VetScan UA14 Urine Test Strips

ENGLISH

PLEASE CAREFULLY READ THIS PACKAGE INSERT BEFORE USE.

For Veterinary Use Only. For Use with the VetScan UA Analyzer.

INTENDED USE

The VetScan UA14 urine reagent strips provide tests for the semi-quantitative measurement of leukocytes, ketones, nitrite, urobilinogen, bilirubin, glucose, protein, specific gravity, pH, blood, ascorbic acid, microalbumin, calcium and creatinine in veterinary urine samples. UA14 strips are to be read with the VetScan UA analyzer only. Manual reading of the strips is not recommended. Not for human diagnostic use.

SUMMARY

VetScan UA14 urine reagent strips consist of a plastic strip affixed with reagent paper pads and a calibration pad. This feature facilitates measurement of multiple urine chemistries in a single analysis. The calibration pad, which is not impregnated with reagents, allows automatic analyzer interference correction to the natural color of urine to obtain accurate results.

TEST PRINCIPLES AND LIMITATIONS

Leukocytes (LEU): This test reveals the presence of granulocyte esterases. These esterases cleave an indoxyl ester, and the indoxyl so liberated reacts with a diazonium salt to produce a violet dye.

Leukocyte esterase results may be positive in the absence of observable cells if the leukocytes have lysed. Positive results may occasionally be found with random specimens from females due to contamination of the specimen by vaginal discharge. Elevated glucose concentrations (1000 mg/dL or ≥ 55 mmol/L) or high specific gravity may cause decreased test results. The presence of cephalexin, cephalothin, or tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction. The test area does not react with intact lymphocytes. Reactivity may also vary with temperature.

Ketones (KET): The test is based on the principle of Legal's test and is more sensitive to acetoacetic acid than to acetone. The reagent area does not react with β-hydroxybutyric acid. Some high specific gravity/low pH urines may give reactions up to and including Trace. Normal urine specimens usually yield negative results with this reagent. False positive results (Trace) may occur with highly pigmented urine specimens.

Nitrite (NIT): The test is based on the principle of Griess's test and is specific to nitrite. Any degree of uniform pink color development should be interpreted as a positive. The presence of nitrite indicates the presence of 10^5 or more organisms per mL, but color development is not proportional to the number of bacteria present. A negative result does not in itself prove that there is no significant bacteriuria. Negative results may occur when urinary tract infections are caused by organisms which do not contain reductase to convert nitrate to nitrite; when urine has not been retained in the bladder long enough (4hrs - 8hrs) for reduction of nitrate to occur; or when dietary nitrate is absent, even if organisms containing reductase are present and bladder incubation is ample. Ascorbic acid concentrations of 25 mg/dL (1.4 mmol/L) or greater may cause false negative results with specimens containing nitrite ion concentrations of 43 µmol/L or less.

Urobilinogen (URO): This test is based on the Azo reaction. This test pad will detect urobilinogen in concentrations as low as 3 µmol/L (approximately 0.2 Azo unit/dL) in urine. The test pad may react with interfering substances known to react with Azo's reagent. Excreted pigments and medications that have an intrinsic red coloration in acidic medium may produce false positive results. This test is inhibited by elevated concentrations of formaldehyde. Strip reactivity increases with temperature; the optimum temperature is 72-79 °F (22-26 °C). The absence of urobilinogen cannot be determined with this test.

Bilirubin (BIL): This test is based on the coupling of bilirubin with diazonium salt in an acid medium. Normally no bilirubin is detectable in urine by even the most sensitive methods. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation. Some urine constituents (medications, urinary indicants) may produce a yellowish or reddish discoloration of the test paper that may interfere with interpreting the result. Ascorbic acid concentrations of 25 mg/dL (1.4 mmol/L) or greater may also cause false negatives.

