KOVA Plastics System for **Standardized Urinalysis**

KOVA PLASTICS 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. The KOVA Plastics System achieves this standardization by reducing variation, including technique differences among technicians.

INTENDED USE

The **KOVA Plastics 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. Standard controls 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 PLASTICS SYSTEM AND SYSTEM COMPONENTS

Product Number	Product Description	Determinations Per Package
87153E	**KOVA Plastics System Super Pac 1000 w/Caps** 100 KOVA Plastics Glasstic Slide 10 (10 chambered), 1000 KOVA Plastics Petters, 1000 KOVA Plastics Super Tubes, 1000 KOVA Plastics Caps	1000
87154E	**KOVA Plastics System Super Pac 1000** 100 KOVA Plastics Glasstic Slide 10 (10 chambered), 1000 KOVA Plastics Petters, 1000 KOVA Plastics Super Tubes	1000
87162E	**KOVA Plastics System Super Pac 1000 with Grids** 100 KOVA Plastics Glasstic Slide 10 (10 chambered) w/Grids, 1000 KOVA Plastics Petters, 1000 KOVA Plastics Super Tubes	1000
87155E	**KOVA Plastics System Pac II** 100 KOVA Plastics Slide II (4 chambered), 400 KOVA Plastics Petters, 400 KOVA Plastics Super Tubes	400
87156E	**KOVA Plastics System Value Pac 500** 50 KOVA Plastics Glasstic Slide 10 with grids 500 KOVA Plastics Economy Tubes, 100 KOVA Plastics Caps	500
87158E	**KOVA Plastics System Value Pac 500 with Grids** 50 KOVA Plastics Glasstic Slide 10 (10 chambered), 500 KOVA Plastics Petters, 500 KOVA Plastics Economy Tubes	500
87141E	**KOVA Plastics KO-LEC-PAC** 500 KOVA Plastics Super Tubes, 500 KOVA Plastics Caps, 500 KOVA Plastics Cups,500 Labels and 5 Transport Racks	500
87100E	**KOVA Plastics Slide II with Grid** for quantitation; 100 x 4 well slides; with each 1mm x 1mm grid square	400
87118E	**KOVA Plastics Slide II** (without grid) 100 x 4 well slides	400
87146E	**KOVA Plastics Glasstic Slide I0** 100 x 10 well slides in crystal clear Acrylic	1000
87157E	**KOVA Plastics Glasstic Slide I0** 50 x 10 well slides in crystal clear Acrylic	500
87144E	**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 PLASTICS SYSTEM AND SYSTEM COMPONENTS - CONTINUED

Product Number	Product Description	Determinations Per Package
87137E	**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
87138E	**KOVA Plastics Economy Tube** As above but in economical, break-resistant styrene plastic.	500
87135E	**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
87139E	**KOVA Plastics Cap** Recommended to prevent spillage during transportation, as well as aerosol contamination during centrifugation.	500
87136E	**KOVA Plastics Decanting Rack** Rack for decanting up to 10 specimens.	1 Rack

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.

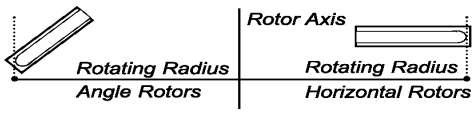
KOVA PLASTICS SYSTEM TEST PROCEDURE

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. Controls should be included in each batch to ensure proper quality control of physical, chemical and microscopic test procedures.
3. Centrifuge the KOVA Plastics Tubes (each containing 12ml of urine specimen or Control) 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 Plastics Tube.
7. Withdraw the KOVA Plastics Petter from the KOVA Plastics Tube.
8. Add one drop of stain to the 1ml of urine sediment.
   Note: 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.

KOVA PLASTICS SYSTEM TEST PROCEDURE - Continued

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.

