TANNER scientific®

10 Reagent Strips for Urinalysis

INTENDED USE

Tanner Scientific® 10 Reagent Strips for Urinalysis are in vitro diagnostic test devices that use reagents for qualitative and semi-quantitative urinalysis. The strips are for professional use only. They are intended for use to detect conditions indicating possible diabetes, metabolic abnormalities, liver diseases, kidney function, and urinary tract infections. Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed. They can be read visually and instrumentally.

SUMMARY & EXPLANATION OF TESTS

Tanner Scientific® 10 Reagent Strips for Urinalysis provide tests for Glucose, Bilirubin, Ketone (acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes in urine.

TEST PRINCIPLES

Urobilinogen: Based on the Ehrlich reaction in which p-diethylamino benzaldehyde, in conjunction with a color enhancer, reacts with urobilinogen in a strong acid medium to produce a pink-red color.

Bilirubin: The direct bilirubin and dichlorobenzene diazonium produce fuchsia azo dyes in a strong acid medium.

Ketone: The acetoacetate and sodium nitroprusside cause a reaction in the alkaline medium, which produces a violet color.

Blood: Hemoglobin acts as a peroxidase. It can cause peroxidase to release neo-ecotypes oxide (O). (O) oxidizes the indicator and causes the color change.

Protein: The test is based on the protein-error-of-indicators principle. An ion in the specific pH indicator, attracted by cations on the protein molecule, makes the indicator further ionized, which changes its color.

Nitrite: Nitrite in the urine and aromatic amino sulphanilamide are diazotized to form a diazonium compound. The diazonium compound reacting with tetrahydro benzo(h) quinolin 3-phenol causes the color change.

Leukocytes: Granulocyte leukocytes in urine contain esterase that catalyzes the hydrolysis of the pyrrole amino acid ester to liberate 3-hydroxy-5-pheny pyrrole. This pyrrole reacting with diazonium forms a purple color.

Glucose: The glucose oxidized by glucose oxidase catalyzes the formation of glucuronic acid and peroxide hydrogen. Peroxide hydrogen releases neo-ecotypes oxide (O) under the function of peroxidase. (O) oxidizes iodide potassium, which causes the color change.

Specific Gravity: Electrolyte (M^+X^-) in the form of salt in urine reacts with poly methyl vinyl ether and maleic acid (-COOH), which is a weak acid ionic exchanger. The reaction produces hydrogenous ionogen, which reacts with a pH indicator that causes the color to change.

pH: This test is based on a double indicator principle that gives a broad range of colors covering the entire urinary pH range.

REACTIVE INGREDIENTS *(based on dry weight at time of impregnation)*

Urobilinogen: 0.2% w/w fast blue B salt; 98.0% w/w buffer; 1.8% w/w nonreactive ingredients

Bilirubin: 0.6% w/w 2,4-dichlorbenzene amine diazonium salt; 57.3% w/w buffer; 42.1% w/w nonreactive ingredients

Ketone: 5.7% w/w sodium nitroprusside; 64.4% w/w buffer; 29.9% w/w nonreactive ingredients

Blood: 26.0% w/w diisopropylbenzene dihydro peroxide; 1.5% w/w tetramethyl-benzidine; 35.3% w/w buffer; 37.2% w/w nonreactive ingredients

Protein: 0.1% w/w tetrabrompenol blue; 97.4% w/w buffer; 2.5% w/w nonreactive ingredients

Nitrite: 1.3% w/w p-arsanilicacid-N-(1-Naphthol)-ethylenediamine; 0.9% w/w tetrahydro-quinoline; 89.6% w/w buffer; 8.2% w/w nonreactive ingredients

Leukocytes: 4.3% w/w pyrrole amino acid ester; 0.4% w/w diazonium salt; 92.6% w/w buffer; 2.7% w/w nonreactive ingredients

Glucose: 1.7% w/w glucose oxidase (microbial, 123U); 0.2% w/w peroxidase (horseradish, 203IU); 71.8% w/w buffer; 0.1% w/w potassium iodide; 26.2% w/w nonreactive ingredients

Specific Gravity: 4.8% w/w bromthymol blue; 5.0% w/w sodium hydroxide; 90.2% w/w poly (methyl vinyl ether co maleic anhydride)

pH: 3.3% w/w bromcresol green; 55.0% w/w bromthymol blue; 41.7% w/w nonreactive ingredients

