Mission® Expert

Urinalysis Reagent Strips (Urine) Package Insert

REF U034-011	REF U034-051	REF U034-091	English
REF U034-021	REF U034-061	REF U034-101	
REF U034-031	REF U034-071	REF U034-111	
REF U034-041	REF U034-081		

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

INTENDED USE

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: Specific Gravity, pH, Leukocytes, Nitrite, Protein, Glucose, Ketone Bodies, Urobilinogen, Bilirubin, Blood, and Ascorbic Acid. The *Mission® Expert* Urinalysis Reagent Strips (Urine) are for single use in professional near-patient (point-of-care) and centralized laboratory locations.
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. The Urinalysis Reagent Strips (Urine) can be read visually and on the *Mission® Expert* Urine Analyzers, and are intended for professional use only.

SUMMARY

Urine undergoes many changes during states of disease or body dysfunction before blood composition is altered to a significant extent. Urinalysis is a useful procedure as an indicator of health or disease, and as such, is a part of routine health screening. The 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

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.[3] Twenty-four hour urine from healthy adults with normal diets and fluid intake will have a Specific Gravity of 1.016-1.022.[3] In cases of severe renal damage, the Specific Gravity is fixed at 1.010, the value of the glomerular filtrate.
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.[4] The expected range for other normal urine specimens is pH 4.5-8, with an average result of pH 6.[4]
Leukocytes: This test reveals the presence of granulocyte esterases. The esterases cleave a derivatized pyrazole amino acid ester to liberate derivatized hydroxy pyrazole. Then react with a diazonium salt to produce a violet dye. The test detects both intact and lysed Leukocytes.
Nitrite: This test depends upon the conversion of nitrate to nitrite by the action of Gram negative bacteria, or common urinary tract infection causing organisms like E. coli in the urine. It is based on the Griess' test principle. 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.[4] 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.
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. High pH (up to 9), chloroquine, tolbutamide, quinine, or quinidine do not affect this test. Colors range from yellow to yellow-green for negative results and green to green-blue for positive results. This test is particularly sensitive to albumin.
Glucose: This test is not affected by the presence of Ketones, or the pH of the urine. This test is a specific glucose-oxidase/peroxidase (GOD/POD) reaction based method.
Ketone Bodies: 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.[5-7] In starvation diets, or in other abnormal carbohydrate metabolism situations, Ketones appear in the urine in excessively high concentration before serum Ketones are elevated.[8] Legal's test principle is the test basis.
Urobilinogen: This test is based on the azo-coupling reaction of a stable diazonium salt with Urobilinogen in a strongly acidic medium to produce a red azo 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).[3] A result of more than 1.0 mg/dL (17 μmol/L) should be examined further.
Bilirubin: This test is based on the 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.
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 yellow to green to dark blue. Any green spots or green color development on the reagent area within 60 seconds is significant and should be examined further. Blood is often, but not invariably, found in the urine of menstruating females. The significance of a trace reading varies among patients and clinical judgment is required in these specimens.
Ascorbic Acid: This test involves decolorization of Tillmann's reagent. The presence of 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.

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
Specific Gravity (SG)	60 seconds	bromthymol blue indicator; buffer and non-reactive ingredients	Determines urine Specific Gravity between 1.000 and 1.030. Results correlate with values obtained by refractive index method within ±0.005.
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.
Leukocytes (LEU)	120 seconds	derivatized pyrrole amino acid ester; diazonium salt; buffer; non-reactive ingredients	Detects Leukocytes as low as 10-15 white blood cells (Leu/μL) in clinical urine.
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.
Protein (PRO)	60 seconds	tetrabromophenol blue; buffer and non-reactive ingredients	Detects albumin as low as 12~15 mg/dL (0.12~0.15 g/L).
Glucose (GLU)	60 seconds	glucose oxidase; peroxidase;; buffer; 3,3',5,5'-tetramethylbenzidine (TMB) non-reactive ingredients	Detects Glucose as low as 25-40 mg/dL (1.25-2 mmol/L) in urine with a low Specific Gravity.
Ketone Bodies (KET)	60 seconds	sodium nitroprusside; buffer	Detects acetoacetic acid as low as 5 mg/dL (0.5 mmol/L).
Urobilinogen (URO)	60 seconds	4-methoxybenzene diazonium tetrafluoroborate; buffer and non-reactive ingredients	Detects Urobilinogen as low as 0.8-1.0 mg/dL (13.6-17 μmol/L).
Bilirubin (BIL)	60 seconds	2,6-dichloroaniline; buffer and non-reactive ingredients	Detects Bilirubin as low as 0.6-0.8 mg/dL (10.2-13.6μmol/L).
Blood (ERY, Hb)	60 seconds	3,3',5,5'-tetramethylbenzidin e (TMB); diisopropylbenzene dihydroperoxide; buffer and non-reactive ingredients	Detects intact Erythrocytes as low as 5~10 Ery/μL or 0.015~0.03mg/dl Hemoglobin in urine specimens with ascorbic acid content of < 50 mg/dL.
Ascorbic Acid (ASC)	60 seconds	2,6-dichlorophenolindophen ol; buffer and non-reactive ingredients	Detects Ascorbic Acid as low as 5-10 mg/dL (0.28-0.56 mmol/L).

