TRANSFERRIN

Diagnostic reagent for determination of transferrin concentration.

Liquid. Mono Reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
TA190	5 x 25 mL	DMT190	990 Tests	BY191	3535 Tests	NAB190	848 Tests
TA191	5 x 10 mL	RAB190	370 Tests	MAB190	1364 Tests	KAB190	2439 Tests
TAB190	1167 Tests	SAB191	545 Tests	MAB191	682 Tests	KAB191	1220 Tests
LAB190	2667 Tests						

INTENDED USE

The test is applied for the quantitative determination of transferrin in serum or plasma.

This test is applied for the quantitative determination of transferring concentration in human serum or plasma.

Iron is normally transported via the specific binding of Fe3+ by transferrin in blood plasma. The specific iron uptake is regulated according to the individual needs of the various cells.

Elevated transferrin values are found in the presence of iron deficiency (particularly in pregnancy). The transferrin level may also be raised by drug-based induction.

Low transferrin values are found in infectious diseases, malignant tumors, nephrotic syndrome and cirrhosis.

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

TEST PRINCIPLE

Transferrin in the sample precipitates in the presence of anti-human transferrin antibodies. The light scattering of the antigen-antibody complexes is proportional to the transferrin concentration and can be measured by turbidimetry.

TEST PARAMETERS

Method : Turbidimetric
Wavelength : 540 nm
Temperature : 37°C
Sample : Serum / Plasma
Linearity : 4.8 mg/dL - 700 mg/dL

REAGENT COMPOSITION

Reagent 1:
Imidazole buffer < 0.12 mol/L,
Goat anti-human transferrin antibodies
Sodium azide < 1 g/L,
pH 7.5

REAGENT PREPARATION

Reagent is ready for use.

REAGENT STABILITY AND STORAGE

The Reagent is stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during its use.

Indications of deterioration: Presence of particulate material, turbidity, absorbance of the blank over 0.300 at 540 nm.

Once opened vials (reagent 1) are stable minimum 30 days at 2-8°C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

SAMPLE

Serum or plasma collected by standard procedures. Use heparin or EDTA as anticoagulants. Lipemic samples are not suitable for testing.

Transferrin in serum or plasma is stable for 7 days at 2-8°C and 6 months at -20°C.

TEST PROCEDURE

Sample Start
There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

Calibration curve: Plot the absorbance values

of each calibrator against its transferrin concentration. Use the Blank as the calibrator of 0 concentrations. Transferrin concentration in the sample is calculated by interpolation of its absorbance on the calibration curve.

REFERENCE INTERVAL (NORMAL VALUES) (Based on CLSI C28-P Document)*

Serum, adults: 200 - 360 mg/dL

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

It is recommended to use the Protein Control Serum level I (Cod. PCN01) and II (Cod. PCN05) to verify the performance of the measurement procedure.

Protein Calibrators set contains 5 different levels of transferrin concentration and it should be used to prepare the calibration curve. The calibrators are supplied ready to use.

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 10 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 4.8 mg/dL transferrin

High Linearity: The test is linear up to 700 mg/dL. For higher values dilute sample 1/5 with distilled water and repeat measurement.
Linearity may considerably vary depending on the instrument used.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatibility (within run) (Intra-assay)

Mean concentration	CV	n
167 mg/dL	1.8%	20
394 mg/dL	3.0%	20

Reproducibility (run to run) (Inter-assay)

Mean concentration	CV	n
167 mg/dL	3.6%	25
394 mg/dL	2.4%	25

Sensitivity (LOD) (Based on CLSI EP17 document): Limit of detection is 2.0 mA□dL/mg at 360 mg/dL.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Prozone effect: Falsely low values are obtained when transferrin is present in the sample at a concentration higher than 1500 mg/dL.

Interferences: Hemoglobin (10 g/L), bilirubin (20 mg/dL) and rheumatoid factors (300 IU/mL) do not interfere. Lipemia (triglycerides > 7.5 g/L) may affect the results. Other drugs and substances may interfere.

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1 & R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The reagents contain sodium azide (< 0.1%) as a preservative.
8. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general “Good Laboratory Practice” (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.

S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

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SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

CE

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