UC VET Series Urine Reagent Strips

PLEASE CAREFULLY READ THIS PACKAGE INSERT BEFORE USE. For In Vitro Diagnostic Use Only. For use with the UC-32A/B Vet Instrument.

INTENDED USE

URIT UC VET series urine reagent strips provide tests for the semi-quantitative measurement of leukocytes, ketone, nitrite, urobilinogen, bilirubin, glucose, protein, specific gravity, pH, blood, ascorbic acid, microalbumin, calcium and creatinine in veterinary urine sample, not for human diagnostic use.

Product type and parameter

Type	Parameter			
UC VET10	WBC, KET, NIT, BIL, URO, BLD, GLU, pH, PRO, SG			
UC VET11	WBC, KET, NIT, BIL, URO, BLD, GLU, pH, PRO, SG, VC			
UC VET12	WBC, KET, NIT, CR, MA, BLD, GLU, pH, PRO, SG, BIL, URO			
UC VET13 Plus	WBC, KET, CR, MA, BLD, GLU, pH, PRO, SG, BIL, URO, VC, Ca			
If the strip contains PRO and CR, the test results show a ratio of protein to creatinine(PCR).				

SUMMARY

URIT UC VET series urine reagent strips consist of a plastic strip affixed with reagent papers and a calibration pad. This feature facilitates measurement of multiple urine constituents and use for everyday diagnosis and group examinations. The calibration pad, which is not impregnated with reagents, allows instrumental correction interference from natural color of urine automatically and obtains accurate result.

TEST PRINCIPLES AND LIMITATIONS

Leukocytes: The 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 (≥55mmol/L) or high specific gravity may cause decreased test results. The presence of cephalexin, cephalothin, tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction. The test area does not react with lymphocyte. Reactivity may also vary with temperature.

Ketone: This 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 urine 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 or those containing large amounts or levodopa metabolites.

Nitrite: The test is based on the principle of Griess's test and is specific to nitrite. Any degree of uniform pink colour development should be interpreted as a positive.

Nitrite test suggests the presence of 10⁵ or more organisms per mL, but colour 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 1.4mmol/L or greater may cause false negative results with specimens containing nitrite ion concentrations of 43µmol/L or less.

Urobilinogen: This test is based on the Ehrlich reaction.

This test area will detect urobilinogen in concentrations as low as 3µmol/L(approximately 0.2 Ehrlich unit/dL) in urine. The reagent area may react with interfering substances known to react with Ehrlich's reagent. Excreted pigments and medicaments that have a red intrinsic 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 23°C- 27°C. The absence of urobilinogen cannot be determined with this test.

Bilirubin: 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 (medicines, urinary indicants) may produce a yellowish or reddish discoloration of the test paper that may interfere with interpreting the result. Ascorbic acid concentrations of 1.4mmol/L or greater may cause false negatives.

Glucose: 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. Ascorbic acid of more than 1.4mmol/L and/or high ketone concentrations (8mmol/L) may cause false negatives for specimens containing small amounts of glucose (5.5mmol/L). The reactivity of the glucose test decreases as the SG of the urine increases. False positive reactions may be caused by hypochlorite or peroxide (cleaning agents). Reactivity may also vary with temperature.

Protein: 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) may affect the test. The residues of disinfectants containing quaternary ammonium groups or chlorhexidine are present in the urine vessel

Specific Gravity: This test contains a detergent and bromothymol blue that indicates the presence of ionic constituents in the urine by changing color from green to vellow.

The specific gravity test permits determination of urine specific gravity between 1.000 and 1.060. In general, it correlates within 0.010 with values obtained with the refractive index method. Strips are automatically adjusted for pH by the instrument when $pH \ge 7.0$. Highly buffered alkaline urine may cause low readings relative to other methods. Elevated specific gravity readings may be obtained in the presence of moderate quantities (5g/L) of protein.

pH: This test contains a mixed indicator which assures a marked change in colour between pH5.0 and pH9.0.

Blood: 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. The sensitivity of this test may be reduced in urine with high specific gravity. The test is equally sensitive to myoglobin as to hemoglobin (Hemoglobin concentration of $150 \mu g/L - 620 \mu g/L$ is approximately equivalent to 5-15 intact red blood cells per microlitre). Captopril and Lodine may also cause decreased reactivity. Blood is often found in the urine of menstruating females. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction. Ascorbic acid concentrations of 1.4mmol/L or greater may cause false negatives at the trace levels.

Ascorbic Acid: The test involves the decolorization of Tillman's reagent. False positive reaction with other reducing agent.

