



VET-UAC Test Strips

Reagent Strips for Semi-Quantitative Determination of Micro-albumin and Creatinine in Urine

INTENDED USE

Teco Diagnostics' VET-UAC test strips are used for semi-quantitative determination of micro-albumin and creatinine in urine. Affixed to each firm plastic strip are two reagent areas that test for micro-albumin and creatinine in urine. Measurement of the two tests at the same time from a random single-void urine sample allows for determination of the micro-albumin to creatinine ratio (ACR).

For *in vitro* Use Only

SUMMARY AND EXPLANATION OF THE TEST

Micro-albuminuria, an abnormal elevation of the urinary albumin excretion rate, is often one of the first signs of renal disease or damage that can lead to renal failure. Patients with hypertension or diabetes have the highest risk of renal disease where micro-albumin may be present¹.

Creatinine is a byproduct of muscle metabolism and creatinine excretion into the urine is usually constant². Creatinine measurement is used in the diagnosis and treatment of renal diseases, to monitor renal dialysis, and as a calculation basis for measuring other urine analytes. Though the concentration (or dilution) of urine varies throughout the day, the urinary creatinine level is relatively stable which allows its measurement to be used as a corrective factor in random/spot urine samples. When micro-albumin and creatinine are measured simultaneously from a single-void / random urine sample, the micro-albumin to creatinine ratio (ACR) can be determined. The ACR is the preferred test for screening of Micro-albuminuria recommended by the Veterinary Medicine Association³.

The VET-UAC Test Strips are packaged with a drying agent in a bottle with a twist off cap. The tests are ready to use and results are obtained by direct comparison of the test areas to color blocks printed on the bottle label. Each strip should only be used once and the entire reagent strip is disposable.

TEST PRINCIPLE

Micro-Albumin: At a constant pH, albumin binds with sulfonephthalein dye to develop of any blue color. The resulting color ranges from pale green to aqua blue.

Creatinine: In this assay, creatinine reacts with a creatinine indicator to form a green color complex. The concentration of creatinine is directly proportional to the color intensity of the test pad.

REAGENTS (Based on dried weight at time of impregnation)

Micro-albumin: 1.9% w/w sulfonephthalein color; 94.2% w/w buffer; 3.9% w/w non-reactive ingredients.

Creatinine: 2.5% w/w copper sulfate; 4.5% w/w benzidine; 56.4% buffer; 36.6% w/w non-reactive ingredients.

WARNINGS AND PRECAUTIONS

The VET-UAC Test Strips are for *in vitro* use. They have been determined to be non-hazardous under the guidelines issued by OSHA in 29 CFR 1910.1200(d).

STORAGE AND HANDLING

Store at 15°C-30°C (59°F-86°F) and out of direct sunlight. Do not use after expiration date. Do not touch test areas. Replace cap immediately and tightly. All unused strips must remain in the original bottle. Transfer to any other container may cause reagent strips to deteriorate and become nonreactive. Do not remove desiccant from bottle. Do not open container until ready to use. Opened bottles should be used within 3 months after first opening.

Protection against moisture, light and heat is essential to guard against altered reagent reactivity. Discoloration or darkening of reagent areas may indicate deterioration. If this is evident, the reagent strips should be discarded.

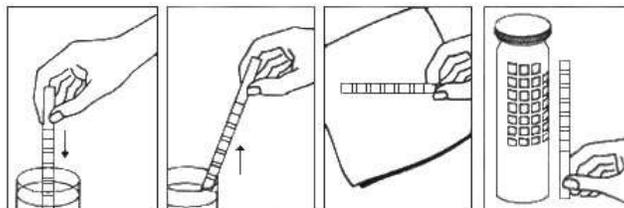
Please consult local authorities for proper disposal of used product.

SPECIMEN COLLECTION AND PREPARATION

Collect urine in a clean container and test as soon as possible. Do not centrifuge. The use of urine preservatives is not recommended. If testing cannot be performed within one hour after voiding, refrigerate the specimen immediately. Allow refrigerated specimen to return to room temperature before testing.

TEST PROCEDURE

1. Remove from the bottle only enough strips for immediate use and replace cap tightly.
2. Completely immerse reagent areas of the strip in fresh, well-mixed urine. Remove the strip immediately to avoid dissolving out the reagent areas.
3. While removing, touch the side of the strip against the rim of the urine container to remove excess urine. Blot the lengthwise edge of the strip on an absorbent paper towel to further remove excess urine and avoid running over (contamination from adjacent reagent pads.)
4. Obtain results by direct color chart comparison or a device specifically designed for VET-UAC strips.
5. For visual test, compare each reagent area to its corresponding color blocks on the color chart and read at the times specified. Proper read time is critical for optimal results.



QUALITY CONTROL

For best results, confirm performance of reagent strips whenever a new bottle is first opened by testing known negative and positive controls that include values for micro-albumin and creatinine. Each laboratory should establish its own goals for adequate standards of performance, and should question handling and testing procedures if these standards are not met.

LIMITATIONS OF PROCEDURE

1. The strips are to be read visually or analyzed by a device specifically designed for VET-UAC strips.
2. Comparison to the color chart is dependent on the interpretation of the individual. It is therefore, recommended that all laboratory personnel interpreting the results of these strips be tested for color blindness.
3. The presence of hemoglobin (≥ 5 mg/dL or visibly bloody urine), bilirubin (≥ 15 mg/dl or visibly dark brown color urine) may cause erroneous results with the micro-albumin and creatinine tests. Vitamin C over 100mg/dl does not affect the results of micro-albumin and creatinine.
4. Substances that cause abnormal urine color, such as drug containing azo dyes (e.g., Pyridium, AZO Gantrisin, AZO Gantanol), nitrofurantoin (Macrochantin, Furochantin) and riboflavin may affect the readability of the reagent areas on urinalysis reagent strips.
5. Urinary micro-albumin excretions can be elevated by exercise, urinary tract infections, and acute illness with fever. It is recommended that individuals avoid strenuous exercise prior to testing.

