Transferrin FS*

Diagnostic reagent for quantitative in vitro determination of transferrin (Trf) in serum or plasma on photometric systems

Order Information

Cat. No.	Kit size
1 7252 99 10 930	R1 4 x 20 mL + R2 2 x 8 mL
1 7252 99 10 935	R1 2 x 20 mL + R2 1 x 8 mL
5 9200 99 10 037	3 x 1 mL TruCal Protein high
5 9200 99 10 039	5 x 1 mL TruCal Protein: Calibrator set with 5 different levels

Summary [1,2]

Transferrin is a glycoprotein of various isoforms with a molecular weight of 79570 daltons which can bind two Fe^{3+} ions. It transports iron in plasma between the gastrointestinal tract, the iron storage organs as liver, spleen and bone marrow and the iron-consuming organs as the hemopoietic tissue. The synthesis of transferrin in the liver is dependent on the iron requirements and iron reserves of the body; transferrin concentrations can therefore indicate iron overload and iron deficiency. The determination of the transferrin saturation is used in screening for hemochromatosis, for exclusion of iron overload in iron distribution disorders e.g. in liver diseases and in monitoring the erythropoietin treatment of patients with renal failure. The measurement of transferrin saturation has replaced the total iron binding capacity.

Method

Immunoturbidimetric test

Principle

Determination of the transferrin concentration through photometric measurement of antigen-antibody-reaction among antibodies to transferrin and transferrin present in the sample.

Reagents

Components and Concentrations

R1:	TRIS	pH 7.5	100 mmol/L
	NaCl		180 mmol/L
R2:	TRIS	pH 8.0	100 mmol/L
	NaCl		300 mmol/L
	Anti-human Transferrin antibody (goat)		< 1%

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
2. Reagent 2: contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
3. In very rare cases, samples of patients with gammopathy might give falsified results [6].
4. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
5. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, heparin plasma or EDTA plasma

Stability [3]:	8 days	at	20 – 25°C
	8 days	at	4–8°C
	6 months	at	–20°C

Only freeze once!
Discard contaminated specimens.

Assay Procedure for Analyzers

Application sheets for automated systems are available on request.

Wavelength	570 nm
Optical path	1 cm
Temperature	37°C
Measurement	Against reagent blank

	Blank	Sample or calibrator
Sample or calibrator	-	2 µL
Dist. water	2 µL	-
Reagent 1	250 µL	250 µL
Mix, incubate for 3 – 5 min., read absorbance (A1), then add:		
Reagent 2	50 µL	50 µL
Mix, incubate for 5 min., read absorbance (A2).		

$\Delta A = (A2 - A1)$ sample or calibrator

Calculation

The concentration of transferrin in unknown samples is derived from a calibration curve using an appropriate mathematical model such as logit/log. The calibration curve is obtained with 5 calibrators at different levels and NaCl solution (9 g/L) for determination of the zero value.
Stability of calibration: 4 weeks

$$\text{Transferrin saturation [\%]} = \frac{\text{Iron [µg/dL]} \times 79.57 \times 2 \times 56 \times 10}{\text{Transferrin [mg/dL]}}$$

Conversion factor

Transferrin [mg/dL] x 0.126 = Transferrin [µmol/L]

Calibrators and Controls

For the calibration of automated photometric systems the DiaSys TruCal Protein calibrator set or the TruCal Protein high calibrator is recommended. The assigned values of the calibrators have been made traceable to the reference material ERM®-DA470k/IFCC. For internal quality control a DiaSys TruLab Protein control should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruLab Protein Level 1	5 9500 99 10 046	3 x 1 mL
TruLab Protein Level 2	5 9510 99 10 046	3 x 1 mL

Performance Characteristics

Measuring Range

The test has been developed to determine transferrin concentrations within a measuring range from 3 – 800 mg/dL, at least up to the concentration of the highest calibrator. When values exceed this range samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Prozone Limit

No prozone effect was observed up to a transferrin value of 2000 mg/dL.

* fluid stable

Specificity/Interferences

Due to its antibodies, DiaSys Transferrin FS is a specific immunoassay for human transferrin. No interference was observed by conjugated and unconjugated bilirubin up to 60 mg/dL, hemoglobin up to 1000 mg/dL, lipemia up to 2000 mg/dL triglycerides and RF up to 1700 IU/mL. For further information on interfering substances refer to Young DS [5].

Sensitivity/Limit of Detection

The lower limit of detection is 3 mg/dL.

Imprecision

According to protocol EP-5 of the NCCLS (National Committee of Clinical Laboratory Standards)

Within-run precision n = 40	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	222	5.29	2.38
Sample 2	394	7.25	1.84
Sample 3	543	9.08	1.67

Between day precision n = 40	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	222	0.91	0.41
Sample 2	394	0.93	0.24
Sample 3	543	7.45	1.37

Method Comparison

A comparison of DiaSys Transferrin FS (y) with an immunoturbidimetric test (x) using 70 samples gave following results: y = 0.98 x - 0.93 mg/dL; r = 0.993

A comparison of DiaSys Transferrin FS (y) with a nephelometric test (x) using 71 samples gave following results:
y = 1.10 x - 16.6 mg/dL; r = 0.974

Reference Range [4]

200 – 360 mg/dL (25.2 – 45.4 µmol/L)

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Wick M, Pingerra W, Lehmann P. Iron metabolism: diagnosis and therapy of anemias. 3rd ed. Vienna, New York: Springer Verlag, 1996.
2. Fairbanks VF, Klee GG. Biochemical aspects of hematology. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1642-1710.
3. Guder WG, Narayanan S et al. List of Analytes; Preanalytical Variables. 1st ed. Darmstadt: Git Verlag, 1996: 22-3.
4. Dati F, Schumann G, Thomas L, Aguzzi F, Baudner S, Bienvenu J et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference ranges for 14 proteins in serum based on the standardization against the IFCC/BCR/CAP reference material (CRM 470). Eur J Clin Chem Clin Biochem 1996; 34: 517-20.
5. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
6. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.

Manufacturer

IVD CE

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