

## Package Insert

For rapid detection of multiple analytes in animal urine.  
For veterinary use only.

### SUMMARY

The Urinalysis Reagent Strips (Urine) are firm plastic strips onto which several separate reagent areas are affixed. The test is for the qualitative and semi-quantitative detection of one or more of the following analytes in urine: Ascorbic acid, Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes. The Urinalysis Reagent Strips (Urine) are for single use. For veterinary use only. Refer to kit box label for the specific analyte(s) listed, and compare to the appropriate analyte(s) and color blocks on the color chart for results.

### PRINCIPLE AND EXPECTED VALUES

**Ascorbic acid:** This test involves decolorization of Tillmann's reagent. The presence of ascorbic acid causes the color of the test field to change from blue-green to orange. Patients with adequate diet may excrete 2-10 mg/dL daily. After ingesting large amounts of ascorbic acid, levels can be around 200 mg/dL.

**Glucose:** This test is based on the enzymatic reaction that occurs between glucose oxidase, peroxidase and chromogen. Glucose is first oxidized to produce gluconic acid and hydrogen peroxide in the presence of glucose oxidase. The hydrogen peroxide reacts with potassium iodide chromogen in the presence of peroxidase. The extent to which the chromogen is oxidized determines the color which is produced, ranging from green to brown. Glucose should not be detected in normal urine. Small amounts of glucose may be excreted by the kidney. Glucose concentrations as low as 100 mg/dl may be considered abnormal if results are consistent.

**Bilirubin:** This test is based on azo-coupling reaction of bilirubin with diazotized dichloroaniline in a strongly acidic medium. Varying bilirubin levels will produce a pinkish-tan color proportional to its concentration in urine. In normal urine, no bilirubin is detectable by even the most sensitive methods. Even trace amounts of bilirubin require further investigation. Atypical results (colors different from the negative or positive color blocks shown on the color chart) may indicate that bilirubin-derived bile pigments are present in the urine specimen, and are possibly masking the bilirubin reaction.

**Ketone:** This test is based on ketones reacting with nitroprusside and acetoacetic acid to produce a color change ranging from light pink for negative results to a darker pink or purple color for positive results. Ketones are normally not present in urine. Detectable ketone levels may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. In starvation diets, or in other abnormal carbohydrate metabolism situations, ketones appear in the urine in excessively high concentration before serum ketones are elevated.

**Specific Gravity:** This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration to green and yellow-green in urine of increasing ionic concentration.

**Blood:** This test is based on the peroxidase-like activity of hemoglobin which catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from orange to green to dark blue.

**pH:** This test is based on a double indicator system which gives a broad range of colors covering the entire urinary pH range. Colors range from orange to yellow and green to blue.

**Protein:** This reaction is based on the phenomenon known as the "protein error" of pH indicators where an indicator that is highly buffered will change color in the presence of proteins (anions) as the indicator releases hydrogen ions to the protein. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow to yellow-green for negative results and green to green-blue for positive results.

**Urobilinogen:** This test is based on a modified Ehrlich reaction between p-diethylaminobenzaldehyde and urobilinogen in strongly acidic medium to produce a pink color.

**Nitrite:** This test depends upon the conversion of nitrate to nitrite by the action of Gram negative bacteria in the urine. In an acidic medium, nitrite in the urine reacts with p-arsanilic acid to form a diazonium compound. The diazonium compound in turn couples with 1 N-(1-naphthyl) ethylenediamine to produce a pink color.

**Leukocytes:** This test reveals the presence of granulocyte esterases. The esterases cleave a derivatized pyrazole amino acid ester to liberate derivatized hydroxyl pyrazole. This pyrazole then reacts with a diazonium salt to produce a beige-pink to purple color. Normal urine specimens generally yield negative results. Trace results may be of questionable clinical significance.

### REAGENTS AND PERFORMANCE CHARACTERISTICS

Based on the dry weight at the time of impregnation, the concentrations given may vary within manufacturing tolerances. The following table below indicates read times and performance characteristics for each parameter.

