Mission®

Urinalysis Reagent Strips U031-101 (Urine)

Package Insert

Type of Strip		
10U - Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes	**10A - Ascorbic Acid, Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite**	**English**

For rapid detection of multiple analytes in human urine.
For in vitro diagnostic use only. Rx Only

INTENDED USE

The *Mission*® Urinalysis Reagent Strips (Urine) are for the qualitative and semi-quantitative detection of one or more of the following analytes in human urine: Ascorbic acid, Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes. The *Mission*® Urinalysis Reagent Strips (Urine) are for single use in professional near-patient (point-of-care) and centralized laboratory locations and are intended for professional use only. The strips are intended for use in screening at-risk patients to assist diagnosis in the following areas: kidney function, urinary tract infections, carbohydrate metabolism (e.g. diabetes mellitus), liver function, acid-base balance and urine concentration. The results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed.

The *Mission*® Urinalysis Reagent Strips (Urine) can be read visually and on the *Mission*® U120, U120 Smart, U120 Ultra and U500 Urine Analyzers.

SUMMARY

Urine undergoes many changes during states of disease or body dysfunction before blood composition is altered to a significant extent. Unnalysis is a useful procedure as an indicator of health or disease, and as such, is a part of routine health screening. The *Mission*® Urinalysis Reagent Strips (Urine) can be used in general evaluation of health, and aids in the diagnosis and monitoring of metabolic or systemic diseases that affect kidney function, endocrine disorders and diseases or disorders of the urinary tract.[1,2]

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.[3] 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.[4-6] In starvation diets, or in other abnormal carbohydrate metabolism situations, ketones appear in the urine in excessively high concentration before serum ketones are elevated.[7]

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. Randomly collected urine may vary in specific gravity from 1.003-1.035.[8] Twenty-four hour urine from healthy adults with normal diets and fluid intake will have a specific gravity of 1.016-1.022.[8] In cases of severe renal damage, the specific gravity is fixed at 1.010, the value of the glomerular filtrate.

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 light orange to dark green. The significance of a trace results, or a 5 – 10 non-hemolyzed result, varies among patients, and clinical judgment is required for these specimens on an individual basis. Small amounts of blood with a strip result of 1+ hemolyzed, or a 50 Ery/µL non-hemolyzed result, within 60 seconds are sufficiently abnormal to request a further investigation. Blood is often, but not invariably, found in the urine of menstruating females.

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. The expected range for normal urine specimens from newborns is pH 5-7.[9] The expected range for other normal urine specimens is pH 4.5-8, with an average result of pH 6.[9]

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. 1-14 mg/dL of protein may be excreted by a normal kidney.[10] A color equal or greater than 30 mg/dL indicates significant proteinuria. Clinical judgment is required to evaluate the significance of trace 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. Urobilinogen is one of the major compounds produced in heme synthesis and is a normal substance in urine. The expected range for normal urine with this test is 0.2-1.0 mg/dL (3.5-17 µmol/L).[8] A result of 2.0 mg/dL (35 µmol/L) may be of clinical significance, and the patient specimen should be further evaluated.

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. Nitrite is not detectable in normal urine.[9] The nitrite area will be positive in some cases of 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 cases where little bladder incubation occurred, to as high as approximately 80% in cases where bladder incubation took place for at least 4 hours.

Leukocytes: This test reveals the presence of granulocyte esterases. The esterases cleave a derivatized pyrazole amino acid ester to liberate derivatized hydroxy 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. When trace results occur, it is recommended to retest using a fresh specimen from the same patient. Repeated trace and positive results are of 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. The sensitivities are based on visual read studies.

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	bromothymol blue indicator; buffer and non-reactive ingredients; poly (methyl vinyl ether/maleic anhydride); sodium hydroxide	Determines urine specific gravity between 1.000 and 1.030. 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; bromothymol 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.

The performance characteristics of the *Mission*® Urinalysis Reagent Strips (Urine) have been determined in both laboratory and 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 parameters to be measured with the exceptions of the interferences listed. Please refer to the Limitations section in this package insert.

Interpretation of visual results is dependent on several factors: the variability of color perception, the presence or absence of inhibitory factors, and the lighting conditions when the strip is read. Each color block on the chart corresponds to a range of analyte concentrations.