The performance characteristics of the 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.

PRECAUTIONS

- For *in vitro* diagnostic 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.
- The desiccant is a silicate-based non-toxic substance. Do not eat.

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 to avoid questionable results in high humidity conditions. **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 or stabilizers 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.
Do not leave urine specimen at room temperature for more than 2 hours. Prolonged storage of unpreserved urine at room temperature may result in microbial proliferation with resultant changes in pH. Do not expose urine specimens to sunlight. Sunlight causes Urobilinogen and Bilirubin to oxidize, giving artificially low results.
Contamination of the urine specimen with skin cleansers containing chlorhexidine may

affect Protein (and to a lesser extent, Specific Gravity and Bilirubin) test results. Detergent or strongly oxidizing disinfectant residues found in specimen collection containers may cause false positive results for Glucose, Protein, and Blood.

MATERIALS

Materials Provided

- Strips
- Color chart
- Package insert

Materials Required But Not Provided

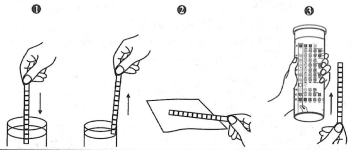
- Specimen collection container
- Timer

DIRECTIONS FOR USE

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

1. 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.
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. Read results after 60 seconds for all reagent areas, except Leukocytes after 60-120 seconds, by comparing the reagent areas to the closest corresponding color blocks on the color chart. See illustration 3 below.

   Note:
   - Always hold the strip close to the color chart and compare carefully.
   - Do not read results after 2 minutes from the specified times.
   - Do not read results if color changes only appear along the edge of the reagent areas.
   - The results for Blood include Erythrocytes (ERY) and Hemoglobin (Hb). Read results according to both groups of color blocks.
   - Results may also be read using the *Mission® Expert* 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 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, 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.

QUALITY CONTROL

For best results, performance of reagent strips should be confirmed by testing known positive and negative specimens/controls whenever a new test is performed, or whenever a new canister from a new lot is first opened. Each laboratory should establish its own goals for adequate standards of performance.

LIMITATIONS

Note: The 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.[3] The color development on the test pad may be masked or a color reaction may be produced that could be interpreted as false results. 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. **Specific Gravity:** Ketoacidosis or Protein concentrations 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.
pH: The pH readings are not affected by variations in urinary buffer concentration.
Leukocytes: The result should be read after 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 (≥ 2000 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 (> 500 mg/dL) may diminish the intensity of the reaction color. This test will not react with Erythrocytes, trichomonads or bacteria common in urine.[3] False positive results may occur in urine containing 20% or more Formaldehyde.
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 Nitrite-forming 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 bacteria. 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 present.
Protein: This test is highly sensitive for albumin, and less sensitive to Hemoglobin, globulin and mucoprotein.[3] Contamination of urine specimens with quaternary ammonium compounds or skin cleansers containing chlorhexidine may produce false positive results. False positive results can also be caused by blood infusion with polyvinylpyrrolidone.
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). Effects of Ascorbic Acid on Glucose have been greatly reduced. Glucose concentrations of 100 mg/dL and above are not effected by Ascorbic Acid concentrations, and high Ascorbic Acid concentrations will unlikely produce false negative results. The reactivity of the test decreases as the Specific Gravity of urine increases.
Ketone Bodies: The test is more sensitive to acetoacetic acid than to acetone.[3] Urine specimens of high pigment, captopril, mesna, and other substances containing sulfhydryl groups occasionally react may give false positive results.[4] Phenylketone and phthalein compounds can produce red coloration on the edges of the reagent area, but are different than the violet colors caused by the presence of Ketone bodies and should be considered negative.
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 will not react with interfering substances known to react with Ehrlich's reagent. False negative results may be obtained if formalin is present. The test cannot be used to detect porphobilinogen.
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 rifampen that might be mistaken for positive Bilirubin.[4] 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.
Blood: A uniform blue color indicates the presence of myoglobin, Hemoglobin or hemolyzed Erythrocytes.[3] Scattered or compacted blue spots indicate intact Erythrocytes. To enhance accuracy, separate color scales are provided for Erythrocytes (ERY) and Hemoglobin (Hb). Positive results with this test are often seen with urine from menstruating females. Microbial peroxidase, associated with urinary tract infection, may cause a false positive reaction. Moderate to high concentration of ascorbic acid may inhibit color formation. In urine with 5-50 Ery/µL concentrations, hemolysis which may occur on prolonged standing of the urine can cause for higher concentration values than what are given for intact Erythrocytes.
Ascorbic Acid: No interference is known.

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Index of Symbols

	Consult instructions for use	Σ	Contains sufficient for <n> tests		Manufacturer
IVD	*In vitro* diagnostic medical device		Use by		Do not reuse
2°C 30°C	Temperature limit	LOT	Lot Number	REF	Catalogue number
EC REP	Authorized representative in the European Community				

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CE

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