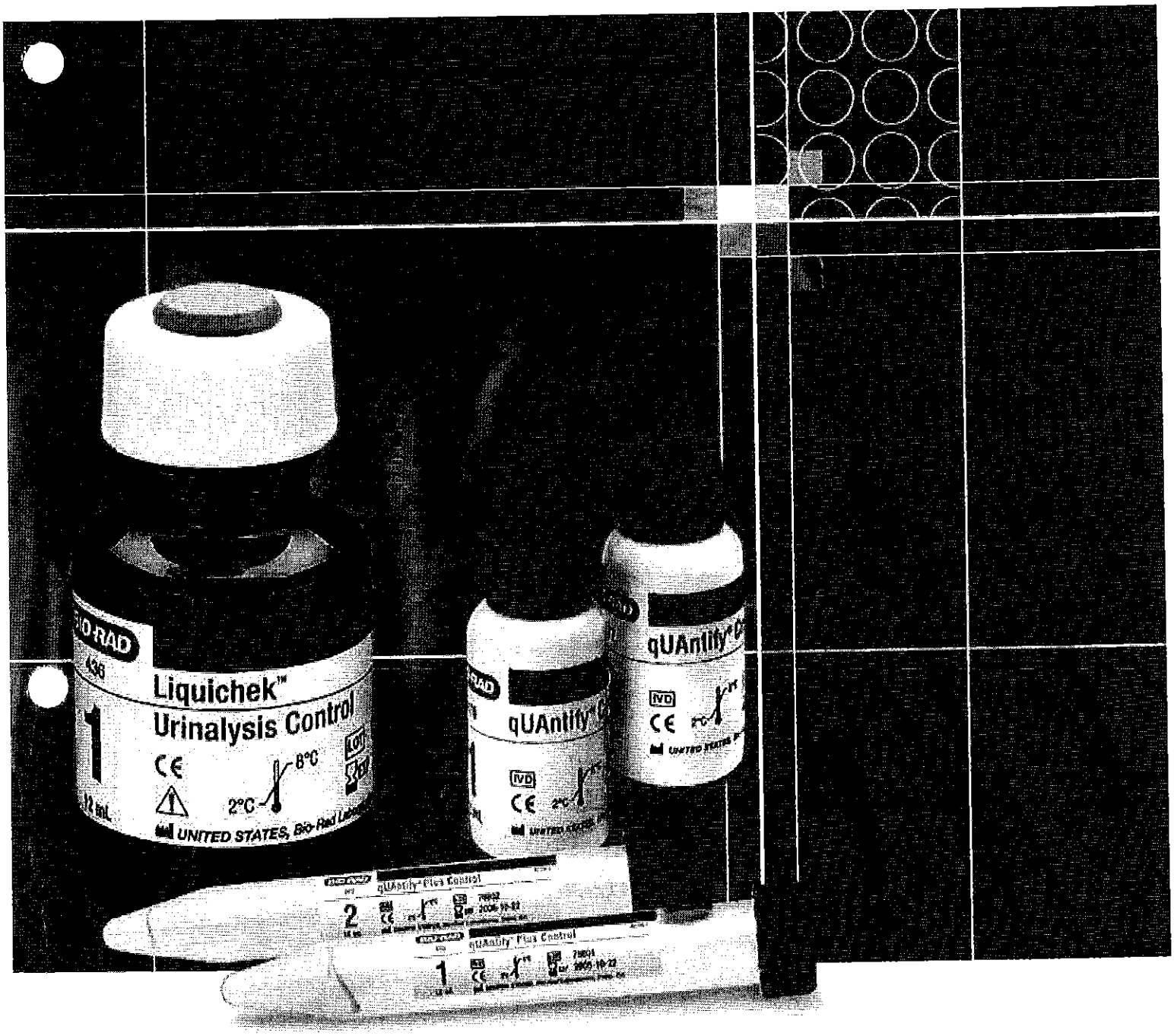
