

## Transferrin FS\*

### Order Information

<b>Cat. No.</b>	<b>Kit size</b>
1 7252 99 10 921	 400 (4 x 100)

### Intended Use

Diagnostic reagent for quantitative in vitro determination of transferrin in human serum or heparin plasma on automated respons<sup>®</sup>910.

### 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<sup>3+</sup> 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

<b>R1:</b>	TRIS	pH 7.5	100 mmol/L
	NaCl		180 mmol/L
<b>R2:</b>	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

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 2 contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [3].
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
- 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.
- 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.
- 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. The bottles are placed directly into the reagent rotor.

### 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.

### Calibrators and Controls

DiaSys TruCal Protein is recommended for calibration. Calibrator values have been made traceable to the reference material ERM<sup>®</sup>-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

Measuring range from 1.02 mg/dL up to 800 mg/dL, depending on the concentration of the highest calibrator. Linearity is given within ± 5%.	
In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	1.02 mg/dL
Limit of quantitation**	1.02 mg/dL
No prozone effect up to 2600 mg/dL.	
Onboard stability	6 weeks
Calibration stability	5 days

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
<b>Bilirubin</b> (conjugated)	70 mg/dL	220
	60 mg/dL	421
<b>Bilirubin</b> (unconjugated)	60 mg/dL	220
	70 mg/dL	404
<b>Hemolysis</b>	1200 mg/dL	199
	1200 mg/dL	378
<b>Lipemia</b> (triglycerides)	2000 mg/dL	200
	2000 mg/dL	355
<b>Rheumatoid factor</b>	700 IU/mL	156

For further information on interfering substances, refer to the literature [5-7].

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	117	359	669
CV [%]	2.58	3.14	3.74
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	117	369	680
CV [%]	6.15	3.34	5.22
Method comparison (n=95)			
Test x	DiaSys Transferrin FS (Hitachi 917)		
Test y	DiaSys Transferrin FS (respons <sup>®</sup> 910)		
Slope	1.07		
Intercept	-11.8 mg/dL		
Coefficient of correlation	0.992		

\*\* according to CLSI document EP17-A, Vol. 24, No. 34

### Conversion Factor

Transferrin [mg/dL] x 0.126 = Transferrin [ $\mu$ mol/L]

### Reference Range [8]

200 – 360 mg/dL                      25.2 – 45.4  $\mu$ mol/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

1. Wick, Pingerra, Lehmann Clin Aspects Iron Metabolism and Anemias 5th ed. Springer Vienna New York 2003 p. 152-57
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. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
4. Guder WG, da Fonseca-Wollheim F, Heil W, et al. The Quality of Diagnostic Samples, German United Society for Clinical Chemistry and Laboratory Medicine. 3rd ed; 2010.
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. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, <https://clinfx.wiley.com/aaccweb/aacc/>, accessed in May 2024. Published by AACC Press and John Wiley and Sons, Inc.
7. Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendation of drugs and their concentrations to be used in drug interference studies. Ann Clin Biochem. 2001 Jul;38:376-85.
8. 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.

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



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\* Fluid Stable

## Transferrin FS

### 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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	TRF
Shortcut:	
Reagent barcode reference:	719
Host reference:	719

Technic	
Type:	End point
First reagent:[ $\mu$ L]	200
Blank reagent	Yes
Sensitive to light	
Second reagent:[ $\mu$ L]	40
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	546
Secondary wavelength:[nm]	
Polychromatic factor:	
1 st reading time [min:sec]	(04:24)
Last reading time [min:sec]	08:00
Reaction way:	Increasing
Linear Kinetics	
Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics	
Substrate depletion: Absorbance limit	
Endpoint	
Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [ $\mu$ L]	0 (no hemolysis)
Cleaner	
Sample [ $\mu$ L]	0
Technical limits	
Concentration technical limits-Lower	2.0000
Concentration technical limits-Upper	800.0000
SERUM	
Normal volume [ $\mu$ L]	2.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	2.0
Above normal dilution (factor)	6
URINE	
Normal volume [ $\mu$ L]	2.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	2.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [ $\mu$ L]	2.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	2.0
Above normal dilution (factor)	6
CSF	
Normal volume [ $\mu$ L]	2.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	2.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [ $\mu$ L]	2.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	2.0
Above normal dilution (factor)	6

Results	
Decimals	1
Units	mg/dL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	>=200.0 <=360.0
URINE	
PLASMA	>=200 <=360
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants	
Please refer to r910 Carryover Pair Table	

Calibrators details	
Calibrator list	Concentration
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*
	Max delta abs.
Cal. 1	0.0100
Cal. 2	0.0100
Cal. 3	0.0100
Cal. 4	0.0150
Cal. 5	0.0200
Cal. 6	0.0300
Drift limit [%]	2.00

Calculations	
Model	Akima Spline
Degree	

\* Enter calibrator value