KOVA PLASTICS

KOVA® Plastics System for **Standardized Urinalysis**

KOVA SYSTEM FOR STANDARDIZED URINALYSIS

Urinalysis, as currently performed in many laboratories, is carried out using various nonstandard procedures. These procedures vary from laboratory to laboratory and often the actual technique within the laboratory varies depending on the person performing the tests.

Sources of variation in conventional urinalysis:

- variable urine volumes
- different centrifugal conditions creating varying amounts of sediment for microscopic examination
- different amounts of sediment collected and suspended under the cover glass
- technique variations among individuals performing the procedure.

To standardize the urinalysis procedure, a constant specimen volume, centrifugal force and sediment volume must be maintained and a consistent method of microscopic examination and reporting of results should be used. Kova's KOVA System achieves this standardization by reducing variation, including technique differences among technicians.

INTENDED USE

The **KOVA System** offers a procedure and products that can be used to produce standardized results during routine urinalysis. Volume control, consistency and hygiene are provided from collection and transport to microscopic analysis of urine sediment. **KOVA–Trol™** can be used for complete quality control of physical, chemical and microscopic examination test procedures.

ADVANTAGES

If the described procedure is followed consistently, one can use the values obtained in urinalysis with confidence. Clinicians can follow the progress and treatment of patients with certainty; any changes that occur outside the narrower limits that this system allows can be considered significant.

Laboratories may be compared and patients under observation can have their urinalysis done at different laboratories with comparable results.

KOVA SYSTEM AND SYSTEM COMPONENTS

Product Number	Product Description	Determinations Per Package
87153	**KOVA Plastics System Super Pac 1000 w/Caps** 100 KOVA Glasstic® Slide 10 (10 chambered), 1000 KOVA Petters, 1000 KOVA Super Tubes, 1000 KOVA Caps	1000
87154	**KOVA Plastics System Super Pac 1000** 100 KOVA Glasstic® Slide 10 (10 chambered), 1000 KOVA Petters, 1000 KOVA Super Tubes,	1000
87162	**KOVA Plastics System Super Pac 1000 with Grids** 100 KOVA Glasstic® Slide 10 (10 chambered) w/Grids, 1000 KOVA Petters, 1000 KOVA Super Tubes,	1000
87155	**KOVA Plastics System Pac II** 100 KOVA Slide II (4 chambered), 400 KOVA Petters, 400 KOVA Super Tubes,	400
87159	**KOVA Plastics Mini Pack** 5 KOVA Glasstic® Slide 10, 20 KOVA Petters, 20 KOVA Tube, 20 KOVA Caps	50
87156	**KOVA Plastics System Value Pac 500** 50 KOVA Glasstic Slide 10 with grids 500 KOVA Economy Tubes, 100 KOVA Caps	500
87158	**KOVA Plastics System Value Pac 500 with Grids** 50 KOVA Glasstic Slide 10 (10 chambered), 500 KOVA Petters, 500 Economy Tubes	500
87141	**KOVA Plastics KO-LEC-PAC®** 500 KOVA Super Tubes, 500 KOVA Caps, 500 KOVA Cups, 500 Labels and 5 Transport Racks	500
87100	**KOVA Plastics Slide II with Grid** for quantitation; 100 x 4 well slides; with each 1mm x 1mm grid square	400
87118	**KOVA Plastics Slide II** (without grid) 100 x 4 well slides	400
87146	**KOVA Plastics Glasstic® Slide I0** 100 x 10 well slides in crystal clear Acrylic	1000
87157	**KOVA Plastics Glasstic® Slide I0** 50 x 10 well slides in crystal clear Acrylic	500
87144	**KOVA Plastics Glasstic® Slide I0 with Grid** 100 x 10 well slides in crystal clear Plexiglas* with quantitation grids; each chamber contains 6.6 µl and has a 3 mm x 3 mm grid with fine divisions of 0.33 mm x 0.33 mm. The test procedure includes a method for quantitating cells per µl of patient samples.	1000

KOVA SYSTEM AND SYSTEM COMPONENTS - CONTINUED

Product Number	Product Description	Determinations Per Package
87137	**KOVA Plastics Super Tube** Graduated non-sterile disposable collection and centrifuge tubes made of high impact, unbreakable plastic to eliminate cracking or breaking during centrifugation.	500
87138	**KOVA Plastics Economy Tube** As above but in economical, break-resistant styrene plastic.	500
87135	**KOVA Plastics Petter** Disposable plastic transfer pipette designed to retain 1.0 ml of urine after centrifugation. The unique lock tip provides a one-step contamination-free decanting method.	500
87139	**KOVA Plastics Cap** Recommended to prevent spillage during transportation, as well as aerosol contamination during centrifugation.	500
87136	**KOVA Plastics Decanting Rack** Rack for decanting up to 10 specimens.	1 Rack
87116	**KOVA Stain** Modified Sternheimer Malbin stain, facilitates differentiation of formed elements.	3 x 25 mls

KOVA SYSTEM FOR QUALITY CONTROL - KOVA Controls

Human urine controls for physical, chemical and microscopic quality control.

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

Simulated urine controls for physical, chemical and microscopic quality control.

