

KOVA-Trol® I High Abnormal with Urobilinogen Value Assignment Human Urinalysis Control

| KOVA-Trol                           |  | Lot No: K605927   |                               |                             |                             |                  |                                | Expiration Date: 2025-01-31 |   |                                 |
|-------------------------------------|--|---|-------------------------------|-----------------------------|-----------------------------|------------------|--------------------------------|-----------------------------|---|---------------------------------|
| CONSTITUENT                         | REAGENT TEST STRIP RESULTS <sup>1, 7</sup> |   |                               |                             |                             |                  |                                |                             |   |                                 |
|                                     | SIEMENS REAGENT STRIP <sup>a</sup>         |   |                               |                             |                             |                  |                                |                             | McKesson <sup>i</sup><br>Consult® Diagnostics<br>REAGENT STRIPS | IRIS REAGENT STRIP <sup>g</sup> |
|                                     | Visual                                     | Clinitek®50   | Clinitek®<br>STATUS / STATUS+ | Clinitek®100                | Clinitek®<br>500 / Advantus | Clinitek®Atlas   | Clinitek®Novus                 |                             | 120 URINE ANALYZER  | iChem® VELOCITY™                |
| pH                                  | 7.0 - 8.0                                  | 7.0 - 8.0   | 7.0 - ≥ 9.0                   | 7.0 - 8.0                   | 7.0 - 8.5                   | N/A              | 7.0 - 8.0                      |                             | 7.0 - 8.0   | N/A                             |
| Protein <sup>5,6</sup>              | 100 - ≥ 300 mg/dL                          | 100 - ≥ 300 mg/dL   | 100 - ≥ 300 mg/dL             | 100 - ≥ 300 mg/dL           | 100 - ≥ 300 mg/dL           | N/A              | 100 - ≥ 1000 mg/dL             |                             | 100 - 300 mg/dL   | N/A                             |
| Glucose <sup>5</sup>                | 250 - 2000 mg/dL                           | 500 - ≥ 1000 mg/dL  | 250 - ≥ 1000 mg/dL            | 500 - ≥ 1000 mg/dL          | 500 - ≥ 1000 mg/dL          | N/A              | 250 - ≥ 1000 mg/dL             |                             | 250 - 1000 mg/dL  | N/A                             |
| Ketones                             | 40 - 160 mg/dL                             | 40 - ≥ 80 mg/dL   | 40 - ≥ 160 mg/dL              | 40 - ≥ 80 mg/dL             | 15 - ≥ 80 mg/dL             | N/A              | 15 - ≥ 160 mg/dL               |                             | 40 - 80 mg/dL   | N/A                             |
| Bilirubin <sup>5</sup>              | 2 + - 3 + <sup>8</sup>                     | Moderate - Large  | Moderate - Large              | Moderate - Large            | Moderate - Large            | N/A              | Moderate - Large               |                             | 2 - 4 mg/dL   | N/A                             |
| Blood (hemoglobin)                  | 2 + - 3 + <sup>8</sup>                     | Moderate - Large  | Moderate - Large              | Moderate - Large            | Moderate - Large            | N/A              | Moderate - Large               |                             | 80 - 200 Ery/µL   | N/A                             |
| Nitrite <sup>5</sup>                | Positive                                   | Positive  | Positive                      | Positive                    | Positive                    | N/A              | Positive                       |                             | Positive  | N/A                             |
| Urobilinogen                        | 4 - 8 EU/dL                                | 4.0 - ≥ 8.0 EU/dL   | 4.0 - ≥ 8.0 EU/dL             | 4.0 - ≥ 8.0 EU/dL           | 4.0 - ≥ 8.0 EU/dL           | N/A              | 1.0 - ≥ 8.0 EU/dL              |                             | 4 - 8 mg/dL   | N/A                             |
| Specific Gravity                    | 1.010 - 1.025                              | 1.010 - 1.025   | 1.010 - 1.025                 | 1.010 - ≥ 1.030             | 1.010 - 1.025               | N/A <sup>9</sup> | 1.010 - 1.020 <sup>9</sup>     |                             | 1.010 - 1.020   | N/A <sup>9</sup>                |
| Leukocyte Esterase <sup>3,4,5</sup> | 1 + - 3 +                                  | Moderate - Large  | Moderate - Large              | Small - Large               | Small - Large               | N/A              | Moderate - Large               |                             | 125 - 500 Leu/µL  | N/A                             |
| Microalbumin                        | N/A  | 30 - 150 mg/L <sup>12</sup>                                     | 30 - 150 mg/L <sup>12</sup>   | 30 - 150 mg/L <sup>12</sup> | N/A                         | N/A              | 30 - 150 mg/L <sup>11</sup>    |                             | N/A   | N/A                             |
| Creatinine                          | 50 - 300 mg/dL                             | 50 - 300 mg/dL  | 50 - 300 mg/dL                | 50 - 300 mg/dL              | 50 - 300 mg/dL              | N/A              | 50 - ≥ 300 mg/dL <sup>11</sup> |                             | N/A   | N/A                             |
| A : C                               | N/A  | 30 - 300 mg/g Abnormal - > 300 mg/g High Abnormal <sup>12</sup> |                               |                             | N/A                         | N/A              | 150 - ≥ 300 mg/g <sup>11</sup> |                             | N/A   | N/A                             |
| Ascorbic Acid                       | N/A  | N/A   | N/A                           | N/A                         | N/A                         | N/A              | N/A                            |                             | N/A   | N/A                             |

