URINE REAGENT STRIPS (CLA-10P) FOR URINALYSIS

This Package Insert is for CLA-10P

For the semi-quantitative detection of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, and Leukocytes in urine. ***For use only with the Clarity Platinum Urine Chemistry Test System, not for Visual Read.***

INDICATIONS FOR USE:

The Clarity Platinum Urine Analyzer System consists of the Clarity Platinum Urine Analyzer and the Clarity Diagnostics Urine Reagent Strips (CLA-10P). The Clarity Platinum urine analyzer is an automated, bench top instrument which is intended for point-of-care, in vitro diagnostic use only. This analyzer is intended to be used together with the Clarity Diagnostics Urine Reagent Strips (CLA-10P) as a system for semi-quantitative detection of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes in urine. These measurements are used to aid in the diagnosis of metabolic disorders, kidney function anomalies, urinary tract infections, and liver function.

CLIA WAIVER INFORMATION

Clarity Urine Reagent Strips (CLA-10P) are CLIA waived when used with the CLIA-waived Clarity Platinum Urine Analyzer. Your facility must have a CLIA Certificate of Waiver in order to perform waived tests. *A Certificate of Waiver can be obtained from the Centers for Medicare & Medicaid Services (CMS). Visit www.cms.gov to obtain an application (Form CMS-116).* The test is only waived for urine samples. You must follow the manufacturer's instructions to perform tests 42 CFR 493.15(e)(1). You should read the complete test procedure before performing the test. See the device manual for Waived Tests for complete information. It is considered off-label use if the administrator fails to perform QC testing or fails to adhere to the intended use instructions and limitations. Off-label test results are considered to be in the high complexity category and subject to all CLIA regulations. If there is a concern regarding the testing performance, contact Clarity Diagnostics technical support at 1-877-722-6339 (M-F; 8am-5pm EST).

SUMMARY

Clarity Urine Reagent Strips (CLA-10P) for Urinalysis are firm plastic strips to which several different reagent areas are affixed. Clarity Urine Reagent Strips provide tests for Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, and Leukocytes in Urine. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and bacteriuria.[1,2] Please refer to the outside box and bottle label for the specific test parameters of the product you are using.

Clarity Urine Reagent Strips are packaged along with a drying agent in a plastic bottle with a twist-off cap. Each strip is stable and ready to use upon removal from the bottle. The entire reagent strip is disposable. Results are obtained by testing the urine reagent strip with the Clarity Platinum Urine Analyzer.

TEST PRINCIPLE

Glucose: This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with potassium iodide chromogen to oxidize the chromogen to colors ranging from blue-green to greenish-brown through brown and dark brown.

Bilirubin: This test is based on the coupling of bilirubin with a diazotized dichloroaniline in a strongly acidic medium. The colors range from light tan to reddish-brown.

Ketone: This test is based on the reaction of acetoacetic acid with sodium nitroprusside in a strongly basic medium. The colors range from a beige or buff-pink color for a "Negative" reading to pink and pink-purple for a "Positive" reading.

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

Blood: This test is based on the pseudoperoxidase action of hemoglobin and erythrocytes which catalyzes the reaction of 3,3',5,5'-tetramethyl-benzidine and buffered organic peroxide. The resulting colors range from orange to yellow-green and dark green. Very high blood concentration may cause the color development to continue to dark blue.

pH: This test is based on the double pH indicator method, where bromothymol blue and methyl red give distinguishable colors over the pH range of 5-9. The colors range from red-orange to yellow and yellow-green to blue-green.

Protein: This test is based on the protein error-of-indicator principle. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow for a "Negative" reaction to yellow-green and green to blue-green for a "Positive" reaction.

Urobilinogen: This test is based on a modified Ehrlich reaction in which *p*-diethylaminobenzaldehyde reacts with urobilinogen in a strongly acidic medium. Colors range from light pink to bright magenta.

Nitrite: This test depends on the conversion of nitrate to nitrite by the action of Gram-negative bacteria in the urine. The nitrite reacts with *p*-arsanilic acid to form a diazonium compound in an acidic medium. The diazonium compound in turn couples with 1,2,3,4-tetrahydrobenzo(h) quinolin to produce a pink color.

