TRANSFERRIN (TF)

IMMUNOTURBIDIMETRIC ASSAY FOR SERUM TRANSFERRIN
RX SERIES

INTENDED USE

A Transferrin test system is a device intended for the quantitative *in vitro* determination of transferrin concentration in serum. This product is suitable for use on the RX **imola**.

Cat. No.

TF 3831	R1. Assay Buffer	6 x 20 ml
	R2. Antibody Reagent	3 x 14 ml

GTIN: 05055273206494

CLINICAL SIGNIFICANCE

Plasma levels of Transferrin are regulated by the availability of iron and increase when plasma iron is low. Levels correlate well with the Total Iron Binding capacity of serum. Transferrin levels increase during pregnancy and oestrogen administration and are also associated with a range of conditions including anaemia, iron deficiency, inflammation or malignancy, liver disease, malnutrition and protein loss.

PRINCIPLE

Sample is reacted with a buffer containing antibody specific for human transferrin (siderophilin). The absorbance of the resulting turbid solution is proportional to the concentration of transferrin in the sample. By constructing a standard curve from the absorbance of standards, transferrin concentration of sample can be determined.

SAMPLE COLLECTION AND STORAGE (1)

Serum should be stored at between +2°C to +8°C for a maximum of 72 hr, or stored frozen at –20°C for a maximum of 6 months (do not refreeze).

REAGENT COMPOSITION

Contents	Initial Concentration of Solutions
R1. Assay Buffer	
Polyethylene Glycol	6% (w/v)
Tris/HCl buffer	20 mmol/l, pH 7.4
Sodium Chloride	150 mmol/l
Sodium Azide	0.09% w/v
R2. Antibody Reagent	
Anti (human) transferrin	
Tris/HCl buffer	20 mmol/l, pH 7.4
Sodium Chloride	150 mmol/l
Sodium Azide	0.05% w/v

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Solution R1 and R2 contain Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

Safety Data Sheets are available on request.

The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

STABILITY AND PREPARATION OF REAGENTS

R1. Assay Buffer

Supplied ready for use. Stable up to expiry date when stored at +2°C to +8°C.

R2. Antibody Reagent

Supplied ready for use. Stable up to expiry date when stored at +2°C to +8°C.

Reagent 1 = Assay Buffer
Reagent 2 = Antibody Reagent

MATERIALS PROVIDED

Transferrin Assay Buffer
Transferrin Antibody Reagent

MATERIALS REQUIRED BUT NOT PROVIDED

Randox Liquid Assayed Specific Protein Calibrator, Cat. No. IT 2691
Randox Liquid Assayed Specific Protein Controls:

Level 1	Cat. No. PS 2682
Level 2	Cat. No. PS 2683
Level 3	Cat. No. PS 2684

RX **series** Saline (Cat. No. SA 3854)

PROCEDURE NOTES

To avoid the potential for reagent carryover, it is recommended that the testing order of the reagents is confirmed. Please consult the reagent carryover document available on www.randox.com under support and documentation - Reagent product inserts or by contacting Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

The Chemistry parameters for Randox Dedicated RX **imola** Assays are predefined on the hard drive of the analyser PC. The required programs should be downloaded to the analyser software. Please note that the predefined chemistry parameters use SI units. If alternative units are required, these can be edited by the user. In this case, the technical range should be edited in accordance with the users selected units. All necessary instructions are encoded on the bar code. If the barcode cannot be read by the analyser, enter manually the series of numbers given beneath the barcode. If problems continue, contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 94451070.

CALIBRATION
0.9% NaCl as zero calibrator and Randox Liquid Assayed Specific Protein Calibrator is recommended for calibration. Values have been established using CRM 470 as reference material.

QUALITY CONTROL
Randox Liquid Assayed Specific Protein Controls Levels 1, 2 and 3 are recommended for Quality Control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check cleanliness of all equipment in use.
3. Check water. Contaminants i.e. bacterial growth may contribute to inaccurate results.
4. Check reaction temperature.
5. Check expiry date of kit and contents.
6. Contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 94451070.

Quality control requirements should be determined in conformance with government regulations or accreditation requirements.

INTERFERENCE
The analytes below were tested up to the following levels and were found not to interfere:

Haemoglobin	1000 mg/dl
Free Bilirubin	25 mg/dl
Conjugate Bilirubin	25 mg/dl
Triglycerides	250 mg/dl
Intralipid®	200 mg/dl

Physiological changes in serum or plasma analyte concentrations can be caused by a number of substances. Comprehensive discussion of possible interfering substances, their serum or plasma concentrations, and their possible physiological involvements is beyond the scope of this document. The listed reference contains specific details on known potential interfering substances [6]. The user must remain vigilant to the possible effect on results of unknown interferences from medications or endogenous substances. All patient results must be evaluated in light of the total clinical status of the patient.

NORMAL RANGES [2]
Healthy Adults:
200 - 380 mg/dl (2.00 - 3.8 g/l) (23 - 42.8 µmol/l)

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

CONVERSION FACTORS

mg/dl	x	0.01	=	g/l
mg/dl	x	0.114	=	µmol/l
µmol/l	x	8.80	=	mg/dl
mg/dl	x	0.408	=	IU/ml
IU/ml	x	2.45	=	mg/dl

1 mg transferrin is approximately equal to 1.27 µg iron[3]
mg transferrin/dl x 1.27 = TIBC (µg/dl)
mg transferrin/dl x 0.2275 = TIBC (µmol/l)

SPECIFIC PERFORMANCE CHARACTERISTICS
The following performance data were obtained using an RX **series** analyser at 37°C.

ASSAY RANGE
Approximately 7.60 - 497 mg/dl (0.080 - 5.23 g/l) depending on the lot specific value of calibrator in use.

PROZONE EFFECTS
Antigen excess effects are not noted until transferrin levels approach 1500 mg/dl.

SENSITIVITY
The minimum detectable concentration of Transferrin with an acceptable level of precision was determined as 7.60 mg/dl (0.080 g/l).

PRECISION

Intra Assay

	Level 1	Level 2	Level 3
Mean (mg/dl)	103	229	341
SD	2.90	8.11	16.5
CV (%)	2.82	3.55	4.84
n	20	20	20

Inter Assay

	Level 1	Level 2	Level 3
Mean (mg/dl)	109	225	348
SD	5.20	8.60	11.5
CV (%)	4.79	3.82	3.31
n	20	20	20

CORRELATION
This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

Y = 0.96 X + 7.81
and a correlation coefficient of r = 0.98

40 patient samples were analyzed spanning the range 87.9 to 464 mg/dl.

REFERENCES
1. Tietz, N. Clinical Guide to Laboratory Tests, 2nd Edition.p550.
2. *Ferritin in iron metabolism: diagnostic strategies* (Editors: Wick, M., W. Pinggera and P. Lehmann), 1991, pp 33-34 Published by Springer Vienna - New York.
3. Weippl. G. *Blut* (1973) **27:**376.
4. Becker, W.: *Laboratoriumsblätter* (1980) **30:**25.
5. Geiger, H. & Hoffman, P.: *Z. Kinderheilk* (1970) **109:**22-40.
6. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Washington, DC: AACC Press; 2000.

The presence of a vertical bar in the margin indicates a Technical update from the previous revision.

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