PRECISTIX 10P

(Urinalysis Dipstick Test Strips)

FOR IN-VITRO DIAGNOSTICS USE ONLY

A) INTRODUCTION

Urine strip test is a basic diagnostic tool used to determine pathological changes in a patient's urine in standard urinalysis. Which react (change color) when immersed in, and then removed from, a urine sample. The test can often be read in as little as 60 seconds after dipping. The urine stick test is the first step in the diagnosis of a wide range of diseases. The analysis includes testing for the presence of Blood, Bilirubin, Urobilinogen, Ketone, Protein, Nitrate, Glucose, pH, Specific Gravity & Leucocytes in human urine.

This type of analysis is very common in the control and monitoring of various malfunctioning of human body through human urine.

B) PRODUCT CATEGORY PARAMETER WISE

Name of Product	Parameters									
	Blood	Bilirubin	Urobilinogen	Ketone	Protein	Nitrite	Glucose	pH	SG	Leucocyte
Urine Strip 10P	✓	✓	✓	✓	✓	✓	✓	✓	✓	

C) TEST PRINCIPLE:

- LOOD (RBC/µL): This test is based on the peroxidase-like activity of hemoglobin, which catalyzes the reaction of organic hydroperoxide and TMB. The resulting color ranges from yellow to greenish blue
- BILIRUBIN (mg/dL): This test is based on azo-coupling reaction of bilirubin with a diazonium salt in an acid medium to form an azodye. The resulting color ranges from white to dark pink.
- UROBILINOGEN (mg/dL): This test is based on a modified Ehrlich reaction, in which 4-diethylaminobenzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium to produce a pink color. The resulting color ranges from light tan to pink.
- KETONE (mg/dL): This test is based on the reaction of acetoacetic acid (the physiological ketone) with sodium nitroprusside in a strongly basic medium. The colors range from beige or light tan for a 'negative' reading, to pink and pink-purple for a 'positive' reading.
- PROTEIN (mg/dL): The test is based on the 'Protein-error' of the indicator. The protein in the urine combines with the blue divalent anionic form of the indicator. This results in the dissociation of the yellow monovalent anion into the blue divalent anion. Although the test strip is buffered to a constant pH, a color change from yellow through green to blue will occur in the presence of protein.
- NITRITE (mg/dL): This test is based on diazotization reaction of nitrite with an aromatic amine to produce a diazonium salt. It is followed by an azo-coupling reaction of this diazonium salt with an aromatic compound on the reaction pad. The azo dye produced causes a color change from white to pink.
- GLUCOSE (mg/dL): 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.
- pH (pH value): The test is based on the 'Protein-error' of the indicator. The protein in the urine combines with the blue divalent anionic form of the indicator. This results in the dissociation of the yellow monovalent anion into the blue divalent anion. Although the test strip is buffered to a constant pH, a color change from yellow through green to blue will occur in the presence of protein.
- SPECIFIC GRAVITY (SG value): The test reflects the ion concentration of urine and correlates well with the refractometric method. In the presence of cat ions, protons are released by a complexing agent and produce a color change in the indicator bromothymol blue from blue via blue-green to yellow.
- LEUCOCYTES (WBC/µL): Granulocytic leucocytes contain esterases that catalyze the hydrolysis of the derivatized pyrrole amino acid ester to liberate 3-hydroxy-5-phenyl pyrrole. This pyrrole then reacts with a diazonium salt to produce a red-purple product.

D) INTENDED USE

Urine Strip 10P test Strips for semi-qualitative determination of Blood, Bilirubin, Urobilinogen, Ketone, Protein, Nitrate, Glucose, pH, Specific Gravity & Leucocytes in human urine.

E) CONTENTS OF KIT

01. Urinalysis Test Strips	: 100 Nos.
02. Desiccant pouch	: 01 No.
03. Product insert	: 01 No.

F) STORAGE & STABILITY

Store at room temperature between 2 ~ 30°C. Do not store at refrigerator. Do not use product after expiration date. Do not store the product in direct sunlight. the product shelf-life is 24 months from date of manufacturing. Once the bottle has been opened; the remaining strips are stable for up to 08 months.