The reading value range for parameters of pH, protein, urobilinogen, and glucose are different between visual and analyzer methods, please refer to the *Mission*® U120, U120 Smart, U120 Ultra and U500 Urine Analyzer Manuals for the respective parameters reading range.

The sensitivities of parameters are based on the visual read studies and may vary between visual reading and the results obtained from analyzer including the *Mission*® U120, U120 Smart, U120 Ultra and U500. For visual readings, if the color of a pad is in-between negative and trace, the result should be read as a negative.

PRECAUTIONS

- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The strip should remain in the closed canister or the sealed pouch 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 or the sealed pouch either at room temperature or refrigerated (2-30°C or 36-86°F). Keep out of direct sunlight. The strip is stable through the expiration date printed on the canister label or the sealed pouch. 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. Strips packaged in the sealed pouch should be used immediately after opening. 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. Urine containing glucose may decrease in pH as organisms metabolize the glucose. Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein (and to a lesser extent, specific gravity and bilirubin) test results.

MATERIALS

Materials Provided

- Strips
- Package insert

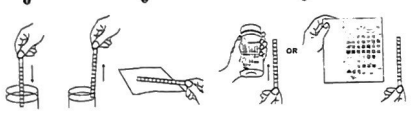
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow the strip, urine specimen, and/or controls to reach room temperature 59-86°F(15-30°C) prior to testing.

1. Remove the strip from the closed canister or the sealed pouch 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.
2. 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.
3. Compare the reagent areas to the corresponding color blocks on the color chart 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 on the *Mission*® U120, U120 Smart, U120 Ultra and U500 Urine Analyzers. Refer to the *Mission*® U120, U120 Smart, U120 Ultra and U500 Urine Analyzer Instruction Manuals for instructions of using the test strips with the analyzers.



INTERPRETATION OF RESULTS

Results are obtained by direct comparison of the color blocks printed on the color chart. 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 or the sealed pouch, 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. For US customers, call customer service toll-free at 1-(800)-838-9502. For customers outside the US, contact your local distributor.

QUALITY CONTROL

For best results, performance of reagent strips should be confirmed by testing known positive and negative specimens/controls in the following conditions.

- Test QC per your laboratory policies and follow local, state and federal regulations.
- Test commercially available positive and negative quality controls with each new lot, each new shipment of strips, and when you open a new bottle of reagent strips. Please note: Water is NOT an appropriate negative control.
- Test the strips monthly that are stored for more than 30 days.
- Run QC tests to ensure reagent storage integrity; train new users; confirm test performance; and when patients' clinical conditions or symptoms do not match the results obtained on the test strips.

For US customers, call customer service toll-free at 1-(800)-838-9502 for additional information. For customers outside the US, contact your local distributor.

LIMITATIONS

Note: As with all laboratory tests, diagnostic and therapeutic decisions should not be based on any single result or method and must be considered with other clinical information available to the physician.

The *Mission*® Urinalysis Reagent Strips (Urine) may be affected by substances that cause abnormal urine color such as drugs containing azo dyes (e.g. Pyridium®, Azo Gantrisin®, Azo Gantanol®), nitrofurantoin (Microdantin®, Furadantin®), and riboflavin.[8] The color development on the test pad may be masked or a color reaction may be produced that could be interpreted as false results.

Ascorbic acid: Sample pH>9 would generate false low results on ascorbic acid.

Glucose: The reagent area does not react with lactose, galactose, fructose or other metabolic substances, nor with reducing metabolites of drugs (e.g. salicylates and nalidixic acid). Sensitivity may be decreased in specimens with high specific gravity (>1.025) and with ascorbic acid concentrations of ≥ 25 mg/dL. High ketone levels ≥ 100 mg/dL may cause false negative results for specimens containing a small amount of glucose (50-100 mg/dL). Sample pH from 5.0 to 9.0 does not affect the results of glucose.