Microalbumin: The albumin's reaction is more sensitive than the reaction of globulin, hemoglobin. Bence-Jones protein and mucin, thus the negative result does not rule out the existence of above mentioned proteins in urine. When the results is 20mg/L - 200mg/L, it is indicated as microalbuminuria, and when the results is beyond 200mg/L, it is indicated as clinical albuminuria. This action is few effected by creatinine and hemoglobin etc. High cushion of urine and alkaline urine may cause false positive result.

Calcium: The test is based on the calcium ion in urine react with OCPC to produce a color change.

A great number of magnesium ion in urine may affect the test.

Creatinine: The test is based on the principle of displacement reaction. Creatinine displace the dyes from the compound of metallic chloride and acid dyes. The color will change from green to yellow. Some compounds, physical properties (e.g. high pH, high SG) and high-concentrations of yellow pigment may lead to higher CR readings.

Protein to Creatinine Ratio (PCR): This reported result is a calculation made by dividing the PRO (mg/dl) result by the CR (mg/dl) result. Normally, the ratio is lower than 0.2(mg/mg), when the ratio is between 0.2 to 0.5(mg/mg,cat:0.2~0.4), it is suspected abnormal, when the ratio is between 0.5(cat:0.4) to 2.0 (mg/mg), it is abnormal, and when it is beyond 2.0(mg/mg), it is highly abnormal. The PCR parameters can only be given while using the strips that contain PRO and CR.

REAGENTS COMPOSITION

Based on the dry weight content of each area of 100 strips (W/W):

Leukocytes: indoxyl ester 0.94%, diazonium salt 0.47%mg, buffer 98.59%.

Ketone: sodium nitroprusside 15.9%, buffer 84.1%.

Nitrite: Sulfonamide1.06%, N-(naphthyl)-ethylenediammonium dihydrochloride 0.88%, buffer 98.1%.

Urobilinogen: fast blue B salt 0.12%, buffer 99.88%.

Bilirubin: 2.4-dichlorobenzene diazonium 4.04%, buffer 95.96%.

Glucose: glucose oxidase 1.2%, peroxidase 0.55%, 4-aminoantipyrine 0.15%, buffer 98.1%.

Protein: tetrabromphenol blue 0.6%, buffer 99.4%.

Specific Gravity: bromthymol blue 2.4%, poly(methyl vinyl ester-co-maleic acid)-

sodium 2.1%, buffer 95.5%.

pH: bromocresol green 0.3%, bromxylenol blue 0.2%, buffer 99.5%.

Blood: cumene hydroperoxide 3.5%, 3,3',5,5'-tetramethylbenzidine 2.0%, buffer 94.5%.

Ascorbic acid: 2,6-dichloroindophenol sodium salt 0.5%, buffer 99.5%.

Microalbumin: fluorescein dye 0.36%, buffer 99.64%.

Calcium: O-Cresolphthalein complexone 2.5%, buffer 97.5%.

Creatinine: metallic chloride 0.15%, acid dyes 0.4%, buffer 99.45%.

STORAGE AND STABILITY

If necessary, strips may be stored from 10-30°C (50-86°F). For longer term storage, strips may also be stored between 2-8°C (36-46°F). Store only in original bottle with desiccant pack, avoiding humidity, direct sunlight and heat. Unused strips that remain in the original capped container are stable within 3 months after it is opened

NOTE: Be sure to tightly recap the vial immediately after removing strips.

EXPIRY

Valid for 24 months.

AVAILABILITY 50/100 strips per container.

MEASURING INTERVAL SI units (Conventional Units)

Parameter	Range SI Units (Conventional)	Parameter	Range SI Units (Conventional)		
Leukocytes	15-500 CELL/ μ L (same)	Specific Gravity	1.000-1.060 (same)		
Ketone	0.5-8.0 mmol/L (5-80 mg/dL)	pН	5.0-9.0 (same)		
Nitrite	+	Blood	10-200 CELL/ μ L (0.03-0.6 mg/dL)		
Urobilinogen	33-131 μmol/L (2.0-8.0 mg/dL)	Ascorbic Acid	0.6-5.6 mmol/L (10-100 mg/dL)		
Bilirubin	8.6-100 μmol/L(0.5-6.0 mg/dL)	Microalbumin	10mg/L~150mg/L(1~15 mg/dL)		
Glucose	2.8-55 mmol/L (50-1000 mg/dL)	Calcium	1.0-10 mmol/L (4.0-40 mg/dL)		
Protein	0.15-3.0 g/L (15-300 mg/dL)	Creatinine	0.9-26.4 mmol/L (10-300 mg/dL)		
PCR	22.6~226mg/mmol(0.2~2.0 mg/mg)				

