TRANSFERRIN

For discrete analyzers
Method: Immunoturbidimetry
Product code: 1418-0740 4 x 5 mL (R1) + 4 x 5 mL (R2)
1418-0747 4 x 10 mL (R1) + 4 x 10 mL (R2)
Store at 2 – 8°C
For *in vitro* use

INTENDED USE
MEDICON Transferrin is a set of immunoturbidimetric reagents for the quantitative determination of Transferrin in human serum and plasma, with BECKMAN COULTER AU400/600/600-IVD/640/2700/5400 and other discrete analyzers. For *in vitro* diagnostic use only.

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

METHOD PRINCIPLE
The immunoturbidimetric method is applied. When the sample is mixed with the appropriate buffer (R1) and anti-serum solution (R2), Transferrin reacts selectively with anti- human Transferrin antibodies, leading to formation of insoluble aggregates. The absorbance of these aggregates (520 nm) is proportional to Transferrin concentration 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".
The reagent is designed for in vitro diagnostic use only. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratories practices and techniques. Avoid inhalation and contact with eyes and skin.

REAGENT COMPOSITION
Reagent R1
Polyethylenic glycol in Tris buffer (pH 8.0): 150 mM
Non reactant components and preservatives.
Reagent R2
Goat antihuman Transferrin antibodies
Non reactant 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.
- Dispose all waste according to national laws.
- MSDS is available by MEDICON upon request.

PREPARATION
Reagent 1 and 2 are ready to use. Vials bear barcode for recognition by BECKMAN COULTER AU Series 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 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 can be stored refrigerated on the instrument for 1 month.

SAMPLE
Use serum or EDTA-, heparinised-plasma as specimen. Analyze preferably within 48 hrs. Transferrin is stable in serum and plasma for 3 days when stored at 2 – 8°C, for 6 months when stored at –20°C, and indefinitely at –70 °C.

CALIBRATION
MEDICON Protein Standard Set (1578-1190) traceable to CRM 470 from IRMM or BECKMAN COULTER ODR 3021 (MEDICON code: 4478-0754) can be used for calibration. Calibrate the assay every 1 week. Recalibrate following preventive maintenance or replacement of a critical part of the analyser, when using a new reagent kit or a new reagent lot number, or when Quality Control results are out of range.

QUALITY CONTROL
MEDICON provides the following products for quality control: Immunology Control levels 1,2,3 (1578-1195-04, 1578-1196-04, 1578-1197-04) or BECKMAN COULTER ODC0014 ITA Control Serum 1, ODC0015 ITA Control Serum 2, ODC0016 ITA Control Serum 3 (MEDICON code: 4478-1190, 4478-1191, 4478-1192).
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
Automated biochemistry analyzer
Common laboratory equipment

REFERENCE INTERVALS
Plasma 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
Linearity
The assay is linear within measuring range 3 – 600 mg/dL. When values exceed this range samples should be diluted accordingly.
Prozone Tolerance
No hook effect is observed up to 6000 mg/dL.
Sensitivity
The lowest detectable level of Transferrin is estimated at 0.7 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

Level (mg/dl)	Within run CV%	Total CV%
129	1.17	1.94
240	0.75	1.48

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

Lipemic:	insignificant up to 400 mg/dL intralipid®
Hemoglobin:	insignificant up to 500 mg/dL
Non Conj. Bilirubin:	insignificant up to 20 mg/dL
Conj. Bilirubin:	insignificant up to 20 mg/dL
Ascorbic acid:	insignificant up to 3 mg/dL

Refer to Young[5] for further information on interfering substances.
Method Comparison
A comparison was performed between this reagent and another commercially available product. The results were as follows:
Y = 1.0574X – 3.8692 R=0.9946 N=90 Sample range: 78 – 462 mg/dL

BIBLIOGRAPHY

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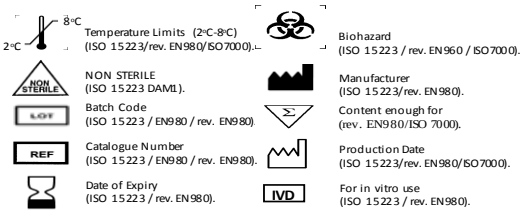
2. Burtis, CA and Ashwood, ER, ed. Tietz Textbook of Clinical Chemistry. 2nd. ed. Philadelphia: W.B. Saunders Company Ltd., 1994.
3. Jacobs, DJ, Demott, WR, Grady, HJ, Horvat, RJ, Huestis, DW and Kasten, BL, JR, eds. Laboratory Test Handbook. 4th. ed. Ohio, Hudson: Lexi-Comp Inc., 1996.
4. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd. ed. Washington, DC: The American Association for Clinical Chemistry Press, 1997.
5. Bernard A., Lawyers R. Turbidimetric latex immunoassay for serum ferritin. Journal of Immunological methods 1984; 71:141-147.

SYMBOLS


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Version 16 Last updated: 22/02/2010