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## VETI STX-7

Glucose, Bilirubin, Creatinine, Blood, pH, Urobilinogen,  
 Protein, and **Protein / Creatinine Ratio (UPC RATIO)**  
**SUMMARY AND EXPLANATION:** The KACEY™ Vet-Stx-7 Urine  
 Screen Test Strips are ready to use upon removal from the bottle. The reagent strips must  
 be kept in the bottle with the cap tightly closed to maintain reagent reactivity. The entire  
 reagent strip is disposable. The KACEY™ Vet-Stx-7 Urine Screen Test provides a  
 visual result. No additional laboratory equipment is necessary for testing unless the  
 KACEY™ Vet-Stx-7 Urine Screen Test is used on a specific Kacey Urine Reader.

**INTENDED USE:** KACEY™ Vet-Stx-7 Urine Screen Test are plastic strips to  
 which are affixed several separate reagent pads. The KACEY™ Vet-Stx-7 Urine Screen  
 Test provides semi-quantitative measures of Glucose, Bilirubin, Creatinine, Blood pH,  
 Urobilinogen, Protein and a Protein / Creatinine Ratio which can be calculated (see chart  
 in last section) This ratio is the "TRUE MEASURE" of proteinuria rather than the  
 protein alone. The results provide information regarding the status of kidney function and  
 metabolism.

### 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. Leptosporis).

#### 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.

#### CENTESIS SAMPLE

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. All urine  
 specimens should be tested usually within one (1) hour of collection. The specimen  
 should be protected from direct light and refrigerated (not frozen) if unable to test within  
 one (1) hour. If refrigerated the specimen should be brought up to room temperature  
 before testing. Stored specimens should be tested with twelve (12) hours since bacteria  
 growth could occur and may cause inaccurate results and may be also interfering with other  
 tests on the Vet-Stx-7.

### VETI STX-7 Urine Screen Test Reagent Pad Principles

**PROTEIN:** This test is based on the protein error-of pH -indicators 2 principle. At a  
 constant Ph, the development of any green color is due to the presence of protein. Colors  
 range from yellow for Negative, through yellow-green and reed to green-blue for Positive  
 reactions. The minimum sensitivity of this test is 5-10 mg/dL of protein in urine. The test is  
 more sensitive to albumin than to gamma-globulin, Bence-Jones protein (immunoglobulin  
 light chains), and mucoprotein. A negative result does not rule out the presence of these  
 other proteins, and such proteins do not interfere with the reaction of albumin

**CREATININE:** The creatinine test should be read between one (1) and two (2)  
 minutes. High Specific Gravity in the animal may cause low creatinine results. The  
 method is based on the Benedict & Behr reaction first described in 1936. The reaction  
 occurs between creatinine and the indicator ion in an alkaline medium to form a colored  
 complex. The color intensity of this complex is directly proportional to creatinine  
 concentration in the specimen.

**BILIRUBIN:** Ascorbic Acid (vitamin C) in concentrations exceeding 25 mg/dl  
 (1.4 mmol/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 The test pad is sensitive to approximately 0.5 mg/dL bilirubin.

**pH:** If proper procedure is not followed and excess urine remains on the test strip,  
 "runover" from the neighboring pads onto the pH pad interfere with results.

**BLOOD:** False positive may result from the presence of strong oxidizing agents such as  
 hypochlorite or from microbial peroxidases associated with urinary tract infections.  
 Ascorbic acid concentration of 10 mg/dl and greater can cause falsely low or negative  
 results. Very high nitrite concentration, elevated specific gravity or elevated protein levels  
 may reduce strip activity.

**GLUCOSE** Small amounts of glucose are normally excreted by the kidney. These  
 amounts are usually below the sensitivity (50 to 150 mg/dL glucose) of this test but on  
 occasion may produce a color between the negative end trace color blocks that could be  
 interpreted as positive. Results at the trace level may be considered abnormal if  
 found consistently.

**UROBILINOGEN:** Values up to 1.0 mg/dL (1 mg/dL is approximately  
 equal to 1 mg/dL) are considered normal. Urobilinogen excretion is enhanced  
 in alkaline urine, therefore urobilinogen concentration is generally greater in  
 the afternoon.