Leukocytes: This test is based on the action of esterase present in leukocytes, which catalyzes the hydrolysis of an indoxyl ester derivative. The indoxyl ester liberated reacts with a diazonium salt to produce a beige-pink to purple color.

REAGENTS (Based on dried weight at time of impregnation)

Glucose: 16.3%w/w glucose oxidase (Aspergillus niger, 1.3IU); 0.6%w/w peroxidase (horseradish, 3300 IU); 7.0% w/w potassium iodide; 76.1% w/w buffer and non-reactive ingredients.

Bilirubin: 0.4% w/w 2,4-dichloroaniline diazonium salt, balanced with buffer and non-reactive ingredients.

Ketone: 7.7% w/w sodium nitroprusside balanced with buffer and non-reactive ingredients.

Specific Gravity: 2.8% w/w bromothymol blue, 69.0%; poly (methyl vinyl ether/maleic anhydride); 28.2% sodium hydroxide

Blood: 6.6% w/w cumene hydroperoxide; 4.0% w/w 3, 3', 5, 5'-tetramethylbenzidine; 89.4% w/w buffer and nonreactive ingredients.

pH: 0.2% w/w methyl red; 2.8% w/w bromothymol blue; 97% w/w nonreactive ingredients.

Protein: 0.3% w/w tetrabromophenol blue; 99.7% w/w buffer and nonreactive ingredients.

Urobilinogen: 2.9% w/w *p*-diethylaminobenzaldehyde balanced with buffer and nonreactive ingredients.

Nitrite: 1.4% w/w *p*-arsanilic acid, balanced with buffer and nonreactive ingredients.

Leukocytes: 0.4% w/w indoxyl ester derivative; 0.2%w/w diazonium salt; 99.4% w/w buffer and nonreactive ingredients.

WARNINGS AND PRECAUTIONS

Urine Reagent Strips are for *in vitro* diagnostic use. Do not touch the test areas of Urine Reagent Strips.

STORAGE

Store at room temperature between 59°-86°F (15°-30°C) and relative humidity (20%) and out of direct sunlight. Do not use after expiration date.

RECOMMENDED HANDLING PROCEDURES

All unused strips must remain in the original bottle. Transfer to any container may cause reagent strips to deteriorate and become nonreactive. Do not remove desiccant from bottle. Do not open container until ready to use. Opened and properly sealed bottles are stable and should be used within 3 months when stored at optimal conditions (59°-86°F and 20% relative humidity). Protection against moisture, light, and heat is essential to guard against altered reagent reactivity. Discoloration or darkening of reagent areas may indicate deterioration. If this is evident, strips should be discarded. The strips should remain in the tightly closed canister until use. If strips are stored and exposed to extreme temperature ≥113°F (45°C) and humidity conditions (≥90% relative humidity), then the shelf life of the strips is reduced to 4 weeks after opening the bottle.

MATERIALS

Provided: Clarity Urine Reagent (CLA-10P) Strips

Not provided: Urine collection container, paper towel, gloves, and Clarity Platinum Urine Analyzer (CLA-PLTUA).

SPECIMEN COLLECTION AND PREPARATION

Collect urine in a clean container and test it 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.

TEST PROCEDURE

1. Remove one strip from the bottle and replace cap tightly.
2. Dip the strip into the urine sample and remove it immediately. Be sure that all pads on the strip are wet with the urine sample. The dipping process should not exceed 10 seconds.
3. Press the "Start" button on the Clarity Platinum Urine Chemistry Test system.
4. After pressing the Start button, the Clarity Platinum analyzer starts 10 seconds of self-calibration. During this time, touch the long edge of the strip onto a paper towel to remove the excess urine.
5. Place the test strip, with the pads facing upward, on the strip bed. Be sure that the test strip is fully inserted to the back of the strip bed.
6. An internal timer will count down while the test is processing.
7. The test results will be displayed on the screen and printed automatically.
8. Remove the test strip from the strip bed and dispose it off according to the laboratory procedure.

Note: For the best performance, ensure that the analyzer is operated under temperature 59°–86°F (15° to 30°C) and 18% to 80% relative humidity.