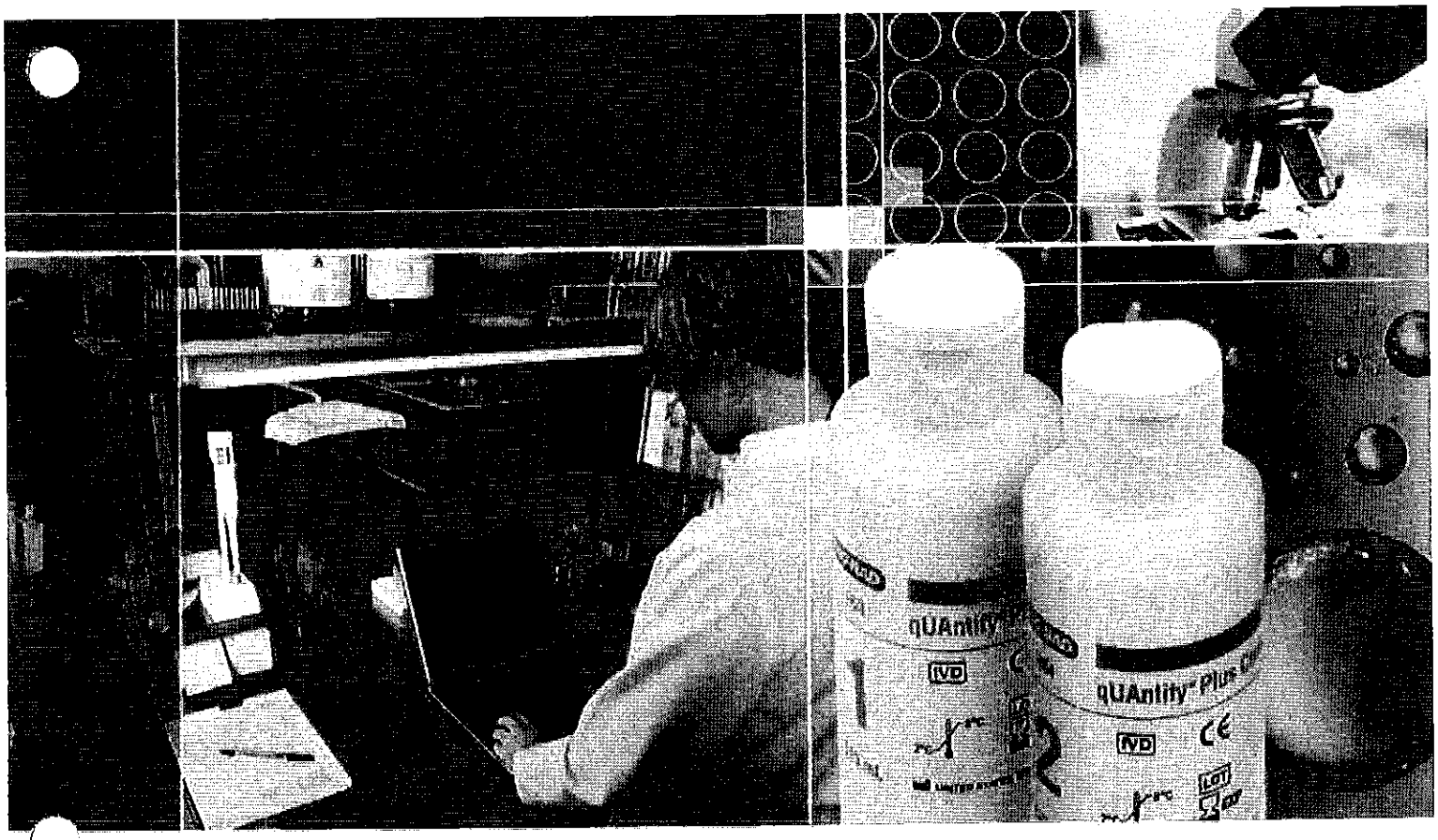


