SPECIFIC PERFORMANCE CHARACTERISTICS:
The performance characteristics of VET- STX 7 urine reagent 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, this test has been developed to be specific for the constituent to be measured with the exception of interferences listed previously (see LIMITATIONS OF PROCEDURE).

SENSITIVITY
Glucose Test: This reagent test area may be read at 10 seconds for qualitative results or 30 seconds for quantitative results. The test is specific for glucose; no substance excreted in urine other than glucose is known to give a positive result. The reagent area does not react with lactose, galactose, fructose, nor reducing metabolites of drugs; e.g., Salicylates and Nalidixic acid. This test may be used to determine whether the reducing substance found in urine is glucose. Approximately 0.1 g of glucose per dL or urine is detectable.
Bilirubin Test: The test has a sensitivity of 0.2 - 0.4 mg Bilirubin/dL. The test is considered specific for Bilirubin in urine.1
Creatinine: This test is sensitive to Creatinine up to a low of 5 mg/dl and detect values as low as o mg/dL. The upper value of urinary Creatinine may vary within the same animal but the lower level of the upper limit is about 20 mg/dL
Blood Test: The test when read as instructed has a sensitivity to free hemoglobin of 0.015 mg/dL or 5 to 10 intact red blood cells/uL in urines with a specific gravity of 1.005 and ascorbic acid content of <5mg/dL. The test is slightly more sensitive to free hemoglobin and Myoglobin than to intact erythrocytes.
pH Test: The pH test area permits quantitative differentiation of pH values to one unit within the range of 5 - 9. pH readings are not affected by variation in the urinary buffer concentration.
Urobilinogen Test: This test area gives quantitative results and will detect Urobilinogen in concentrations as low as an Ehrlich unit/dL in urine. The absence of Urobilinogen in the specimen being tested cannot be determined.
Protein: The sensitivity of this test is about 10 mg/dL.

PROTEIN / CREATININE MATHEMATICAL RATIO CALCULATIONS
Accuracy of the protein test zone can be enhanced by rationing the protein reading to the Creatinine reading. The following guidelines may be used in differentiating between normal and abnormal provided evaluation of the sediment is negative. USE **VETI-STAIN™ Sedimentation Stain** to evaluate to see if sediment is negative.

Protein ÷ Creatinine = Ratio Results (A,B,C,D)
mg / dL ÷ mg / dL = Protein : Creatinine Ratio

EXAMPLE: Protein (10mg/dL) ÷ Creatinine (150mg/dL) = 0.06 Ratio = Normal

RATIO INTERPETATION
(A) Less than 0.5 (NORMAL)
(B) 0.5 – 1.0 (POTENTIALLY ABNORMAL)
(C) Greater than 1, and less than 5 (ABNORMAL)
(D) Greater than 5 --Proteins Losing Glomerular Nephropathy

VETERINARY USE ONLY.

TO ORDER CALL: 828.685.3569 Fax 828.685.7126

Veti Stx-9™
Part# 40404 (10 strips per bottle)
Part# 40405 (25 strips per bottle)
Part# 40406 (50 strips per bottle)

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Veti Stx-9 (Blood, Urobilinogen, Protein, pH, Bilirubin, Glucose, Creatinine, Leukocytes, Ketones Urine Test)

INTENDED USE: KACEY™ Veti-Stx for Urinalysis are plastic strips to which are affixed several separate reagent pads. KACEY™ Veti-Stx 9 provide tests for the semi-quantitative determination of glucose, Bilirubin, Ketone, blood, pH, protein, nitrite urine. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and bacteriurea.1,2

SUMMARY AND EXPLANATION:
The KACEY™ Veti-Stx 9 are ready to use upon removal from the bottle. The entire reagent strip is disposable. They provide a visual result. No additional laboratory equipment is necessary for testing unless the Veti-Stx 9 is used on a specific reader for the Veti-Stx 9 The reagent strips must be kept in the bottle with the cap tightly closed (as specified on the bottle) to maintain reagent reactivity.

TEST PRINCIPLES

Blood: This test is based on the Peroxidase-like activity of hemoglobin which catalyzes the reaction of Cumene-hydroperoxide and 3,3',5,5' Tetramethylbenzidine. The resulting color ranges from orange through green to dark blue.
Urobilinogen: This tests is based on a modified Ehrlich reaction in which p-diethylaminobenzaldehyde reacts with Urobilinogen in a strong acid medium to produce a pink color.
Protein: The detection of protein is based on the so called "Protein error of pH indicators." The protein pad is more sensitive to albumin than to some other proteins such as globulins, mucoproteins etc. A negative reaction does not rule out the presence of these proteins.
pH: This test is based on a double indicator principle that gives a broad range of colors covering the entire urinary pH range. Colors range from orange through yellow and green to blue.
Bilirubin: Ascorbic Acid (Vitamin C) in concentrations exceeding 25mg/dL (1.4mmol/L) may influence and cause "FALSE" negatives when in trace amounts. In canine hepatic disorders and other types of conditions may also be associated with the condition of "Bilirubinuria".
Glucose: This test is specific for glucose but levels of Ascorbic Acid above 50 mg/dL (3mmol/L) may influence the sensitivity of the test. The renal threshold in dog is approximately 180 mg/dL (11mmol/L) therefore, a positive result should be considered significant.
Creatinine: This test is based on the coupling reaction of 3,5 Dinitrobenzoate (Benedict-Behre reaction). The Creatinine test pad should be read at 60 seconds or between 60 and 120 seconds. The Creatinine test is particularly useful for interpreting protein test results.
Ketones: This test is based on a reaction of Acetoacetic acid in the urine with Nitroprusside. The resulting color ranges from tan when no reaction takes place to buff pink through pink to purple for a positive reaction.
Leukocytes: This test reveals the presence of granulocytic Esterases. The Esterases cleave a derivatized Thiazole amino acid ester to liberate derivatized Hydroxythiatole. This Thiazole then reacts with a Diazonium salt to produce a purple product.

