

KOVA-Trol™

Human Urinalysis Controls

INTENDED USE

KOVA-Trol is a freeze-dried preparation of human urine. It is intended for use in the clinical laboratory as a urine control for qualitative procedures used in physiochemical and chemical determinations and for microscopic sediment analyses. KOVA-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. It generally consists of 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 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. Paralleling the development of chemical tests was the development of medical microscopy. The identification of cells and casts in the 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-Trol is prepared from normal human urine to which is added predetermined amounts of chemicals, stabilized human red cells and organic particles to simulate leukocytes. KOVA-Trol serves as a control for physical, chemical and microscopic tests routinely performed in urinalysis.

KOVA-Trol contains 0.008% gentamicin as a preservative.

STABILITY AND STORAGE

Un-reconstituted KOVA-Trol is stable until the expiration date stated on the label when stored between 2° and 8°C. Following reconstitution, keep the liquid KOVA-Trol stoppered and refrigerated. When KOVA-Trol is properly reconstituted and stored at 2°-8°C, the constituents are stable from the date of reconstitution for a maximum of seven (7) days. The useful life may be extended up to one month by storing reconstituted KOVA-Trol in single-use 7mL aliquots frozen at -20° to -40°C.

IMPORTANT: Some constituents are labile and will degrade if shaken roughly or exposed to air, light or room temperature for excessive amounts of time. Following reconstitution, keep the KOVA-Trol stoppered and refrigerated except when aliquoting the test samples.

- Use KOVA-Trol I - High Abnormal, or KOVA-Trol II - Low Abnormal - as a negative hCG control and KOVA-Trol III - Normal - with hCG as a positive hCG control.

If you desire to freeze the control, we recommend the following:

- Frozen aliquots have been validated for strip testing and hCG testing only. Other test usage should be confirmed by the laboratory.
- Prepare a minimum of 7 mL aliquots from freshly reconstituted KOVA-Trol.
- Do only one freeze/thaw cycle and discard after use. Allow the aliquot to come to room temperature naturally; do not use a warming block. Keep the product out of direct light during the thawing process.
- Make sure the aliquots have an airtight seal and are maintained at -20°C to -40°C.
- Test the aliquots within one hour after room temperature is achieved and discard the sample.
- Use a minimum of 7mi aliquots to ensure total saturation of the reagent pads.
- You may note amorphous debris when using frozen samples for microscopic analysis.

PRECAUTIONS

All human serum source material used in this product was tested for the presence of antibody specific to human immunodeficiency virus (HIV-1, HIV-2), as well as for 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-Trol is available in three different levels, providing the laboratory a means of controlling reproducibility and accuracy over a range of clinically significant values.

MATERIALS PROVIDED

- KOVA-Trol, a freeze-dried preparation of human urine.
- Assay value sheet for physical, chemical and microscopic constituents.
- Daily control sheet.
- Directions for use.

Product Number	Description KOVA-Trol	Packaging
87329	KOVA-Trol I High Abnormal Without Abnormal Urobilinogen Value Assignment	4 x 15ml
87325	KOVA-Trol I High Abnormal Without Abnormal Urobilinogen Value Assignment	4 x 60ml
87326	KOVA-Trol I High Abnormal Without Abnormal Urobilinogen Value Assignment	10 x 60ml
87334	KOVA-Trol I High Abnormal With Urobilinogen Value Assignment	4 x 15ml
87332	KOVA-Trol I High Abnormal With Urobilinogen Value Assignment	4 x 60ml
87333	KOVA-Trol I High Abnormal With Urobilinogen Value Assignment	10 x 60ml
87130	KOVA-Trol II Low Abnormal	4 x 15ml
87128	KOVA-Trol II Low Abnormal	10 x 60ml
87331	KOVA-Trol III Normal with hCG	4 x 15ml
87327	KOVA-Trol III Normal with hCG	4 x 60ml
87328	KOVA-Trol III Normal with hCG	10 x 60 ml