Urinalysis Controls

BIO-RAD



Urinalysis Controls from Bio-Rad

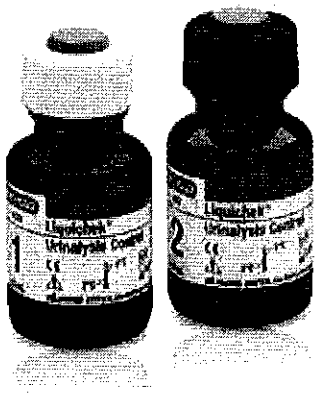
Versatile packaging and comprehensive analytes for today's laboratory

Urinalysis is widely documented as the first clinical laboratory test developed and dates back over 6,000 years. Even today, modern urinalysis is still one of the most widely performed tests in routine health screening.

Bio-Rad Urinalysis Controls are available in a variety of convenient packaging options, including dropper bottles, flip-top squeeze bottles and centrifuge tubes.

Covering an extensive menu of analytes to monitor physical, chemical and microscopic examination of urine specimens, Bio-Rad Urinalysis controls are well suited for manual or automated methods for dipstick or microscopic analysis of urine specimens.

Participating in the Unity™ Interlaboratory Program provides valuable peer group comparisons with distinctive, easy-to-read color coded reports.



Liquichek™ Urinalysis Control

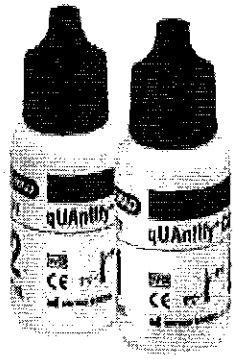
Specifically designed for urine dipstick and microscopic testing.
The control is available in 12 mL glass vials.

- Liquid, human urine based
- Designed for dipstick and microscopic analysis
- 30 day open-vial stability at 2–25°C
- 2.5 year shelf life at 2–8°C

Analytes

Bilirubin
Blood
Casts
Clarity
Color
Creatinine
Glucose
Ketones
Leukocytes
Microalbumin
Microscopics
(RBC, WBC, Crystals)
Nitrite
Osmolality
pH
Pregnancy (hCG)
Protein (Total)
Protein-to-Creatinine Ratio
Specific Gravity
Urobilinogen

Refer to the package insert of currently available lots for specific analyte and stability claims



qUAntify® Control

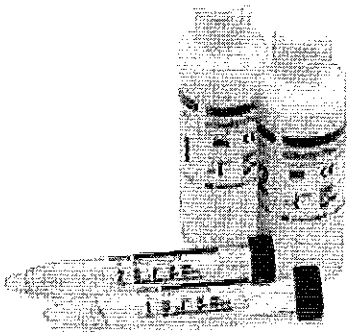
Designed to monitor the precision of urine dipstick testing.
The control is available in 12 mL ready-to-use dropper bottles.

- Liquid
- Designed for dipstick testing
- 2 year shelf life at 2–8°C
- 31 day open-vial stability at 2–25°C
- Color-coded peer group reports available

Analytes

Albumin
Albumin-to-Creatinine Ratio
Ascorbic Acid*
Bilirubin
Blood
Creatinine
Glucose
Hemoglobin
Ketones
Leukocytes
Microalbumin
Nitrite
pH
Pregnancy (hCG)
Protein (Total)
Protein-to-Creatinine Ratio
Specific Gravity
Urobilinogen

* Tested and found to be negative.
Refer to the package insert of currently available lots for specific analyte and stability claims



qUAntify® Plus Control

A combination urine dipstick and microscopic control. The control is available in either 12 mL centrifuge tubes or 120 mL flip-top squeeze bottles.

- Liquid
- Designed for dipstick and microscopic analysis
- 2 year shelf life at 2–8°C
- 31 day open-vial stability at 2–25°C
- Color-coded peer group reports available

Analytes

Albumin
Albumin-to-Creatinine Ratio
Ascorbic Acid*
Bilirubin
Blood
Creatinine
Glucose
Hemoglobin
Ketones
Leukocytes
Microalbumin
Microscopics
(RBC, WBC, Crystals)
Nitrite
pH
Pregnancy (hCG)
Protein (Total)
Protein-to-Creatinine Ratio
Specific Gravity
Urobilinogen

* Tested and found to be negative.
Refer to the package insert of currently available lots for specific analyte and stability claims

Ordering Information

Cat #	Product Name	Quantity
	Liquichek™ Urinalysis Control	
435	Bilevel (6 of each level)	12 x 12 mL
436	Level 1	12 x 12 mL
437	Level 2	12 x 12 mL
435X	Bilevel MiniPak (1 of each level)	2 x 12 mL

Cat #	Product Name	Quantity
	qUAntify® Control	
975	Bilevel (3 of each level)	6 x 12 mL
975X	Bilevel MiniPak (1 of each level)	2 x 12 mL
	qUAntify® Plus Control	
995	Bilevel (5 of each level)/Tube	10 x 12 mL
995X	Bilevel MiniPak (1 of each level)/Tube	2 x 12 mL
962	Bilevel (2 of each level)/Bottle	4 x 120 mL
963	Level 1/Bottle	4 x 120 mL
964	Level 2/Bottle	4 x 120 mL
962X	Bilevel MiniPak (1 of each level)/Bottle	2 x 120 mL

These controls are featured in the Unity™ Interlaboratory Program. Participation in the Unity™ Interlaboratory Program can help improve the quality of your laboratory test results and help you meet regulatory and accreditation requirements worldwide. You may also subscribe to one of our Unity™ QC Data Management Solutions designed to improve the effectiveness of your statistical process control. Ask your Bio-Rad Account Representative for more information.

Discover the power of Unity™ Solutions at www.QCNet.com.

