

Transferrin FS*

Diagnostic reagent for quantitative in vitro determination of transferrin (Trf) in serum or plasma on DiaSys respons[®]920

Order Information

Cat. No. 1 7252 99 10 921

4 twin containers for 100 determinations each

Method

Immunoturbidimetric test

Principle

Determination of the transferrin concentration by 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. DiaSys respons containers provide protection from light. Do not freeze the reagents!

Warnings and Precautions

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
- Reagent 2: contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
- To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons[®]920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
- In very rare cases, samples of patients with gammopathy might give falsified results [6].
- 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.
- For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Specimen

Serum, heparin plasma or EDTA plasma

Stability [1]:

8 days	at	20 – 25°C
8 days	at	4 – 8°C
6 months	at	-20°C

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

DiaSys TruCal Protein calibrator set is recommended for calibrator. The assigned values of the calibrators have been made traceable to the ERM[®]-DA470k/IFCC reference material. 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
TruCal Protein (5 levels)	5 9200 99 10 039	5 x 1 mL
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 up to 800 mg/dL transferrin, at least up to the concentration of the highest calibrator (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	1.0 mg/dL transferrin
No prozone effect up to 2000 mg/dL transferrin	
On-board stability	4 weeks
Calibration stability	4 weeks

Interferences < 10% by
Bilirubin up to 60 mg/dL
Hemoglobin up to 1000 mg/dL
Rheumatoid factor up to 1700 IU/mL
Lipemia (triglycerides) up to 2000 mg/dL
For further information on interfering substances refer to Young DS [2].

Precision			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	198	393	550
Coefficient of variance [%]	1.50	2.78	2.79
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	230	387	435
Coefficient of variance [%]	1.35	2.06	1.78

Method comparison (n=120)	
Test x	DiaSys Transferrin FS (Hitachi 917)
Test y	DiaSys Transferrin FS (respons [®] 920)
Slope	1.03
Intercept	-7.94 mg/dL
Coefficient of correlation	0.993

** lowest measurable concentration which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

Conversion factor

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

Reference Range [3]



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

- Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 22-3.
- 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.
- 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.
- Wick M, Pingerra W, Lehmann P. Iron metabolism: diagnosis and therapy of anemias. 3rd ed. Vienna, New York: Springer Verlag, 1996.
- 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.
- Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007;45(9):1240–1243.

Manufacturer

  DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Transferrin FS

Application for serum and plasma

Test Details		Test Volumes		Reference Ranges	
Test	: TRF			Auto Rerun	<input type="checkbox"/>
Report Name	: Transferrin			Online Calibration	<input type="checkbox"/>
Unit	: mg/dL	Decimal Places	: 1	Cuvette Wash	<input type="checkbox"/>
Wavelength-Primary	: 578	Secondary	: 0	Total Reagents	: 2
Assay Type	: 2-Point	Curve Type	: Polynomial	Reagent R1	: TRF R1
M1 Start	: 15	M1 End	: 15	Reagent R2	: TRF R2
M2 Start	: 33	M2 End	: 33		
Sample Replicates	: 1	Standard Replicates	: 3	Consumables/Calibrators:	
Control Replicates	: 1	Control Interval	: 0	Blank/Level 0	: 0
Reaction Direction	: Increasing	React. Abs. Limit	: *	Calibrator Level 1	: **
Prozone Limit %	: 97	Prozone Check	: Lower	Calibrator Level 2	: **
Linearity Limit %	: 0	Delta Abs./Min.	: 0.00	Calibrator Level 3	: **
Technical Minimum	: *	Technical Maximum	: *	Calibrator Level 4	: **
Y = aX + b	a = 1.00	b =	: 0.00	Calibrator Level 5	: **

Technical limits are automatically defined by the software via the upper and lower calibrator level.

** Enter calibrator value.

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