Transferrin FS*

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

Kits for use in conjunction with DiaSys CE applications.

Intended Use

Diagnostic reagent for quantitative in vitro determination of transferrin in human serum or heparin plasma on automated photometric systems.

Summary

Transferrin is a glycoprotein of various isoforms that plays a crucial role in the transport and metabolism of iron throughout the body. It is mainly synthesized in the liver and has a molecular weight of 79570 daltons. Transferrin can bind two Fe^{3+} ions in a tightly regulated process, facilitating the delivery of iron to cells via specific receptors on the cell surface. This process is essential for hemoglobin synthesis and various metabolic functions [1]. The measurement of transferrin levels, along with other iron tests (such as serum iron and ferritin), is critical in the diagnosis and management of disorders related to iron metabolism. These include iron deficiency anemia, hemochromatosis, and anemia due to chronic disease. Transferrin saturation represents the ratio of serum iron to total iron-binding capacity. It is a useful indicator of the body's iron status. A low transferrin saturation may indicate iron deficiency, while a high saturation may indicate iron overload [2].

Method

Immunoturbidimetric test

Determination of transferrin concentration by photometric measurement of antigen antibody reaction between 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 and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 18 months until expiry date.

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 material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [3].
4. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
5. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
6. Please refer to the safety data sheets (SDS) 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.
7. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagents are ready to use.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [4]:		
4 months	at	20 – 25°C
8 months	at	4 – 8°C
6 months – 2 years	at	-20°C

Only freeze once. Discard contaminated specimens.

Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	571 nm
Temperature	37°C
Measurement	Endpoint
Sample/Calibrator	1.0 µL
Reagent 1	125 µL
Reagent 2	25 µL
Addition reagent 2	Cycle 19 (286 s)
Absorbance 1	Cycle 17/18 (231 s/244 s)
Absorbance 2	Cycle 41/42 (586 s/600 s)
Calibration	Logit Log 2

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.

$$\text{Transferrin [\%]} = \frac{\text{Iron [µg/dL]}}{\text{Transferrin [mg/dL]}} \times 70.9$$

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

Calibrators and Controls

DiaSys TruCal Protein is recommended for calibration. Calibrator values have been made traceable to the reference material ERM®-DA470k/IFCC. Use DiaSys TruLab Protein Level 1 and Level 2 for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal Protein	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

Data evaluated on BioMajesty® JCA-BM6010/C

Measuring range up to 7.7 g/L, depending on the concentration of the highest calibrator. Linearity is given within ± 5%. When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.	
Limit of detection**	0.01 g/L
No prozone effect up to 19.9 g/L.	

Interference by	Interferences ≤ 10% up to	Analyte concentration [g/L]
Bilirubin (conjugated)	60 mg/dL	2.22
Bilirubin (unconjugated)	60 mg/dL	2.21
Hemolysis	800 mg/dL	2.22
Lipemia (triglycerides)	2000 mg/dL	2.22
For further information on interfering substances, refer to the literature [5-7].		

Precision			
Repeatability (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/L]	1.65	2.65	4.11
CV [%]	1.69	1.50	2.15
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/L]	1.63	2.46	3.14
CV [%]	2.24	3.45	2.31

Method comparison (n=100)	
Test x	Competitor Transferrin (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Transferrin FS (BioMajesty® JCA-BM6010/C)
Slope	1.02
Intercept	-0.012 g/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.

Reference Range [8]

200 – 360 mg/dL 25.2 – 45.4 µmol/L

The level of transferrin saturation can be determined by taking into account the level of iron in the blood. Refer to “Calculation” section.

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

Literature

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IVD CE

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* Fluid Stable