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Bio-Rad Laboratories

Clinical Diagnostics Group

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  - CLIA Waived Multi Drug Cup
  - Fastect II Drug Testing
  - Fastect Drug Testing
  - Generic Drug Test Cards
  - iCup - One Step Cup

1 Set of KOVA-Trol I & II Urinalysis Control Combo

1 Set of KOVA-Trol I & II Urinalysis Control Combo
HYC-87329-1/HYC-87130-1 COMBO
1 vial each high/low (15mL)
Hycor Urinalysis Control Set - (KOVA-Trol I - constituents in high abnormal range, & KOVA-Trol II - constituents in low abnormal range) KOVA-Trol is a stable human urine control for complete quality control of physical, chemical and microscopic examination of urine specimens. All constituents are stable for seven days at 2-8°C and 30 days - 20°C after reconstitution. KOVA-Trol is available in three levels to monitor the entire decision ranges for urine strip chemistries. Values are assigned for visual and instrument reading on all major systems. (This item must be re-consititued with distilled water) REFRIGERATED ITEM! PLEASE SELECT 2ND DAY AIR SHIPPING. THIS ITEM MUST BE RECONSTITUTED WITH DISTILLED WATER.

$49.95

Qty: 1

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More Info
Product Insert

The KOVA® system for standardized urinalysis provides the assurance of quality results and personnel safety for urinalysis in both laboratory and point-of-care environments. KOVA urinalysis products from HYCOR are designed to minimize exposure to biohazardous samples and to ensure samples are properly collected and handled for chemical tests using urine dipstick chemistry, confirmatory and pregnancy tests and microscopic examination of cells and particles. The KOVA® system flags potential inaccuracies and ensures reliable, reproducible results. The KOVA® system includes everything the lab needs to standardize critical steps from sample collection to centrifugation, decanting and resuspension of sediment, slide preparation and reporting results.

BENEFITS

- Essential disposable components and quality control materials to ensure high-quality results and personnel safety
- Convenient disposable microscope slides with optional counting grid
- Multi-level dipstick controls in convenient lyophilized and liquid formats
- Multi-level serum protein controls for refractometry

HYCOR

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 7ml 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

1. KOVA-Trol, a freeze-dried preparation of human urine.
2. Assay value sheet for physical, chemical and microscopic constituents.
3. Daily control sheet.
4. 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

1. 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.
2. Remove the seal and rubber stopper from the KOVA-Trol bottle.
3. Using a graduated cylinder or other suitable means, add a volume of deionized or distilled water (with pH between 6 and 7) equal to the volume stated on the freeze-dried KOVA-Trol bottle label.
4. 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.
5. 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.
6. Using the standardized urinalysis procedure below, test the aliquot within one hour and discard the sample.

STANDARDIZED URINALYSIS PROCEDURE

SPECIMEN COLLECTION

1. For the best chemical and microscopic results, analyze a clean, voided, fresh, first morning urine specimen.
2. 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.
3. 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.
4. 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.
5. 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.

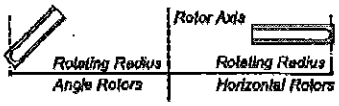
CENTRIFUGATION AND MICROSCOPIC EXAMINATION

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:

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

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.



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 Stain[4] 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 effected.
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

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.
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4. Sternheimer, R., and Malbin, D.: Clinical recognition of pyelonephritis with a new stain for urinary sediments. Am J. Med. 11:312, 1951.
5. 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

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URINALYSIS CONTROLS

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- Dropper Urine Dipstick Control
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- Dip&Spin Urine Dipstick/Microscopics Control
- QuanTscopics Urine Microscopics Control

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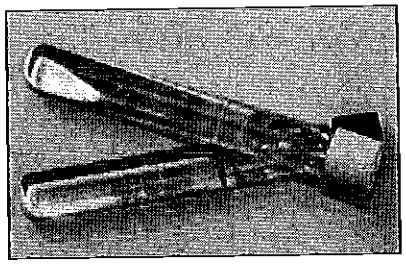
Dipper™
Urine Dipstick Control

UDC Quality Control Log
Dipper Flyer

- Simulates patient testing
- Liquid, made with real human urine
- 18 month unopened and 3 month (or 20 dips) open vial stability when stored at 2-8 C*



This is the one that started it all. We craft Dipper Urine Dipstick Control to monitor the performance of visual and instrumental readings of urine dipsticks by immersing the dipstick into the control – the same way you test your patient samples. We include values for all dipstick analytes plus microalbumin and creatinine; and qualitative results for hCG early pregnancy detection test methods. Dipper Urine Dipstick Control is designed for use with most urinalysis reagent strips. It can also be used for confirmatory tests and refractometry. Dip it, read it, done.