Bilirubin: Bilirubin is absent in normal urine, so any positive result, including a trace positive, indicates an underlying pathological condition and requires further investigation. Reactions may occur with urine containing large doses of chlorpromazine or rifampin that might be mistaken for positive bilirubin.[9] Ponstel® (mefenamic acid) administration, Thorazine®, Ornazine® (chlorpromazine), rifampin, and etodolac may result in false-positive reactions. Indoxyl sulfate interferes both with negatives and positives.[11] The presence of bilirubin-derived bile pigments may mask the bilirubin reaction. This phenomenon is characterized by color development on the test patch that does not correlate with the colors on the color chart. Large concentrations of ascorbic acid may decrease sensitivity. Sample pH from 5.0 to 9.0 does not affect the results of bilirubin.

Ketone: The test does not react with acetone or β-hydroxybutyrate.[8] Urine specimens of high pigment, and other substances containing sulfhydryl groups may occasionally give reactions up to and including trace (±).[9] Sample pH from 5.0 to 9.0 does not affect the results of ketone.

Specific Gravity: Ketoacidosis or protein higher than 300 mg/dL may cause elevated results. Results are not affected by non-ionic urine components such as glucose. If the urine has a pH of 7 or greater, add 0.005 to the specific gravity reading indicated on the color chart. Sample pH>9 would generate false high results on specific gravity.

Blood: A uniform green color indicates the presence of myoglobin, hemoglobin or hemolyzed erythrocytes.[8] Scattered or compacted green spots indicate the presence of non-hemolyzed erythrocytes (last two blocks to the right on the color chart). To enhance accuracy, separate color scales and reporting units are provided for hemolyzed and non-hemolyzed erythrocytes. Positive results with this test are often seen with urine from menstruating females. It has been reported that urine of high pH reduces sensitivity, while moderate to high concentration of ascorbic acid may inhibit color formation. Microbial peroxidase, associated with urinary tract infection, may cause a false positive reaction. The test is slightly more sensitive to free hemoglobin and myoglobin than to intact erythrocytes. Sample pH>9 would generate false low results on blood.

pH: If the 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 the pH result to appear artificially low. pH readings are not affected by variations in urinary buffer concentration.

Protein: This test is highly sensitive for albumin, and less sensitive to hemoglobin, globulin and mucoprotein.[8] A negative result does not rule out the presence of these other proteins. False positive results may be obtained with highly buffered or alkaline urine. Contamination of urine specimens with quaternary ammonium compounds or skin cleansers containing chlorhexidine may produce false positive results.[8] The urine specimens with high specific gravity may give false negative results. Sample pH>8 would generate false high results on protein.

Urobilinogen: All results lower than 1 mg/dL urobilinogen should be interpreted as normal. A negative result does not at any time preclude the absence of urobilinogen. The reagent area may react with interfering substances known to react with Ehrlich's reagent, such as p-aminosalicylic acid and sulfonamides.[9] False negative results may be obtained if formalin is present. The test cannot be used to detect porphobilinogen. Sample pH from 5.0 to 9.0 does not affect the results of urobilinogen.

Nitrite: The test is specific for nitrite and will not react with any other substance normally excreted in urine. Any degree of uniform pink to red color should be interpreted as a positive result, suggesting the presence of nitrite. Color intensity is not proportional to the number of bacteria present in the urine specimen. Pink spots or pink edges should not be interpreted as a positive result. Comparing the reacted reagent area on a white background may aid in the detection of low nitrite levels, which might otherwise be missed. Ascorbic acid above 30 mg/dL may cause false negatives in urine containing less than 0.05 mg/dL nitrite ions. The sensitivity of this test is reduced for urine specimens with highly buffered alkaline urine or with high specific gravity. A negative result does not at any time preclude the possibility of bacteruria. Negative results may occur in urinary tract infections from organisms that do not contain reductase to convert nitrate to nitrite; when urine has not been retained in the bladder for a sufficient length of time (at least 4 hours) for reduction of nitrate to nitrite to occur; when receiving antibiotic therapy or when dietary nitrate is absent. Sample pH>9 would generate false low results on nitrite.

Leukocytes: The result should be read between 60-120 seconds to allow for complete color development. The intensity of the color that develops is proportional to the number of leukocytes present in the urine specimen. High specific gravity or elevated glucose concentrations (≥ 2,000 mg/dL) may cause test results to be artificially low. The presence of cephalexin, cephalothin, or high concentrations of oxalic acid may also cause test results to be artificially low. Tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction. High urinary protein may diminish the intensity of the reaction color. This test will not react with erythrocytes or bacteria common in urine.[8] Sample pH>9 would generate false high results on leukocytes.

