diatron

HbA1c

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

2°C – 8°C | REF 1419-1152 **Packaging:** 2 x 15 mL (R1) + 2 x 15 mL (R2) + 2 x 25 mL (THR) | Σ 200

INTENDED USE
Reagents for In Vitro quantitative automated determination of Hemoglobin A1c - HbA1c in samples of human whole blood from the general patient population. Measurements of HbA1c are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid for diagnosis and management of diabetes mellitus.

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
HbA1c is formed by non-enzymatic glycation of the free amino-groups on the N-terminal of the β chain of hemoglobin. This forms a Schiff base which is itself converted to 1-deoxyfructose in an Amadori rearrangement. Since hemoglobin molecules remain glycated in red cells during their entire life cycle, measuring HbA1c provides an indication of the mean daily concentration of blood glucose for the past two months that is the average life expectancy of red cells. The measurement of HbA1c is, therefore, considered to be a significant diagnostic tool for monitoring of diet control and therapies during treatment of diabetes. The effective control of blood glucose levels is essential for the prevention of ketosis and hyperglycemia, and can possibly reduce the predominance and severity of secondary diabetic complications, such as retinitis, neuropathy, nephropathy and cardiac diseases.

METHOD PRINCIPLE
The Immunoturbidimetric method is applied. The concentrations of both HbA1c and Total hemoglobin are determined. The HbA1c/Total hemoglobin ratio is expressed as a percentage of HbA1c (HbA1c%). The HbA1c percentage test includes the use of four reagents: Total hemoglobin R1, HbA1c antibodies reagent R1, Reagent R2 and Denaturant (code 1518-1059). In the preparation stage, total blood is mixed with the Denaturant (1:41) and incubated at room temperature for at least five minutes. Red blood cells are lysed and hemoglobin chains are hydrolyzed by proteases in the reagent. Total Hemoglobin is determined through the transformation of all hemoglobin products into hematin in an alkaline solution of a non-ionized detergent. Adding pretreated sample into the Total hemoglobin reagent results to a green solution, which is measured at 590/700 nm. HbA1c is determined by a latex agglutination inhibition reaction. An agglutinator, composed of a synthetic polymer bearing multiple copies of immunoreactive HbA1c fractions, causes agglutination of latex particles bound to mouse monoclonal anti-HbA1c antibodies. In the absence of HbA1c in the sample, antibody bound latex particles in HbA1c R1 and the agglutinator in HbA1c R2 will form insoluble complexes that result in increase of the optical absorbance of the suspension. HbA1c present in the sample reduces the rate of agglutination of antibody bound latex particles in HbA1c R1 ant the agglutinator in HbA1c R2.
The OD measured at 700 nm is, thus, inversely proportional to HbA1c concentration 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 customer support at Diatron or Medicon.

REAGENT COMPOSITION

HbA1c R1	HbA1c R2	Total Hemoglobin R1 (THR)
HbA1c antibody (rat) covered particles Bovine Serum Albumin Buffer pH 8.1 Surfactant: 0.6% non-ionic Preservative 0.1% Proclin	HbA1c Hapten Bovine Serum albumin Buffer pH 2.0 Surfactant Preservative 0.1% Proclin	Sodium hydroxide 0.4% pH 13 Surfactant: 0.7% non-ionic

⚠ **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.
- All products of a human origin are potentially biologically hazardous. They should be handled according to good laboratory techniques.
- 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**
Total Hemoglobin Reagent R1 and HbA1c Reagents R1 and R2 are ready to use when placed in the corresponding positions of the analyzer. Mix HbA1c R1 well before first use. The vials bear barcodes for automatic recognition by Diatron Pictus® P700 / P500 analyzers.

⚠ **REAGENT DETERIORATION**
Do not use this reagent:
- When it does not exhibit the specified linearity or control values lie outside the acceptable range after recalibration.
- After prolonged exposure to sunlight or high temperature.

⚠ **SHELF LIFE**
Unopened, the reagents are stable at 2°– 8°C, up to the expiry date stated on their labels. Once opened, R1, R2 and Total Hemoglobin R1 remain stable for 1 month stored in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** Specimens of heparinized whole blood must be used. Prepare hemolyzate by adding 25 µL of sample to 1000 µL Hemoglobin denaturant (HbA1c 1518-1059). Incubate at room temperature for 5 minutes before use. Samples (not pretreated) are stable for up to 1 week when stored at 25°C, 2 weeks when stored at 2°– 8°C and up to 6 months when frozen to ≤–70°C. Hemolyzed (pretreated) samples are stable for up to 8 hours when stored at room temperature, and up to 48 hours when stored at 2°– 8°C, stored inside an airtight container.

CALIBRATION Diatron offers MEDICON HbA1c calibrator (1578-1058), traceable to the IFCC2 HbA1c reference method, for calibration. Gently invert each vial several times before use to ensure homogenous mix.
To calibrate the Total Hemoglobin reagent, only use Calibrator 1. To calibrate HbA1c use Calibrators 1 to 6. Calibration should take place every 1 week on Diatron Pictus® P700 or P500 analyzers, or when there is a significant diversion from control limits. 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.

QUALITY CONTROL Diatron offers MEDICON HbA1c Control (code: 1578-1057) for quality control. Add 25 µL of the control to 1000 µL of Hemoglobin Denaturant. Incubate at room temperature for 5 minutes before use. 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
- Diatron Pictus® analyzer
- Hemoglobin denaturant (HbA1c 1518-1059)
- Common laboratory equipment

REFERENCE INTERVALS
4.0 – 6.2% / Non-diabetics: < 6% / For glycemic control of diabetics: < 7%
Reference values are based on current bibliography. Each laboratory should determine its own expected values as dictated by good laboratory practices.

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: HbA1c: 2.6% – 11% **THb:** 7 – 23 g/dL
Lowest detection limit: HbA1c: 0.14 g/dL
The 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 (20 consecutive days, 2 runs per day, 2 repeats per run):

Pictus® P700 and P500	
Level (%)	**%CV**
5.0	2.40
9.4	1.70
Level (%)	**TOTAL %CV**
5.0	2.42
9.4	2.51

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

	(Insignificant up to)
Triglycerides	1600 mg/dL
Bilirubin	30 mg/dL
Urea	5 g/L
Ascorbic Acid	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:
Y = 0.997X + 0.423 R=0.9736 N=63 Sample range = 4.6 – 9.6 %HbA1c

BIBLIOGRAPHY

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SYMBOLS

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

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