BIOLOGICAL REFERENCE INTERVALS

Parameter	Dog	Cat	Rabbit	Horse	Cattle	Sheep/Goat
Leukocytes	0 CELL/μL	0 CELL/μL	0 CELL/μL	0 CELL/μL	0 CELL/μL	0 CELL/μL
Ketones	0 mmol/L	0 mmol/L	0 mmol/L	0 mmol/L	0 mmol/L	0 mmol/L
Nitrite	0μmol/L	0μmol/L	0μmol/L	0μmol/L	0μmol/L	0μmol/L
Urobilinogen	(3.2-16) μmol/L	(3.2-16) μmol/L	(3.2-16) µmol/L	(3.2-16) µmol/L	(3.2-16) µmol/L	(3.2-16) μmol/L
Bilirubin	0μmol/L	0μmol/L	0μmol/L	0μmol/L	0μmol/L	0μmol/L
Glucose	<2.8mmol/L	<2.8mmol/L	<2.8mmol/L	<2.8mmol/L	<2.8mmol/L	<2.8mmol/L
Protein	<0.15g/L	<0.15g/L	<0.15g/L	<0.15g/L	<0.15g/L	<0.15g/L
Specific Gravity	1.015-1.045	1.015-1.060	1.010-1.040	1.020-1.050	1.020-1.040	1.020-1.045
pН	5.0-7.0	5.5-7.5	8.0-8.5	7.5-9.0	7.0-8.5	7.5-8.5
Blood	0 CELL/μL	0 CELL/μL	0 CELL/μL	0 CELL/μL	0 CELL/μL	0 CELL/μL
Ascorbic Acid	0mmol/L	0mmol/L	0mmol/L	0mmol/L	0mmol/L	0mmol/L
Microalbumin	<25mg/L	<25mg/L	<25mg/L	<25mg/L	<25mg/L	<25mg/L
Calcium	(1.0-10) mmol/L	(1.0-10) mmol/L	(1.0-10) mmol/L	(1.0-10) mmol/L	(1.0-10) mmol/L	(1.0-10) mmol/L
Creatinine	(0.9-26.4) mmol/L	(0.9-26.4) mmol/L				
Protein to Creatinine Ratio(PCR)	<0.2 mg/mg	<0.2 mg/mg	<0.2 mg/mg	<0.2 mg/mg	<0.2 mg/mg	<0.2 mg/mg

TESTING PROCEDURE

1.Additional materials required: UC-32A/B Vet urine analyzer. Detailed operating instructions can be found in the instruction manual of the instrument

- 2. Completely immerse the pads into fresh, well mixed urine, and the sample tube of urine should be higher than 88mm. make sure that all pads are wetted. Remove the strip after 2 seconds. The drip method also permitted.
- 3. While removing the strip, dragging the edge of the strip against the rim of the urine container to remove excess urine. Blot the strip on length-wise edge, on absorbent paper. Avoid running over contamination from adjacent reagent pads.
- 4. When interpreting the result by urine analyzer, please follow the respective operating manual.

PRECAUTIONS

- 1. The test is intended to use by veterinary professionals only.
- 2. Collect a fresh urine specimen in a clean, dry container. 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. If the sample will not be tested immediately, it may be stored at room temperature (68-86°F, 20-30°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) (68-86 °F, 20-30 °C) prior to testing. Do not test cold urine. Be sure not to freeze the sample.
- 3. No touching with hand, the reaction block of reagent strips should keep clean to avoid contamination.
- 4.Do not remove desiccants. Replace cap immediately and tightly after removing reagent strip, a long time (more than 5 minutes) exposing to moist air can easily lead to inaccurate test results.
- 5.Do not use reagent strips after expiry date, and do not use deteriorated, discolored or blackened test strips.
- 6. Strips should be returned to room temperature before use.
- 7. 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.
- 8. The used test strip can not be reused, but should be disposed as general medical waste.

PLEASE NOTE

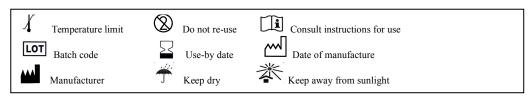
On principle, diagnosis or therapy should not be based on one test result alone but should be established in the contest of all other medical findings. Knowledge of the effects of drugs or their metabolites upon the individual tests is not yet complete. In doubtful cases, it is therefore advisable to 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.

BIBLIOGRAPHY

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EXPLANATIONS FOR SYMBOLS ON THE LABEL



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