**Refer to the package insert of currently available lots for specific analyte and stability claims*

CATALOG NO.	PRODUCT	SIZE
1440-01	Dipper Urine Dipstick Control Set	6x15 mL
1442-61	Dipper Urine Dipstick Control, Level 2	6x15 mL

ORDER NOW | PRODUCT INSERT | MSDS

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Quantimetrix Corporation

Dipper™

Urine Dipstick Control

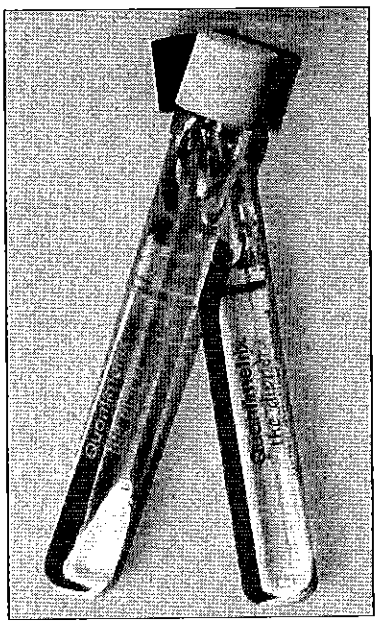
- Simulates patient testing
- Liquid, made with real human urine
- 18 month unopened and 3 month (or 20 dips) open vial stability when stored at 2-8 C*

Analytes*

Bilirubin	Creatinine	hCG	Leukocytes	Nitrite	Protein	Urobilinogen
Blood	Glucose	Ketones	Microalbumin	pH	Specific Gravity	

**Refer to the package insert of currently available lots for specific analyte and stability claims*

This is the one that started it all. We craft Dipper Urine Dipstick Control to monitor the performance of visual and instrumental readings of urine dipsticks by immersing the dipstick into the control – the same way you test your patient samples. We include values for all dipstick analytes plus microalbumin and creatinine; and qualitative results for hCG early pregnancy detection test methods. Dipper Urine Dipstick Control is designed for use with most urinalysis reagent strips. It can also be used for confirmatory tests and refractometry. Dip it, read it, done.



ORDERING INFORMATION:

1440-01 2 Level Set.....6 x 15 mL

1442-61 Level 2.....6 x 15 mL

For More Information: phone +1.310.536.0006 email info@4qc.com web www.4qc.com

DIPF8-5/10

Quantimetrix Corporation

Dropper

Urine Dipstick Control

- Easy-to-use, dropper bottles
- Liquid, made with real human urine
- 18 month unopened and open vial stability when stored at 2-8 C*

Analytes*

Bilirubin	Creatinine	hCG	Leukocytes	Nitrite	Protein	Urobilinogen
Blood	Glucose	Ketones	Microalbumin	pH	Specific Gravity	

**Refer to the package insert of currently available lots for specific analyte and stability claims*

Take convenience to a whole new level. We craft Dropper Urine Dipstick Control to monitor the performance of visual and instrumental readings of urine dipsticks by dropping the control directly onto the dipstick with an easy-to-use, dropper bottle for outrageously simple dispensing and maximum use. We include values for all dipstick analytes plus microalbumin and creatinine; and qualitative results for hCG early pregnancy detection test methods. Dropper Urine Dipstick Control is designed for use with most reagent strips. It can also be used for confirmatory tests and refractometry. No hassle, no waste, no problem.

ORDERING INFORMATION:

1440-02 2 Level Set.....4 x 25 mL

For More Information: phone +1.310.536.0006 email info@4qc.com web www.4qc.com

DRPF8-5/10

dipper, dropper & dropper plus *urine dipstick control • quality control log*

Quantimetrix Corporation

Level 1 Normal Lot No._____ Expiration Date_____ Level 2 Abnormal Lot No._____ Expiration Date_____

Date	Reagent Strip Lot No. Exp. Date	Dipstick Tests										Confirmatory Tests				Additional Tests				
		Leukocytes	Nitrites	Urobilinogen	Protein	pH	Blood	Spec. Gravity	Ketones	Bilirubin	Glucose	Protein Method Lot No.	Acetest Lot No.	Clintest Lot No.	Ictotest Lot No.	hCG Kit Lot No.	Refractometer	Microalbumin	Creatinine	Initial

dipper, dropper & dropper plus *urine dipstick control • quality control log*

Quantimetrix Corporation

Level 1 Normal Lot No._____ Expiration Date_____ Level 2 Abnormal Lot No._____ Expiration Date_____

