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 and semi-quantitative procedures used in physiochemical and chemical determinations and for microscopic sediment analyses.

For professional laboratory use only.

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].

SUMMARY AND PRINCIPLE
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.

MATERIALS PROVIDED
Provided in Kit:
1. KOVA-Trol, a freeze-dried preparation of human urine.

Available for Download from company website (www.seracare.com/resource library):
2. Assay value sheet for physical, chemical and microscopic constituents.
3. Daily control sheet.
4. Directions for use.

Product Number	Description: KOVA-Trol	Pack Size
87334	KOVA-Trol I High Abnormal with Urobilinogen	4 x 15 mL
87332	KOVA-Trol I High Abnormal with Urobilinogen	4 x 60 mL
87533	KOVA-Trol I High Abnormal with Urobilinogen	8 x 60 mL
87130	KOVA-Trol II Low Abnormal	4 x 15 mL
87331	KOVA-Trol III Normal with hCG	4 x 15 mL
87327	KOVA-Trol III Normal with hCG	4 x 60 mL
87528	KOVA-Trol III Normal with hCG	8 x 60 mL

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.

NOTE: 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.

MATERIALS NOT PROVIDED
Materials not provided include deionized or distilled water for reconstitution, routine laboratory equipment, and plasticware for urinalysis including cups, tubes, caps, petters. Microscopy supplies including slides and stain are also not provided.

WARNINGS AND PRECAUTIONS
Donors contributing urine for this material have been 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 urine-based products be handled with the same precautions used for patient specimens.

Dispose of all specimens, controls and materials used in testing as though they contain infectious agents. Additional safety information can be found in the product Safety Data Sheet (SDS) found on the company website.

STORAGE AND STABILITY
The lyophilized KOVA-Trol product is stable until the expiration date stated on the label when stored between 2° - 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 aliquots frozen at -10° to -30°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.

FREEZE/THAW: 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.
- A minimum of 7 mL aliquots from freshly reconstituted KOVA-Trol should be used, this will ensure total saturation of the reagent pads.
- 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 -10°C to -30°C.
- Test the aliquots as soon as room temperature is achieved. A gentle mix of the tube is recommended to ensure a homogenous solution. Discard the sample after use.
- You may note amorphous debris when using frozen samples for microscopic analysis.

PROCEDURE (REAGENT STRIPS)
1. Remove the seal and rubber stopper from the KOVA-Trol bottle.
2. 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.
3. 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).
4. Remove a test aliquot (a minimum of 7 mL for reagent strip testing. If testing for microscopics, 12 mL are required). Return the remaining KOVA-Trol to 2°-8°C storage.
5. Allow the test aliquot to reach room temperature prior to testing and test as soon as room temperature is achieved.
6. Use standardized urinalysis procedure (as provided by the test manufacturer or as validated by the laboratory for unknown urine specimens) to test the aliquot. Discard any remaining sample in the test aliquot.

PROCEDURE (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.

PROCEDURE (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.

PROCEDURE (MICROSCOPIC EXAMINATION)
1. Transfer a thoroughly mixed aliquot of KOVA-Trol or urine specimen to an appropriate centrifuge tube.
2. Centrifuge the tubes according to the laboratory's standard procedure for unknown urine samples. For Quality Control testing, KOVA centrifuges 12 mL of 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.
3. Remove the tubes from the centrifuge being careful not to disturb or dislodge the sediment.
4. Decant the supernatant and add appropriate stain to the residual ~1 mL of urine sediment.
5. Mix gently to resuspend the sediment and stain until a homogeneous mixture is obtained. Remove a small sample for microscopic examination. LGC recommends scanning 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)[3].

EXPECTED RESULTS
The expected ranges have been established from 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.

LIMITATIONS OF THE PROCEDURE
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. KOVA-Trol controls must not be substituted for the positive and negative control reagents provided with manufactured test kits.
3. TEST PROCEDURES and INTERPRETATION OF RESULTS provided by manufacturers of test kits must be followed.
4. KOVA-Trol controls are provided for quality assurance purposes and must not be used for calibration or as a primary reference preparation in any test procedure.
5. Variations in instruments and temperature of the testing material may result in accuracy and linearity variations.
6. Adverse shipping and/or storage conditions or use of outdated controls may produce erroneous results.

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 control. There is a range provided for the refractometer.

BIBLIOGRAPHY
1. Henry, J.B. (Ed.): Todd-Sanford-Davidsohn: Clinical Diagnosis and Management by Laboratory Methods. 16th Edition, Vol. 1, W.B. Saunders Co., Philadelphia, 1979.
2. Weller, J.M., and Greene, J.A., Jr.: Examination of the Urine. New York, Meredith Publishing Co., 1966.
3. Siegle, M.D.: Urinoscopy - First the microscope. Lab. Med. 12: 781-784, 1981.

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

For assistance, contact LGC Clinical Diagnostics Technical Support at +1 508.244.6400.

Any serious incident that has occurred in relation to the device shall be reported to LGC Clinical Diagnostics Technical Support and, if in use in the EU, the competent authority of the Member State in which the incident occurred.

Date	Description of Change
April 2026	Clarify the following statement: All human 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. Donors are 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. Removed Value Assignment from the table.

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KOVA-Trol™

Human Urinalysis Controls

CE 2797

EU REP

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Legend of all symbols used in LGC product labeling

Upper limit of temperature

Temperature limitation

EU REP

Authorized Representative in the European Community

Biological risks

Use By

IVD

In Vitro Diagnostic Medical Device

CONTROL -

Negative control

REF

Catalogue number

Consult instructions for use

CONTROL +

Positive control

LOT

Batch code

Manufacturer

CONTROL

Control

Highly Flammable

Toxic by inhalation, in contact with skin and if swallowed

Health Hazard

Single Use

Importer