GLUCOSE

For discrete analyzers.
Method: GOD-P0D
Product Code: 1418-0013
Packaging: 4 x 30 ml
Store at 2 – 8°C
For in vitro use

INTENDED USE
MEDICON Glucose is a reagent for the quantitative determination of Glucose in human serum and plasma, with BECKMAN COULTER AU400/600/600–VD/640/2700/5400 and other discrete analyzers. For in vitro diagnostic use only.

CLINICAL SIGNIFICANCE
Blood sugar levels are regulated by the liver, which ensures that levels are maintained within the precise values. A fall in blood glucose to a critical level leads to dysfunction to the central nervous system. This manifests as hypoglycemia and is characterized by muscle weakness, lack of coordination and mental confusion. Further decrease of blood glucose level leads to hypoglycemic coma. Hypoglycemia most commonly occurs at deficiency of insulin a condition known as diabetes mellitus. This disease is characterized by elevation of blood glucose to such extent that the renal threshold is exceeded and sugar appears to the urine. Blood glucose measurement is used as a screening test for diabetes mellitus where there is suspected hyperglycemia, gestational diabetes, acute hepatitis and pancreatitis. Elevated glucose levels are also seen at endocrine disorders such as pheochromocytoma, thyrotoxicosis, Cushings syndrome, pancreatic diseases like acute and chronic pancreatitis, cystic fibrosis, neoplasms of pancreas. Reduced glucose levels are observed at glucagon deficiency, islet cell tumors, Zellweger’s syndrome, galactosemia etc.

METHOD PRINCIPLE
The GOD-P0D method is applied. Glucose is determined according to the following reactions: Glucose oxidase catalyzes the oxidation of Glucose producing Hydrogen Peroxide and Gluconic acid. The Hydrogen Peroxide reacts with p-hydroxy-benzoic acid and 4-aminoantipyrine in the presence of peroxidase to produce a red pseudoamine dye. The amount of colored complex is proportional to the glucose concentration. The presence of mutarotase accelerate the reaction.

Glucose + O₂ + H₂O → GO
Glucose oxidase
2H₂O₂ + p-Hydroxy benzoic acid + 4-Aminooantipyrine Peroxidase
Quinoneimine + 4H₂O
GO: Glucose oxidase

METHOD LIMITATIONS
Refer to the book “Effects of Preanalytical Variables on Clinical Laboratory Tests” for possible interference of other pharmaceutical agents in this particular test. Interference of other agents is described in the “Clinical Guide to Laboratory Tests”. The reagent is designed especially for use with discrete analyzers. For chemistry protocols and further information contact customer support unit at MEDICON.

REAGENT COMPOSITION
MES buffer pH=6.7
p-HBA
4-Aminooantipyrine
Mutarotase
Glucose oxidase
Preservative

WARNINGS – PRECAUTIONS
● This reagent is designed for in vitro diagnostic use. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory techniques. Avoid inhalation and contact with eyes and skin.
● Samples should be considered as potentially infectious. Handle according to the universal precautions and good laboratory practices.
● The reagent contains sodium azide (NaN₃ < 0.1%). Avoid swallowing and contact of the reagent with skin and mucous membrane.
● Dispose all waste according to national laws.
● MSDS is available by MEDICON upon request.

PREPARATION
Reagent is ready to use and placed in the corresponding position of the analyzer. Vials bear barcode for recognition by BECKMAN COULTER AU Series analyzers.

REAGENT DETERIORATION
The reagent should not be used:
● When it does not exhibit the specified linearity or recovery of control values lies outside the acceptable range after recalibration.
● When there is change in colour of the reagent.
● After prolonged exposure to sunlight or high temperature.

SHELF LIFE
Unopened, reagent is stable up to the expiration date stated on the label when stored at 2 – 8°C. Once opened, it’s stable for 2 months, if stored refrigerated on the instrument.

SAMPLE
Use non hemolyzed serum, or fluoride, isooctoic acid plasma as sample. Do not use tubes with citric, EDTA, heparin or oxalic as anticoagulant for sample collection. Serum samples are stable for 8 hours at 25°C and 72 hours at 4°C. Plasma samples are stable for 24 hours at room temperature. Serum must be separated from red cells as soon as possible, since the rate of glucose concentration reduction is about 7% per hour. Avoid repeated freezing and thawing of samples.

CALIBRATION
MEDICON MIDI-CAL (1578-0891), traceable at the SRM 965 NIST or BECKMAN COULTER System Calibrator, for Clinical Chemistry Analyzers Cat. No. 66300 (MEDICON code: 4478-0891) available by MEDICON can be used for calibration. Calibrate the assay every 1 month. Recalibrate when Quality Control results are out of range, following preventive maintenance or replacement of a critical part of the analyzer, or when using a new reagent lot or a new reagent lot number.

QUALITY CONTROL
MEDICON provides the MEDICON Clinical Chemistry Control Level 1 & 2 (1578-0901-12 & 1578-0902-12 respectively) or the BECKMAN COULTER Control Serum OCD0003 & OCD0004 (MEDICON code: 4478-0941 & 4478-0942 respectively) for serum quality control.

Control values and limits should fall within acceptable intervals adjusted to the requirements of each laboratory. Results outside the specified values even after recalibration could be due to reagent deterioration, unstable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT
Gluconate
Quality control material
Automated biochemistry analyzer
Common laboratory equipment

REFERENCE INTERVALS
Serum, plasma
70 – 115 mg/dL
Each laboratory should determine its own expected values as dictated by good laboratory practice.

WASTE DISPOSAL
This product contains sodium azide (NaN₃), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build up in the drain pipes.

SPECIFIC PERFORMANCE CHARACTERISTICS
Linearity
The assay is linear within measuring range 1.9 to 600 mg/dL. When values exceed this range samples should be diluted accordingly.

Sensitivity
The lowest detectable level of Glucose is estimated at 0.3 mg/dL.

The lowest detection limit (LRL) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times within the assay and the LDL is calculated as the absolute mean plus three standard deviations.

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<th>Level (mg/dL)</th>
<th>Within run</th>
<th>%CV</th>
<th>SD</th>
<th>%CV</th>
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Precision is estimated on two concentration levels of analyte according to NCCLS protocol EP-5T (20 consecutive days, 2 runs per day, 2 repeats per run).

Interference
Lipemic: insignificant up to 200 mg/dL
Hemoglobin: insignificant up to 250 mg/dL
Non-conj. Bilirubin: insignificant up to 20 mg/dL
Bilirubin: insignificant up to 20 mg/dL
Acidic: insignificant up to 3 mg/dL

Refer to Young for further information on interfering substances.

Method Comparison
A comparison was performed between this reagent and another commercially available product. The results were as follows on a BECKMAN COULTER AU Series analyzer:
Y = 0.9441X + 2.2429
R²=0.9996
N=100
Sample range: 5.7 – 420.9 mg/dL

BIBLIOGRAPHY

SYMBOLS

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