G) WARNING & PRECAUTIONS

- Instruction must be followed as per given in product insert prior to test perform.
- Do not use expired kit.
- Use separate or cleaned containers for each sample to avoid cross contamination.
- After strips removing from bottle for test performing, the remaining strips must be kept in original bottle with silica gel and replace the cap tightly closed to maintain test reactivity.
- Do not throw away used strip any were discard it in proper way.
- Urine Reagent Strips are for in vitro diagnostic use only. Do not touch test areas of Urine Reagent Strips.
- Do not re-use the test strips.
- Do not use any human body fluid as a specimen other than urine.
- Use of disposable gloves and bio-hazardous clothing while running the test.
- The Test shall be performed by competent person only.
- All materials used in the assay and samples should be disposed off in accordance with established safety procedures.
- Spills should be decontaminated promptly with IPA or any other suitable disinfectant.

H) SPECIMEN COLLECTION AND PREPARATION/ PRECAUTIONS

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 is not recommended. If testing cannot be done within an hour after sample collection, refrigerate the specimen immediately and let it return to room temperature before testing. Prolonged storage of urine at room temperature may result in microbial proliferation with resultant changes in pH. A shift to alkaline pH may cause false positive results with the protein test area. Urine containing glucose may decrease in pH as organisms metabolize the glucose. Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein test results.

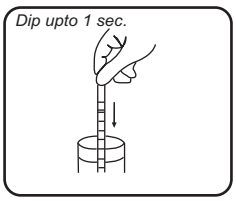
I) TEST PROCEDURE

- Allow all kit components and specimen to room temperature (15-30°C) prior to performing test.
- Collect urine in a clean container and test it as soon as possible. Do not centrifuge.
- Remove the test strips from the closed containers and use it immediately or as soon as possible. close the container tightly after removing the required number of strips.
- Completely immerse the reagent areas of the strips in fresh well mixed urine for ½ seconds and immediately remove the strip.
- While removing the strips from the urine, run the edge of the strip against the rim of the urine container and wipe the excess urine, hold the strip in horizontal position and bring the edge of the strip of the contact with absorbent materials (Example tissue paper) to avoiding mixing chemical from adjacent reagent areas and to remove excess urine.
- Wait for reaction and read the results at 60 seconds. Do not read results after 60 seconds.

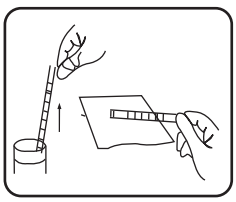
PRECISION®
Be Sure ....

- ICompare the reagent area to corresponding color band on the color-chart label provided in the surface of bottle. see fig-01.

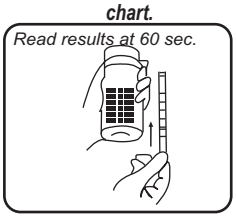
Step-1
Dip the strip in urine sample.



Step-2
Wipe the excess urine.



Step-3
Read Visually with color chart.



.....INSTRUCTION FOR USE.....

J) SENSITIVITY & LIMIT OF DETECTION:

Test Parameters \ Results		Negative (-)	Trace (±)	Positive +	++	+++	++++	
Blood	Conc. (RBCs/µL)	0		10	50	250		
Bilirubin	Conc. (mg/dL)	0		0.5	1	3		
Urobilinogen	Conc. (mg/dL)	(normal) 0.1	(normal) ↔	(normal) 1	4	8	12	
Ketone	Conc. (mg/dL)	0	5	10	50	100		
Protein	Conc. (mg/dL)	0	10	30	100	300	1000	
Nitrite	Conc. (mg/dL)	0		0.5				
Glucose	Conc. (mg/dL)	0	100	250	500	1000	2000	
pH	pH value	5.0	6.0	6.5	7.0	7.5	8.0	9.0
Specific Gravity	SG value	1.000	1.005	1.010	1.015	1.020	1.025	1.030
Leucocyte	Conc. (WBCs/µL)	0		25	75	500		

