TRANSFERRIN

OSR6152	**4 x 7 mL**	**R1**
	4 x 8 mL	**R2**

Intended Use
System reagent for the quantitative determination of Transferrin in human serum on Beckman Coulter AU analyzers.

Summary
Iron in plasma is bound to the transport protein transferrin. Transferrin is responsible for 50% to 70% of the iron binding capacity of serum. Transferrin has two iron-binding sites and is largely, but not exclusively, synthesized by the liver.

Transferrin levels rise with iron deficiency and fall in cases of iron overload. An increase in transferrin is seen in iron deficiency anemia. It may also be increased late in pregnancy and in women on oral contraceptives. It is decreased in conditions associated with increased protein loss, such as nephrotic syndrome, chronic renal failure, severe burns, and protein-deficiency states and in severe liver disease. Transferrin is a negative acute-phase protein and will be decreased during any inflammatory state or severe illness.

Methodology
Immune complexes formed in solution scatter light in proportion to their size, shape and concentration. Turbidimeters measure the reduction of incident light due to reflection, absorption, or scatter.
In the procedure, the measurement of the decrease in light transmitted (increase in absorbance) through particles suspended in solution as a result of complexes formed during the antigen-antibody reaction, is the basis of this assay.

System Information
For AU400/400^{e}/480, AU600/640/640^{e}/680 and AU2700/5400/AU5800 Beckman Coulter Analyzers.

Reagents
Final concentration of reactive ingredients:

Tris buffer (pH 7.2)	30 mmol/L
Polyethylene glycol 6000	0.8 % w/v
Goat anti-Transferrin antiserum	
Also contains preservatives.	

Precautions
1. For *in vitro* diagnostic use.
2. Do not ingest. Harmful if swallowed.
3. Contains sodium azide as a preservative which may react with lead joints in copper plumbing to form explosive compounds. Even though the reagent contains minute quantities of sodium azide, drains should be well flushed with water when discarding the reagent.

Preparation of reagents
The Transferrin reagent is ready for use. No preparation is required.

Storage and stability
1. The unopened reagents are stable until the expiration date printed on the label when stored at 2 - 8°C.
2. Opened bottles of reagent are stable for 90 days when stored in the refrigerated compartment of the analyzer.

Indications of Deterioration
Visible signs of microbial growth, turbidity, precipitate, or change of color in the Transferrin reagents may indicate degradation and warrant discontinuation of use.

Specimen Collection and Preparation
Fasting serum specimen, free from hemolysis, is the recommended specimen.[1]

Sample Storage and Stability
Transferrin is stable at ≤ -20°C for over 40 days and can be repeatedly frozen and thawed without loss of immunological activity.[2]

Interfering Substances
Results of studies[3] show that the following substances may interfere with this Transferrin procedure:

The criteria for no significant interference is recovery within 10% of the initial value.

Bilirubin:	No significant interference up to 40 mg/dL Bilirubin
Hemolysis:	No significant interference up to 500 mg/dL Hemolysate
Lipemia:	No significant interference up to 1000 mg/dL Intralipid*

* Intralipid, manufactured by KabiVitrium Inc., is a 20% IV fat emulsion used to emulate extremely turbid samples.

The information presented is based on results from Beckman Coulter studies and is current at the date of publication Beckman Coulter Inc. makes no representation about the completeness or accuracy of results generated by future studies. For further information on interfering substances, refer to Young[4] for a compilation of reported interferences with this test.

Procedure
A complete list of test parameters and operational procedure can be found in the User's Guide appropriate to the analyzer.

Transferrin

Materials Provided
Transferrin Reagents

Materials required But Not Provided
Serum Protein Multi-Calibrator (Cat # ODR3021)
MC Cal A (Cat # ODR30037) for Mastercurve enabled systems

Stability of Final Reaction Mixture
The Beckman Coulter AU analyzers automatically compute every determination at the same time interval.

Calibration
The frequency of calibration for the Transferrin turbidimetric procedure is every 90 days. Calibration of this Transferrin procedure is accomplished by use of the Serum Protein Multi-Calibrator (Cat # ODR3021), which is traceable to IFCC international reference preparation CRM470 (RPPHS). Use MC Cal A Cat. No. ODR30037 for Mastercurve enabled systems only. Please refer to User Guide for further instructions.

Recalibration of this test is required when any of these conditions exist:
1. A reagent lot number has changed or there is an observed shift in control values.
2. Major preventative maintenance was performed on the analyzer.
3. A critical part was replaced.

Quality Control
During operation of the Beckman Coulter AU analyzer, at least two levels of an appropriate Immunology control material should be tested a minimum of once a day. In addition, these controls should be performed after calibration, with each new lot of reagent, and after specific maintenance or troubleshooting steps described in the appropriate User's Guide. Quality control testing should be performed in accordance with regulatory requirements and each laboratory's standard procedure.

Results
Automatically printed out for each sample in mg/dL at 37°C.

Dynamic Range
The Transferrin turbidimetric procedure is linear from 75 – 750 mg/dL. Samples exceeding the upper limit of linearity should be diluted and repeated. The sample may be diluted, repeated and multiplied by the dilution factor automatically utilizing the AUTO REPEAT RUN.

Expected Values
Serum:[5] 203 – 362 mg/dL
Expected values may vary with age, sex, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practice.

Specific Performance Characteristics
The following data was obtained using the Transferrin Reagent on Beckman Coulter AU analyzers according to established procedures. Results obtained in individual laboratories may differ.

Precision[7]
Estimates of precision, based on CLSI recommendations[6], are consistent with typical performance. The within run precision is less than 3% CV and the total precision is less than 5% CV. Assays of serum pools and control sera were performed and the data reduced following CLSI guidelines above.

N = 100	Within run		Total	
Mean, mg/dL	SD	CV%	SD	CV%
93.3	0.7	0.8	1.4	1.5
204.8	1.1	0.5	2.9	1.4

Method Comparison[7]
Patient samples were used to compare this Transferrin Reagent. The table below demonstrates representative performance on AU analyzers.

Y Method	AU640
X Method	AU600
Slope	0.994
Intercept	3.1
Correlation Coeff. (r)	0.9993
No. of Samples (n)	177
Range (mg/dL)	79 – 574

References

1. Henry, J.B., et. al., Clinical Diagnosis and Management by Laboratory Methods, Nineteenth Edition, WB Saunders, 1996.
2. Pesce, A.J., Kaplan, L.A., Methods in Clinical Chemistry, CV Mosby Co.,1987.
3. CLSI/NCCLS, Interference Testing in Clinical Chemistry, EP7-P, 1986.
4. Young, D.S., Effects of Drugs on Clinical Laboratory Tests, 5th Edition, AACC Press, 2000.
5. Beckman Coulter Inc.,data on samples collected from 200 blood donors in North Texas.
6. CLSI/NCCLS Evaluation Protocol EP5-T2, 1992.
7. Data is on file for specific AU analyzers.

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