BIOLABO
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TRANSFERRIN Turbidimetric Immunoassay

Reagent for quantitative determination of Transferrin in human serum.

REF 92208 **R1** 1 x 120mL **R2** 1 x 30 mL

TECHNICAL SUPPORT AND ORDERS
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Latest revision: www.biolabo.fr

IVD

Made in France

I: corresponds to significant modifications

I INTENDED USE

This reagent is designated for professional use in laboratory (automated method).
It is used for quantitative determination of transferrin (TRF) by Turbidimetric Immunoassay in human serum to assess the maximum concentration of iron that serum protein can bind.

I GENERALITIES (1) (2)

Transferrin transports iron in plasma preventing iron intoxication and loss via kidneys. Elevated levels are founded in iron deficiency, pregnancy, or hormonal contraception. Decreased levels may be sign of iron overload (hemochromatosis), inflammation, important proteins loss (nephrotic syndrome, chronic renal deficiency), malnutrition, liver diseases, some malignancies, atransferrinemia (rare genetic disease)
No clinical diagnosis should be based on the conclusions of a single test, it should integrate all clinical data and other tests results as serum iron and ferritin.

PRINCIPLE

Turbidimetric Immunoassay (TIA): the addition of antiserum to the sample starts the formation of TRF - anti-TRF complexes. The complexes precipitate and enhance the turbidity of the mixture. The photometric measurement of this agglutination is realised by end-point method at 340 nm. TRF concentration is determined by means of a nonlinear calibration curve.

REAGENTS

R1	**TRF**	Buffer
TRIS buffered saline		pH 7.5
Polyethylene glycol (PEG)		50 g/L
Sodium azide		0.90 g/L

R2	**TRF**	Anti-TRF
TRIS buffered saline		pH 7.5
Polyclonal anti human Transferrin antibody (goat)		
Sodium azide		0.90 g/L

Reagents R1, R2 are not classified as dangerous according to 1272/2008/EC regulation.

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Ready for use.

STABILITY AND STORAGE

Stored away from light, well caped in the original vial at 2-8°C, when used and stored as described, reagents are stable:

Unopened,
- Until the expiry date stated on the label of the Kit.

Once opened:
- When free from contamination, 2 separated reagents are stable :
  - at least for 2 months at 2-8° C

SPECIMEN COLLECTION AND HANDLING (3)

Use fresh serum.

If the test cannot be carried out on the same day, the serum may be stored at 2-8°C for 3 days or 6 months at -20°C.

Specimen without lipemia or haemolysis are preferred

LIMITS (5) (6) (7)

In rare cases, multiple myeloma (Walden Strom's macroglobulinemia) can cause unreliable results.
For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Spectrophotometer or Biochemistry Clinical Analyzer
3. Saline (NaCl 9 g/L)

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with

QUALITY CONTROL

- REF TIA CONT21 Control Set
- External quality control program.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test.
2. If control is still out of range, use a new vial of calibrator or a fresh calibrator and repeat the test.
3. If control is still out of range, repeat the tests with a new vial of reagent.

If control is still out of range, please contact BIOLABO technical support or your local Agent.

REFERENCE INTERVAL (4)

Values: 200 – 360 mg/dL

Each laboratory should establish its own normal ranges for the population that it serves.

I PERFORMANCES

On Kenza 240TX, at 340 nm, 37°C

Linearity Range: between 50 mg/dL and 780 mg/dL

Hook effect:: >1500 mg/dL

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High level*	*Between run N = 20*	*Low level*	*Normal level*
Mean (mg/dL)	111	217	391	Mean (mg/dL)	111	228
S.D. mg/dL	1,1	3,3	8,9	S.D. mg/dL	7,1	8,4
C.V. %	1%	1,5%	2,3%	C.V. %	6,4%	3,7%

Analytical sensitivity:
≥ 0,100 for 100 mg/dL and ≥ 0,300 for 400 mg/dL

Interferences:

Turbidity	Negative interference from 0.155 OD
Total bilirubin	Negative interference from 295 µmol/L
Direct bilirubin	Negative interference from 219 µmol/L
Ascorbic acid	No interference up to 2500 mg/dL
Glucose	No interference up to 976 mg/dL
Haemoglobin	Negative interference from 181 µmol/L

Other substances may interfere (see § Limits)

On Board Stability: 2 months

Calibration Stability:

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

CALIBRATION

- Use REF TRF CALSET51: TRANSFERRIN Standard Set and saline as zero point to generate standard curve as indicated in §Procedure

Calibration values are traceable to ERM-DA470k/IFCC Reference material.

The calibration frequency depends on proper instrument functions and on the preservation of the reagent.

PROCEDURE

Manual Procedure:

Let stand reagents, standards, control, assays at room temperature.

Before use:

- mix reagent R2 by gentle swirling.
- Predilute calibrators, controls and specimens 1/10 in saline.

Generate standard curve using 5 different levels of TRF CALSET51 prediluted and zero point

Perform tests as follows on calibrators/controls and specimen prediluted:

Pipette into well identified test tubes:	Blank	Calibration	Assays
Buffer (R1)	1000 µL	1000 µL	1000 µL
Saline	40 µL		
Standards (1/10)		40 µL	
Specimen 1/10)			40 µL
Mix well. Record absorbance A1 against blank at 340 nm			
Anti-TRF (R2)	200 µL	200 µL	200 µL
Mix and let stand for 5 minutes at 37°C. Record absorbance A2 against blank at 340 nm.			

1- With Manual Procedure on Spectrophotometer, performances and stability data should be validated by user

2- Upper of linear limit, re-dilute specimen 1/5 with saline. Multiply the results by 5 to take into accounted post-dilution Factor

3- Applications proposal are available on request of other analysers

CALCULATION

Manual procedure:

Calculate ΔAbs (Abs A2 – Abs A1) for standards, controls and assays.
Plot a Standard Curve "Concentration = f(ΔAbs)".
Read the concentration of controls and samples on the graph.

Automatic Biochemistry analyzer:

The analyzer provides directly final result.
For more details about calibration and calculation of results, refer to User's manual and specific application.

REFERENCES

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