For Gridded slide analysis, refer to KOVA PLASTICS SYSTEM TEST PROCEDURE – GRIDDED

EXPECTED VALUES - MICROSCOPY†

1 + = Occasional form noted
2 + = Noted in every field
HPF = High Power Field 400X 3 + = Large amounts in every field
LPF = Lower Power Field 100x 4 + = Full field

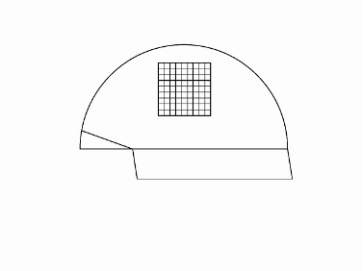
Analyte	Normal	Abnormal	Reporting Results
WBC	0-5/HPF	> 5/HPF	Numbers/HPF
RBC	0-3/HPF	> 3/HPF	Numbers/HPF
Epithelial Cells	0	Any (other than squamous)	Numbers/HPF
Crystals	0-3/HPF (non-pathogenic)	> 3 Any abnormal	Numbers/HPF
Yeasts	0	Any	1 + to 4 +/HPF
Trichomonads	0	Any	1 + to 4 +/HPF
Casts	0	Any especially > 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

1. Bradley, G.M., Benson, E.S., Todd-Sanford Clinical Diagnosis by Laboratory Methods, 15th Edition, Phila. Saunders, 1974.
2. Kurtzman, N.A. and Rogers, P.W. (1974). A Handbook of Urinalysis and Urinary Sediment. Chas. C Thomas, Springfield, IL.
3. Little, P.J. (1962). Urinary white-cell excretion. Lancet. pp. 1149-1151.
4. Little, P.F. (1964). A comparison of the urinary white cell concentrations with the white cell excretion rate. Brit. J. Urol. 36, 360-363.
5. Thomas, M.(1971). A rapid slide method of urine cell counts. Med. Lab Technol. 28, 38-39.
6. Moore, T., Hira, N.R., and Stirland, R.M. (1965). Differential urethrovesical urinary cell count. Lancet. pp. 626-627.
7. Siegle, M.D., Lab Med., 12:781, 1981.
8. Sternheimer, R. and Malbin, B. (1951). The clinical recognition of pyelonephritis with a new stain for urinary sediments. Am. J. of Med., 11:312-323.
9. Muschetta, P.A. and Waters , Jr. F.O. (1962). Manual of Medical Laboratory Techniques. Herbert-Spence, Inc. New York, N.Y., Second Edition, pp 44-45.
10. Lippman, R. W. (1957). Urine and the Urinary Sediment. Chas. C Thomas, Springfield, IL.
11. Dudas, H.C., Lab Med. 12:765. 1981.
12. Weller, J.M. and Greene, J.A. (1966). Examination of the Urine. Meredith Publishing Co., New York.
13. Albert Rabinovitch MD, PhD, Clinical And Laboratory Standards Institute, GP16-A3, Urinalysis; approved guideline – third edition Feb 2009, Volume 29 number 4

VALUE TABLE



Low Cell Count Samples:
Count the total cells of a specific type contained in **10** small grids within different quadrants of the counting grid.

Total Cells	Cells / µL
1	1
2	2
3	2
4	3
5	4
6	5
7	5
8	6
9	7
10	8
11	8
12	9
13	10
14	11
15	11
16	12
17	13
18	14
19	15
20	15
21	16
22	17
23	18
24	18
25	19
26	20
27	21
28	21

Higher Cell Count Samples:
Count the total cells of a specific type contained in **5** small grids within different quadrants of the counting grid.

Total Cells	Cells / µL
5	8
6	9
7	11
8	12
9	14
10	15
11	17
12	18
13	20
14	21
15	23
16	24
17	26
18	28
19	29
20	31
21	32
22	34
23	35
24	37
25	38
30	46
35	54
40	61
45	69
50	77
60	92
70	107

NOTE: For samples that are less than 12mL, reduce the centrifuged quantity to 6mL and double the results obtained before using the table (above).

Cell Type	Normal
Leukocytes	0-4/µL
Erythrocytes	0-2/µL

Borderline	Pathological*
4-6/µL	> 6/µL
2-3/µL	> 3/µL

Alternative Calculation: Determine the **average** number of cells per **small** grid and then use the following multiplication factor to calculate the cells per µL.

To calculate cells / µL using KOVA Plastics Glasstic Slide 10 with Grid:

- For uncentrifuged or neat samples, multiply the average cells obtained per small grid x **90**.
- For 10mL samples concentrated to 1mL, multiply the average cells obtained per small grid x **9**.
- For 10mL samples concentrated to 0.5mL, multiply the average cells obtained per small grid x **4.5**.
- For 12mL samples concentrated to 1mL (KOVA System), multiply the average cells obtained per small grid x **7.5**.