Glucose (GLU): The test is based on the specific glucose oxidase/peroxidase reaction. The test is specific for glucose. No substance excreted in urine other than glucose is known to give a positive result. False positive reactions may be caused by hypochlorite or peroxide (bleach, cleaning agents). Ascorbic acid of more than 1.4 mmol/L and/or high ketone concentrations (80 mg/dL or 8 mmol/L) may cause false negatives for specimens containing small amounts of glucose (100 mg/dL or 5.5 mmol/L). The reactivity of the glucose test decreases as the specific gravity (SG) of the urine increases. Reactivity may also vary with temperature.

Protein (PRO): The test is based on the principle of the protein error of a pH indicator. The reagent area is more sensitive to albumin. An elevated pH (up to 9.0) may affect the test. The residues of disinfectants containing quaternary ammonium groups or chlorhexidine present in the urine vessel may lead to a false positive result.

Specific Gravity (SG): This test contains a detergent and bromothymol blue that indicates the presence of ionic constituents in the urine by changing color from green to yellow. The specific gravity test permits determination of urine specific gravity between 1.000 and 1.060. In general, it correlates within 0.005 with values obtained with the refractive index method. Strips are automatically adjusted for pH by the analyzer when pH ≥ 7.0 or pH ≤ 5.0. Highly buffered alkaline urine may cause low readings relative to other methods. Elevated specific gravity readings may be obtained in the presence of very high quantities of protein (500 mg/dL, 5 g/L).

pH: This test contains a mixed indicator which assures a marked change in colour between pH 5.0 and pH 9.0.

Blood (BLD): Hemoglobin and myoglobin catalyze the oxidation of the indicator by means of organic hydroperoxide contained in the test paper. This test is highly sensitive to hemoglobin and thus complements the microscopic examination for the presence of red blood cells (RBC). (Hemoglobin concentration of 150 - 620 µg/L ($9.31x10^6$ – $3.85 x10^5$ mmol/L) is approximately equivalent to 5-15 intact red blood cells per microliter.) The sensitivity of this test may be reduced in urine with high specific gravity. The test is equally sensitive to myoglobin as it is to hemoglobin. Captopril and Etodolac may also cause decreased reactivity. Blood is often found in the urine of intact females in the proestrus stage. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with a urinary tract infection may cause a false positive reaction. Ascorbic acid concentrations of 24.66 mg/dL (1.4 mmol/L) or greater may cause false negatives at the trace blood levels.

Ascorbic Acid (ASC): The test involves the decolorization of Tillman's reagent. False positive reactions can occur with other reducing agents.

Microalbumin (MA): The albumin reaction is more sensitive than the reactions for globulin, hemoglobin, Bence-Jones protein and mucin, so a negative result in this test does not rule out the existence of the above mentioned proteins in urine. When the result is > 2.5 mg/dL (> 25 mg/L), it indicates microalbuminuria. High creatinine or hemoglobin may increase microalbumin readings. If the strip is not properly blotted (excess urine left on pads) or the urine sample is a darker color or highly alkaline, false positives may result.

Calcium (CA): The test is based on the calcium ions in urine reacting with O-Cresolphthalein complexone (OCPC) to produce a color change. A large concentration of magnesium ions in urine will elevate the calcium result.

Creatinine (CR): The test is based on the creatinine in urine reacting with 3,5-Dinitrobenzoic acid to produce a color change. Some compounds, physical properties (e.g. high pH, high SG) and high-concentrations of yellow pigment may lead to higher CR readings.

Urine Protein Creatinine Ratio (PRO/CR): This reported result is a calculation made by dividing the PROTEIN result by the CREATININE result. Increased UPC ratios can indicate increasing levels of protein loss suggestive of early to more advanced renal disease. A higher PRO / CR ratio indicates more significant damage to the glomeruli itself.

REAGENTS COMPOSITION

Based on the dry weight content of each pad in 100 strips:

Leukocytes: indoxyl ester 1.4 mg; diazonium salt 0.7 mg.

Ketone: sodium nitroprusside 30.0 mg.

Nitrite: arsanilic acid 0.7 mg; N-(naphthyl)-ethylenediammonium dihydrochloride 0.5 mg.

Urobilinogen: fast blue B salt 1.2 mg.