STORAGE

Strips can be stored in room temperature and closed package up to 18 months from the manufacture date. If exposed to air with temperature of 15-30°C and relative humidity of 65-85%, the strips can be stored at least 12 hours. Strips must be kept in the original bottle. Transfer to any other container may shorten the expiration date of product. Store at temperatures between 2-30°C (39-86°F). Keep away from direct sunlight and moisture. Do **NOT** remove desiccants in the bottles. Replace the cap immediately after removing reagent strips. Protect against exposure to light, heat, and ambient moisture to guard against altered reagent reactivity.

SPECIMEN COLLECTION & PREPARATION

Collect fresh urine in a clean and dry container. Do **NOT** centrifuge the urine. Mix the sample well before testing it.[1] The container should allow for complete dipping of all reagent strip areas. Test the urine within four hours after voiding, sooner if testing for bilirubin or urobilinogen.[2]

EXPECTED RESULTS

The sensitivity of ***Tanner Scientific® 10 Reagent Strips for Urinalysis*** in testing clinical urine specimens may vary depending upon several factors, such as the variability of color perception, specific gravity, pH values, and the lighting conditions when strips are read visually. Visual reading results may not exactly match instrumental reading results because of the difference between the perception of human eyes and the optical instrument. Most visual and instrument readings are within one level of the true value. The following table shows expected values for all tests analytes for a normal healthy population based on published literatures.[2][5]

Urobilinogen	0.2-1mg/dL
Bilirubin	Neg
Ketone	Neg
Blood	Neg
Protein	Neg or Trace
Nitrite	Neg
Leukocytes	Neg
Glucose	Neg
Specific Gravity	1.000-1.030
pH	5.0-8.0

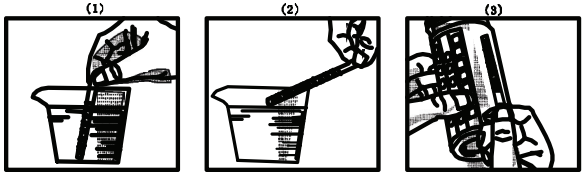
PROCEDURE

Gather Materials

1) Dry and Clean Plastic Container
2) Toilet Paper
3) Watch w/Second Hand or Stopwatch (if reading visually)
4) Urinalysis Reagent Strips
5) Urine Analyzer (if reading instrumentally)

PERFORM TESTS

1) Immerse the reagent area of the strip in the urine specimen and take it up quickly and immediately. Start timing if reading visually.
2) Run the edge of the strip against the rim of the container to remove excess urine. Lay the strips on a paper towel with the reagent areas upward.
3) If reading visually, hold the strip up horizontally in good light and compare the reagent areas on the strip to the corresponding color chart on the bottle label at the exact times specified. Hold strips close to the color blocks and match carefully. Make note of the result. Color changes after 2 minutes are of no diagnostic value. If reading by instrument, carefully follow the directions given in the operating instructions. The instrument will automatically read each reagent area at a specified time.
4) Dispose of strips with laboratory waste. Do **NOT** flush down toilet.



QUALITY CONTROL

Remove one strip from the bottle and check against the color blocks on the color chart. If the color of the reagent area is darker than the lowest block on the chart (except for specific gravity and pH), the strip is unusable. Discard the strip and check all strips from the bottle before using or discard the bottle. When a new bottle is first opened, use two strips to test known negative and positive controls.

+ Test QC per your laboratory policies and follow local, state and federal regulations.
+ Test commercially available positive and negative quality controls with each new lot, each new shipment of strips, and when you open a new bottle of reagent strips.
+ **Note: Water is NOT an appropriate negative control.**
+ Test the strips monthly that are stored for more than 30 days.
+ Run QC tests to ensure reagent storage integrity, train new users, confirm test performance, and when patients' clinical conditions or symptoms don't match the results obtained on the test strips.

IMPORTANT NOTES

1) Do **NOT** take the strips from the bottle unless they are for immediate use.
2) Do **NOT** touch reagent areas of strips.
3) Do **NOT** use strips beyond the expiration date.
4) Each strip can be used only once.
5) Large amounts of ascorbic acid may affect the test for glucose, bilirubin, nitrite, and blood.[2][4]
6) Deterioration may result in discoloration or darkening of the reagent areas of the strip. If this happens, or the test results are questionable or inconsistent with expected results, check and make sure the strips are within the expiration date, and also check results with the control urine.

