Urineysis Reagent Strips (Urine) Package Insert

REF U031-001
REF U031-002
REF U031-061
REF U031-101
English

For rapid detection of albumin, bilirubin, leukocytes and pH in urine.

INTENDED USE

The Mission Urineysis Reagent Strips (Urine) are for the qualitative and semiquantitative detection of albumin, bilirubin, leukocytes and pH in urine. These reagent strips are intended for professional use only. The strips are intended for use in screening at risk populations when albumin in urine is being used as an indicator of health or disease, and as such, is part of routine medical screening. The Mission Urineysis Reagent Strips (Urine) are designed to provide a rapid, accurate, and easy-to-read result presentation that allows for the detection and aids in the diagnosis and monitoring of metabolic or systemic diseases that affect kidney function, metabolism, liver and intestinal function.

PRINCIPLE AND EXPECTED VALUE

Glia:me: This test is based on the enzymatic reaction that occurs between glucose oxidase, diaphorase and tetramethylbenzidine. Glucose is first oxidized to gluconic acid catalyzed by glucose oxidase. The oxidized glucose oxidase is then reduced by diaphorase to produce a blue color. The intensity of the color that develops is proportional to the number of glucose molecules oxidized.

Bilirubin: This test is based on the reaction of bilirubin with nitric acid and catalyzed by tetramethylbenzidine to produce a pink color. The intensity of the color that develops is proportional to the number of bilirubin molecules present.

Leukocytes: This test is developed to be specific for the parameters to be measured with the exceptions of the leukocyte, which is determined by a derivatized pyrazole amino acid ester to liberate derivatized hydroxy pyrazole. This test reveals the presence of granulocyte esterases. The esterases cleave a derivatized pyrazole amino acid ester to liberate derivatized hydroxy pyrazole. This test develops a color change ranging from light pink for negative results to a darker pink or brown for positive results.

pH: This test is based on the pH indicator principle. The reagents are impregnated with the pH indicator (tetrazolium tetrahydrobromide) so that its color can be read on the color chart. The intensity of the color that develops is proportional to the number of hydrogen ions in the urine specimen.

Ketone: This test is based on ketones reacting with nitroprusside and catalyzed by tetramethylbenzidine to produce a pink color. The intensity of the color that develops is proportional to the number of ketone bodies present in the urine specimen.

Specific gravity: This test is based on the phenol red indicator principle. The reagents are impregnated with phenol red so that its color can be read on the color chart. The intensity of the color that develops is proportional to the number of hydrogen ions in the urine specimen.

PRODUCER'S LITERATURE

Urineysis Reagent Strips (Urine) for detecting albumin, bilirubin, leukocytes and pH in urine.

METHOD

Using undermagnified changes during state of disease or body dysfunction present. The result is the expected value for each parameter. The expected range for each parameter in urine is given in Table 2. The expected range for normal urine is shown in Fig. 1. The expected range for normal urine is shown in Table 4.

PRECAUTIONS

Proteinuria: This test is based on the phenomenon known as the "protein error" of pH measurement. It has been reported that urine of high pH reduces sensitivity, while moderate to high pH increases sensitivity, and may result in false positive results. The pH test is highly sensitive for albumin, and less sensitive to hemoglobin, globulin and other proteins.

Bilirubin: This test is specific for bilirubin. The presence of bilirubin is known to be a major cause of jaundice in newborns. Bilirubin is produced by the breakdown of red blood cells and is excreted in the urine. Bilirubin is highly colored and gives a strong positive reaction.

Specific gravity: This test is based on the phenomenon known as the "protein error" of pH measurement. It has been reported that urine of high pH reduces sensitivity, while moderate to high pH increases sensitivity, and may result in false positive results. The pH test is highly sensitive for albumin, and less sensitive to hemoglobin, globulin and other proteins.

Urobilinogen: All results lower than 1 mg/dL, urobilinogen should be interpreted as normal. A negative result does not at any time preclude the detection of the disease state.

Leukocytes: The pH test is specific for bilirubin and will not react with any other substance in the urine. The pH test is used to determine the degree of glycogen storage in the urine. The pH test is used to determine the degree of glycogen storage in the urine.

Ketone: This test is based on ketones reacting with nitroprusside and catalyzed by tetramethylbenzidine to produce a pink color. The intensity of the color that develops is proportional to the number of ketone bodies present in the urine specimen.

INTERPRETATION OF RESULTS

For best results, performance of reagent strips should be confirmed by testing known positive and negative specimens. The following times should be used for reading the results:

- Albumin: 65 seconds
- Bilirubin: 3 minutes
- Ketone: 2 minutes
- pH: 1 minute
- Leukocytes: 2 minutes
- Specific Gravity: 2 minutes

Therefore, the color that develops is proportional to the number of glucose molecules oxidized.

- For in vitro diagnosis only. Do not use after the expiration date.
- Do not store the reagent strips past the expiration date.
- Do not touch the reagent strips and do not discard them after use.
- All samples should be considered potentially hazardous and handled in the same manner as other clinical specimens.

Stips: Strips should not be used if the reagent strips are not within the expiration date.

For urine specimens used for testing of urine, serum, plasma and milk, the following times should be used for reading the results:

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- Bilirubin: 3 minutes
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- Specific Gravity: 2 minutes

This test is based on the phenomenon known as the "protein error" of pH measurement. It has been reported that urine of high pH reduces sensitivity, while moderate to high pH increases sensitivity, and may result in false positive results. The pH test is highly sensitive for albumin, and less sensitive to hemoglobin, globulin and other proteins.

Note: As with all laboratory tests, diagnostic and therapeutic decisions should not be based on a single test result. Additional laboratory testing should be performed to confirm the accuracy of the test result. Consult your laboratory manual for additional information.

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