Bilirubin: 2,4-dichlorobenzene diazonium 14.3 mg.

Glucose: glucose oxidase 800 I.U; peroxidase 200 I.U; 4-aminoantipyrine 0.1 mg.

Protein: tetrabromphenol blue 0.4 mg.

Specific Gravity: bromothymol blue 0.4 mg; sodium poly methyl vinyl acetate maleic 16.0 mg.

pH: bromocresol green 0.2 mg; bromxylenol blue 3.3 mg.

Blood: cumene hydroperoxide 35.2 mg; 3,3',5,5'-tetramethylbenzidine 2.0 mg.

Ascorbic acid: 2,6-dichloroindophenol sodium salt 0.5 mg.

Microalbumin: fluorescein dye 0.4 mg.

Calcium: O-Cresolphthalein complexone 2.5 mg.

Creatinine: Di-chloro palladium 0.2 mg; Mordant Blue29 0.4 mg

INSTRUCTIONS FOR USE

1. Additional materials required: VetScan UA urine analyzer, absorbent lint-free tissue, dropper pipette (optional), disposable gloves, UA printer (if printout desired, optional). Consult the VetScan UA User's Manual for more detailed information.
2. Acquire a urine sample by any of the three methods below:
   a. Cystocentesis
   b. Catheter
   c. Mid-stream urine sample
3. Place the VetScan UA analyzer on a stable, flat surface in a room at room temperature (59-77 °F, 15-25 °C).
4. Remove a strip from the tube and immediately recap the tube. Do not touch pads on the strip. Place the strip with pads facing up on a clean paper towel or tissue.
5. Start a test on the Vetscan UA by selecting Strip Type as UA14, select the Species and enter the Patient ID (PID). Then touch the Test button (Test Tube icon). A timer will appear onscreen and a beep will sound in several seconds. The application of urine and blotting in steps 6-10 must be performed within 30 seconds.
6. Thoroughly mix the fresh, room temperature (59-77 °F, 15-25 °C) urine sample immediately prior to testing by inverting the syringe or tube/ container multiple times.
7. Quickly apply the urine sample to the strip. The urine may be applied to the strip by either of two methods:
   a. Dip the UA14 strip into urine sample, completely immersing all the pads. The sample tube of urine should be deeper than 88 mm. Be sure that all pads are completely wetted. Remove the strip after 2 seconds.
   b. A transfer pipette or syringe may alternatively be used to drop well-mixed urine onto each pad, covering each pad completely – do not leave urine on strip for more than 2 seconds (proceed to step 5 immediately). The latter method is preferable if cultures need to be performed. If the sample has been refrigerated, test the urine only after it has warmed to room temperature. (59-77 °F, 15-25 °C)
8. If using a dip method, remove the strip from the tube, dragging the edge of the strip against the rim of the urine container to remove excess urine.
9. Blot the strip on the long edge to clean, absorbent paper to remove excess urine to prevent cross-contamination from adjacent reagent pads. Avoid contacting the surface of the pads directly with the absorbent paper to prevent contamination from the paper.
10. Place strip on UA strip tray with the end of the strip at the edge of the analyzer opening. The tray will slide into analyzer automatically approximately 30 seconds after the Test button was pressed. Results will appear onscreen in another 30 seconds, for a total test time of approximately one minute.

