diatron

STFR

SOLUBLE TRANSFERRIN RECEPTORS

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

2°C – 8°C

REF 1419-0748 **Packaging:** 4 x 9 mL (R1) + 4 x 4.5 mL (R2)

Σ 200

INTENDED USE
Reagents for In Vitro quantitative automated determination of Soluble Transferrin Receptors – sTfR in samples of human serum or plasma from the general patient population. Measurements of sTfR are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid for diagnosis of anemia and assessment of bone marrow activity and mass.

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
The extracellular transport of iron is accomplished by binding to transferrin and by a surface receptor that mediates the flow of iron transfer into the cells. The soluble transferrin receptor (sTfR) is the fraction of the receptor that is cleaved from the cell membrane, and shed into the bloodstream as truncated forms of transferrin receptor monomers, complexed with apo transferrin. As 85-90% of the sTfR molecules are found in hemopoietic cells the concentration of sTfR in serum reflects the hemopoietic activity and it can be a marker of functional iron. sTfR levels are not influenced from acute phase conditions so they can be used for the differential diagnosis of anemia due to chronic diseases (ACD) from iron deficiency anemia (IDA). Increased sTfR is observed at hemolytic anemia, sickle cell anemia, B_{12} deficiency and at pregnancy when there is functional iron deficiency.

METHOD PRINCIPLE
The Immunoturbidimetric method is applied. When the sample is mixed with the appropriate buffer (R1) and latex particles coated with anti-sTfR (R2), sTfR reacts with the antibodies leading to the agglutination of latex particles. This agglutination is detected as change in turbidity at 590 nm. and it is proportional to sTfR 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

Reagent 1 (R1)	Reagent 2 (R2)
Tris buffer pH=8.0: 20mM Non-reactive ingredients	Latex particles coated with mouse anti-sTfR monoclonal antibodies Non-reactive ingredients 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.
- 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 1 and 2 are liquid, ready to use, when placed in the corresponding positions of the analyzer reagent tray. Vials bear barcode for identification by Diatron Pictus® P700 / P500 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 it appears cloudy
- After prolonged exposure to high temperature.

⚠ **SHELF LIFE**
Unopened, the reagents are stable up to the expiry date stated on the label. Once opened, the reagents are stable for 2 Months when refrigerated on 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. Use iron free plastic tubes for sampling. 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. sTfR remains stable in serum for 4 weeks at 2 – 8°C and for 1 month at –20°C. Do not freeze thawed samples.

CALIBRATION Diatron offers MEDICON sTfR Calibrator (1478-0749) traceable to NIBSC 07/202 for calibration. Calibrate the assay every 15 days. 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 kit or a new reagent lot number.

QUALITY CONTROL Diatron offers MEDICON sTfR Control (1478-0748) for Quality Control.
Control target values and limits should fall within acceptable intervals adjusted to the requirements of each laboratory. Target values for sTfR 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
- sTfR calibrator
- Quality control material
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS
Serum, Plasma: 9.1 – 26.2 nmol/L
Note: These values have been calculated based on typical transferrin receptor monomers complexed with apo transferrin. 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 by Medicon. The results taken in your laboratory may differ from these values.
Linearity: Up to 1.9 - 250 nmol/L
Hook Effect: >700 nmol/L
Lowest Detection Limit: 1.25 nmol/L
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 three concentration levels of analyte according to CLSI protocol EP05A3 (20 consecutive days, 2 runs per day, 2 repeats per run).

Pictus® P700 and P500	
Level (nmol/L)	**%CV**
13.1	3.43
30.0	1.22
67.0	0.90
Level (nmol/L)	**TOTAL %CV**
13.1	3.87
30.0	2.85
67.0	2.48

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

	(Insignificant up to)
Triglycerides	1800 mg/dL
Hemoglobin	500 mg/dL
Bilirubin	20 mg/dL
Ascorbic acid	3 mg/dL

Correlation: A comparison was performed between this reagent on a Diatron Pictus® P700 and P500 analyzer and another commercially available reagent. The results were as follows:
Y = 0.8985X + 1.5258 R=0.9444 N=40 Sample range = 13.2–32.2 nmol/L

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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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