Reagent	Read Time	Composition	Description
Ascorbic Acid (ASC)	30 seconds	2,6-dichlorophenolindophenol; buffer and non-reactive ingredients	Detects ascorbic acid as low as 5-10 mg/dL (0.28-0.56 mmol/L).
Glucose (GLU)	30 seconds	glucose oxidase; peroxidase; potassium iodide; buffer; non-reactive ingredients	Detects glucose as low as 50-100 mg/dL (2.5-5 mmol/L).

Bilirubin (BIL)	30 seconds	2, 4-dichloroaniline diazonium salt; buffer and non-reactive ingredients	Detects bilirubin as low as 0.4-1.0 mg/dL (6.8-17 μmol/L).
Ketone (KET)	40 seconds	sodium nitroprusside; buffer	Detects acetoacetic acid as low as 2.5-5 mg/dL (0.25-0.5 mmol/L).
Specific Gravity (SG)	45 seconds	bromthymol blue indicator; buffer and non-reactive ingredients; poly (methyl vinyl ether/maleic anhydride); sodium hydroxide	Determines urine specific gravity between 1.000 and 1.060. Results correlate with values obtained by refractive index method within ± 0.005.
Blood (BLO)	60 seconds	3,3',5,5'-tetramethylbenzidine (TMB); diisopropylbenzene dihydroperoxide; buffer and non-reactive ingredients	Detects free hemoglobin as low as 0.018-0.060 mg/dL or 5-10 Ery/μL in urine specimens with ascorbic acid content of < 50 mg/dL.
pH	60 seconds	methyl red sodium salt; bromthymol blue; non-reactive ingredients	Permits the quantitative differentiation of pH values within the range of 5-9.
Protein (PRO)	60 seconds	tetrabromophenol blue; buffer and non-reactive ingredients	Detects albumin as low as 7.5-15 mg/dL (0.075-0.15 g/L).
Urobilinogen (URO)	60 seconds	p-diethylaminobenzaldehyde; buffer and non-reactive ingredients	Detects urobilinogen as low as 0.2-1.0 mg/dL (3.5-17 μmol/L).
Nitrite (NIT)	60 seconds	p-arsanilic acid; N-(1-naphthyl) ethylenediamine; non-reactive ingredients	Detects sodium nitrite as low as 0.05-0.1 mg/dL in urine with a low specific gravity and less than 30 mg/dL ascorbic acid.
Leukocytes (LEU)	120 seconds	derivatized pyrrole amino acid ester; diazonium salt; buffer; non-reactive ingredients	Detects leukocytes as low as 9-15 white blood cells Leu/μL in clinical urine.

### PRECAUTIONS

- For veterinary use only. Do not use after the expiration date.
- The strip should remain in the closed canister until use.
- Do not touch the reagent areas of the strip.
- Discard any discolored strips that may have deteriorated.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used strip should be discarded according to local regulations after testing.

### STORAGE AND STABILITY

Store as packaged in the closed canister either at room temperature or refrigerated (2-30°C). Keep out of direct sunlight. The strip is stable through the expiration date printed on the canister label. Do not remove the desiccant. Remove only enough strips for immediate use. Replace cap immediately and tightly. **DO NOT FREEZE.** Do not use beyond the expiration date.

Note: Once the canister has been opened, the remaining strips are stable for up to 3 months. Stability may be reduced in high humidity conditions.

### SPECIMEN COLLECTION AND PREPARATION

A urine specimen must be collected in a clean and dry container and tested as soon as possible. Do not centrifuge. The use of urine preservatives is not recommended. If testing cannot be done within an hour after voiding, refrigerate the specimen immediately and let it return to room temperature before testing.

Prolonged storage of unpreserved urine at room temperature may result in microbial proliferation with resultant changes in pH. A shift to alkaline pH may cause false positive results with the protein test area.