REAGENTS: (Based on dry weight at time of impregnation)
Glucose: 16.3% w/w glucose oxidase (Aspergillus niger, 1.3 IU); 0.6% w/w Peroxidase (Horseradish, 3300 IU); 7.0% w/w of potassium iodide; 76.1% w/w buffer and nonreactive ingredients.
Bilirubin: 0.4% w/w 2,4-Dichloroaniline Diazonium salt, balanced with buffer and nonreactive ingredients
Creatinine: 1.61% Creatinine reactive indicator, 5.5% alkaline buffer and 92.81% non reactive ingredients
Blood: There should not be present in the urine any blood in normal animals. Most urine test cannot differentiate between red blood cells, Hemoglobin, or Myoglobin. To determine which of these components are present, an examination of the serum should be made. If the serum is not red, it is unlikely to be due to Hemoglobinemia. Myoglobeniemia is rare in dogs and cats and should be accompanied by a clear serum and evidence of muscle trauma or disease. Hematuria is also elevated in urine sedimentation Microscopically and is reported as cells per high power field.(HPF)
pH: Urine pH will be affected by many things including the diet, handling of the actual sample and acid-base balance o the animal. An alkaline pH is most indicative of an infectious process. Normal pH is between 6-8 for most animals depending on their diet..
Urobilinogen: 2.9% w/w p-diethylaminobenzaldehyde, balanced with buffer and nonreactive ingredients
Protein: 0.36% Tetrabromophenol blue, 99% buffer, 0.46% non reactive ingredients

WARNINGS AND PRECAUTIONS:
Urine reagent strips are for *in vitro* diagnostic use. They have been determined to be non-hazardous under the guidelines issued by OSHA in 29CRF 1910.1200(d)
STORAGE: Store at temperature between 15C-30°C (59 - 86° F) and out of direct sunlight. Do not use after expiration date. Do not touch test area. Replace cap immediately and tighten. All unused strips must remain in the original bottle. Transfer to any other container may cause reagent strips to deteriorate and become inactive.
RECOMMENDED HANDLING PROCEDURES: 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(s) from bottle. Protect against moisture, light and heat is essential to guard against altered reagent reactivity. Discoloration or darkening of reagent area may indicate deterioration. If this is evident, the reagent strip should be discarded.
Please consult local authorizes for proper disposal of used product.

SPECIMEN COLLECTION AND PREPARATION COLLECTION FOR ANALYSIS
There are several different methods of collection for urinalysis and each has its own benefits and also draw backs. Collection methods will often sometimes be indicated by the information the labortorian is seeking to obtain.

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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 (recommend Kacey urine collection supplies –collection cups w/ extension collection cup holder).

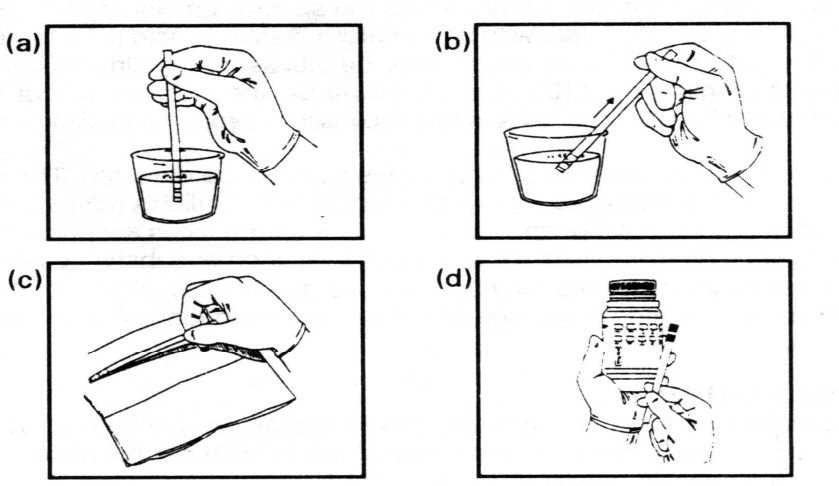
Manual Expression:
This collection method is most often performed on small animals (dogs &cats). It is sometimes difficult, and can results in some sort of trauma in the form of red blood cells (RBC's) in the urine. This method might result in contamination from the lower urinary tract.