Date	Reagent Strip Lot No. Exp. Date	Dipstick Tests										Confirmatory Tests				Additional Tests				
		Leukocytes	Nitrites	Urobilinogen	Protein	pH	Blood	Spec. Gravity	Ketones	Bilirubin	Glucose	Protein Method Lot No.	Acetest Lot No.	Clintest Lot No.	Ictotest Lot No.	hCG Kit Lot No.	Refractometer	Microalbumin	Creatinine	Initial

M0442-1/05

SENTRY URINE DIPSTICK CONTROL

INTENDED USE

The Thermo Scientific SENTRY Urine Dipstick Control is intended to confirm the performance of MultiStix®, Chemstrip®, DiaScreen®, and other urinalysis reagent strips for quality control purposes. It is also intended to be used to verify the performance of various hCG test kits.

PRODUCT DESCRIPTION

The Thermo Scientific SENTRY Urine Dipstick Controls are supplied in two levels, 2 x 25 mL each level per box. They are ready to use liquid controls that DO NOT require any dilution or reconstitution. The two Sentry controls are prepared with human and animal proteins and with various chemical additives. These chemicals interact with the dipstick reactant pads to produce specific color changes that mimic actual normal and/or abnormal urine samples. Level 1 is an Abnormal control, and Level 2 is a Normal control with hCG and microalbumin. Preservatives have been added to inhibit microbial growth.

WARNINGS & PRECAUTIONS

FOR IN VITRO DIAGNOSTIC USE ONLY

POTENTIALLY BIOHAZARDOUS MATERIAL Contains human sourced materials. All human sourced materials used in the manufacture of this product have been tested and found non-reactive for Hepatitis B Surface Antigen, Hepatitis C, and HIV 1&2 antibody when tested by FDA accepted methods. Because no test method can provide complete assurance that HBsAg, HIV, or other infectious agents are absent, it is recommended that samples be handled according to the Centers for Disease Control's Bio-Safety Level 2 recommendations.

DISPOSE OF PROPERLY. Sodium Azide may form metal azides in plumbing and pose a threat of explosion. Flush with excess water upon disposal.

STORAGE & STABILITY

The Sentry Urine Dipstick Control Kit should be stored at 2-8°C when not in use. DO NOT FREEZE. When stored at 2-8°C the controls are stable until the expiration date printed on the label. When stored at Room Temperature the controls are stable for 12 months. Discard the controls if there is any evidence of turbidity, or microbial contamination.

PROCEDURE FOR DIPSTICK TESTING

1. Allow controls to come to room temperature. Mix gently by inversion to assure homogeneity of the contents. Avoid Foaming.
2. Remove cap and invert bottle. While holding dipstick, gently squeeze the sides of the bottle, and touch the tip of the bottle to the dipstick. Draw across all of the reagent pads, thoroughly saturating each pad. Turn dipstick on its side and drain excess control onto an absorbent material. Do not aspirate excess control back into the bottle.
3. Read the urine dipsticks, visually or with an instrumental reader in accordance with the dipstick manufacturers' instructions.
4. Wipe off dropper tips and recap controls. Store at 2-8°C when not in use to enjoy the full shelf-life of the product.

PROCEDURE FOR hCG TESTING

Note: The SENTRY Controls are supplied in dropper tip bottles for the convenience of easily dispensing the control onto the urine dipsticks. Most manufacturers of hCG kits require a specific sample size to be used with their kits in order to obtain proper results. It is important to ensure that the proper amount of sample is used in order to obtain the correct results.

1. Allow controls to come to room temperature.
2. Treat the controls as patient samples in accordance with the hCG kit manufacturer's instructions.
3. Immediately recap the controls and store at 2-8°C when not in use to enjoy the full shelf-life of the product.

EXPECTED VALUES

For visual readings, the controls are expected to give readings within the visual assay ranges provided with this kit. For instrument readings, the controls are expected to give readings within the instrument assay ranges provided with this kit.

The Level 1 Abnormal Control is intended to provide a negative test result for hCG and a positive test result for microalbumin. Some hCG lateral flow test kits may not exhibit background clearing with the Abnormal Control but should continue to yield a negative hCG test result.

The Level 2 Normal control is intended to give positive test results for hCG and microalbumin.

LIMITATIONS

Any future changes made by the manufacturer of a test method may give different values from the indicated range. Detailed information on the limitations of each test method is included in the limitations section of the manufacturer's package insert.

