EXPECTED VALUES

Albumin: Normal albumin levels in random urine are under 20 mg/L. Microalbuminuria is indicated by results of 20-200 mg/L. Values above 200mg/L indicate clinical Albuminuria. The detection of Albuminuria at levels at or above 30mg/L will help veterinarians to better diagnose diabetes in its early stages.[6]

Creatinine: Creatinine is normally present in random urine in concentrations of 10 to 300 mg/dL (0.9 to 26.5 mmol/L).

Albumin/Creatinine Ratio: Albumin is normally present in urine at concentrations of less than 30 mg Albumin / g Creatinine (<3.4 mg/mmol). Microalbuminuria 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).[6]

SPECIFIC PERFORMANCE CHARACTERISTICS

The performance characteristics of Kacey Diagnostics Micro-albumin VETI STX-2 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, Kacey Diagnostics Micro-albumin VETI STX-2 Strips have been developed to be specific for the constituent to be measured with the exception of interferences listed above. (See LIMITATIONS OF PROCEDURE)

For visually read strips, accuracy is a function of the manner in which the color blocks on the bottle label are determined and the discrimination of the human eye in reading the test. Precision is difficult to assess in a test of this type because of the variability of the human eye. It is for this reason that users are encouraged to develop their own standards of performance.

Accuracy:

A total of 86 random urine specimens were collected from outpatients. These samples were assayed for albumin and Creatinine using Bayer Clinitek Micro-albumin and Kacey Diagnostics Micro-albumin Veti Stx-2 Strips. In order to cover assay range, some of urine specimens were spiked with known concentrations of albumin and Creatinine. Sensitivity is defined as the percentage of positive results obtained by Micro-albumin Veti Stx-2 Strip to those obtained by the comparative methods, while specificity refers to the percentage of negative results.

Kacey Diagnostics Micro-albumin Veti Stx-2 detects urinary albumin in concentration as low as 10 mg/L.
Percent agreement with Bayer Clinitek Microalbumin in micro-albumin test: 91.9%.
Positive Agreement: 96.5%
Negative Agreement: 98.3%

Kacey Diagnostics Micro-albumin Veti Stx-2 Strip detects urinary Creatinine in concentration as low as 100 mg/L.
Percent agreement with Bayer Clinitek Micro-albumin in Creatinine tests: 86%

Precision:

Urine specimens of different levels of concentration of albumin and Creatinine were assayed. Each level was assayed 25 times. The following percentages were obtained.
Percent agreement of replicate reading in Micro Albumin: 96.8%
Percent agreement of replicate reading in Creatinine: 92%

VETERINARY USE ONLY.

TO ORDER CALL: 828.685.3569 Fax 828.685.7126

Veti Stx-2™
Part# 40401 (10 strips per bottle)
Part# 40402 (25 strips per bottle)
Part# 40403 (50 strips per bottle)

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.
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KACEY® DIAGNOSTICS

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Veti Stx-2 (Micro-Albumin/Creatinine Urine Test)

INTENDED USE - *For Veterinary Use Only*

Kacey Diagnostics' Micro-albumin Veti Stx-2 Strips are used for semi-quantitative determination of albumin and Creatinine in urine. Affixed to each firm plastic strip are two reagent areas that test for 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 Albumin to Creatinine Ratio (A:C Ratio).
For *in vitro* Diagnostic Use Only
For Professional Use Only

SUMMARY AND EXPLANATION OF THE TEST

Microalbuminuria, 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. Microalbuminuria refers to small detectible amounts of albumin in the urine.

