diatron

GLUCOSE

Specifically for use with Diatron PICTUS® 700 and PICTUS® 500 Analyzers

2°C – 8°C

REF 1419-0012 **Packaging:** 6 x 60 mL

Σ 1800

INTENDED USE

Reagents for In Vitro quantitative automated measurement of the concentration of Glucose in samples of human serum, plasma, urine or cerebrospinal fluid from the general patient population. Measurements of Glucose are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid in the assessment of glycemic status and in screening, diagnosis and management of chronic and acute carbohydrate metabolism disorders.
This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers.
For in vitro diagnostic use only by trained laboratory professionals.

CLINICAL SIGNIFICANCE

Blood sugar levels are regulated by the liver, which ensures that glucose levels are maintained within certain values. A fall of blood glucose to a critical level leads to dysfunction of the central nervous system. This hypoglycemia manifests by muscle weakness, lack of coordination and mental confusion. Further decrease of blood glucose levels can lead to hypoglycaemic coma.
Hyperglycaemia most commonly occurs in insulin deficiency, a condition known as diabetes mellitus. This disease is characterized by elevation of blood glucose concentration to such an extent that the renal threshold is exceeded and sugar appears in urine. Blood glucose measurement is used as a screening test for diabetes mellitus where there is suspected hyperglycaemia, gestational diabetes, acute hepatitis and pancreatitis. Elevated glucose levels are also seen at endocrine disorders such as pheochromocytoma, thyrotoxitis, Cushing's syndrome, pancreatic diseases like acute and chronic pancreatitis, cystic fibrosis, and neoplasms of the pancreas. Reduced glucose levels are observed in glucagon deficiency, adrenal gland carcinoma, carcinoma of the stomach, fibrosarcoma, hypopituitarism, Addison's disease, hypothyroidism, automatic nervous system disorder, ketotic hypoglycemia, Zitterson's syndrome, galactosemia etc.

METHOD PRINCIPLE

The method followed is GOD-POD. The enzymatic, photometric determination of glucose in serum or plasma takes place according to the following reactions:

$$\text{Glucose} + O_2 + 2H_2O \xrightarrow{\text{Glucose oxidase}} \text{Gluconic acid} + 2H_2O_2$$

$$2H_2O_2 + \text{Phenol} + \text{4-Aminoantipyrine} \xrightarrow{\text{Peroxidase}} \text{Quinone} + 4H_2O$$

The absorbance at 505/590 nm is proportional to the concentration of glucose in the sample.

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". This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers. For additional information please contact the customer support at Diatron or Medicon.

REAGENT COMPOSITION

Phosphate Buffer (pH 7.4):	100 mM	4 – Aminophenazone:	0.9 mM
Glucose oxidase:	> 18000 U/L	Phenol:	5 mM
Mutarotase:	200 U/L	Peroxidase:	> 2500 U/L
Non reactive components and preservatives			

⚠ **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 with special caution.
- The reagent contains sodium azide (NaN_3) ≤ 0.1%. Avoid swallowing and contact of the reagent with skin and mucous membranes.
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON upon request.
- Any serious incident that may occur in relation to this device must be reported by the user to the manufacturer and the competent authority of the country in which the user and/or the patient is established!

⚠ **PREPARATION**

Reagent ready-to-use when placed in the corresponding position on the analyzer. The vials bear barcodes for automatic recognition by Diatron Pictus® P700 / P500 analyzers.

⚠ **REAGENT DETERIORATION**

The reagents should not be used:

- When they do not exhibit the specified linearity or control values lie outside the acceptable range after recalibration.
- When change in reagent color is observed.
- After prolonged exposure to sunlight or high temperature.

⚠ **SHELF LIFE**

Unopened, the reagent is stable at 2 – 8°C up to the expiry date stated on the label. Once opened, it remains stable for 2 months when stored in the reagent tray of the Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** Serum, or Li-heparin plasma may be used as specimen. Use established Good Laboratory Practices for sampling, transport and separation from blood cells. Do not use hemolyzed, contaminated or turbid sample specimens. Anti-coagulants other than Li-heparin have not been tested and should not be used. Centrifuge sample as soon as possible, since the rate of glucose concentration reduction is about 7% per hour. and store properly if analysis cannot take place right after sample separation. Glucose remains stable in serum or plasma for 8 hours at 20 - 25°C, and 3 days at 2 - 8°C. Do not freeze thawed samples.
Urine: Collect sample in a dark cup and place container on ice. To preserve 24-hour urine, add 5 ml crystalic acetic acid or 5 g sodium benzoate or sodium fluorate. Let sample reach room temperature before testing. **CSF:** Perform procedure as soon as possible to avoid falsely low result

CALIBRATION Diatron offers MEDICON MEDI-CAL (code 1578-0891) traceable to SRM 965 NIST for serum calibration. Recalibrate the assay every 1 month when used on Pictus® P700 or P500 analyzers. Calibration should also be repeated after major maintenance is performed on the analyzer, after a critical part is replaced, or when a significant shift in control values occurs. Urine Applications are pre-programmed on the analyzer to automatically acquire a calibration factor after every successful serum calibration.

QUALITY CONTROL Diatron offers MEDICON Clinical Chemistry Control Level 1 & 2 (code 1578-0901-12 & 1578-0902-12 respectively) for serum quality control. Control recovery should lie within the acceptable range. Results outside the acceptable range even after recalibration could be due to reagent deterioration, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

- Glucose calibrator
- Quality control material
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS

Serum, plasma: 70 – 115 mg/dL
Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practices.

⚠ **WASTE DISPOSAL**

This product contains sodium azide (NaN_3), 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

The following values are representative of the reagent performance on Diatron Pictus® P700 or P500 analyzers. The reagent performance has been evaluated on other types of analyzers, covering all requirements of the 98/79 IVD Directive. A list of analyzers with the corresponding performance characteristics is available in the special leaflet accompanying the insert. The results taken in your laboratory may differ from these values.

Linearity **Serum:** up to 580 mg/dL
Urine: up to 1200 mg/dL

Lowest detection limit **Serum:** 1.5 mg/dL
Urine: 11.4 mg/dL

Lowest detection limit (LDL) 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.

Precision: Precision is estimated on two concentration levels of analyte according to CLSI protocol EP-5T (20 consecutive days, 2 runs per day, 2 repeats per run).

Pictus® P700 and P500	
Level (mg/dL)	**%CV**
95.2	1.08
234	0.73
Level (mg/dL)	**TOTAL %CV**
95.2	1.99
234	1.85

INTERFERENCES - Criterion: recovery within ±10% from target value

Serum	(Insignificant up to)	**Urine**	(Insignificant up to)
Hemoglobin	500 mg/dL	Hemoglobin	200 mg/dL
Bilirubin	20 mg/dL	Bilirubin	50 mg/dL
Conj. Bilirubin	20 mg/dL	Ascorbic Acid	3 g/L
Ascorbic acid	3 mg/dL	Urea	50 g/L
		Uric Acid	2.5 g/L
		Creatinine	3 g/dL

Correlation: A comparison was performed between this reagent on a Diatron Pictus® P700 and P500 analyzer, and another, commercially available product. The results were as follows:

SERUM: Y = 0.991X – 2.326 R=0.998 N=40 Sample range = 16.5 – 322 mg/dL
URINE: Y = 1.060X + 0.27 R=0.975 N=50 Sample range = 0.5 – 20.4 mg/dL

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SYMBOLS

Manufacturer	IVD *In vitro* diagnostic medical device
Temperature Limit	REF Catalogue Number
Caution	Σ Contains sufficient for <n> tests

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