### MATERIALS

#### Materials Provided

- Strips
- Package insert
- Materials Required But Not Provided
- Specimen collection containers

### DIRECTIONS FOR USE

Allow the strip, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

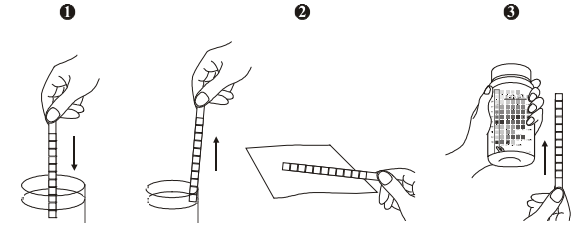
- Remove the strip from the closed canister and use it as soon as possible. Immediately close the canister tightly after removing the required number of strip(s). Completely immerse the reagent areas of the strip in fresh, well-mixed urine and immediately remove the strip to avoid dissolving the reagents. See illustration 1 below.
- While removing the strip from the urine, run the edge of the strip against the rim of the urine container to remove excess urine. Hold the strip in a horizontal position and bring the edge of the strip into contact with an absorbent material (e.g. a paper towel) to avoid mixing chemicals from adjacent reagent areas and/or soiling hands with urine. See illustration 2 below.
- Compare the reagent areas to the corresponding color blocks on the canister label at the specified times. Hold the strip close to the color blocks and match carefully. See illustration 3 below.

Note: Results may be read up to 2 minutes after the specified times. Results may also be read using the Urine Analyzers. Refer to the Instruction Manual for details.

### INTERPRETATION OF RESULTS

Results are obtained by direct comparison of the color blocks printed on the canister label. The color blocks represent nominal values; actual values will vary close to the nominal values. In the event of unexpected or questionable results, the following steps are recommended: confirm that the strips have been tested within the expiration date printed on the canister label,

compare results with known positive and negative controls and repeat the test using a new strip. If the problem persists, discontinue using the strip immediately and contact your local distributor.



### LIMITATIONS

**Ascorbic acid:** No interference is known.

**Glucose:** Small amounts of glucose are normally excreted by the kidney. Concentrations 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: for semi-quantitative results, read at 30 seconds only.

**Bilirubin:** Normally, no bilirubin is detectable in urine by even the most sensitive method. 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.

**Ketone:** Normally, no ketones are present in urine. Detectable levels of ketone may occur in urine during physiological stress conditions such as pregnancy and frequent strenuous exercise. In starvation diets, or in other abnormal carbohydrate metabolism situations, ketones appear in the urine in excessively large amounts before serum ketones are elevated.

**Specific Gravity:** Random urine may vary in specific gravity from 1.003-1.060 and can vary greatly between species.

**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

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

**Protein:** In 24-hour urine, 1-14 mg/dl of protein may be excreted by the normal kidney. A color matching any color block greater than trace indicates significant proteinuria. For urine with high specific gravity, the test area may most closely match the trace color block even though only normal concentrations of protein are present. Clinical judgment is needed to evaluate the significance of trace results

**Urobilinogen:** In a healthy population, the normal urine urobilinogen range obtained with this test is 0.2-1.0 Ehrlich Unit/dl. A result of 2.0 EU/dl may be of clinical significance and the same patient sample should be evaluated further.

**Nitrite:** Normally no detectable amount of nitrite is present in urine. The nitrite area will be positive in a proportion of cases of significant infection, depending on how long the urine specimens were retained in the bladder prior to collection. Retrieval of positive cases with the nitrite test ranges from as low as 40%, in instances where little bladder incubation occurred, to as high as 80% in instances where a minimum of 4 hours incubation occurred.

**Leukocytes:** Normal urine specimens generally yield negative results with this test. A trace result may be of questionable clinical significance and it is recommended that the test be repeated using a fresh sample from the same one. Repeated trace and positive results are of clinical significance.

### Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
	Manufacturer		Batch code		Catalogue number
	Do not use if package is damaged and consult instructions for use		Use-by date		Do not re-use



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