BIOLABO
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TRANSFERRIN Turbidimetric Immunoassay

Reagent for quantitative determination
of Transferrin in human serum

I REF K1208	**R1** 2 x 16 mL	**R2** 1 x 8 mL
I REF K2208	**R1** 1 x 32 mL	**R2** 1 x 8 mL
I REF K4208	**R1** 1 x 40 mL	**R2** 1 x 10 mL

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

CE

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.

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 cap in the original vial at 2-8°C, reagent is stable when stored and used as described in the insert:

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

Once opened:
- When free from contamination, 2 separated reagents are stable 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. Medical analysis laboratory equipment.
2. Biochemistry Clinical Analyzer Kenza One, Kenza 240TX/ISE or Kenza 450TX/ISE
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

REFERENCE INTERVAL (4)

Values: 200 – 360 mg/dL

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

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*
Mean (mg/dL)	111	217	391
S.D. mg/dL	1,1	3,3	8,9
C.V. %	1%	1,5%	2,3%

Between run N = 20	*Low level*	*Normal level*
Mean (mg/dL)	111	228
S.D. mg/dL	7,1	8,4
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 the 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

- REF TRF CALSET51: TRANSFERRIN Standard Set
- Use saline as zero point.

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.

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.

PROCEDURE

Refer to the application of Kenza Analyzer used

CALCULATION

The analyzer provides directly result (mg/dL)

REFERENCES

(1) Schreiber, W.E., Iron porphyrin, and bilirubin metabolism, Clin. Chem: Theory, Analysis, Correlation, 4th ed., Kaplan, L.A., Pesce, A.J., Kazmiersack, S.C., (Mosby Inc. eds St Louis USA), (2003), 657 and appendix

(2) Evaluation report from HAS/Service evaluation of professional acts /March 2011 - 49

(3) Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 1062-1065

(4) Dati F., et al., Eur J. Clin. Chem. Biochem. (1996), 34, 517

(5) Berth, M. & Delanghe J., Protein precipitation as a possible important pitfall in the clinical analysis of blood samples containing monoclonal immunoglobulins: 2 cases reports and a review of literatures, Acta Clin. Belg., (2004), 59, 263

(6) Young D.S., Effects of preanalytical variables on clinical laboratory tests, 2nd ed. AACC Press (1997)

(7) Young D.S., Effects of drugs on clinical laboratory tests, 4th ed., AACC Press, (1995), 3-572