DIRECTIONS FOR USE WITH REAGENT STRIPS

- Compare the lot number given on the value sheet enclosed in the package with the lot number on the bottle of KOVA-Trol; they should match.
- Remove the seal and rubber stopper from the KOVA-Trol bottle.
- Using a graduated cylinder or other suitable means, add a volume of deionized or distilled water (with pH between 5 and 7) equal to the volume stated on the freeze-dried KOVA-Trol bottle label.
- Immediately replace the rubber stopper in the KOVA-Trol bottle and gently rotate the bottle intermittently until all of the material has dissolved (approximately 15 minutes). On each of the six days following reconstitution of KOVA-Trol I, KOVA-Trol II and KOVA-Trol III, remove the KOVA-Trol from 2°-8°C storage and gently rotate the bottle to mix the contents well.
- Remove a test aliquot and promptly return the remaining KOVA-Trol to 2°-8°C storage. Allow the test aliquot to reach room temperature prior to testing.
- Using the standardized urinalysis procedure below, test the aliquot within one hour and discard the sample.

STANDARDIZED URINALYSIS PROCEDURE

SPECIMEN COLLECTION

- For the best chemical and microscopic results, analyze a clean, voided, fresh, first morning urine specimen.
- 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.
- 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.
- 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.
- 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.

PHYSICAL TESTS

1. Appearance: Record the color and turbidity.
2. Specific Gravity: Measure and record the specific gravity using a temperature compensated refractometer, hydrometer or urinometer.
3. Osmolality: Measure and record the osmolality using an osmometer.

NOTE: When the urine specimen appears turbid, perform the refractometer measurement on a clear drop of urine obtained following centrifugation before decanting the supernatant urine.

CHEMICAL TEST

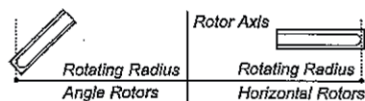
1. Mix the KOVA-Trol or urine specimen to be tested thoroughly to resuspend any sediment.
2. Transfer the sample to a test tube and label the tube for identification.
3. Using reagent test strips perform chemical testing according to the manufacturer's instructions.
4. Record the results.

CENTRIFUGATION AND MICROSCOPIC EXAMINATION

1. Transfer a thoroughly mixed aliquot of KOVA-Trol or urine specimen to a KOVA Tube, filling it to the 12ml graduation.
2. Centrifuge the KOVA Tubes (each containing 12ml of urine specimen or KOVA-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:

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

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 KOVA Tubes from the centrifuge being careful not to disturb or dislodge the sediment.
4. Insert a KOVA Petter into the KOVA Tube. Push the KOVA Petter to the bottom of the KOVA Tube until it seats firmly (at the 1ml graduation).
5. Decant and discard 11ml from the KOVA Tube while the KOVA Petter is locked in position in the KOVA Tube. This will retain 1ml of urine sediment at the bottom of the KOVA Tube. Through the use of the KOVA Decanting Rack, 10 tubes can be decanted simultaneously. To release the KOVA Tubes, squeeze the top of the rack while pulling the tube straight up.
6. Withdraw the KOVA Petter from the KOVA Tube.
7. Add one drop of KOVA Stain⁴ to the 1ml of urine sediment.
8. Using the KOVA 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 KOVA Petter.
10. Transfer the sediment mixture to the 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 KOVA 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

EXPECTED RANGE

The expected ranges have been established from interlaboratory data using a representative lot of manufacturers' reagent strips or reagent tablets. Due to variation that can occur from different materials and techniques in different laboratories, we recommend that each laboratory establish its own ranges for good quality control.

MATERIALS NOT PROVIDED

Materials not provided include deionized or distilled water for reconstitution, routine laboratory equipment, KOVA Cups, KOVA Tubes, KOVA Caps, KOVA Petters, KOVA Slides and KOVA Stain.

LIMITATIONS

1. If KOVA-Trol is not mixed well prior to use, urine sediment may settle and microscopic readings may be affected.
2. The organic particles added to the KOVA-Trol to simulate the size of leukocytes do not have the same staining characteristics as naturally occurring white blood cells.
3. Contamination of the sample may occur from strip reagent bleeding. To prevent this use a maximum of five reagent strips for each 12ml aliquot or up to two strips when testing smaller volumes.

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.
- Ensure good saturation of the pads with the KOVA-Trol (dip 2-3 seconds); then 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

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

RE33,826 4,563,332 4,937,415 4,997,266 5,128,802

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