MICROSCOPIC QUALITY CONTROL  
CELL COUNTS<sup>2</sup>

| Property         | Value Range             | Method                          |
|------------------|-------------------------|---------------------------------|
| Appearance       | Clear - Slightly Cloudy | Visual                          |
| Color            | Amber                   | Visual                          |
| Specific Gravity | 1.013 - 1.017           | Refractometer<br>(Room Temp.)   |
| Osmolality       | 225 - 325               | mOsm Freezing Pt.<br>Depression |
| pH               | 7.0 - 8.0               | pH Meter                        |

| Constituent/Method                               | Value Range   |
|--|---------------|
| Bilirubin/Ictotest® <sup>a</sup>                 | Postive       |
| Protein/Sulfosalicylic Acid (3%) <sup>6</sup>    |               |
| Qualitative                                      | 3 + - 4 +     |
| Glucose/AimTab™ Reducing Substances <sup>j</sup> | 1/4 - 1%      |
| Ketone/K-Check® <sup>m</sup>                     | Small - Large |
| Nitrazine Paper/pHizatest <sup>n</sup>           | 7.0 - 7.5     |

| Constituent                 | Fixed Rotor | Swing Rotor | Sysmex <sup>c</sup><br>UF-5000 | Iris <sup>g</sup><br>iQ200 | Mindray <sup>l</sup><br>EH-20 Series | Siemens <sup>a</sup><br>Atellica UAS 800 |
|-----------------------------|-------------|-------------|--------------------------------|----------------------------|--------------------------------------|--|
| Qualitative                 |             |             |                                |                            |                                      |  |
| Red Cells/hpf               | 18 - 55     | 31 - 77     | ---                            | ---                        | ---                                  | 21 - 199                                 |
| White Cells/hpf             | 13 - 59     | 29 - 79     | ---                            | ---                        | ---                                  | 32 - 65                                  |
| Quantitative                |             |             |                                |                            |                                      |  |
| Red Cells/μL <sup>†</sup>   | 123 - 245   | 202 - 332   | 0 - 100                        | N/A                        | N/A                                  | 93 - 876                                 |
| White Cells/μL <sup>†</sup> | 138 - 260   | 234 - 382   | 4 - 15                         | N/A                        | N/A                                  | 141 - 284                                |
| Crystals <sup>*</sup>       | Present     | Present     | ---                            | ---                        | ---                                  | (+)                                      |
| Casts (low power)           | <1          | <1          | ---                            | ---                        | ---                                  | (-)                                      |
| Bacteria                    | Present     | Present     | ---                            | ---                        | ---                                  | (+---)                                   |

PREGNANCY TESTING

| Method   | Result       |
|--|--------------|
| Beckman Coulter ICON® 20 hCG <sup>e</sup>            | Negative     |
| Quidel QuickVue® hCG <sup>d</sup>                    | Negative     |
| Siemens Clinitest® hCG <sup>a</sup>                  | Not Assigned |
| McKesson Consult® hCG Dipstick/Cassette <sup>i</sup> | Negative     |
| Cardinal Health® hCG Dipstick/Cassette <sup>k</sup>  | Negative     |
| Fisher Sure-Vue™ hCG/Strips/STAT <sup>o</sup>        | Negative     |

Note: Other manufacturers’ methods will work and should be confirmed by the laboratory.

† Iris iQ200 cell/hpf.  
\* Calcium oxalate, amorphous material, occasional bilirubin. Urinary artifacts may be present.

