AU

Instructions For Use

TFR
TRANSFERRIN

REF OSR6152 4 x 7 mL R1, 4 x 8 mL R2

For *in vitro* diagnostic use only.

PRINCIPLE

INTENDED USE

Immuno-turbidimetric test for the quantitative determination of transferrin in human serum and plasma on Beckman Coulter analysers.

SUMMARY AND EXPLANATION

Reference[1,2]

Transferrin is the principle plasma protein for the transport of iron. Transferrin has two binding sites for iron; they are strong at physiological pH but weaken with decreasing pH. Transferrin is largely but not exclusively synthesised by the liver.

Measurement of plasma transferrin levels is useful in the differential diagnosis of anemia, and will rise with iron deficiency anemia. In congenital atransferrinemia, a very low level of transferrin is accompanied by iron overload and a severe hypochromic anemia resistant to iron therapy. High levels of transferrin occur in pregnancy and during oestrogen administration. It is decreased in conditions, which are associated with increased protein loss such as nephrotic syndrome, protein-deficiency states, and in chronic liver disease. Transferrin is a negative acute phase reactant and will decrease during any inflammatory state or malignancy.

Transferrin is often used in conjunction with iron to calculate transferrin saturation.

METHODOLOGY

When a sample is mixed with R1 buffer and R2 antiserum solution, human transferrin reacts specifically with anti-human transferrin antibodies to yield insoluble aggregates. The absorbance of these aggregates is proportional to the transferrin concentration in the sample.

SPECIMEN

TYPE OF SPECIMEN

Serum and EDTA or heparinised plasma.

SPECIMEN STORAGE AND STABILITY

Stable in serum and plasma for 8 months when stored at 2…8°C and 4 months when stored at 15…25°C.[3]

REAGENTS

WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents.

Dispose of all waste material in accordance with local guidelines.

This product contains material of animal origin. The product should be considered as potentially capable of transmitting infectious diseases.

REACTIVE INGREDIENTS

Final concentration of reactive ingredients:

Tris buffer (pH 7.2)	30 mmol/L
Polyethylene glycol 6000	0.8% w/v
Goat anti-transferrin antibodies	Variable
Preservative	

The concentrations of the reactive components of the reagents shown on the kit label are the actual concentrations in the individual R1/R2 vials. The reagent composition which is shown in the Instructions For Use is the final concentration of these components in the reaction cuvette after addition of R1, Sample, and R2.

⚠ CAUTION

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

GHS HAZARD CLASSIFICATION

Transferrin R1	WARNING	
	H316	Causes mild skin irritation.
	P332+P313	If skin irritation occurs: Get medical advice/attention.
		Tris(hydroxymethyl)– aminomethane 1 - 5%

SDS	Safety Data Sheet is available at beckmancoulter.com/techdocs

REAGENT PREPARATION

The reagents are ready for use and can be placed directly on board the instrument

Changes in antisera lots can influence the color of the R2 reagent component. R2 reagent may appear as a light brown/amber clear solution or a colorless to yellow clear solution depending on the reagent lot. This does not affect the performance of the reagent.

REAGENT STORAGE AND STABILITY

The reagents are stable, unopened, up to the stated expiry date when stored at 2…8°C. Once open, reagents stored on board the instrument are stable for 90 days.

INDICATIONS OF DETERIORATION

Visible signs of microbial growth, turbidity, precipitate, or change of color, other than that specified in the reagent preparation section in the Transferrin reagents may indicate degradation and warrant discontinuation of use.

CALIBRATION

CALIBRATION INFORMATION

Serum Protein Multi-Calibrator Cat No. ODR3021.

The calibrator values are traceable to the IFCC (International Federation of Clinical Chemistry) standard CRM 470.

Recalibrate the assay every 90 days or when the following occur:

Change in reagent lot or significant shift in control values;

Major preventative maintenance was performed on the analyser or a critical part was replaced.

Following calibration, the resulting curve should be visually reviewed for acceptability, on the Beckman Coulter analyser, using the software options to access the Calibration Monitor. Quality control procedures should be undertaken immediately following calibration in accordance with good laboratory practice.

QUALITY CONTROL

ITA Control Sera ODC0014, ODC0015 and ODC0016 or other control materials with values determined by this Beckman Coulter system may be used.

Each laboratory should establish its own control frequency however good laboratory practice suggests that controls be tested each day patient samples are tested and each time calibration/blanking is performed.

The results obtained by any individual laboratory may vary from the given mean value. It is therefore recommended that each laboratory generates analyte specific control target values and intervals based on multiple runs according to their requirements. These target values should fall within the corresponding acceptable ranges given in the relevant product literature.

If any trends or sudden shifts in values are detected, review all operating parameters.

Each laboratory should establish guidelines for corrective action to be taken if controls do not recover within the specified limits.

