

BEACONIC US 14

Code	Product Name	Pack Size
RA029A	Beaconic US 14	100 Strips

INTENDED USE

Urine reagent strips are intended to be used in urine analysis for the qualitative and semi-quantitative detection of -glucose, protein, ketone, blood, leukocytes, bilirubin, urobilinogen, nitrite, pH, specific gravity, ascorbate, micro albumin, creatinine and calcium.

KIT CONTENTS

Reagent 1 : Urine Strip 14 Parameter

RFID Card, Colour Chart, and Instructions for Use

SPECIMEN COLLECTION AND PREPARATION

Urine should only be collected in clean, dry container and tested within 1 hour. Entire operation needs to take place in a clean atmosphere.

STORAGE

Store the container between 2-30°C in dry condition. Do not refrigerate. Keep away from direct sunlight. Do not touch test area of the reagent strip.

TEST PROCEDURE

1) Humidity affects the performance of the test strip, hence, open the container only when testing is to be performed. Remove one strip from the bottle and quickly close the bottle's lid.

2) Dip the reagent pads of the strip completely into the urine sample and remove it immediately. If the urine collection container is small, bend the strip to dip all the reagent pads under the urine sample.

3) Wipe off excess urine by gently tapping the strip sideways on a tissue paper. Always position the strip so that the membrane side is facing up.


4) In 60 seconds, carefully examine the test results while placing the test area close to the relevant colour chart on the bottle label under adequate lighting. Changes in colour, that only occurs at the test pad edges or, after 2 minutes have passed are not diagnostically significant.


5) If Urine analyzer is used to read the test result, then scan the RFID Card (Read next paragraph on steps to scan RFID) before starting the assay procedure. If RFID Card is not scanned, the analyzer will not read the urine strip. If reading instrumentally, carefully follow the direction given in the Urine Analyzer operating manual.


SCANNING RFID CARD

- Switch on the Urine Analyzer.

- Press the Setting Icon  on the home screen.

- Press the RFID Icon  that appears after entering Settings.

- RFID Reader is present on the right side of the Urine Analyzer [depicted by RFID Symbol ].

- To read the RFID, place the RFID Card on the RFID symbol  which is on the right side of the analyzer.

- As the reader will read the RFID, Single beep sound can be heard and screen will show updated Lot number and expiry of the Urine bottle. Balance shall

show the number 100 since each RFID Card of Urine Strip bottle is recharged with 100 nos. Thereafter, to take the measurement, follow the procedure as per operation manual of the Urine analyzer.

- The balance progressively reduces every time a strip is scanned and becomes Zero once a full bottle of 100 strips is consumed.

REACTION PRINCIPLE

Glucose: Glucose oxidase catalyzes the formation of gluconic acid and hydrogen peroxide from oxidation of glucose. A 2nd enzyme, peroxidase, catalyzes the reaction of Hydrogen peroxide with potassium iodide chromogen resulting in colour change.

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 colour in the presence of proteins (anions) as the indicator releases hydrogen ions to the protein.

Ketone: The acetoacetate and sodium nitroprusside cause reaction in alkaline medium, which produces purplish red compounds.

Blood: This test is based on the peroxidase-like activity of haemoglobin which catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine.

Leukocytes: This test reveals the presence of granulocyte esterase. The esterase cleaves a derivatized pyrazole amino acid ester to liberate derivatized hydroxy pyrazole. This pyrazole then reacts with a diazonium salt to produce a beige-pink to purple colour.

Bilirubin: This test is based on azo-coupling reaction of Bilirubin with diazotized dichloroaniline in a strongly acidic medium.

Urobilinogen: This test is based on the azo-coupling reaction of a stable diazonium salt with Urobilinogen in a strongly acidic medium.

Nitrite: Nitrite and aromatic amino-sulfanilamide react to diazo compound, and the diazo compound couple reacts with tetrahydro-benzo quinoline-3-phenol, which produces azo dyes.

pH: This test is based on a double indicator system which gives a broad range of colours covering the entire urinary pH range.

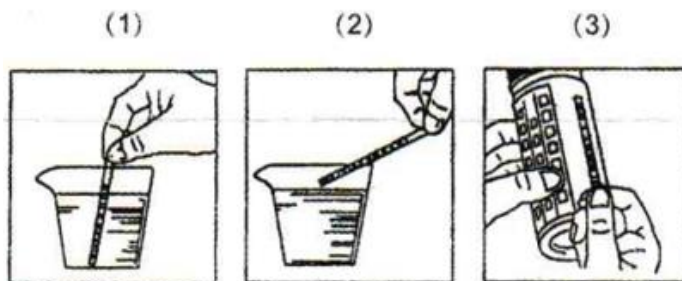
Specific gravity: This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colours range from deep blue-green in urine of low ionic concentration to green and yellow-green in urine of increasing ionic concentration.

Ascorbic acid: This test involves decolorization of Tillmann's reagent. The presence of ascorbic acid causes the colour change.

Microalbumin: The basis for the test is a high affinity sulfonephthalein dye, using the dye binding method to produce any blue colour if albumin is present at a constant pH.

Creatinine: The test is based on the creatinine in urine reacting with 3,5-Dinitrobenzoic acid to produce a colour change.

Calcium: The test is based on colour reaction of metal ions with chelators. The complex of calcium ion with o-cresolphthalein produce a purple colour proportional to calcium concentration in urine.



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VISUAL RANGE

Items	Visual Range
Glucose (mmol/L)	Neg. - 110
Protein (g/L)	Neg. - 20.0
Ketone (mmol/L)	Neg. - 16
Blood (ca cells/(μL))	Neg. - 200
Leukocytes (ca cells/μL)	Neg. - 500
Bilirubin (μmol/L)	Neg. - 100
Urobilinogen (μmol/L)	3.2 - 128
Nitrite (μmol/L)	Neg.- Pos
pH	5.0 - 8.5
Specific Gravity	1.000 - 1.030
Ascorbic Acid (mmol/L)	0-5.0
Microalbumin (mg/L)	10-150
Creatinine (mmol/L)	0.9-26.5
Calcium (mmol/L)	≤1.0 - ≥10

ATTENTION

Water cannot be used as negative quality control liquid. Urine preservative cannot prevent the ketone, Bilirubin and urobilinogen from deterioration. For long term stored urine specimen, the test result for glucose, pH, nitrite and blood can be affected because of bacterial growth.

WARNINGS AND PRECAUTIONS

- After removing the strip, quickly close the bottle's lid.

- Do not remove desiccant from the bottle.

- Do not touch test area of Urine reagent strip.









- Do not store the sample long time (one hour or longer) before testing.

LIMITATION

Comparison with the colour chart is dependent on the interpretation of the individual. It is therefore, recommended that all laboratory personnel interpreting the result of these strip be tested for colour blindness. As with all laboratory tests, definitive diagnostic or therapeutic decision should not be based on any single test or method. Substances that cause abnormal urine color, such as visible levels of blood and bilirubin and drugs containing dyes (ex. Pyridium), nitrofurantoin (ex. Macrochantin), or riboflavin may affect the readability of the reagent pad areas on the strip. The color development on the reagent pads maybe masked or a color reaction produced that could be interpreted as a false positive. These specimens should be sent to the main laboratory for testing.



SYMBOLS USED ON LABELS

 REF	Catalogue Number	 Manufacturer	 See Instruction for Use
 LOT	Lot Number	 CONT	Content
 Expiry Date		 IVD	In Vitro Diagnostics
		 Storage Temperature	

BEA/24/U10/RA/IFU Ver-00
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