KOVA-Trol® I High Abnormal with Urobilinogen Value Assignment Human Urinalysis Control

| KOVA-Trol                           |  | Lot No: K605927               |                            |                  |                    |   |                            | Expiration Date: 2025-01-31                |  |   |
|-------------------------------------|--|-------------------------------|----------------------------|------------------|--------------------|---|----------------------------|--|--|---|
| CONSTITUENT                         | REAGENT TEST STRIP RESULTS <sup>1, 7</sup> |                               |                            |                  |                    |   |                            |  |  |   |
|                                     | ROCHE REAGENT STRIP <sup>b</sup>           |                               |                            |                  |                    |   |                            | DIRUI <sup>f</sup><br>DIRUI REAGENT STRIP® | ARKRAY <sup>h</sup><br>Aution Reagent Strip<br>Aution Hybrid <sup>TM</sup> | Mindray <sup>i</sup><br>Hyssen Urinalysis<br>Reagent Strips |
|                                     | Combur-Test®<br>Visual                     | Chemstrip®<br>Visual          | Chemstrip<br>Criterion II™ | URISYS 1800™     | URISYS 1100™       | Cobas® U 411                                | Cobas® U 601               | DIRUI<br>H-100                             | AU-4050  | UA-5600, 5800, 6600, 6800                                   |
| pH                                  | 7 - 8                                      | 7 - 8                         | 7 - 8                      | 7 - 8            | 7 - 8              | 7 - 8                                       | 7 - 8                      | N/A  | 7.0 - 8.0  | N/A   |
| Protein <sup>5,6</sup>              | 100 - 500 mg/dL                            | 100 - 500 mg/dL               | 100 - 500 mg/dL            | 150 - 500 mg/dL  | 100 - 500 mg/dL    | 100 (150) - 500 (500) mg/dL <sup>10</sup>   | 100 - 500 mg/dL            | N/A  | 100 - 600 - over mg/dL   | N/A   |
| Glucose <sup>5</sup>                | 300 - 1000 mg/dL <sup>8</sup>              | 500 - 1000 mg/dL <sup>8</sup> | 250 - 1000 mg/dL           | 300 - 1000 mg/dL | 250 - > 1000 mg/dL | 250 (300) - 1000 (1000) mg/dL <sup>10</sup> | 250 - 1000 mg/dL           | N/A  | 300 - 1000 - over mg/dL  | N/A   |
| Ketones                             | 1 + - 3 +                                  | 1 + - 3 +                     | 15 - 150 mg/dL             | 50 - 150 mg/dL   | 15 - 150 mg/dL     | 50 - 150 mg/dL                              | 50 - 150 mg/dL             | N/A  | 40 - 150 - over mg/dL  | N/A   |
| Bilirubin <sup>5</sup>              | 2 + - 3 + <sup>8</sup>                     | 2 + - 3 + <sup>8</sup>        | 3 - 6 mg/dL                | 3 - 6 mg/dL      | 3 - 6 mg/dL        | 3 - 6 mg/dL                                 | 3 - 6 mg/dL                | N/A  | 6.0 - 10.0 - over mg/dL  | N/A   |
| Blood (hemoglobin)                  | 50 - 250 Ery/µL <sup>8</sup>               | 50 - 250 Ery/µL <sup>8</sup>  | 150 - 250 Ery/µL           | 150 - 250 Ery/µL | 50 - 250 Ery/µL    | 150 - 250 Ery/µL                            | 150 - 250 Ery/µL           | N/A  | 0.2 - 1 - over mg/dL   | N/A   |
| Nitrite <sup>5</sup>                | Positive <sup>8</sup>                      | Positive <sup>8</sup>         | Positive                   | Positive         | Positive           | Positive                                    | Positive                   | N/A  | 1 + - 2 +  | N/A   |
| Urobilinogen                        | 4 - 12 mg/dL <sup>8</sup>                  | 4 - 12 mg/dL <sup>8</sup>     | 4 - 12 mg/dL               | 4 - 12 mg/dL     | 4 - ≥ 12 mg/dL     | 4 - 12 mg/dL                                | 4 - 12 mg/dL               | N/A  | 4 - 12 - over mg/dL  | N/A   |
| Specific Gravity                    | 1.005 - 1.020                              | 1.005 - 1.020                 | 1.005 - 1.020              | 1.005 - 1.020    | 1.005 - 1.020      | 1.010 - 1.020                               | 1.010 - 1.020 <sup>9</sup> | N/A  | 1.005 - 1.020  | N/A   |
| Leukocyte Esterase <sup>3,4,5</sup> | 10 - 25 - 500 Leu/µL                       | 1 + - 2 +                     | 100 - 500 Leu/µL           | 100 - 500 Leu/µL | 75 - 500 Leu/µL    | 100 - 500 Leu/µL                            | 100 - 500 Leu/µL           | N/A  | 250 - 500 Leu/µL   | N/A   |
| Microalbumin                        | N/A  | N/A                           | N/A                        | N/A              | N/A                | N/A   | N/A                        | N/A  | N/A  | N/A   |
| Creatinine                          | N/A  | N/A                           | N/A                        | N/A              | N/A                | N/A   | N/A                        | N/A  | N/A  | N/A   |
| A : C                               | N/A  | N/A                           | N/A                        | N/A              | N/A                | N/A   | N/A                        | N/A  | N/A  | N/A   |
| Ascorbic Acid                       | N/A  | N/A                           | N/A                        | N/A              | N/A                | N/A   | N/A                        | N/A  | N/A  | N/A   |