RESULTS

Results are obtained by direct comparison of the color blocks printed on the bottle label. The color blocks represent nominal values; actual values will vary around the nominal values.



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TABLE OF RESULTS

The following table shows the results that can be obtained visually in both conventional and SI units:

Test	Abbr.	Conventional Units		S.I. Units
Micro-albumin	ALB	10mg/L		10mg/L
		30mg/L		30mg/L
		80mg/L		80mg/L
		150mg/L		150mg/L
Creatinine	CRE	10mg/dL	0.1g/L	0.9mmol/L
		50 mg/dL	0.5g/L	4.4mmol/L
		100mg/dL	1g/L	8.8mmol/L
		200mg/dL	2g/L	17.7mmol/L
		300mg/dL	3g/L	26.5mmol/L
		600mg/dL	6g/L	53.1mmol/L

CALCULATIONS

Determine Albumin/Creatinine Ratio (ACR) as follows:

ACR = ALB Reading (mg/L) / CRE Reading (g/L)

Example: ALB read at 10 mg/L and CRE read at 1g/L

The ratio of ALB / CRE is 10/1, Result < 30 mg/g (Normal)

The following table provides a quick reference for the range of ACR based on the ALB and CRE readings

CRE (g/L)	ALB (mg/L)			
	10	30	80	150
0.1	Can Not be Determined	30-300mg/g Abnormal	>300mg/g High Abnormal	>300mg/g High Abnormal
0.5	< 30mg/g Normal	30-300mg/g Abnormal	30-300mg/g Abnormal	30-300mg/g Abnormal
1	< 30mg/g Normal	30-300mg/g Abnormal	30-300mg/g Abnormal	30-300mg/g Abnormal
2	< 30mg/g Normal	< 30mg/g Normal	30-300mg/g Abnormal	30-300mg/g Abnormal
3	< 30mg/g Normal	< 30mg/g Normal	< 30mg/g Normal	30-300mg/g Abnormal
6	< 30mg/g Normal	< 30mg/g Normal	< 30mg/g Normal	< 30mg/g Normal

EXPECTED VALUES

Micro-Albumin: Normal micro-albumin levels in random urine are under 20 mg/L. Micro-albuminuria is indicated by results of 20-200 mg/L. Values above 200mg/L indicate clinical albuminuria.

Creatinine: Creatinine is normally present in random urine in concentrations of 50 to 300 mg/dL (4.4 to 26.5 mmol/L).

Albumin/Creatinine Ratio: Albumin is normally present in urine at concentrations of less than 30 mg micro-albumin / g creatinine (<3.4 mg/mmol). Micro-albuminuria is indicated at a ratio result of 30-300 mg/g (3.4-33.9 mg/mmol) (Abnormal) and clinical albuminuria at a ratio result of >300 mg/g (>33.9 mg/mmol) (High Abnormal).

SPECIFIC PERFORMANCE CHARACTERISTICS

The performance characteristics of Teco Diagnostics VET-UAC Strips have been determined both in the laboratory and in clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy, and precision. Generally, Teco Diagnostics VET-UAC Strips have been developed to be specific for the constituent to be measured with the exception of interferences listed above. (See LIMITATIONS OF PROCEDURE)

Accuracy:

Teco Diagnostics VET-UAC Strips were compared with Siemens' Clinitek Micro-albumin.

Percent agreement of exact match in Micro-albumin: 95%

Percent agreement of ± 1 color block in Micro-albumin: 99%

Percent agreement of exact match in Creatinine: 80%

Percent agreement of ± 1 color block in Creatinine: 98%

Precision:

Urine specimens of different levels of concentration of micro-albumin and creatinine were assayed. Each level was assayed 25 times. The following percentages were obtained.

Percent agreement of replicate reading in Micro-albumin: 96%

Percent agreement of replicate reading in Creatinine: 92%

Sensitivity:

Teco Diagnostics VET-UAC Strip detects urinary micro-albumin in concentration as low as 10 mg/L.

Teco Diagnostics VET-UAC Strip detects urinary creatinine in concentration as low as 10 mg/dL.

BIBLIOGRAPHY

1. Levey AS, Coresh J, Balk E, et al. National Kidney Foundation practice guidelines for chronic kidney disease: evaluation, classification, stratification. *Ann Intern Med.* 139:137-147, 2003.
2. Mary Anna Thrall, Glade Weiser, Robin Allison. Et al. *Veterinary Hematology and Clinical Chemistry*, John Wiley & Sons, Jul 2, 2012.
3. Whittemore JC, Miyoshi Z, Jensen WA, et al. Association of microalbuminuria and the urine albumin-to-creatinine ratio with systemic disease in cats. *J Am Vet Med Assoc.* 230(8):1165-9, 2007.

LEGEND

SYMBOL



DEFINITION

Consult Instructions for Use

Caution, Consult Accompanying Documents

Manufacturer

Batch of Lot Number

Use by Expiration Date

Storage Temperature

VET-UAC: 12/2015



Teco Diagnostics
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