INTERFERENCE STUDIES

Interference studies were performed using 3 levels urine samples with different concentrations of the interfering substances. Separate aliquots of each of the urine samples were spiked with different concentrations of the possible interfering substances. Each sample was tested in triplicate. Results of the substances at the indicated concentration which were found to interfere with the test are summarized in the table below:

Reagent pad	Interference substances	Conc. Tested	Interference on Testing Result
Glucose	Ascorbic acid	25 – 50 mg/dL 200 mg/dL	-1 Block -3 Blocks
	Ketone (Acetoacetate)	100 – 250 mg/dL	-1 Block
Bilirubin	Ascorbic acid	50 – 100 mg/dL 200 mg/dL	-1 Block -2 Blocks
	Blood	5%	+1 Block
Ketone	Blood	5%	+1 Block
Specific gravity	Protein (Albumin)	300 mg/dL 6000 – 30000 mg/dL	+1 Block +2 Blocks
Blood	Ascorbic acid	50 mg/dL 100 mg/dL 200 mg/dL	-1 Block -2 Blocks -4 Blocks
Urobilinogen	Blood	5%	+1 Block
Protein	Hemoglobin	20 mg/dL 50 mg/dL 100 mg/dL 200 – 400 mg/dL	+1 Block +2 Blocks +3 Blocks +4 Blocks
	Blood	0.05% 0.5% 1% 5%	+1 Block +2 Blocks +3 Blocks +4 Blocks
Nitrite	Ascorbic acid	≥30 mg/dL	False decreased results
	Blood	≥1%	False increased results
Leukocyte	Glucose	2000 mg/dL 5000 mg/dL	-1 Block -2 Blocks
	Blood	0.05 – 0.5% 1% 5%	+1 Block +2 Block +4 Blocks

Glucose: Ascorbic acid concentrations of 25 - 50 mg/dL cause interference of -1 block and higher concentrations of 200 mg/dL cause interference of -3 blocks on the testing result. Ketone concentration of 100 - 250 mg/dL causes interference of -1 block on the testing result.

Bilirubin: Ascorbic acid concentrations of 50-100 mg/dL cause interference of -1 block and higher concentrations of 200 mg/dL cause interference of -2 blocks on the testing result. Blood concentration of 5% causes interference of +1 block on the testing result.

Ketone: Blood concentration of 5% causes interference of +1 block on the testing result.

Specific Gravity: Protein (Albumin) concentrations of 300 mg/dL cause interference of +1 block and higher concentrations of 6000-30000 mg/dL cause interference of +2 blocks on the testing result.

Blood: Ascorbic acid concentrations of 50 mg/dL cause interference of -1 block, concentrations of 100 mg/dL cause interference of -2 blocks, and higher concentrations of 200 mg/dL cause interference of -4 blocks on the testing result.

Urobilinogen: Blood concentration of 5% causes interference of +1 block on the testing result.

Protein: Hemoglobin concentrations of 20 mg/dL cause interference of +1 block, concentrations of 50 mg/dL cause interference of +2 blocks, concentrations of 100 mg/dL cause interference of +3 blocks, and higher concentrations of 200-400 mg/dL cause interference of +4 blocks on the testing result. Blood concentrations of 0.05% cause interference of +1 block, concentrations of 0.5% cause interference of +2 blocks, concentrations of 1% cause interference of +3 blocks, and higher concentrations of 5% cause interference of +4 blocks on the testing result.

Nitrite: Ascorbic acid concentrations higher than 30 mg/dL cause false decreased results. Blood concentrations higher than 1% cause false increased results.

Leukocyte: Glucose concentrations of 2000 mg/dL cause interference of -1 block and higher concentrations of 5000 mg/dL cause interference of -2 blocks on the testing result. Blood concentrations of 0.05-0.5% cause interference of +1 block, concentrations of 1% cause interference of +2 blocks, and higher concentrations of 5% cause interference of +4 blocks on the testing result.

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***ACON* Laboratories, Inc.**
San Diego, CA 92121, USA
Toll Free Phone: 1-(800)-838-9502

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