition of Pyelonephritis with a New Stain for Urinary Sediments. Am J. Med. 11:312, 1951.
5. Siegle, M.D.: Urinoscopy - First the Microscope. Lab. Med. 12: 781-784, 1981.

Products referenced herein are covered by one or more of the following U.S. patent numbers:

RE 33,826 4,022,576 4,299,441 4,563,332

4,637,693 4,937,415 4,997,266 D258,388

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