BioMajesty

Transferrin FS*

Diagnostic reagent for quantitative in vitro determination of transferrin (Trf) in serum or plasma on BioMajesty JCA-BM6010/C

Order Information

Cat. No. 1 7252 99 10 964
R1:   6 x 100 tests
R2:   6 x 100 tests

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. 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. 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

Freeze only once!
Discard contaminated specimens.

Calibrators and Controls

For the calibration the DiaSys TruCal Protein calibrator set 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		
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 7.7 g/L (97.0 µmol/L) 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**	0.01 g/L (0.126 µmol/L) transferrin
No prozone effect up to 19.9 g/L (251 µmol/L) transferrin	
On-board stability	6 weeks
Calibration stability	6 weeks

Interferences < 10% by
Conjugated Bilirubin up to 60 mg/dL
Unconjugated Bilirubin up to 60 mg/dL
Hemoglobin up to 800 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
For further information on interfering substances refer to Young DS [5].

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/L]	1.65	2.65	4.11
Mean [µmol/L]	20.8	33.4	51.7
Coefficient of variance [%]	1.69	1.50	2.15
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/L]	1.63	2.46	3.14
Mean [µmol/L]	20.5	31.0	39.6
Coefficient of variance [%]	2.24	3.45	2.31

Method comparison (n=100)	
Test x	Competitor Transferrin
Test y	DiaSys Transferrin FS
Slope	1.02
Intercept	-0.012 g/L (-0.151 µmol/L)
Coefficient of correlation	0.999

** 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 [2]

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. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 22-3.
2. 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.
3. Wick M, Pingerra W, Lehmann P. Iron metabolism: diagnosis and therapy of anemias. 3rd ed. Vienna, New York: Springer Verlag, 1996.
4. 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.
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

DiaSys Diagnostic Systems GmbH
Alte Strasse 9   65558 Holzheim   Germany

BioMajesty

Transferrin FS

Chemistry code 10 725

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	125
R2e volume	0
R2 volume	25
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1
Sample vol (U)	1
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Endpoint Method	
Re.absorb (u)	9.999
Re.absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Sub-analy. Conditions	
Name	TRF
Digits	2
M-wave L.	571
S-wave.L	****
Analy.mthd.	EPA
Calc.mthd.	MSTD
Qualit. judge	No

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Prozone	
Prozone form	No
Prozone limit	9.999
Prozone judge	Upper limit
Judge limit	9.999
M-DET.P.m	0
M-DET.P.n	0
S-DET.P.p	0
S-DET.P.r	0

Analysis Test Condition Setting (M)	Serum	Urine
Sample Type		
Reac. sample vol.	1	1
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

MULTI-STD Setting				
Formula	Logit Log 2	**Axis Conv**	No conv	
Blank	Blank is 0	**Points**	6	

	FV	Reac. smp. vol.	Dil. method	Dil. smp. vol.	Diluent vol.	Diluent pos.	STD H	STD L
BLK	#	1	No dil	0	0	0	9.999	-9.999
1	#	1	No dil	0	0	0	9.999	-9.999
2	#	1	No dil	0	0	0	9.999	-9.999
3	#	1	No dil	0	0	0	9.999	-9.999
4	#	1	No dil	0	0	0	9.999	-9.999
5	#	1	No dil	0	0	0	9.999	-9.999

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