Urinalysis reagent strips (Urine)

Labgene® biotech

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

INTENDED USE

The Reagent Strip for Urinalysis are firm plastic strips onto which several separate reagent areas are affixed. Reagent Strip for Urinalysis are intended for the semi-quantitative, qualitative Urinalysis of Glucose, Protein, Ketone, pH, Leukocytes, Bilirubin, Specifi Gravity,Blood, Urobilinogen, Nitrite in human urine sample. The Reagent Strips for Urinalysis are for single use in professional near-patient (point-of-care) and centralised laboratory locations.

SUMMARY

The Reagent Strip for Urinalysis 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.

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, colours 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 colours covering the entire urinary pH range. Colours 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 testreveals the presence of granulocyte esterases. The esterases cleave a derivatisedpyrazole amino acid ester to liberatederivatisedhydroxy 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 1N-(1-naphthyl)-ethylenediamineto produce a pink colour. Nitrite is not detectable in normal urine.4The 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 colourin the presence of Proteins (anions) as the indicator releases hydrogen ions to the Protein. At a constant pH, the development of any green colouris due to the presence of Protein. High pH (up to 9), chloroquine, tolbutamide, quinine, or quinidine do not affect this test. Colours 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: 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 concentrations before serum Ketones are elevated.8 The test is based on the Legal test principle.

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 colour. 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 mol/L).3 A result of more than 1.0 mg/dL (17 mol/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 colour 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 (colours different from the negative or positive colour blocks shown on the colour 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 colourranges from yellow to green to dark blue. Any green spots or green colour 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.

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)	60 Seconds	derivatised pyrrole amino acid ester; diazonium salt; buffer; non-reactive ingredients	Detects Leukocytes as low as 10-15white 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 0.05-0.1mg/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 12~15mg/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 25-40mg/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 5mg/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'-tetramethylbenzidine (TMB); diisopropylbenzene dihydroperoxide; buffer and non-reactive ingredients	Detects intact Erythrocytes as low as 5~10 Ery/µL or 0.015~0.03mg/dl Hemoglobinin urine specimens with ascorbic acid content of < 50 mg/dL.

The performance characteristics of the Reagent Strips for Urinalysis (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 colour perception, the presence or absence of inhibitory factors, and the lighting conditions when the strip is read. Each colour block on the chart corresponds to a range of analyte concentrations.

PRECAUTIONS

- For in vitrodiagnostic 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 discoloured 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 consume.

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.

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 stabilisers 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 PROVIDED

- Strips
- Colour chart
- Package insert

MATERIALS NOT PROVIDED

- Timer
- Specimen collection container

Urinalysis reagent strips (Urine)

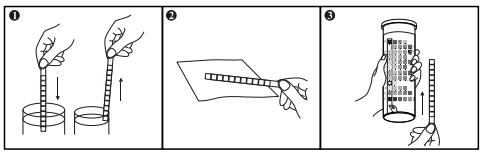
DIRECTIONS FOR USE

Allow the strip, urine specimen, and/or controls to reach room temperature (2-30ºC) prior to testing.

1. Remove the strip from the closed Container and use it as soon as possible. Immediately close the Container 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 at 60 seconds for all reagent areas, by comparing the reagent areas to the closest corresponding colour blocks on the colour chart.

Note:

- Always hold the strip close to the colourchart and compare carefully.
- Do not read results after 2 minutes from the specified times.
- Do not read results if colourchanges 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 colourblocks.
- Results may also be read using the Urine Analyzer. Refer to the Instruction Manual for details.



INTERPRETATION OF RESULTS

Results are obtainedby direct comparison of the colourblocks printed on the colourchart. The colourblocks 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 Reagent Strips for Urinalysis may be affected by substances that cause abnormal urine colour such as drugs containing azo dyes (e.g. Pyridium®, Azo Gantrisin®, Azo Gantanol®), nitrofurantoin (Microdantin®, Furadantin®), and riboflavin.3The colour development on the test pad may be masked or a colour reaction may be produced that could be interpreted asfalse 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 300mg/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 colourchart.

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 colour development. The intensity of the colour that develops is proportional to the number ofLeukocytes 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 colour. 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 colour should be interpreted as a positive result, suggesting the presence of Nitrite. Colour 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 absent.

Protein: This test is highly sensitive for albumin, and less sensitive to Hemoglobin, globulin and mucoprotein.3Contamination 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 5.5 mmol/Land 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.3Urine specimens of high pigment, captopril, mesna, and other substances containing sulfhydryl groups occasionally react may give false positive results.4Phenylketone and phthalein compounds can produce red colouration on the edges of the reagent area, but are different than the violet colours 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 atrace positive, indicates an underlying pathological condition and requires further investigation. Reactions may occur with urine containing large doses of chlorpromazine orrifampenthat might bemistaken for positive Bilirubin.4The presence of Bilirubin-derived bile pigments may mask the Bilirubin reaction. This phenomenon is characterized by colour development on the test patch that does not correlate with the colours on the colourchart. Largeconcentrations of Ascorbic Acid may decrease sensitivity.

Blood: A uniform blue colourindicates the presence of myoglobin, Hemoglobin or hemolyzed Erythrocytes.3Scattered or compacted blue spots indicate intact Erythrocytes. To enhance accuracy, separate colourscales 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 colourformation.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.

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INDEX OF SYMBOLS

REF	Product Reference No.	ISO 13485	International Organization or Standardization
	Manufacturer		Keep out of Sunlight
	Expiry date	IVD	For invitro diagnostic use only
LOT	Lot (batch) number		Read product insert before use.
2°C 30°C	Store between 2-30°c		Do not use if package is damaged
	Do not reuse		Keep Away From Moisture
	Contains sufficient for test	ART/IFU-306-00	

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