The Level 1 Abnormal control may exhibit significant background color when used on some hCG lateral flow test kits but should continue to yield a negative hCG test result.

MULTISTIX USERS

Colors produced by the bilirubin reaction on the MultiStix reagent strips with the Urine Dipstick Control may not be characteristic of those shown on the manufacturer's label when reading the dipsticks visually. The bilirubin reactions are consistent, intensify with the increase in the bilirubin concentration and give correct instrument readings but may not provide an exact color match to those shown on the label.

DIASCREEN USERS

Colors produced by the bilirubin reaction on the DiaScreen reagent strips with the Abnormal Urine Dipstick Control may not be characteristic of those shown on the manufacturer's label when reading the dipsticks visually. Detailed information on the limitation of each test method is included in the limitations section of the manufacturer's package insert.

To place an order or to receive technical assistance, please call Thermo Fisher Scientific at: (401) 438-0386 or (800) 556-7575.

NERL Diagnostics LLC
East Providence, RI 02914
800-556-7575

NRL753AI
Rev. 12/08

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Thermo
SCIENTIFIC

AUDIT.
MicroControls

Audit® Micro*DROP*™ Urine Dipstick Control

Cat. No. **K065M-4**
Contents 4 x 25mL (Multi-Level)

Lot No. Level 1 – 06168
Level 2 – 06169

Expires 03/21/2011

For In Vitro Diagnostic Use Only.

©Audit® MicroControls™, Inc., Las Vegas, NV 89102

INTENDED USE

Audit® Micro*DROP*™ Urine Dipstick Control is a bi-level reference control which may contain human source materials fortified to target levels with compounds that produce the desired reaction when tested by the methods indicated. It is intended to simulate human patient urine samples for the purpose of monitoring the precision of the Multistix®, Chemstrip®, and vChem™ urinalysis reagent strips, the iChem™ 100 and Clintek Status® urine chemistry analyzers, as well as for confirmatory tests such as Acetest® and Clinitest®.

SUMMARY AND PRINCIPLE

Good laboratory practices require that stable reference materials be used to verify the accuracy and precision of testing methods and techniques. Audit® Micro*DROP*™ Urine Dipstick Control may be used as one would use human urine to obtain the stated urine dipstick values.

WARNINGS AND PRECAUTIONS

Because this product may contain human urine, it should be handled as though capable of transmitting infectious diseases. Components used in the preparation of this material were tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV and nonreactive for HBSAg. Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples be handled at the Centers for Disease Control's Biosafety Level 2.

Audit® Micro*DROP*™ Urine Dipstick Control is intended solely for in vitro diagnostic use for the purpose described on the labeling. Audit® MicroControls™, Inc. shall not be liable for any unclaimed damages arising from any other usage.

STORAGE AND STABILITY

When used to monitor the precision of urinalysis reagent strips, Audit® Micro*DROP*™ Urine Dipstick Control is stored at 2-8°C and will remain stable in the dropper bottle at 2-8°C until the expiration date. After opening, the contents should be used according to the manufacturer's instructions and are stable at room temperature for 30 days. If you choose not to keep the product at room temperature then immediately return the dropper bottle to 2-8°C. Leaving the bottle uncapped, or prolonging its time at room temperature, will void this stability claim. Make sure the contents of the bottle are well mixed before use.

PROCEDURE

Follow the manufacturer's instructions provided for urinalysis reagent strips. Verify that the lot number on the bottle matches the assay sheet. To avoid evaporation, do not leave the bottle uncapped. Q.C. requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements. Controls should be run:

1. daily, in conjunction with patient samples.
2. as recommended by the manufacturer.
3. as required by the relevant regulatory agency.

Materials provided
- Audit® Micro*DROP*™ Urine Dipstick Control, Bi-Level, 4 x 25mL

EXPECTED VALUES

The expected ranges for visual readings for each level, based on interlaboratory data established by comparing the dipstick reaction that occurs with the controls to the color comparison chart with multiple lots of each manufacturers' dipsticks or reagent tablets, is provided below.

INSTRUCTIONS FOR USE

1. The Audit® Micro*DROP*™ Urine Dipstick Control should be stored at 2-8°C. Do not shake. Do not mix mechanically.

2. Remove the controls from the refrigerator and allow to come to room temperature (20-25°C) at least 15 minutes, depending on the remaining volume. Mix gently by inversion to assure complete mixing of the contents.

3. Remove cap and invert bottle. While holding the dipstick, gently squeeze the dropper bottle, and touch the lip of the bottle to the dipstick, thoroughly saturating each pad. Turn dipstick on its side to drain excess control material onto an absorbent material.