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

Product Number	Description KOVA Liqua-Trol without Microscopics	Packaging
87112	**KOVA Liqua-Trol** Level II (Normal with hCG) Control	3 x 15ml
	KOVA Liqua-Trol Level I (Abnormal) Control	3 x 15ml

SPECIMEN COLLECTION AND TRANSPORT

The KOVA Plastics System KO-LEC-PAC® is recommended for use in the following manner:

1. Label the KOVA Plastics Tube and give the patient a 3 ½ oz. KOVA Plastics Cup.
2. Instruct the patient to collect the voided urine in the KOVA Plastics Cup.
3. Transfer the urine specimen from the KOVA Plastics Cup to the KOVA Plastics Tube, filling it to the 12 ml graduation.
4. Secure the KOVA Plastics Cap on the KOVA Plastics Tube and place it in the KOVA Plastics Transport Rack for transportation and storage.
5. Deliver to the laboratory as soon as possible, preferably within two hours, but no more than four hours following specimen collection.

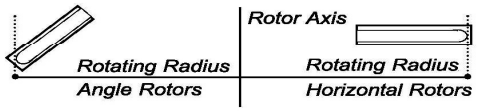
KOVA SYSTEM TEST PROCEDURE

1. Check the specific gravity by placing one or two drops of urine in a temperature-compensated refractometer or use a chemistry test strip containing a specific gravity parameter and record the results.
2. Using reagent test strips, perform chemical testing according to the manufacturer's instructions. Record the observed results. KOVA-Trol I, II and III should be included in each batch to assure proper quality control of physical, chemical and microscopic test procedures.
   Note: KOVA-Trol I, II or III may be used individually or as a set to evaluate the specific range or application.
3. Centrifuge the KOVA Plastics 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:

$$rcf = 28.38\ (R)\ \left(\frac{N}{1000}\right)^2$$

R = radius of rotor in inches
N = 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.



4. Remove the KOVA Plastics Tubes from the centrifuge being careful not to disturb or dislodge the sediment.
5. Insert a KOVA Plastics Petter into the KOVA Plastics Tube. Push the KOVA Plastics Petter to the bottom of the KOVA Plastics Tube until it seats firmly (at the 1ml graduation).
6. Decant and discard 11ml from the KOVA Plastics Tube while the KOVA Plastics Petter is locked in position in the KOVA Plastics Tube. This will retain 1ml of urine sediment at the bottom of the KOVA T Plastics ube.
7. Withdraw the KOVA Plastics Petter from the KOVA Plastics Tube.
8. Add one drop of KOVA Stain to the 1ml of urine sediment.
   Note: KOVA Stain is an aid to assist in the cellular differentiation of elements and is optional.
9. Using the KOVA Plastics Petter, gently resuspend the sediment and stain until a homogeneous mixture is obtained.
10. Withdraw a small sample of the urine sediment stain mixture by squeezing the bulb of the KOVA Plastics Petter.
11. Transfer the sediment mixture to the KOVA Plastics Slide by placing one drop in the cut-out notch of each chamber. When chambers 1-5 are on the top row, the notch is at the top left corner of chambers, when chambers 6-10 are on the top row, the notch is at the top right corner of chambers. The chamber will fill by capillary action. Avoid touching the V-shaped barrier between the chambers while dispensing fluid. Incorrect positioning in dispensing may cause overflowing from one chamber to the next.
12. Remove any excess specimen remaining on the open recessed area by touching the open edge with absorbent material.
13. Place the KOVA Plastics Slide on a microscopic stage under the objective lens.
14. 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). Do not reuse KOVA Plastics products.

EXPECTED VALUES - MICROSCOPY†

HPF = High Power Field 400X
LPF = Lower Power Field 100x

1 + = Occasional form noted
2 + = Noted in every field
3 + = Large amounts in every field
4 + = Full field

Analyte	Normal	Abnormal	Reporting Results
WBC	0-5/HPF	> 5/HPF	Numbers/HPF
RBC	0-3/HPF	> 3/HPF	Numbers/HPF
Epithelial Cells	0	Any (other than squamous)	Numbers/HPF
Crystals	0-3/HPF (non-pathogenic)	> 3 Any abnormal	Numbers/HPF
Yeasts	0	Any	1 + to 4 +/HPF
Trichomonads	0	Any	1 + to 4 +/HPF
Casts	0	Any especially > 1 hyaline cast/LPF	Numbers/LPF
Bacteria	0-5/HPF	> 5/HPF	1 + to 4 +/HPF
Fat	0	Oval fat bodies or free fat	1 + to 4 +/HPF

† Bernard Statland, MLO. p 13-14; Jan. 1985

References for General Information

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U.S. PATENT NUMBERS
4,022,576
4,563,332
4,299,441
D258,388
4,637,693
4,937,415
4,997,266
RE 33,826

CE

Symbols

LOT	Batch/Lot Code	REF	Catalog Number	UDI	Unique Device Identifier	US	Manufactured in Country
	Expiration/Use By	Σ	Contains Quantity	IVD	Invitro Diagnostics Use	30°C 15°C	Storage Limits
	Manufacturer		Do not reuse	www.kovaplastics.com	Instructions for Use/Electronic Instructions for Use		

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