Creatinine is a byproduct of muscle metabolism and Creatinine excretion into the urine is usually constant. Creatinine measurement is used in the diagnosis and treatment of renal diseases, 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 albumin and Creatinine are measured simultaneously from a single-void / random urine sample, the albumin to Creatinine ratio (A:C Ratio) can be determined.
The A:C Ratio is the preferred test for screening of Microalbuminuria recommended for the determination also of the possibility of diabetes in animals

The Micro albumin Veti Stx-2 Strips are packaged with a special drying agent sprayed in bottle. 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

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 in an alkaline condition to form a purplish-brown 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 Micro-albumin Veti Stx-2-Strips are for *in vitro* diagnostic 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

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

COLLECTION FOR ANALYSIS

MIDSTREAM:

This collection method is often for the animal but can be quite difficult for the collector. Collection is accomplished by a direct method from the animal. It is recommended using the Kacey Collection Cup & Kacey Collection cup holder to minimize the possible exposure to animal body fluids that may be contaminated
(ex. Leptospirsis).

MANUAL EXPRESSION

This collection method is often performed on small animals(dogs & cats). It is sometimes difficult and can result in some sort of trauma in the form of red blood cells
(RBC's) in the urine. This method might result in the contamination from the lower urinary tract.

CATHERIZATION:

This method of collection can be used on male dogs for the assessment of urethral potency and upper urinary tract infection. This method often times results in iatrogenic presence of red blood cells (RBC) in the urine.

CYSTOCENTISIS

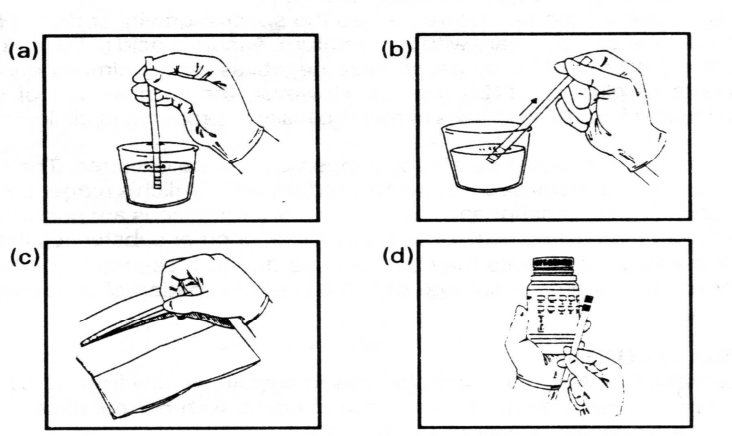
This method requires penetration of the bladder through the body wall and can be accomplished by minimal bleeding. This is the preferred way to analyze upper tract infection. Urine specimens can be collected from animals by a variety of ways as described in the above sections. It is recommended that cleansing be performed at the collection site to insure uncontaminated samples. The preferred method of choice would be Cystocentesis it provides specimens with the minimal amount of contamination.

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

Remove from the bottle only enough strips for immediate use and replace cap tightly.

1. **(a.)** Completely immerse reagent areas of the strip in fresh, well-mixed urine. Remove the strip immediately to avoid dissolving out the reagent areas.
2. **(b.)** While removing, touch the side of the strip against the rim of the urine container to remove excess urine.
3. **(c.)** 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. **(d.)** 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 can be read visually or by the Kacey **STEALTH** Instrument to enhance the accuracy over visual interpretation. **Call for Details. The STEALTH Instrument is available at "NO CHARGE" on a "Consignment Program**".
2. Comparison to the color chart is dependent on the interpretation of the individual. It is recommended laboratory personnel reading 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 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 (Macrodantin, Furadantin) and Riboflavin may affect the readability of the reagent areas on urinalysis reagent strips.
5. Urinary 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. As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single test result or method.

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
Microalbumin	ALB	10mg/L 30mg/L 80mg/L 150mg/L		10mg/L 30mg/L 80mg/L 150mg/L
Creatinine	CRE	10mg/dL 50 mg/dL 100mg/dL 200mg/dL 300mg/dL	0.1g/L 0.5g/L 1g/L 2g/L 3g/L	0.9mmol/L 4.4mmol/L 8.8mmlo/L 17.7mmol/L 26.5mmol/L

CALCULATIONS

Determine Albumin/Creatinine Ratio (A:C Ratio) as follows:
A:C Ratio = 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 next table provides a reference for the range of A:C Ratio based on the ALBUMIN and CREATININE 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