GLUCOSE

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

2°C – 8°C

REF 1419-0018 **Packaging:** 6 x 34 mL (R1) + 6 x 12 mL (R2)

Σ 1320

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 hypoglycemic coma. Hyperglycemia 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 hyperglycemia, 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 Hexokinase UV method is applied. The enzymatic determination of glucose, according to the hexokinase method, is based on the following reactions:

Glucose + ATP $\xrightarrow{\text{Hexokinase}}$ 6-phosphate glucose + ADP

6- phosphate glucose + NAD $\xrightarrow{\text{G-6PDH}}$ 6-phopshate gluconic acid + NADH

The absorbance at concentration 340/380 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

Reagent 1 (R1)		Reagent 2 (R2)	
Tris Buffer (pH 7.8):	150 mM	Tris Buffer (pH 7.8): 0.5 M	
NAD+:	3 mM ATP:	Hexokinase:	< 22 kU/L
3 mM		G-6-PDH:	< 26 kU/L
Non-reactive components and preservatives		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.
- 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!
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON upon request.

PREPARATION
The reagents are ready-to-use. 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.
- After prolonged exposure to sunlight or high temperature.
- When they appear turbid or discolored.

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 1 month when stored in the cooled 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 (1578-0891) traceable to SRM 965 NIST for serum calibration. Calibrate the assay every 2 weeks for Diatron 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 (1578-0901-12 & 1578-0902-12 respectively) for serum quality control. Any commercially available quality control can be used for other types of samples. 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: 70 – 115 mg/dL
Urine: 1 – 15 mg/dL
Urine 24h: <0.5 g/day
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/plasma:** 1000 mg/dL **Urine:** up to 1000 mg/dL
Lowest detection limit: **Serum:** 0.8 mg/dL **Urine:** 0.8 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	
Mean (mg/dL)	**%CV**
63.9	1.90
109.5	2.40
Mean (mg/dL)	**TOTAL %CV**
63.9	3.00
109.5	3.30

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

Serum	(Insignificant up to)	**Urine**	(Insignificant up to)
Triglycerides	3000 mg/dL	Bilirubin	20 mg/dL
Hemoglobin	500 g/dL	Hemoglobin	500 mg/dL
Bilirubin	20 mg/dL	Urea	50g/L
Conj. Bilirubin	20 mg/dL	Uric Acid	2.5 g/L
Ascorbic acid	3 mg/dL	Ascorbic Acid	5 g/L

In very rare cases of γ-globulinemia, especially in monoclonal IgM (Waldenström) macroglobulinemia, results may be falsely elevated.
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 = 1.014X + 0.255 R=0.9985 N=135 Sample range = 10.9 – 311 mg/dL
Urine: Y = 1.0201X + 4.7739 R=0.9982 N=40 Sample range = 3.0 – 320.0 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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