PRECAUTIONS AND WARNINGS

1. The test is intended for veterinary use only.
2. The strip is NOT intended to be read visually, but only with a VetScan UA analyzer.
3. Collect a fresh urine specimen in a clean, dry container or syringe. Do not expose urine specimens to sunlight as this induces oxidation of bilirubin and urobilinogen and hence leads to artificially lower results for these two parameters.
4. If the sample will not be tested immediately, it may be stored at 59-77 °F, (15-25 °C) for up to one hour before testing. If it will not be tested within 1 hour of collection, the sample may be refrigerated up to 4 hours. When testing refrigerated samples, be sure to warm the sample to room temperature (at least 15 minutes on counter or warm in palms of your hand) (59-77 °F, 15-25 °C) prior to testing. **Do not test cold urine. Be sure not to freeze the sample.**
5. Only use strips that are at room temperature (59-77 °F, 15-25 °C). If they have been refrigerated, allow them to warm to room temperature before use. Only perform tests at room temperature of 59-77 °F, 15-25 °C.
6. Use gloves when handling the strips to avoid touching the reaction pads on the reagent strips to prevent contamination.
7. Do not remove the desiccant pouch from the tube of strips. Replace cap immediately and tightly after removing a reagent strip. Exposure of unused strips to humid air (more than 5 minutes) can easily lead to inaccurate test results.
8. Do not use reagent strips after the expiration date, and do not use deteriorated, discolored or blackened test strips.
9. False-positive readings for blood and glucose can result from residues of strongly oxidizing disinfectants in the specimen collection vessel. Do not add preservatives to the urine. Avoid contamination by volatile chemicals.
10. The used test strip cannot be reused, but should be disposed of as biohazardous waste.
11. When cleaning the strip tray, use alcohol wipes or a tissue moistened with a mild soap and water. Dry tray thoroughly before replacing it into the UA analyzer.

LINEAR RANGE Conventional Units (SI Units)

Analyte	Range	Analyte	Range
Leukocytes	15-500 Cell/µL (15-500 Cell/uL)	Specific Gravity	1.000-1.060 (same)
Ketone	0.5-8.0 mmol/L (2.9-46.5 mg/dL)	pH	5.0-9.0 (same)
Nitrite	+	Blood	10-200 Cell/µL (10-200 Cell/uL)
Urobilinogen	2.0-8.0 mg/dL (33-131 µmol/L)	Ascorbic Acid	10-100 mg/dL (0.6-5.6 mmol/L)
Bilirubin	0.5-6.0 mg/dL (8.6-100 µmol/L)	Microalbumin	< 2.5 mg/dL ~ ≧ 2.5mg/dL (< 25 mg/L ~ ≧ 25mg/L)
Glucose	50-1000 mg/dL (2.8-55 mmol/L)	Calcium	4.0-40 mg/dL (1.0-10 mmol/L)
Protein	15-300 mg/dL (0.15-3.0 g/L)	Creatinine	10-300 mg/dL (0.9-26.4 mmol/L)

PLEASE NOTE

In principle, diagnosis or therapy should not be based on one test result alone but should be established in the context of all other medical findings. Knowledge of the effects of drugs or their metabolites upon the individual tests is not yet complete. In doubtful cases, it is therefore advisable to repeat the test after discontinuing a particular drug. Large amounts of ascorbic acid in the urine can produce artificially low to false-negative results for glucose, blood, nitrite and bilirubin.

STORAGE AND STABILITY

Strips in the tube may be stored from 36-86 °F (2-30 °C). Abaxis recommends to store at room temperature 59-77 °F (15-25 °C) as strips should be gently warmed or cooled to room temperature, as appropriate, prior to opening the tube to retrieve a test strip. Store only in original tube with desiccant pack, avoiding humidity, direct sunlight and heat. **NOTE: Be sure to tightly recap the tube immediately after removing strips for use.**

EXPIRATION

Unopened tubes of strips are usable until the expiration date. NOTE: Unused strips that remain in the original capped container with the desiccant are stable for 3 months after first opening of the tube. After the tube has been opened, the strips must be used within 90 days (3 months).

PART NO.

1500-0014-50 VetScan UA14 Urine Strips, 50 strips/vial.
1500-0014-25 VetScan UA14 Urine Strips, 25 strips/vial

EXPLANATIONS FOR SYMBOLS ON THE LABEL

Temperature limit · Do not re-use · Number of items included
Consult instructions for use · LOT Lot number · REF Part number
Manufacturer · Date of Manufacture · Keep away from Sunlight
Keep Dry · Good for 3 months after first opened · Use-by-date
FOR VETERINARY USE ONLY For veterinary use only

California Prop. 65 WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm. Bisphenol A CAS-No. 80-05-7. Revision Date 2017-09-27

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