RESULTS INTERPRETATION

Results are obtained by testing the urine reagent strip (CLA-10P) with Clarity Platinum Urine Analyzer. Repeat testing and confirmatory testing should be performed for abnormal or flagged results.

QUALITY CONTROL

The quality control function is designed to detect, reduce, and correct deficiencies in a laboratory's internal process prior to the release of patient results. Failing to conduct Quality Control testing or carrying out QC procedures would lead to unreliable

performance of the test system which could result in misdiagnosis, delayed treatment, and increased costs due to retesting. It is, therefore, of great importance to ensure all results provided are both accurate and reliable. Each lab should establish its own standard and procedures for performance. Test known positive and negative specimens/controls at each of the following events in accordance with local, state, and/or federal regulations or accreditation requirements. For CLIA waived settings, quality controls must be tested under following conditions:

- When a new canister of strips is opened OR
- Test results seem inaccurate OR
- A new operator uses the analyzer OR
- At the beginning of each new day of testing OR
- After performing maintenance or service on the analyzer

QUALITY CONTROL TEST PROCEDURE

1. Under Main menu, select Advanced and then select Quality Control function.
2. Scan or enter barcode from the CLA-10P reagent strip bottle.
3. Select Perform QC test and scan or enter the barcode from the Urine Control I bottle.
4. Dip the strip in Urine control I or drop the Urine control I on each pad. Be sure that all pads on the strip are wet with the urine control.
5. Press "Start" button. After pressing the Start button, the Clarity Platinum Urine Chemistry Test System starts 10 seconds of self-calibration. During this time, touch the long edge of the strip onto a paper towel to remove the excess urine control sample.
6. Place the test strip, with the pads facing upward, on the strip bed. Be sure that the test strip is fully inserted to the back of the strip bed.
7. A timer will count down until the end of the test.
8. The QC test result for Control I will be displayed on the screen and printed automatically. Remove the test strip from the strip bed and dispose it off according to the laboratory procedure.
9. Once QC test for Control I passes, then you press “Next Test" to QC test with Urine Control II solution.
10. Repeat steps 3 – 7 using Urine Control II bottle and the QC test result for Control II will be displayed on the screen and printed automatically.
11. Remove the test strip from the strip bed and dispose it off according to the laboratory procedure.

If the QC tests do not provide expected results, perform the following checks:

- Ensure the strips used are not past their expiration date.
- Ensure strips are fresh from a new canister.
- Ensure the controls are at room temperature.
- Ensure the controls are not past their expiration date.
- Repeat the test to ensure no errors were made during the test.
- If QC testing still does not provide expected results, call Clarity Diagnostics Technical Support at 1(877) 722-6339.

COMPARISON AND ACCURACY:

Clinical studies using patient urine samples were conducted at three point-of-care (POC) sites for Clarity Platinum Urine Analyzer System in comparison with COBAS 6000 analyzer, pH meter, refractometer, and semi-quantitative analyzer to demonstrate accuracy and exhibit insignificant risk of an erroneous result in the hands of the operator. The exact agreement of the total tests between quantitative and semi-quantitative comparator Methods (lab professionals) and proposed Waived Method (untrained operators) was ≥97.5% overall for all the URS parameters and 97% of data points falls within the designed Allowable Total Error (ATE) zones for each color block for every analyte. In conclusion, the result of the statistical analysis demonstrates that the proposed Waived Method meets the Performance criteria for CLIA Waiver.

LIMITATIONS OF PROCEDURE

Interfering substance studies were performed to assess the interfering effect of various substances on the performance of CLA-10P strips on the Clarity Platinum Urine Analyzer. The concentrations of the potential interfering substances that did not have any influence on the test results are listed below:

Interfering Substance	Highest Concentration of substance tested which demonstrated no Interference
Ascorbic Acid	30 mg/dL
Ammonium Chloride	200 mg/dL
Albumin	≤125 mg/dL
Bilirubin	8 mg/dL
Creatine	10 mg/dL
Lithium Acetoacetate	≤60 mg/dL
Calcium Chloride	100 mg/dL
Citric Acid	50 mg/dL
Creatinine	200 mg/dL
D (+) Glucose	1500 mg/dL
Glycine	450 mg/dL
Hemoglobin	10 mg/dL
Potassium Chloride	1500 mg/dL
Sodium Chloride	4000 mg/dL
Oxalic Acid	35 mg/dL
Sodium Acetate	25 mg/dL
Sodium Nitrate	10 mg/dL
Sodium Nitrite	10 mg/dL
Sodium Phosphate	500 mg/dL
Uric Acid	150 mg/dL
Urea	4000 mg/dL
Riboflavin	10 mg/L
Theophylline	100 mg/L
D (+) Galactose	80 mg/dL
Fructose	100 mg/dL
Lactose	10 mg/dL
Leucocytes	3000 cells/µL
Blood	≤0.01%
Human Immunoglobulins	25 mg/dL
Formalin	92.5 mg/dL
Amoxicillin	30 mg/dL
Nitrofurantoin	60 mg/dL
Gentamicin sulfate	6 mg/dL
Acetaminophen	40 mg/dL

The following table shows the substances which did interfere with one or more of the Clarity Diagnostics CLA-10P strip analytes. Results are expressed as the lowest concentration of interfering substance that exhibited interference and the resulting change in output of color block.

Analyte	Concentration of Substance at which Interference was observed	Change in Color block Output
Glucose	Blood (≥ 5%), Hypochlorite (≥ 0.6%), Pyridium (≥ 50 mg/dL)	+1,
	Ascorbic Acid (≥ 75 mg/dL), Amoxicillin (≥ 100 mg/dL), Acetylcysteine (≥ 135 mg/dL)	-1
Protein	Hemoglobin (≥ 20 mg/dL), Blood (≥ 1%), Sodium Bicarbonate (1500 mg/dL), Chloroquine (≥ 20 mg/dL), Pyridium (≥ 50 mg/dL), pH (> 8.5)	+1, +2 to +3, +1 to +2, +1
	Amoxicillin (≥ 100 mg/dL), Hypochlorite (≥ 0.6%), SG (> 1.030)	-1
Bilirubin	Blood (≥ 5%), Pyridium (≥ 50 mg/dL)	+2 to +3
	Formalin (≥ 185 mg/dL), Boric Acid (≥ 500 mg/dL), Acetylcysteine (≥ 67.5 mg/dL), Hypochlorite (≥ 0.6%)	-1
Urobilinogen	Blood (≥ 1%)	+1
	Hypochlorite (≥ 0.6%)	-2
SG	Albumin (≥ 200 mg/dL), Blood (≥ 1%)	+1
	Nitrofurantoin (≥ 120 mg/dL)	-1 to -2
pH	SG (> 1.030), Sodium Bicarbonate (≥ 750 mg/dL), Sodium Phosphate (≥ 250 mg/dL), Creatinine (≥ 200 mg/dL)	+1 to +2
	Ascorbic Acid (≥75 mg/dL), Calcium Chloride (≥ 275 mg/dL), Citric Acid (≥ 50 mg/dL), Sodium Chloride (≥ 6000 mg/dL), Oxalic Acid (≥ 35 mg/dL)	-1 to -2
Blood	Albumin (200 mg/dL), Hypochlorite (≥ 0.6%)	+2
	Acetylcysteine (≥ 67.5 mg/dL)	-1
Nitrite	Blood (≥ 1%), Hypochlorite (≥ 0.6%), Pyridium (≥ 50 mg/dL)	+1
Leukocytes	Blood (≥ 1%), Pyridium (≥ 50 mg/dL)	+1 to +2,
	Glucose (≥ 2000 mg/dL), Boric Acid (≥ 500 mg/dL), Chloroquine (≥ 20 mg/dL), Amoxicillin (≥ 100mg/dL), Hypochlorite (≥ 0.6%)	-1, -1 to -2
Ketone	Blood (≥ 5%), Acetylcysteine (≥ 67.5 mg/dL), Pyridium (≥ 50 mg/dL)	+1, +2 to +3
	Hypochlorite (≥ 0.6%)	-1 to -2

Note: Use Clarity Diagnostics Urine Reagent (CLA-10P) Strips with the Clarity Platinum Analyzer. Not for visual read