2. Read the urine dipstick in accordance with the manufacturer's instruction manual.

3. After sampling, wipe off dropper tip, replace cap and return to 2-8°C when not in use.

LIMITATIONS OF THE PROCEDURE

Some analytes may take longer to develop than the indicated times. Bilirubin and urobilinogen may not show characteristic colors on some strips. Make sure that the vial is brought to room temperature before testing. If the liquid in the vial becomes frozen, discard and use another vial, as the results will not be valid.

ORDERING INFORMATION

Multistix®, Acetest®, Clinitest® and Status® are registered trademarks of Siemens Healthcare Diagnostics. Chemstrip® is a registered trademark of Roche Diagnostics. iChem™ is a registered trademark of IRIS International, Inc.

Product Number	Product Description	Product Packaging
K065M-4	Audit® Micro*DROP*™ Urine Dipstick Control	4x25mL

Siemens Multistix® Urinalysis Reagent Strips

	Level 1 (Lot # 06168)	*Level 2 (Lot #06169)*
Glucose	Negative	100 – 2000 mg/dL
Bilirubin	Negative	Small (+) – Large (+++)
Ketones	Negative	5 (tr) - ≥180 (Large)
Specific Gravity	1.010 - ≥1.030	1.000 – 1.015
Blood	Negative	Small (+) – Large (+++)
PH	5 – 6.5	7.5 - ≥8.5
Protein	Negative	30 (+) - ≥300 (+++) mg/dL
Urobilinogen	0.2 mg/dL	1 – 8 mg/dL
Nitrite	Negative	Positive
Leukocytes	Negative	Trace – Large (+++)

Iris vChem™ 10 SG Urinalysis Reagent Strips

	Level 1 (Lot # 06168)	*Level 2 (Lot #06169)*
Urobilinogen	Negative	1 - ≥8 mg/dL
Glucose	Negative	50 - ≥1000 mg/dL
Ketones	Negative	Small (+) – Large (+++)
Bilirubin	Negative	Small (+) – Large (+++)
Protein	Negative	30 - ≥500 mg/dL
Nitrite	Negative	Positive
Leukocytes	Negative	25 – 500 Leuk/uL
Blood	Negative	Small (+) – Large (+++)
PH	5 – 6.5	7 - 9
Specific Gravity	1.010 – 1.035	1.000 – 1.015

Roche Chemstrip® Urinalysis Reagent Strips

	Level 1 (Lot # 06168)	*Level 2 (Lot # 06169)*
pH	5 – 6.5	7 - 9
Leukocytes	Negative	Trace – (++)
Nitrite	Negative	Positive
Protein	Negative	30 (+) - ≥500 (+++)
Glucose	Negative	50 - ≥1000 mg/dL
Ketones	Negative	Small (+) – Large (+++)
Urobilinogen	Negative	1 – 12 mg/dL
Bilirubin	Negative	Small (+) – Large (+++)
Blood	Negative	50 (+) - ≥250 (+++) Ery/uL
Specific Gravity	1.010 – 1.030	1.000 – 1.015

	Level 1 (Lot # 06168)	*Level 2 (Lot #06169)*
Acetest	Negative	Positive
Clinitest	Negative	¼ - 1%
Total Protein (sulfosalicylic acid)	Negative	Positive

Clinitek Status® Analyzer

	Level 1 (Lot # 06168)	*Level 2 (Lot #06169)*
pH	5.5 – 6.5	8 – 9
Leukocytes	Negative	Trace – Large (+++)
Nitrite	Negative	Positive
Protein	Negative	250 – 350 mg/dL
Glucose	Negative	250 – 500 mg/dL
Ketones	Negative	≥160 mg/mL
Blood	Negative	Small (+) – Large (+++)
Specific Gravity	1.020 - ≥1.030	1.010 – 1.020
Bilirubin	Negative	Small (+) – Large (+++)
Urobilinogen	0.2 mg/dL	1 – 8 mg/dL

Siemens Uristix®

	Level 1 (Lot # 06168)	*Level 2 (Lot #06169)*
Glucose	Negative	100 – 2000 mg/dL
Protein	Negative	30 - ≥300 mg/dL

	Level 1 (Lot # 06168)	*Level 2 (Lot # 06169)*
hCG	Negative	Positive

Multistix®,Acetest®, Clinitest® and Status® are registered trademarks of Siemens Healthcare Diagnostics. Chemstrip® is a registered trademark of Roche Diagnostics. iChem™ is a registered trademark of IRIS International, Inc.