diatron

TRANSFERRIN

2°C – 8°C

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

REF 1419-0742 **Packaging:** 4 x 22 mL (R1) + 4 x 11 mL (R2)

Σ 400

INTENDED USE
Reagents for In Vitro quantitative automated determination of Transferrin in samples of human serum from the general patient population. Measurements of Transferrin 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 iron deficiency and chronic inflammation.

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
Plasma Transferrin transports iron to the liver and bone marrow. Decreased levels of Transferrin are observed in cases of chronic inflammation or malignancies, mainly hemochromatosis, cirrhosis, or hereditary conditions such as atransferinemia. High transferrin levels are observed in Iron-Deficiency anemia.

METHOD PRINCIPLE
The immunoturbidimetric method is applied. When sample is mixed with the appropriate buffer (R1) and antiserum solution (R2), Transferrin reacts selectively with anti- human Transferrin antibodies, leading to formation of insoluble aggregates. The rate of absorbance increases of these aggregates (520 nm) is proportional to the concentration of Transferrin in the sample. The reaction is two-point kinetic.

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

Reagent 1 (R1)	Reagent 2 (R2)
Polyethylene glycol in Tris buffer (pH 8.0): 150mM Non-reactive components and preservatives.	Goat antihuman Transferrin antibodies 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 according to the universal precautions and good laboratory practices.
- Antisera are manufactured in monitored facilities by clinically healthy animals under constant surveillance.
- The reagent contains sodium azide (NaN_3 < 0.1%). Avoid swallowing and contact of the reagent with skin and mucous membrane.
- 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**
Reagents R1 and R2 are liquid, ready-to-use when placed in the corresponding positions of the analyzer. The vials bear barcodes for automatic recognition by Diatron Pictus® P700 / P500 analyzers.

⚠ **REAGENT DETERIORATION**
The reagent should not be used:
- When they do not exhibit the specified linearity or recovery of control values lies outside the acceptable range after recalibration.
- When they appear cloudy.
- After prolonged exposure to sunlight or high temperature.

⚠ **SHELF LIFE**
Unopened, reagents are stable up to the stated expiry date when stored at 2°– 8°C. Once opened, they are stable for 1 month when stored in the cooled reagent tray on Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** Serum 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. Centrifuge sample as soon as possible, and store properly if analysis cannot take place right after sample separation. Transferrin remains stable in serum for 3 days at 2 – 8°C and for 6 months at –20°C. Do not freeze thawed samples.

CALIBRATION Diatron offers MEDICON Protein Standard Set (1578-1190) traceable to ERM-DA470k for calibration. Calibrate the assay every 2 weeks 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.

QUALITY CONTROL Diatron offers MEDICON Immunology Controls, levels 1,2,3 (1578-1195-04, 1578-1196-04, 1578-1197-04) respectively.
Control target values and limits should fall within acceptable intervals adjusted to the requirements of each laboratory. Target values for Transferrin should be verified with the corresponding working protocol. Results outside the specified values 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
- Transferrin calibrator
- Quality control material
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS

Adults:	200 – 400 mg/dL
2 – 5 years:	280 – 350 mg/dL
6 – 10 years:	260 – 340 mg/dL
11 – 18 years:	260 – 360 mg/dL

Each laboratory should determine its own expected values as dictated by good laboratory practice.

⚠ **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: Up to 900 mg/dL
Hook Effect: > 3450 mg/dL
Lowest Detection Limit: 3.4 mg/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 EP5-A (20 consecutive days, 2 runs per day, 2 repeats per run).

Pictus® P700 and P500	
Level (mg/dL)	**%CV**
123	1.47
361	1.39
Level (mg/dL)	**TOTAL %CV**
123	2.15
361	2.11

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

	(Insignificant up to)
Triglycerides	3000 mg/dL
Hemoglobin	400 mg/dL
Bilirubin	20 mg/dL
Conj. Bilirubin	20 mg/dL
Ascorbate	3 mg/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 = 1.031X – 7.549 R=0.9919 N=48 Sample range = 62.7 – 439 mg/dL

BIBLIOGRAPHY

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3. Jacobs, DJ, Demott, WR, Grady, HJ, Horvat, RJ, Huestis, DW and Kasten, BL, JR, eds. Laboratory Test Handbook. 4th. ed. Ohio, Hudson: Lexi-Comp Inc., 1996.
4. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd. ed. Washington, DC: The American Association for Clinical Chemistry Press, 1997.
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SYMBOLS

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

MEDICON HELLAS S.A. - Melitona 5-7, 153 44 Gerakas, Greece. Tel: +302106606000 - Fax: +302106612666 – www.mediconsa.com

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