### Reagents based on dry weight at time of impregnation

**GLUCOSE:** 16.3% w/w glucoseoxidase (Aspergillus niger 1.3 IU); 0.6%w/w/ peroxidase  
 (Horseradish, 3300IU); 7.0% w/w of potassium iodide; 76.1% w/w buffer an nonreactive  
 ingredients

**BILIRUBIN:** 0.4% ww, 2,4 dichloroaniline balanced with buffer and nonreactive  
 ingredients

**CREATININE:** 1.61% creatinineractive indicator, 5.5% alkaline buffer and 92.81%  
 non reactive ingredients

**pH:** Urine pH will be affected by many things including the diet, handling of the actual  
 sample and acid-base balance of the animal. An alkaline pH is most indicative of an  
 infectious process. Normal pH is between 6-8 in most animals depending on their diet.

**BLOOD:** There should not be present in the urine any blood in normal animals. Most  
 urine tests 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.  
 Myoglobinemia 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).

**UROBILINOGEN:** 2.9% w/w p-diethylaminobenzaldehyde, balanced with a buffer  
 and nonreactive ingredients

**PROTEIN:** 0.36% tetrabromphenol blue, 99% buffer, 0.46% nonreactive ingredients

### STORAGE & STABILITY

Store at room temperature between 15 - 30 C (59-86 F). Do not store the strips  
 in the refrigerator or freezer. Cap the bottle tightly since the strips are sensitive  
 to specific environmental factors, such as moisture, heat and light, do not  
 expose strips to these factors. Do not use test strips after expiration date

**WARNINGS & PRECAUTIONS:** Urine reagent strips are for in vitro  
 diagnostic use only.

### RECOMMENDED HANDLING PROCEDURES

All unused strips must remain in the original bottle. Transfer to any other  
 container may cause the reagent strips to deteriorate and become nonreactive.  
 Do not remove desiccant from the bottle.

Materials Provided:

1. One (1) bottle containing 25 test strips of VETI STX-7
2. A visual color chart for reading results is printed on the bottle

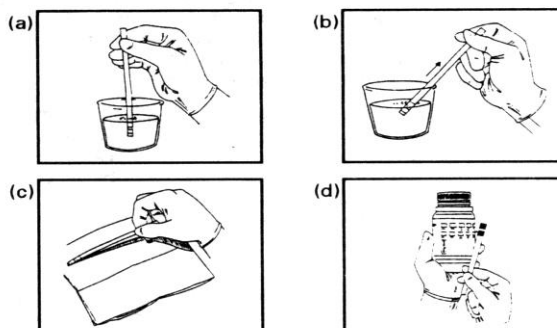
Materials Required But Not Provided

1. A timer capable of reading accurate seconds
2. It is also recommended that controls be used for Q.C Checks

### Procedure

The following procedure must be followed exactly to achieve reliable results.

1. Collect a fresh urine specimen



2. Do not centrifuge the freshly collected specimen
3. Remove the KACEY™ Vet-Stx-7 Urine Screen Test Stx from the bottle.
4. Dip the strip into the urine sample (picture a)
5. Remove excess urine from the strip by touching the edge of the cup as you  
 remove the strip (pic. b)
6. Touch the edge of the strip to an absorbent towel to again remove any  
 excess sample. (pic. c)
7. Read results by comparing the color of the reacted pad with the  
 corresponding color chart on the bottle.

### Results

The results are obtained by comparison of the reacted Vet-Stx-7 strip with the  
 color blocks printed on the color chart.

## Quality Control

The performance of the reagent strips should be confirmed by testing known negative & positive controls whenever a test is performed or a new bottle is first opened. Each laboratory should establish its own goals for adequate standards of performance. Kacey offers a Bi-Level Control to insure accuracy and reproducibility. Part # KCUBLC(Urine Bi Level Control).

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

## LIMITATIONS OF THE PROCEDURES

**Creatinine:** Benedict & Behr reaction for the measurement of creatinine in solution is known for its non-specificity. Drugs that can effect creatinine values in vivo are compiled by Young et al. Creatinine clearance depends upon muscle mass, diet and exercise level. Therefore, the coefficient of variation of creatinine excretion by the same animal may average 10%. Very high Specific gravity >1.040) may cause low Creatinine values. Acidic urines (pH 5 or below) may cause elevated results.

**Protein:** The sensitivity of this test is @ 10 mg/dL of protein in urine. Generally no false positives or negative results are obtained in highly alkaline urines (pH-9). However, false positives results may be found when residues of disinfectants containing quaternary ammonium groups are present in the contaminated urine container.