TESTING PROCEDURE(S)

Refer to the appropriate Beckman Coulter AU analyser User Guide/Instructions For Use (IFU) for analyser-specific assay instructions for the sample type as listed in the Intended Use statement. The paediatric application is suitable for use with small volume serum/plasma samples.

CALCULATIONS

The Beckman Coulter analyzers automatically compute the transferrin concentration of each sample.

REPORTING RESULTS

REFERENCE INTERVALS

Reference[4,5]

Serum (Adults)	2.0 – 3.6 g/L (200 – 360 mg/dL)
Serum (Children)	
0 − 4 day	1.30 – 2.75 g/L (130 – 275 mg/dL)
3 month – 10 year	2.03 – 3.6 g/L (203 – 360 mg/dL)

Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should verify the transferability of the expected values to its own population, and if necessary determine its own reference interval according to good laboratory practice. For diagnostic purposes, results should always be assessed in conjunction with the patient's medical history, clinical examinations and other findings.

PROCEDURAL NOTES

LIMITATIONS

Samples with extremely abnormal optical characteristics, especially turbidity, may produce atypical results.

INTERFERENCES

Results of studies conducted to evaluate the susceptibility of the method to interference were as follows:

Icterus:	Interference less than 10% up to 40 mg/dL or 684 µmol/L bilirubin
Haemolysis:	Interference less than 3% up to 5 g/L haemoglobin
Lipemia:	Interference less than 10% up to 1,000 mg/dL Intralipid

Refer to Young[6] for further information on interfering substances.

PERFORMANCE CHARACTERISTICS

PERFORMANCE CHARACTERISTICS

Data contained within this section is representative of performance on Beckman Coulter systems. Data obtained in your laboratory may differ from these values.

LINEARITY

The test is linear within a concentration range of 0.75 − 7.50 g/L (75 − 750 mg/dL).

SENSITIVITY

The lowest detectable level in serum on an AU5800 analyser was estimated at 0.004 g/L.

The lowest detectable level represents the lowest measurable level of transferrin that can be distinguished from zero. It is calculated as the absolute mean plus three standard deviations of 20 replicates of an analyte free sample.

METHODS COMPARISON

Patient serum samples were used to compare this Transferrin OSR6152 assay on the AU400 against another commercially available transferrin assay. Results of linear regression analysis were as follows:

y = 0.937x + 0.327	r = 0.995	n = 24	Sample range = 0.49 – 4.95 g/L

PRECISION

The following data was obtained on a DxC 700 AU using 3 serum pools analysed over 20 days.

n = 80	Within-run		Total	
Mean g/L	**SD**	**CV%**	**SD**	**CV%**
1.67	0.01	0.76	0.01	0.85
3.12	0.03	0.93	0.04	1.19
6.97	0.07	0.96	0.07	1.05

ADDITIONAL INFORMATION

DxC 700 AU requires that each reagent application has a standard format of abbreviated Closed Test Name. This Closed Test Name is required to allow automated loading of the calibrator information for each application as part of the DxC 700 AU Closed System. Refer to the table below for the Closed Test Name assigned to each application for this assay.

Test Name	Description
TRF1G	Transferrin (Serum)
TRF1GP	Transferrin (Serum Paediatric)

Setting Sheet Footnotes
User defined
† Beckman Coulter Serum Protein Multi-Calibrator Cat. No: ODR3021

* Values set for working in SI units (g/L). To work in mg/dL multiply by 100.

REVISION HISTORY

Added new languages

Preceding version revision history

Revised Reagent Section

REFERENCES

1. Grant GH, Silverman LM, Christenson RH. Amino Acids and proteins. In: Teitz NW, ed. Fundamentals of clinical chemistry. Philadelphia: WB Saunders Company, 1987:333-334pp.

2. Thomas L. Transferrin saturation (TfS). In: Thomas L, ed. Clinical laboratory diagnostics. Use and assessment of clinical laboratory results. Frankfurt/Main: TH-Books Verlagsgesellschaft, 1998:275-277pp.

3. Ehret W, Heil W, Schmitt Y, Töpfer G, Wisser H, Zawta B, et al. Use of Anticoagulants in Diagnostic Laboratory Investigations and Stability of Blood, Plasma and Serum Samples. WHO/DIL/LAB/99.1 Rev.2:43pp.

4. Baudner S, Dati F. Standardization of the measurement of 14 proteins in human serum based on the new IFCC/BCR/CAP International reference material CRM 470. J Lab Med 1996;20:145-152pp.

5. Painter PC, Cope JY, Smith JL. Reference information for the clinical laboratory. In: Burtis CA, Ashwood ER, eds. Tietz textbook of clinical chemistry. Philadelphia:WB Saunders Company, 1999;1836pp.

6. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.

EC REP Beckman Coulter Ireland Inc., Lismeehan, O'Callaghan's Mills, Co. Clare, Ireland +(353) (0) 65 683 1100

Beckman Coulter, Inc., 250 S. Kraemer Blvd., Brea, CA 92821 U.S.A.
www.beckmancoulter.com