CHEMISTRIX™ - AG

BIO LAB DIAGNOSTICS
ISO 9001:2015
ISO 13485:2016
CE

CHEMISTRIX-AG the Dry Chemistry strip is one of its kind to detect various analytes from urine.
CHEMISTRIX-AG for Glucose and Protein in urine.

STORAGE AND STABILITY

When unopened and stored at 15-30°C the test strips are stable until the expiration date printed an each label. Opened bottles, the strips when stored tight capped and not exposed to humidity is stable for atleast bodys at 15-30°C. Do not keep in refrigerator.

PROCEDURE

1. Collect fresh urine and mix well before the test being performed.
2. Remove CHEMISTRIX-AG chemistry strip from the bottle and close the bottle immediately.
3. Identify the reagent area of the strip and corresponding colour chart on the bottle label.
4. Inspect the base colour of reagent area for any spontaneous colour change and avoid using any discoloured reagent strips.
5. Dip the entire reagent area to the well mixed fresh urine for a FRACTION OF S E C O N D AND TAP OUT EXCESS URINE at the brim of the sample container and hold the strip horizontally to avoid contamination.
6. Inspect the test area for ensuring full sample contact which could be made out as wet surface on reagent areas.
7. Compare the reagent area to corresponding colour chart on the CHEMISTRIX-AG bottle label between the specified time.

SAMPLE COLLECTION AND HANDLING

1. To obtain best reliable result take fresh, well mixed sample.
2. Collect urine sample directly to a clean container. Should there any difficulty in collecting samples directly to sample bottle, patient must be instructed to use chemically clean bed pans and perform the test immediately.
3. Fresh catheter sample can be used for test. Avoid contamination of residual excretion that may some times remain in the catheter bags. Avoid using lubricants such as liquid paraffin or glycerine for catheter insertion.
4. Ensure sample collection bottle is free from any chemical contamination usually from detergent, disinfectant or medicines such as Tonics, Syrups which may have added glucose, leading to false results.
5. If sample to be kept for performing test at later time, store it in a closed container at 2-8°C. Where sample to be kept more than 12 hours but less than 24 hours, add few crystals of thymol and then refrigerate.

CAUTION

No reliable result may be observed if the sample is stored unpreserved for more than 4 hours at an ambient temperature.

CHEMICAL PRINCIPLE

GLUCOSE OXIDASE -IODIDE

CHEMISTRIX-AG GOD-IODIDE method is been widely accepted for glucose estimation as the specificity of Glucose Oxidase to p D-glucose alone eliminate false positive result that could be possible by the conventional chemical method described by Benedict's. GOD-IODIDE method is advantageous as the colour variation is distinctly similar to the chemical method. GOD-IODIDE method employ the following reaction.

$$\text{GLUCOSE} + O_2 \xrightarrow{\text{GOD}} \text{Gluconic Acid} + H_2O_2$$

$$H_2O_2 + \text{Potassium Iodide} \xrightarrow{\text{POD}} 2H_2O + \text{Iodine (Brown)}$$

GOD = Glucose Oxidase
POD = Peroxidase
H_2O_2 = Hydrogen peroxide

The brown coloured iodine formed from potassium iodide by the action of hydrogen peroxide and peroxidase is directly proportional to the concentration of Glucose present in the sample.

LIMITATIONS

CHEMISTRIX-AG GOD-IODIDE method is specific to b- D.Glucose therefore, substances other than Glucose like lactose, fructose or various non glucose sugars usually present in non clinical conditions do not react with this test.

FALSE POSITIVE

Highly coloured urine sample in case of some conditions such as porphyrinurea, beetrooturea, salicylicurea, haematurea etc. may visually mimic the colour similar to positive reaction. Therefore, such cases should be confirmed with further investigation. False positive reaction is possible in samples contaminated with

1. Detergents.
2. Hypochlorite, Peroxide or similar Oxidants.
3. Invitro contamination of Glucose from the container that has been used for medicine prepared in glucose.

FALSE NEGATIVE

False negative or reduced sensitivity or reaction in the range of 100 - 250 mGs/dL or less reactive in the range of 1000 - 2000 mGs/dL may be encounter with samples containing.

1) Very high specific gravity (> 1.025).
2) Very high ketone bodies (> 40 mGs/dL).
3) Very high Ascorbic Acid (> 50 mGs/dL)
4) Very high sample temperature (> 50°C).
5) Contamination of sample with metallic salt, aldehydes or alkalies.
6) The chemical content of the test area is washed out due to excessive exposure to samples.
7) The strips are not stored as per the specification mentioned in the storage column.

DETECTION LIMIT

CHEMISTRIX-AG GOD-IODIDE method is sensitive to glucose level from 100 to 2000 mGs/dL. Quantitation of very low glucose must be confirmed with a more sensitive methodology.

EXPECTED RESULT

Normal glomerular filtrate does not contain detectable glucose by this method. Any presence of glucose detected by this method should be further investigated for establishing glycosuria or diabetic melitis.

QUALITY CONTROL

CHEMISTRIX-AG GOD-IODIDE method can be tested for its positive reactivity with diluted non coloured soft drinks containing Glucose or a solution of D-Glucose (10 Gram Glucose-D in 100 mL water, mix and **keep the solution for 2 hours at room temperature** then dilute to different concentrations in normal urine containg no glucose and perform the test with low as well as higher concentration of Glucose solution). To quality control CHEMISTRIX-AG chemistry strip it is better to use a known positive and negative clinical sample. Commercial control preserved in Azide or mercury compound should not be used as control material.

NOTE: Do not use commercial cane sugar as it contains sucrose which may mislead interpretation.

PROTEIN (BPB) ALBUMIN

PRINCIPLE

CHEMISTRIX-AG BPB assay is based on a reaction rated protein error of indicator in which an indicator Bromophenol blue (BPB) change its colour shade from yellow (Negative) to blue green (Positive) in a strong buffered medium. The change of colour is proportionate to the quantity of albumin in test sample.

LIMITATIONS

CHEMISTRIX-AG BPB method is more sensitive to Albumin than globulins. BPB method may not be sensitive to various other proteins such as Bence - Jones protein, haemoglobin or mucoprotein.

FALSE POSITIVE

False positive results may be encountered with samples containing.

1) Highly alkaline pH.
2) Drug therapy with drugs such as quinine groups, Trimethoprime, phenazopyridine.
3) Contamination of sample with quaternary ammonium compound from certain antiseptics and detergent or disinfectant with chlorhexidine such as Cetavilon, Savilon etc. from the sample collection vessels or bottle.
4) Excessive bacterial contamination due to longer storage of sample.
5) Elevated Sp.Gr. of sample may show trace reactivity with BPB dye and to be interpreted with clinical judgment only.

FALSE NEGATIVE

False negative may be observed in

1) Sample contaminated with Acids.
2) Protein denatured due to longer storage.
3) The impregnated chemicals from the test area is washed out due to excessive exposure to sample.

DETECTION LIMIT

CHEMISTIX-AG BPB method is sensitive to Albumin level from 20 - 2000 mGs/dL. Quantitation of very low Albumin must be confirmed with a more sensitive methodology.

EXPECTED RESULT

Normal glomerular filtrate does not contain detectable amount of Albumin by this method. Any presence of Albumin detected by this method should be investigated further for establishing albuminuria or various renal/urinary complication.

CAUTION

CHEMISTRIX-AG chemistry strips are for invitro use only. Keep away from the reach of children Dispose off the used strip immediately after use.

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