**Bilirubin:** Reactions may occur with urine specimens containing large doses of chlorpromazine or rafampen which might be mistaken for positive bilirubin<sup>3</sup> 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

**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 urine is sufficient to produce a false negative result. At glucose levels of 1 g/dL or greater, the color may appear somewhat mottled. The reactivity of the glucose test as the SG of the urine increases reactivity may also vary with the temperature<sup>3</sup>

**pH:** If proper procedures 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 Pad 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.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.

**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.

## EXPECTED VALUES

**Glucose:** Small amounts of glucose are normally secreted by the kidney. Concentrations of as little as 0.1 g/dL glucose. At 10 - 30 seconds results can be interpreted qualitatively negative or positive. For quantitative results read at 60 seconds.

**Bilirubin:** Normally no bilirubin is detectable in urine by even the most sensitive methods. Even trace amounts of bilirubin are sufficiently abnormal to require investigation.

**Protein:** In 24 hour samples 1-14 mg/dL of protein in 1 d/L of urine may be excreted by the kidney. A color matching any block greater than Trace indicate a significant proteinuria

**Blood:** Any green spots or green color developing on the reagent pad 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.

**pH:** 4.5- 8 Average: 6

**Urobilinogen:** The normal urobilinogen range obtained with this test is 0.2 - 1.0 mg/dl dL. A result of 2.0 mg/dL and higher may be of clinically significance and the same animal sample should be evaluated further.

**Creatinine:** The Creatinine test is sensitive to Creatinine in urine up to a low of 5 mg/dL and can detect negative values of 0 mg/dL. The upper valued of urinary Creatinine may vary within the individual animal or among individual animals but the lower limit is 20 mg/dL.

## PERFORMANCE CHARACTERISTICS

Specific performance characteristics of the KACEY Vet-Stx-7 Screen Test Strips are based both on clinical and laboratory studies. Parameters of importance to the user are sensitivity, specificity, accuracy, and precision. Generally, this test has been developed to be specific for the constituents to be measured with the exception of interferences listed previously (see Limitations of Procedures). Sensitivity and limits of test are the generally detectable levels of each test described previously. The sensitivity depends upon several factors; the variability of color perception; the presence or absence of inhibitory factors typically found in urine, the specific gravity, pH, and lighting conditions when the product is read visually. Exact agreement between visual results and instrumental results may not be found because of the inherent differences in the color perception of the human eye and the optical systems of instruments. It is for this reason that each user is encouraged to develop his or her own standards for performance.

## SENSITIVITY

**Creatinine:** The creatinine test is sensitive to creatinine in urine up to a low of 5 mg/dL and can detect negative values of 0 mg/dL. The upper value of urinary creatinine may vary within the individual animal or among individual animals but the lower limit is about 20mg/dL

**Protein:** The test is more sensitive to albumins than gamma-globulin, Bence Jones proteins, and mucoproteins, such proteins do not interfere with the reaction of albumin. However, a negative result does not rule out the presence of these proteins.

**Glucose:** The reagent test area may be read at 10 seconds for qualitative results. The test is specific for glucose; no substance secreted in the urine other than glucose is known to give a positive results. The reagent area does not react with lactose, galactose, fructose. Approximately 0.1 g of glucose per dL of urine is detectable.

**Bilirubin:** The tes is sensitive of 0.2 \* 0.4 mg bilrubin / dL. The test should be considered specific for bilirubin in urine.

**pH:** the pH test area permits quantitative differentiation of pH values to one unit with in the range of 5-9. pH readings are not affected by variation in the urinary buffer concentration.

**Urobilinogen:** The test area gives quantitative results and will detect urobilinogen in concentrations as low as one mg/dL in urine. The absence of urobilinogen in the specimen being tested cannot be determined.

**Blood:** The test when read as instructed has a sensitivity to free hemoglobin of 0.015 mg/dL or 5 - 10 intact red blood cells/uL in urines with a Specific Gravity of 1.005 and ascorbic acid content of <5 mg/dL. The test is slightly more sensitive to free hemoglobin any myoglobin that to intact erythrocytes.

## URINE PROTEIN / CREATININE RATIO

Accuracy of the protein test zone can be enhanced by ratioing 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 Vet-Stain™ Sedimentation Stain to evaluate to see if sediment is negative)

Protein ÷ Creatinine = Ratio Results (A,B,C,D)  
Ex. Protein ÷ Creatinine = Protein : Creatinine Ratio  
10 mg/dL (150 mg/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)

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