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

Glucose: Moderate amounts of ketone bodies (≥ 40mg/dL) may decrease color development in urine containing small amounts of glucose (75-125 mg/dl). However, such concentration of ketone simultaneously with such glucose concentration is metabolically improbable in screening. The reactivity of the glucose test decreases as the ascorbic acid of the urine increases. Reactivity may also vary with temperature.[3]

Bilirubin: Reactions may occur with urine containing large doses of chlorpromazine or rafampen that might be mistaken for positive bilirubin.[3] Strong Indican (indoxyl sulfate) and metabolites of Lodine® may cause false positive or atypical color; [11] treatment with hypochlorite, formalin may cause false negative results.

Ketone: Color reaction that could be interpreted as “positive” may be obtained with urine specimens containing MESNA or large amounts of phenylketones or L-dopa metabolites.[3]

Specific Gravity: The chemical nature of the specific gravity test may cause slightly different results from those obtained with the specific gravity methods when elevated amounts of certain urine constituents are present. Highly buffered alkaline urine 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.

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 false positive reactions.[11]

pH: If proper procedure is not followed and excess urine remains on the strip, a phenomenon known as “running over” may occur, in which the acid buffer from the protein reagent area runs onto the pH area causing a false lowering in the pH result.

Protein: False positive results may be obtained with highly alkaline urine. Contamination of the urine specimen with quarternary ammonium compounds may also produce false positive results.[4]

Urobilinogen: The test area will react with interfering substances known to react with Ehrlich’s reagent, such as porphobilinogen and *p*-aminosalicyclic acid.[3] This 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 this test.[11]

Nitrite: The pink color is not quantitative in relation to the number of bacteria present. Any degree of pink coloration should be interpreted as a positive nitrite test suggestive of 10^5 or more organisms/ml. There are occasional urinary tract infections from organisms, which do not contain reductase to convert nitrate to nitrite.

Leukocytes: Highly colored urine and the presence of the drugs cephalexin (Keflex®), gentamicin, imipenem, and meropenem have been found to interfere with

this test.[12] High urinary protein of 500 mg/dl or above diminishes the intensity of the reaction color. Elevated glucose concentration or strong oxidizing agents may cause decreased results.

EXPECTED VALUES

Glucose: Small amounts of glucose are normally excreted by the kidney.[5]
Bilirubin: Normally no bilirubin is detectable in urine by even the most sensitive method. Even trace amounts of bilirubin 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 fasting, pregnancy, and frequent strenuous exercise.[6-8] In starvation diets, or in other abnormal carbohydrate metabolism situation, ketones appear in the urine in excessively large amounts before serum ketones are elevated.[9]
Specific Gravity: Urine may vary in specific gravity from 1.003-1.040+. Twenty-four-hour urine from normal adults with normal diets and normal fluid intake will have a specific gravity of 1.016-1.022.[10]
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: The normal pH of urine can range from 4.5-8.0. The average pH values in healthy subjects is 6.0.[3]
Protein: In 24-hour urine, 1-14 mg/dl of protein may be excreted by the normal kidney.[4] 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.[3] 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 range 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 patient. Repeated trace and positive results are of clinical significance.

SPECIFIC PERFORMANCE CHARACTERISTICS

The performance characteristics of Clarity Urine Reagent Strips (CLA-10P) have been determined both in the laboratory and in clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy, and precision. Generally, Urine Reagent Strips (CLA-10P) have been developed to be specific for the constituent to be measured with the exception of interferences listed above. (See LIMITATIONS OF PROCEDURE)
The assay reportable range of the Clarity Platinum Urine Analyzer is summarized in the table below:

