TRANSFERRIN
Multi-Purpose (MPR)
Liquid Reagent

Glenbio
Diagnostics & Research Laboratory Solutions

KIT SPECIFICATIONS:

Cat. No.	*Quantity*	*Reagent*	*Storage*
GL305TR	1 x 50 ml	TRANSFERRIN - 1	2-8°C
	1 x 10 ml	TRANSFERRIN - 2	
GL325TR	5 x 50 ml	TRANSFERRIN - 1	2-8°C
	5 x 10 ml	TRANSFERRIN - 2	

INTENDED USE:

In Vitro Diagnostic reagent pack for the determination of Transferrin in serum and plasma on automated and semi-automated analysers.

SUMMARY AND EXPLANATION: [2]

Transferrin is the principal plasma transport protein for Iron. Although it reversibly binds and transports a number of divalent cations, only iron and copper binding have any known clinical significance. Transferrin accounts for most of the total iron in binding capacity in plasma. It is synthesised in the liver and the rate of synthesis is dependent on the body's needs. The valuation of plasma transferrin is useful for anaemia and the monitoring and treatment of Iron deficiency anaemia. In cases of iron deficiency, transferrin levels are increased but the protein is less saturated with iron. If the anaemia is due to a failure to incorporate iron into the erythrocytes instead of a deficiency of iron, the transferrin level may be normal or low but the protein is highly saturated with iron.

PRINCIPLE OF THE TEST: [2]

This assay is based on the reaction between antigen and antibody. This reaction forms an insoluble complex producing a turbidity, which is measured spectrophotometrically. The amount of complex formed is directly proportional to the amount of Transferrin in the sample.

Transferrin antigen + Anti-transferrin antibody ⟶ Antigen/antibody complex

WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only
Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

Components Colour and Appearance:
Reagent 1: Clear colourless liquid.
Reagent 2: Pale beige liquid.
Any significant changes from the above could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

Safety Precautions:
Product is not hazardous under EU specification. Contains Sodium Azide. Material Safety Data Sheet is available upon request.

Handling precautions:
- Take the necessary precautions required for handling all laboratory reagents.
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

INSTRUMENTS:

Instrument applications are available upon request.

COMPONENT COMPOSITION:

Component	*Ingredients*	*Concentration in Tests*
Reagent 1	PHOSPHATE Buffer pH 7.3 with PEG	2.7 mmol/l
	PRESERVATIVES	---
Reagent 2	TRIS Buffer pH 7.6	18.16 mmol/l
	Anti Transferrin antibody	---
	PRESERVATIVES	---

REAGENT PREPARATION AND STABILITY:

Reagent 1 and 2 are ready for use.
Before use, mix reagent by gently inverting each bottle.
If stored and handled properly, components are stable until expiry date stated on the label.

Prepare a range of 6 standards by serially diluting Calibrator (GL969) in saline as follows:

Dilution	Neat	1/2	1/4	1/8	1/16	1/32
Factor	1	0.5	0.25	0.125	0.063	0.032

TYPE OF SPECIMEN: [2]

Use serum or heparin plasma as specimen. *Do not use* EDTA or citrate plasma.

It is recommended to follow CLSI procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification. Serum should be separated from cells within 2 hours after collection.

Stability: up to 8 days at 2-8°C[3].

TEST PROCEDURE:

Materials required but not supplied:

Description	*Catalog. No.*	*Description*	*Catalog. No.*
Transferrin Calibrator	GL969	Photometer	N/A
Specific Protein Control Level 1	GL9006	General Laboratory Equipment	N/A
Specific Protein Control Level 2	GL9016	Saline solution 0.9g/l NaCl	N/A

Assay procedure:
Wavelength: λ: 560 nm
Temperature: 37°C
Optical path: 1 cm light path.

	Blank	Calibrator	Sample
Reagent 1	1000 µl	1000 µl	1000 µl
Sample	----	----	10 µl
Calibrator	----	10 µl	----
Gently mix and Incubate at 37°C Measure the Optical Density (OD1) after 5 minutes.			
Reagent 2	200 µl	200 µl	200 µl
Gently mix and Incubate at 37°C Measure the Optical Density (OD2) after 10 minutes.			

Calibration:
Using recommended Calibrator, calibrate the assay:
- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Controls are out of range.

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At intervals established by the Laboratory Q.C. Programme.

CALCULATION:

- Calculate the ΔAbs for each calibrator (ΔAbs = OD2-OD1) and construct a calibration curve.
- Calculate the ΔAbs for each sample. Determine the corresponding concentration from the calibration curve.

(Conversion Factor: mg/dl x 0.01 = g/l)

EXPECTED VALUES: [2]

	g/l	*mg/dl*
Adult	2.15 – 3.8	215 - 380

Each laboratory should establish its own reference range. Transferrin results should always be reviewed with the patient's medical examination and history.

PERFORMANCE CHARACTERISTICS:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

Linearity:
This assay is linear across the calibration range.
For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.

Prozone:
The system did not show prozone phenomena at least up to 13 g/l. (1300mg/dl)

Interfering substances:
Bilirubin (mixed isomers): Less than 10% interference up to 600 µmol/l Bilirubin.
Haemolysis: Less than 10% interference up to 5 g/l Haemoglobin.
Lipemia: Less than 10% interference up to 5 g/l Intralipid.

Sensitivity:
The Lowest Detectable Level was estimated at 0.04 g/l (4 mg/dl).

Precision:

Within Run N = 20	Mean *(g/l)*	*SD*	*% CV*	*Between Run N = 20*	Mean *(g/l)*	*SD*	*% CV*
Level 1	1.76	0.03	1.56	Level 1	1.77	0.04	2.08
Level 2	2.53	0.07	2.92	Level 2	2.57	0.06	2.17

Method Comparison:
Using 50 samples, a comparison, between this Transferrin test (y) and another commercially available test (x), gave the following results:

y = 0.955x + 0.005	r = 0.973	Sample range: 1.2 to 5.2 g/l

BIBLIOGRAPHY:

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2. Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54, 334 and 1013.
3. Guder WG, Narayanan S, Wisser H, Zawta B. List of Analytes; Pre-analytical Variables. Brochure in: Samples: From the Patient to the Laboratory. Darmstadt: GIT Verlag, 1996.
4. Schumann G, Dati F. Vorlaufige Referenzbereiche fur 14 Proteine im Serum (fur Erwachsene) nach Standardisierung immunchemischer Methoden unter Bezug auf das internationale Referenzmaterial CRM 470. Lab Med 1995;19:401-403.

SYMBOLS:

The following symbols are used in the labelling of Glenbio systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	Ab	Antibody
CAL	Calibrator	SUBS	Substrate
BUF	Buffer	STD	Aqueous Standard

CE Mark - Device comply with the Directives 98/79/EC

Storage temperature → Reconstitute with

Expiry Date (Last day of the month) — Manufactured By

Biological risk — Consult Instruction for Use

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Revision: 07 Issued on: 29 July 2021