1. The values are obtained by testing each lot of control over the seven-day reconstituted stability period by each method. Any changes made by the manufacturers of the test strips or of the methods used may result in different values from those listed. Therefore, these values should be used only as guidelines by the laboratory until it has established its own precision and accuracy parameters.

2. The cell count ranges apply to a microscopic field viewed using a 10X wide eyepiece and a 40X objective lens. The approximate diameter of such a field under high power magnification is 0.50 mm; therefore, an appropriate correction factor should be applied when a microscope with a different field size is used in order to maintain consistency in reporting results.

3. A microscopic examination of the sediment is highly recommended in conjunction with a screening test for leukocyte esterase to detect lysed leukocytes. Testing for leukocyte esterase should not be used to replace microscopic analysis as significant and often critical pathologically diagnostic elements will go undetected.<sup>i, iii, iv</sup>

4. Test strip patches generally detect only 90% of abnormally high concentrations of analytes such as nitrite, glucose, ketones, bilirubin and blood. Possible pathological conditions can go undetected if strips alone are used. Since leukocyte esterase is only found in granulocytes, leukocyturia due to lymphocytes, monocytes or histocytes as seen in certain stages of nephritis may not be detected. In addition, renal tubular epithelial cells and certain casts which are characteristic for certain kidney disease states will go undetected.<sup>i, ii</sup>

5. Certain commonly used antibiotics such as gentamicin and cephalixin as well as high levels of albumin will interfere with the leukocyte esterase reaction. Vitamin C interferes with test strip reactions for albumin, bilirubin, nitrite and glucose. These analytes do not interfere with the microscopic analysis. For further information and precautions using test strips, please consult the manufacturer's direction insert under "Limitations of Procedures."<sup>iv</sup>

6. A decline in protein values may be observed over the seven-day period due to the enzymatic action of leukocyte esterase on this constituent. This degradation will be reflected in both qualitative and quantitative ranges.

7. Variation in the values obtained for constituents in this control may be due to inter-method biases.

8. Atypical color reactions may be observed due to the high concentration of some constituents. Use color intensity for result interpretation.
- Constituent

Method

Color

Constituent

Method

Color

Constituent

Method

Color

Bilirubin

Siemens Strips

Purple - reddish-brown

Blood

Siemens Strips

Navy blue

Glucose

Roche Reagent Strips

Navy blue

Roche Reagent Strips

Pink - purple

Roche Reagent Strips

Roche Combur-Test Strips

Nitrite

Roche Reagent Strips

Orange - pink

Urobilinogen

Roche Reagent Strips

Pink - purple

Roche Combur-Test Strips

Roche Combur-Test Strips

Roche Combur-Test Strips
- a Siemens Medical Solutions Diagnostics

b Roche Diagnostics Corporation

c Sysmex Corporation

d Quidel Corporation

e Beckman Coulter, Inc.

f DIRUI Industrial Co. LTD (For International Use Only)

g Iris Diagnostics

h ARKRAY, Inc.

i McKesson Medical-Surgical/Consult® Diagnostics

j Germaine Laboratories. Inc.

k Cardinal Health®

l Mindray

m Biorex Labs

n Micro Essential Laboratory

o Fisher Healthcare

KOVA  
INTERNATIONAL  
www.kovaintl.com

7272 Chapman Avenue, Suite B  
Garden Grove, California 92841  
UNITED STATES  
(855) 217-6399 • (714) 902-1700  
Fax (714) 908-7945

Advena Ltd.  
Tower Business Centre  
2nd Flr, Tower Street  
Swatar, Bkr 4013  
Malta

9. Value assigned with Normal system settings at .005 increments.
10. Ranges assigned in USA mg/dL and with International mg/dL in parentheses.
11. Values assigned for international use only.
- 12 Microalbumin values are assigned with Siemens Microalbumin strips on the Clinitek 50, STATUS, STATUS + and 100 only.