Analyte	Color Block Output Units	Measuring Range
Glucose	Negative	0.0 – 75 mg/dL
	100 mg/dL	75 – 212.5 mg/dL
	250 mg/dL	212.5 – 437.5 mg/dL
	500 mg/dL	437.5 – 875 mg/dL
	1000 mg/dL	> 875 mg/dL
Bilirubin	Negative	0.0 – 0.5 mg/dL
	Small	0.5 – 1.5 mg/dL
	Moderate	1.75 – 3.0 mg/dL
	Large	> 3.0 mg/dL
Ketone	Negative	0.0 – 3.75 mg/dL
	Trace	3.75 – 10.0 mg/dL
	15 mg/dL	10.0 – 27.5 mg/dL
	40 mg/dL	27.5 – 60.0 mg/dL
	80 mg/dL	> 60.0 mg/dL
Blood	Negative	0 – 7.5 Ery/µL
	Trace	7.5 – 21.25 Ery/µL
	Small	21.25 – 52.5 Ery/µL
	Moderate	52.5 – 170 Ery/µL
	Large	> 170 Ery/µL
Protein	Negative	0.0 – 11.25 mg/dL
	Trace	11.25 – 26.25 mg/dL
	30 mg/dL	26.25 – 65 mg/dL
	100 mg/dL	65 – 200 mg/dL
	300 mg/dL	> 200 mg/dL
Nitrite	Negative	0.0 – 0.075 mg/dL
	Positive	> 0.075 mg/dL
Leukocyte	Negative	0.0 – 11.25 ca cells/µL
	Trace	11.25 – 56.25 ca cells/µL
	Small	56.25 – 111.25 ca cells/µL
	Moderate	111.25 – 406.25 ca cells/µL
	Large	> 406.25 ca cells/µL
Urobilinogen	0.2 mg/dL	0.2 – 0.6 mg/dL
	1.0 mg/dL	0.6 – 1.5 mg/dL
	2.0 mg/dL	1.5 – 3.0 mg/dL
	4.0 mg/dL	3.0 – 6.0 mg/dL
	8.0 mg/dL	> 6.0 mg/dL
pH	5.0 – 8.5	5.0 – 8.5
SG	1.005 – 1.030	1.005 – 1.030

Glucose: This test is specific for glucose; no substances excreted in urine other than glucose is known to give a positive result. The reagent area does not react with lactose, galactose, fructose, or reducing metabolites of drugs, e.g. salicylates and nalidixic acid. This test may be used to determine whether the reducing substances found in urine is glucose. Approximately 100 mg/dl glucose in urine is detectable.
Bilirubin: The test has a sensitivity of 0.4-0.8 mg/dl bilirubin in urine. The test is considered specific for bilirubin in urine.
Ketone: The ketone test area provides semi-quantitative results and reacts with acetoacetic acid in urine. This test does not react with beta-hydroxybutyric acid or acetone. The reagent area detects as little as 5-10 mg/dl acetoacetic acid in urine.
Specific Gravity: The specific gravity test permits determination of urine specific gravity between 1.000 and 1.030. In general, the specific gravity test correlates within 0.005 with values obtained with the reflective index method.
Blood: At the time of reagent manufacture, this test, when read as instructed, has sensitivity to free hemoglobin of 0.015 mg/dl or 5-10 intact red blood cells/µL urine. This test is slightly more sensitive to free hemoglobin and myoglobin than to intact erythrocytes.
pH: The pH test area permits quantitative differentiation of pH values to one unit within the range of 5-8.5. pH reading is not affected by variation in the urinary buffer concentration.
Protein: The test area is more sensitive to albumin than to globulin, hemoglobin, Bence-Jones proteins, and mucoprotein; a negative result does not rule out the presence of these other proteins. The test area is sensitive to 15 mg/dl albumin. Depending on the inherent variability in clinical urine, lesser concentration may be detected under certain conditions.
Urobilinogen: This test will detect urobilinogen in concentrations as low as 0.2 EU/dl in urine. The absence of urobilinogen in the specimen being tested cannot be determined with this test.
Nitrite: At the time of reagent manufacture, this test has sensitivity to sodium nitrite of 0.075 mg/dl. This test is specific for nitrite and will not react with substances normally excreted in the urine.
Leukocytes: This test can detect as low as 10-15 WBC/µL. This test will not react with erythrocytes or bacteria common in urine.

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LEGEND

SYMBOL	DEFINITION
	Consult Instructions for Use
	Caution, Consult Accompanying Documents
	Manufacturer
	Batch of Lot Number
	Use by Expiration Date
	Storage Temperature
	In Vitro Diagnostic Medical Device
Rx Only	Prescription use only

Manufactured For:

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