BIBLIOGRAPHY

(1) "Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline"; NCCLS Document GP16-A (ISBN 1-56238-282-9); 1995. NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA19087, USA.
(2) "European Urinalysis Guidelines", the Scandinavian Journal of Clinical & Laboratory Investigation, Scand J Clin Lab Invest-Vol. 60-Supplement 231.2000.
(3) "Operating Rules Of Clinical Test" (Rev.2), the Ministry of Health of P.R.C. Publishing. Yingwu Ye, Yusan Wang.
(4) "The Clinical Analysis of Urine Recent Period", The Science and Technology Publishing House, Yu Long Cong, Jun Long Ma, Editors; 1998; pp. 37-81, 96-97.
(5) "Compendium – Urinalysis With Test Strips" Roche Diagnostic, Combur® Reagent Strips.

LIMITATIONS

Urobilinogen: The reagent area may react with interfering substances such as sulfonamides. Atypical color reactions may be obtained in the presence of high concentrations of p-amino salicylic acid. False negative results may be obtained if formalin is present and the specimen has been in direct sunlight. The test is not a reliable method for the detection of porphobilinogen.[4]

Bilirubin: Medicines that dye urine red and anything that shows red in an acid medium (Example: phenzaopyridine) may affect the test result. A high concentration of ascorbic acid (2.8 mmol/L) may cause a false negative result.

Ketone: False positive results may occur in highly pigmented urine or those specimens containing a large amount of levodopa metabolites.[2]

Blood: Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction. A high specific gravity in urine may reduce the sensitivity of the test.[2]

Protein: False positive results may be obtained with highly buffered or alkaline urines. Contamination of the urine specimen with quaternary ammonium compounds (from some antiseptics and detergents) or with cleansers containing chlorhexidine may also produce false positive results.[2][4]

Nitrite: A negative result does not rule out significant bacteriuria. False negative results may occur 1) when urine does not contain the organism that caused the conversion from nitrate to nitrite, 2) when urine has not remained in the bladder long enough (up to 4 hrs) for the nitrate to convert into nitrite, or 3) when nitrate in foods is absent. A high specific gravity of urine may reduce the sensitivity of the test. A 2.8 mmol/L concentration of ascorbic acid or less will not affect the test result.[2][4]

Leukocytes: A high glucose concentration (20 g/L) or a high specific gravity in urine may reduce the sensitivity of the test. High concentration of oxalic acid may cause decreased test results. Tetracycline may cause decreased reactivity, and high levels of tetracycline may cause a false negative reaction.[2]

Glucose: Ascorbic acid concentrations of 0.28 mmol/L and/or acetoacetic acid concentrations of 1.1 mmol/L or lower will not influence the test.[2]

Specific Gravity: Urine nonionic constituents such as glucose or highly buffered alkaline urine may produce low readings compared to other methods. Elevated specific gravity readings may occur in the presence of moderate quantities of protein (1.0 g/L). The reagent strip is not suitable for testing newborns because of their low specific gravity (1.002-1.004).[4]

pH: Bacterial growth in a specimen may cause a marked alkaline shift (>8.0), usually because of urea conversion to ammonia.

SENSITIVITY & OUTPUT VALUES OF REAGENT STRIP FOR URINALYSIS

ITEM	SENSITIVITY	OUTPUT VALUE
Urobilinogen (mg/dL)	1.6	0.2-8
Bilirubin (mg/dL)	1	0-6
Ketone (mg/dL)	3	0-160
Blood (cell/µL)	7	0-200
Protein (mg/dL)	10	0-2000
Nitrite (µg/dL)	0.2	Pos-Neg
Leukocytes (cell/µL)	12	0-500
Glucose (mg/dL)	70	0-2000
Specific Gravity	-	1.000-1.030
pH	-	5.0-8.5

NOTES ON SYMBOLS & MARKS

+30°C / +2°C	Store At	LOT	Batch Code
	Use By Expiration Date	2	Single Use
	Please Read Package Insert	IVD	In Vitro Diagnostic Use

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