URINE STRIPS

CAT NO	DESCRIPTION	PACK SIZE
URN10S1	DECASTIX – 10 parameter Urine strips: Leucocytes / Nitrates / pH / Protein / Glucose / UBG / Bilirubin / Ketones / Blood / Specific Gravity	100 Strips
URN11S2	ENDEKASTIX – 11 parameter Urine strips: Leucocytes / Nitrates / pH / Protein / Glucose / UBG / Bilirubin / Ketones / Blood / Ascorbic Acid / Specific Gravity	100 Strips
URN03S3	TRISTIX – 3 parameter Urine strips: Glucose / pH / Proteins	100 Strips
URN02S4	DIOSTIX – 2 parameter Urine strips: Glucose / Ketones	100 Strips

Intended Use:

Urine strips Decastix, Endekastix, Tristix and Diostix are intended for semi-quantitative analysis of urine. This reagent is for In vitro Diagnostic use only.

Summary and Principle:

Analyte wise description of the principle is provided below.

Storage and Stability:

Store the test strips in the tube provided tightly capped at 2-30^{o}C in a dark place. The strips must be stored away from moisture, direct sunlight, elevated temperature and chemical fumes in the laboratory. When stored under these conditions, the test strips are stable up to expiry given on the vial label.

Reagent Composition:

Urine strips	Specific gravity	Poly9methylvinylether/maleic acid) 32%, bromothymol blue 5.1%
	Leucocytes	Indoxyl ester 0.43%, Diazonium salt 0.05%
	Nitrite	Sulphanilamide 5.1%, Tetrahydrobenzoquinoline 5.8%
	pH	Methyl red 0.71%, Bromothymol blue 12.1%
	Ascorbic Acid	Phosphomolybdic acid 26%
	Protein	Tetrabromophthalein ester 0.21%, tetrabromphenol blue 0.35%
	Glucose	Glucose oxidase 1.3%. Peroxidase 1.3%, Tetramethylbendizine 21%
	Ketones	Sodium Nitroprusside 4.9%
	Urobilinogen	Diazonium Salt 2.3%
	Bilirubin	Diazonium salt 0.75%
	Blood	Tetramethylbenzidine 1.5%, Cume hydroperoxide 15.2%

Precautions:

- Treat the used test strip as potentially infectious and dispose of in accordance with the local regulations.

Interferences:

Semi-quantitative analysis is not sufficient for complete diagnosis, use the results obtained in conjunction with results from other diagnostic assays. Knowledge of the effects of drugs or their metabolites upon individual tests is not completely known. Repeat where required or when results are inconclusive.

Principle:

Specific Gravity: This test is based on the principle of ion exchange which runs between polyelectrolyte and ions present in the urine. The result of this is a colour change of the acid base indicator from blue green colour in urine with low concentration of ions, through green and yellow green in urine with increased concentration of ions, to amber yellow colour. Using this test it is possible to determine specific gravity of urine in the range of 1.000 up to 1.3000. The first morning urine of healthy persons should be in the range of 1.015 to 1.025.

Leucocytes: This test is based on enzymatic reaction. The test pad contains an indoxyl ester that is cleaved by granulocyte esterases. The released indoxyl reacts with a diazonium salt and pink or violet colouration is formed. The colour intensity is proportional to the amount of leucocytes in the sample and is evaluated at 120 seconds after dipping the strip into the urine sample.

Nitrites: This test is based on conversion of nitrate to nitrite by the action of certain species of bacteria contained in the urine. The colour test is based on the principle of the Griess test. Any degree of pink colouration should be interpreted as a positive nitrite test suggestive of 10^5 or more organisms in 1ml of urine. The colouration of the pad is not quantitatively proportional to the amount of bacteria present in urine. Negative results do not exclude significant bacteriuria as insufficient incubation may have occurred and some organisms causing urinary tract infections do not contain nitrate reductase to convert nitrate to nitrite. For these reasons the identification of known positive cases with nitrite test is about 70%. We recommend testing the first morning specimen, when long bladder retention has occurred.

pH: This test is based on the double indicator principle and gives a range of colours from orange through yellow and green to blue and permits differentiation to within 0.5 pH unit in the range of pH 5.0 – 9.0.