K) LIMITATION OF PROCEDURES

- As with all diagnostic tests, a definitive clinical diagnostic should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
- Knowledge of the effects of drugs or their metabolism upon the individual tests is not yet complete. In doubtful cases it is therefore advisable to repeat the test after discontinuing a particular drug. Large amounts of ascorbic acid in the urine can produce artificially low to false negative results for nitrite and bilirubin.
- In clinical specimens, the sensitivity depends upon the variability of color perception ; the presence or absence of inhibitory factors typically found in urine, the specific gravity, and the pH; and the lighting conditions when the products is read visually, because the color of each test area changes as the analyte concentration increase , the percentage of specimens detected as positive will increase with analyte concentration.
- Comparison to the color chart is dependent on the interpretation of the individual. It is therefore, recommended that all laboratory personnel interpreting the results of these strips be tested for color blindness.

L) SPECIFIC PERFORMANCE CHARACTERISTICS

Performance characteristics are based on clinical and analytical studies and depend upon several factors like variability of urine specimens the presence or absence of inhibitory and matrix factors typically found in urine and the laboratory conditions in which the product is used (e.g. lighting, temperature and humidity).

Samples	Positive	Negative	Sensitivity & Specificity
Positive (N=150)	149	1	Sensitivity: 99.3 %
Negative (N=200) *Included cross-reactive samples*	0	200	Specificity: 100 %
Total	149	201	

N= Number of samples tested.

M) QUALITY CONTROL

- For best results, performance of reagent strips should be confirmed by testing known positive and negative specimens/controls.
- Test QC as 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. Please note: Water is NOT an appropriate negative control.
- Run QC tests to ensure reagent storage integrity; train new users; confirm test performance; when clinical conditions or symptoms do not match the results obtained on the test strips.

N) BIBLIOGRAPHY OF SUGGESTED READING

- The Use of Urinary Dipstick Tests to Exclude Urinary Tract Infection, A Systematic Review of the Literature Andrew St John, PhD,1 James C. Boyd, MD,2 Andrew J. Lowes, MD,3 and Christopher P. Price, PhD4 DOI: 10.1309/C69RW1BT7E4QAFPV.
- Evaluation of the appropriate time period between sampling and analyzing for automated urinalysis, Biochem Med (Zagreb). 2016 Feb. 15, doi: 10.11613/BM.2016.008.
- Performance Characteristics of Dipstick and Microscopic Urinalysis for Diagnosis of Urinary Tract Infection, Düzce University, School of Medicine, Department of Biochemistry, Düzce, Turkey Eur J Gen Med 2010;7(2):174-178 Received: 12.06.2009 Accepted: 15.09.2009.
- Understanding Urinalysis, 2015 National Kidney Foundation, Inc.
- Dolphe kutter the urine test strip of the future clinica chimica acta 297(2000) 297-304.

Description of symbols used in product labeling

	See instruction for use		Manufactured by
IVD	In-vitro diagnostic use only		Date of manufacturing
2°C 30°C	Store at 2-30°C	Σ	Test per kit/ packets
	Do not use damaged package	REF	Catalog number
LOT	Batch/ Lot number		Do not reuse
	Use by (Date of expiry)		

Close bottle cap immediately after you take out the strip.
Don't leave bottles open way too long.
You can only use the Bottles upon 90 days of opening.
Don`t leave the bottles uncapped

IVD In Vitro Diagnostic Use | See Pack Insert for Procedure | Single Use Only | CE
Temperature Limit | Manufacturer's Address | Manufacturer's Date | Expiry Date | LOT Lot Number

CERTIFIED ISO 9001:2015 13485:2016 COMPANY | GMP GOOD MANUFACTURING PRACTICE QUALITY PRODUCT | MAKE IN INDIA

Manufactred in India by :
PRECISION BIOMED PVT. LTD.
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