

Transferrin

Turbidimetry

Quantitative determination of Transferrin (TRF) IVD

Store 2 - 8°C.

PRINCIPLE OF THE METHOD

The Transferrin is a quantitative turbidimetric test for the measurement of transferrin in human serum or plasma.

Anti-transferrin antibodies when mixed with samples containing TRF, form insoluble complexes. These complexes cause an absorbance change, dependent upon the TRF concentration of the patient sample, that can be quantified by comparison from a calibrator of known TRF concentration.

CLINICAL SIGNIFICANCE

Transferrin is a plasma protein that contains a single polypeptide chain with approximately 6% carbohydrate. It is synthesized in the liver and transfers iron through the serum.

Evaluation of plasma TRF levels is useful for the differential diagnosis of anemia and for monitoring its treatment. In the hypochromic anemia (iron deficiency), the TRF level is increased. On the other hand, if the anemia is due to a failure to incorporate iron into erythrocytes, the TRF level is normal or low but the protein is highly saturated with iron. In iron overload, the TRF concentration is normal but saturation exceeds 55% and may be as great as 90%.

TRF concentration may, in fact, be used for assessing nutritional status. In the congenital defect atransferrinemia, very low level of TRF is accompanied by iron overload and a severe hypochromic anemia that is resistant to iron therapy. High levels of TRF occur in pregnancy and during estrogen administration.

REAGENTS

R1	Tris buffer 20 mmol/L, PEG 8000, pH 8.2. Sodium azide 0.95 g/L.
R2	Goat serum, anti-human transferrin, pH 7.5. Sodium azide 0.95 g/L.
Saline Solution	NaCl 9% (for samples predilution)

CALIBRATION

The assay has been standardized against the Reference Material CRM 470/RPPHS (Institute for Reference Materials and Measurements, IRMM).

PREPARATION

Reagents: Ready to use.

Samples and Controls Pre-Dilution: Before the use, samples and/or controls must be diluted in this way:

- 50 µL sample or control + 1000 µL NaCl 9 g/L(1:20)

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C and contaminations are prevented during their use. Do not use reagents over the expiration date.

Reagent deterioration: The presence of particles and turbidity.

Do not freeze; frozen Antibody or Diluent could change the functionality of the test.

ADDITIONAL EQUIPMENT

- Pipette 100 - 1000 µL
- Pipette 10 - 100 µL
- Cuvettes and microstirrers (ref. code ACC16-037)

SAMPLES

Fresh serum or plasma. EDTA or heparin should be used as anticoagulant. Stable 7 days at 2-8°C or 3 months at -20°C.

The samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.

TEST PARAMETER

Filter: set filter on position B
Reading time: 120 seconds

PROCEDURE

1. Pipette into an appropriate number of cuvettes:

kind of reagent	µL
R1	400
Pre-diluted sample or control	50

2. Incubate the cuvettes in positions 1-4 for at least 1 minute
3. Transfer each cuvette in the reading channel and, when requested on the display, add 100 µL of R2
4. Read the result which will appear automatically on the reader's display after 120 sec

QUALITY CONTROL

Control sera are recommended to monitor the performance of manual and automated assay procedures. Vital Diagnostics SERUM PROT CONTROL BILEVEL (Cod.: ACC16-057) is available. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES²

Between 200 - 360 mg/dL. Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

1. Linearity: Up to 600 mg/dL (Nota 1), under the described assay conditions. Samples with higher concentrations, should be diluted 1/5 in NaCl 9 g/L and retested again. The linearity limit depends on the sample / reagent ratio. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
2. Detection Limit: Values less than 1 mg/dL give non-reproducible results.
3. Prozone effect: No prozone effect was detected upon 2000 mg/dL
4. Sensitivity: Δ 3.0 mA / mg/dL (94 mg/dL).
5. Precision:

	Mean	SD	CV%
Intra-assay (n=10)	102.7	3.2	3.1
Inter-assay (n=10)	115.7	4.2	3.6

6. Accuracy: Results obtained using this reagent (y) were compared to those obtained using the Immage from Beckman. 100 samples ranging from 50 to 700 mg/dL of TRF were assayed. The correlation coefficient (r) was 0.95 and the regression equation $y = 1.046x + 3.843$.

The results of the performance characteristics depend on the used analyzer.

INTERFERENCES

Hemoglobin (10 g/L), bilirubin (20 mg/dL), rheumatoid factors (300 IU/mL) and lipemia (5 g/L), do not interfere. Other substances may interfere ^{5,6}.

NOTES

1. Linearity depends on the calibrator concentration.
2. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

BIBLIOGRAPHY

1. Clinical Guide to Laboratory Tests, Edited by NW Tietz W B Saunders Co., Philadelphia, 483, 1983.
2. Dati F et al. Eur J Clin Chem Clin Biochem 1996; 34:517-520.
3. Pesce AJ and Kaplan, LA. Methods in Clinical Chemistry. The CV Mosby Company, St. Louis MO, 1987.
4. Kreuzer HJH. J Clin Chem Clin Biochem 1976; 14: 401-406
5. Young DS. Effects of drugs on clinical laboratory tests, 4th ed. AACCC Pres, 1995.
6. Friedman and Young. Effects of disease on clinical laboratory tests, 3rd ed. AACCC Pres, 1997.

PACKAGING

Ref.: ACC16-013	Cont.	: 1 x 40 mL R1
		: 1 x 10 mL R2
		: 1 x 50 mL Saline solution