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

Cystocentesis Sample
This method requires penetration of the bladder through the body wall and can be accompanied by minimal bleeding. This is the preferred way to analyze the upper tract for 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 a uncontaminated sample. The preferred method of choice would be by Cystocentesis because it provides a specimen with minimal amount of contamination.
All urine specimens should be tested usually within one (1) hour of collection. The urine specimen should be protected from direct light and refrigerated (not frozen) if unable to test within one hour. If refrigerated the specimen should be brought up to room temperature before testing. Stored specimens should be tested within twelve hours (12) since bacteria growth could occur and may cause inaccurate results and also by interfering with other tests on the pet-STX

Test Procedure
The following procedure must be followed exactly to achieve reliable results.
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, performance of reagent strips should be confirmed by testing known negative and positive specimens or control whenever a new test is performed or whenever a new bottle is first opened. 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. RESULTS: Results are obtained by direct comparison of the color blocks printed on the bottle label. The color blocks values represent nominal values; actual values will vary around the nominal values.

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, AZOGantanol), 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 for Glucose: Large amounts of Ketone bodies (50 mg/dL or greater) may decrease color development. However, it is unlikely that the presence of Ketones simultaneously with glucose in the urine is sufficient to produce false negative results. At glucose levels of 1 g/dL or greater, the color may appear somewhat mottled. The darkest color should be used in interpreting results with the color chart. Reactivity may also vary with temperature.[3]

Bilirubin: Reactions may occur with urine specimens containing large doses of chlorpromazine or rafampen which might be mistaken for positive bilirubin.[3] Indican (indoxyl sulfate) and metabolites of Lodine may cause false positive or atypical color; ascorbic acid (25 mg/dL or greater) may cause false negatives.
Creatinine: Urinary Creatinine concentration depends upon many factors such as muscle mass, gender, age, collection intervals, methodology. Very high specific gravity (>1.040) may cause low Creatinine values. Highly buffered alkaline urines may cause low readings relative to other methods. Elevated specific gravity readings may be obtained in the presence of moderate quantities (100-750 mg/dL) of protein. Acidic urines (pH 5 or below) may cause elevated results.
Blood: The sensitivity of the blood test is reduced in urine with high specific gravity and/or high ascorbic acid content. Microbial Peroxidase, associated with urinary tract infection, may cause a false positive reaction.
pH: If proper procedure is not followed and excess urine remains on the strip, a phenomenon known as "runover" may occur, in which the acid buffer from the protein reagent will run onto the pH area, causing a false lowering in the pH result.
Urobilinogen: The test area will react with interfering substances known to react with Ehrlich's reagent, such as Porphobilinogen and p-aminosalicylic acid.[3] The test is not a reliable method for the detection of Porphobilinogen. Drugs containing azo-dyes (e.g., Azo Gantrisin) may give a masking golden color. The absence of Urobilinogen cannot be determined with the product.
Protein: No false positive or negative results are obtained in alkaline urines. However false positive results may be found when residues of disinfectants containing quaternary ammonium groups are present in urine collection containers.

EXPECTED VALUES:
1. Blood: Any green spots or green color developing on the reagent area within 40 seconds is significant and the urine should be examined further. Blood is frequently, but not invariably, found in the urine of menstruating females.
2.Urobilinogen: In a healthy population, the normal urine Urobilinogen range obtained with this test is 0.2 to 1.0 Ehrlich unit per dL. A result of 2.0 EU/dL may be of clinical significance and the same animal sample should be evaluated further
3. Protein: In 24 hour urine samples, 1 -14 mg of protein in 1 dL of urine may be excreted by the kidney. A color matching any block greater than Trace indicates significant Proteinuria.
4. pH: If proper procedure is not followed and excess urine remains on the strip, a phenomenon known as "runover" may occur, in which the acid buffer from the protein reagent will run onto the pH area, causing a false lowering in the pH result.
5. Bilirubin: 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. Atypical colors (colors produced which are different than the negative or positive color blocks shown on the Color Chart) may indicate that Bilirubin derived bile pigments are present in the urine sample and are possibly masking the Bilirubin reaction.
6.Glucose: Small amount of glucose are normally excreted by the kidney. Concentrations of as little as 0.1 g/dL glucose, read either at 10 or 30 seconds, may be significantly abnormal if found consistently. At 10 seconds, results should be interpreted qualitatively; i.e., negative or positive. for quantitative results, read at 30 seconds only.
7. **Creatinine** is normally present in random urine in concentrations of 10 to 300 mg/dL (0.9 to 26.5 mmol/L). Creatinine
8. Ketone: Normally no Ketones are present in urine. Detectable levels of Ketone may occur in urine during physiological stress conditions, pregnancy, and frequent strenuous exercise. In controlled diets, or in other abnormal carbohydrate metabolism situation, Ketones appear in the urine in excessively large amounts before serum Ketones are elevated.
9.Leukocytes: Normally no leukocytes are detectable in the urine. Individually observed trace results may be of questionable clinical significance. Positive results may be found in random samples from females due to contamination by vaginal fluid.