Ascorbic Acid: This test is based on the reaction of phosphomolybdic acid which is reduced by ascorbic acid to molybdenum blue. The test is not specific for ascorbic acid because the green to greyish blue colour of the test pad is exhibited also by other strongly reducing substances present in urine such as gentisic acid and other acetylsalicylic acid metabolites. We recommend carrying out determination of ascorbic acid in urine especially in cases, in which ascorbic acid may disturb the tests for other urine constituents such as glucose, blood and nitrite.

Protein: This test is based on colour change of acid base indicator which is caused by presence of proteins. It is particularly sensitive to albumin but is much less sensitive to globulin, mucoprotein, haemoglobin and Bence-jones protein.

Glucose: This test is based on the specific glucose oxidase/peroxidase reaction and is specific for D-glucose. The reagent pad does not react with other sugars. It reacts with presence of D-glucose by green to dark green colouration.

Ketones: The test is based on the principle of Legal's test and is more susceptible to acetoacetic acid than to acetone. Test does not react with beta hydroxybutyric acid. The colour scale is calibrated for acetoacetic acid.

Urobilinogen: This test is based on the coupling of urobilinogen with stabilized reagent. The test is specific for urobilinogen and stercobilinogen and is not susceptible to the interfering factors known as Ehrilich's test.

Bilirubin: This test is based on the coupling of bilirubin with stabilized reagent.

Blood: This test is based on the peroxidase activity of haemoglobin which catalyses the oxidation of the indicator due to the presence of the organic hydroperoxide contained in the diagnostic pad. The label contains two colour scales: for detection of intact erythrocytes and free haemoglobin. This test is highly sensitive to free haemoglobin and may detect its presence from concentrations corresponding to approximately 5 Ery/ul

Limitations:

Specific Gravity: The reaction is not affected by pH values of urine over 6.5 shift colour response towards lower values of specific gravity.

Leucocytes: In case a urine sample is more markedly coloured (increased bilirubin) the resulting colour could be affected by a sample colouration. The intensity of the colour reaction is increased by alkaline pH and higher urine density.

Nitrites: Before testing the patient should intake vegetable rich meals and discontinues antibiotic therapy and Vitamin C for 3 days prior to the test. Sensitivity of this test decreases with high specific gravity of the urine. Increased diuresis can cause false negative results. Limited fluid intake prior to testing can prevent from the excessive dilution of urine. Test can be applied only to fresh urine. Inaccurate results may occur in stake urines, in which nitrite can be formed by contamination of the specimen.

Protein: In strongly alkaline urines (pH >8.0) from patients on medication of quinine or quinolone containing drugs, false positive reading may be obtained. False positive reactions may be found when the urine collection vessel contains traces of disinfectants with quaternary ammonium compounds. On the other hand, in the presence of non-ionic or anionic detergents, a false negative reading may be obtained. Do not take the colour of the dry pad into consideration.

Glucose: The reaction is independent upon the pH and presence of ketone bodies.

Ketones: Drugs and diagnosis on the basis of phenolphthalein or sulphophthalein may turn red to purple because of alkaline reaction of the pad.

Urobilinogen: The reaction is not affected by the pH of the urine. The presence of bilirubin gives yellow colour. This colour which turns slowly to greenish-blue does not interfere with urobilinogen determination provided the reading is made 1 minute after wetting. The urine specimen should not be exposed to direct sunlight as this promotes the oxidation of urobilinogen and this leads to artificially low or false negative results.

Bilirubin: The urine specimen should not be exposed to direct sunlight as this promotes the oxidation of bilirubin and thus leads to artificially low or false negative readings. High concentrations of urobilinogen (above 100 umol/l) interfere with the test. Phenozopyridine which turns red in low pH if present in the urine will affect the result. The reaction is not affected by the pH of the urine.

Blood: Microbial peroxidase associated with urinary tract infection may cause a false positive reaction. The sensitivity of the test is influenced by specific gravity or by inhibitors of pharmacological origin.

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		

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