Calculation example (Using KOVA System 12mL to 1mL method):

Cells	Grids Counted	Total Cells	Average Cells / Grids	Multiple x Factor (7.5)	Cells per µL of Samples
Leukoytes	10	5	0.5	0.5 x 7.5	3.8
Erythrocytes	10	14	1.4	1.4 x 7.5	10.5

* Reference: Aiken, C.D. and Sokeland, J. (1983). Urologie. Thiems, Stuttgart, Ninth Edition, p.79

VALUE TABLE
UNDILUTED, UNCENTRIFUGED URINE OR BODY FLUID SPECIMENS

LOW CELL COUNT SAMPLES

Count the total cells of a specific type contained in **36** small grids or 4 complete quadrants of the counting grid.

Total Cells	Cells/µL	Cells/mL
1	3	2,500
2	5	5,000
3	8	7,500
4	10	10,000
5	13	12,500
6	15	15,000
7	18	17,500
8	20	20,000
9	23	22,500
10	25	25,000
11	28	27,500
12	30	30,000
13	33	32,500
14	35	35,000
15	38	37,500
16	40	40,000
17	43	42,500
18	45	45,000
19	48	47,500
20	50	50,000
25	63	62,500
30	75	75,000
40	100	100,000
50	126	125,500

Alternative Calculation:
Multiply the average number of cells per small grid by 90 to obtain cells per µL; multiply by 90,000 to obtain cells per mL.

HIGH CELL COUNT SAMPLES

Count the total cells of a specific type contained in **10** small grids in different quadrants of the counting grid.

Total Cells	Cells/µL	Cells/mL
1	9	9,000
2	18	18,000
3	27	27,000
4	36	36,000
5	45	45,000
6	54	54,000
7	63	63,000
8	72	72,000
9	81	81,000
10	90	90,000
20	180	180,000
25	225	225,000
30	270	270,000
35	315	315,000
40	360	360,000
50	450	450,000
60	540	540,000
70	630	630,000
80	720	720,000
90	810	810,000
100	900	900,000
150	1350	1,350,000
200	1800	1,800,000
250	2250	2,250,000

Alternative Calculation:
Multiply the average number of cells per small grid by 90 to obtain cells per µL; multiply by 90,000 to obtain cells per mL.

DILUTED BODY FLUIDS CALCULATION METHOD:

Cells / µL = Average number of cells per small grid x 90 (multiplication factor) x dilution
e.g., Spinal fluid diluted 1:10; a total of 50 RBC's counted in 10 small grids

$$\text{RBC/µL} = \frac{50 \text{ cells}}{10 \text{ grids}} \times 90 \text{ (factor)} \times 10 \text{ (dilution)}$$

$$= 5 \times 900 = 4{,}500 \text{ RBC's/µL}$$

e.g., Semen diluted 1:20; a total of 150 sperm counted in 5 small grids

$$\text{Sperm/µL} = \frac{150}{5} \times 90 \text{ (factor)} \times 20 \text{ (dilution)}$$

$$= 30 \times 1800 = 54{,}000 \text{ sperm/µL}$$

TOTAL CELL COUNT NORMAL RANGES [1]

FLUID	CELL TYPE	NORMAL	ABNORMAL	FLUID	CELL TYPE	NORMAL	ABNORMAL
Urine (2)	Leukocytes Erythrocytes	0-6/µL 0-3/µL	> 6/µL > 3/µL	Synovial	Leukocytes Erythrocytes	< 200/µL < 2,000/µL	> 200/µL > 2,000/µL
CSF (Adult Range)	Leukocytes	0-5/µL	> 5/µL	Pleural	Leukocytes	< 1,000/µL	> 1,000/µL
				Pericardial	Leukocytes	< 1,000/µL	> 1,000/µL
Seminal	Sperm	40,000/µL - 160,000/µL	< 40,000/µL	Pertoneal	Leukocytes Erythrocytes	< 300/µL < 100,000/µL	> 300/µL > 100,000/µL

References: (1) Strasinger, S.K. (1985) **Urinalysis and Body Fluids**, F.A. Davis, Philadelphia • (2) Alken, C.D., and Sokeland, J. (1983) **Urologie**, Thiems, Stutgart, Nineth Edition, pg. 79

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

Alltrista Plastics LLC 20 Setar Way Reedsville, Pa 17084 United States Customer Service: +1 864-879-8100	EC REP Advena Ltd. Tower Business Centre, 2nd Flr. Tower Street, Swatar, BKR 4013 Malta
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