Transferrin
(Immunoturbidimetric Test, 5 + 1)

<table>
<thead>
<tr>
<th>Cat.No</th>
<th>Package Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>835 100</td>
<td>4 x 20 mL / 2 x 8 mL</td>
</tr>
<tr>
<td>835 002</td>
<td>(Hit I) 4 x 20 mL / 2 x 8 mL</td>
</tr>
</tbody>
</table>

Test principle
Immunoturbidimetric test for determination of Transferrin (TRF) by photometric measurement of the Antibody-Antigen reaction between goat-AB on human TRF and TRF in the sample.

Reagents
Components (concentrations in the test)

R1:
- Phosphate Buffer 100 mmol/l
- NaCl 180 mmol/l
- Accelerator
- Detergents and stabilizers

R2:
- Phosphate Buffer 100 mmol/l
- NaCl 180 mmol/l
- Antibody (goat) against human TRF
- Stabilizers

Storage / Stability
At 2-8 °C reagents are stable up to the given expiration date printed on the labels, if there is no contamination after opening the bottles. Do not freeze reagents!

Precautions / Warnings
Reagents contain Sodiumazide (0.95 g/l) as preservative. Do not swallow! Do not touch skin and/or mucous membranes!

Waste
Handle according to the local legal regulations

Preparation
Reagents are ready for use.

Sample material
Serum, Heparin plasma or EDTA plasma.
Stability 8 days at 2-8 °C
6 months at -20 °C
Freeze, if ever necessary, only once.
Discard contaminated samples.

Analytical Procedure
Wavelength 570 nm
Cuvette 1 cm lightpath
Temperature 37 °C
Measure Against Reagent Blank (RB)

<table>
<thead>
<tr>
<th>Sample / Calibrator</th>
<th>Reagent-Blank</th>
<th>Sample or calibrator</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>2 µl</td>
<td></td>
</tr>
<tr>
<td>Reagent 1</td>
<td>250 µl</td>
<td></td>
</tr>
<tr>
<td>Reagent 2</td>
<td>50 µl</td>
<td></td>
</tr>
</tbody>
</table>

Mix, incubate for 3 min, read absorbance A1, then add:
Mix, incubate for 5 min, read absorbance A2.

ΔA = [(A2–A1) Sample or Calibrator]

Calculation

Multi-Point-Calibration
The concentration in unknown samples is calculated through a calibrations curve using a suitable mathematical procedure e.g. logit/log. The calibrations curve is established by 5 calibrators of different concentrations and NaCl solution (9 g/l) for zero. Stability of calibration is 4 weeks.

Calculation of Transferrin Saturation

\[
TRF - Sat \ [%] = \frac{IRON(\mu g/dl) \times 79570}{TRF(\text{mg/dl}) \times 2 \times 56 \times 10}
\]

Applications for automated systems are available on request

Calibration/Controls
For the calibration of automated photometric systems we recommend Greiner-Transferrin-calibrators. These values are traceable on the “IFCC/BCR/CAP-reference material for 15 Plasmaproteins CRM 470”.

For internal QC use Greiner Protein-controls.
Data of Performance

Range / Linearity
Multi-Point-calibration: The test can, depending on the automated system used, measure transferrin-concentrations from 3 mg/dl up to 800 mg/dl.
At higher concentrations, dilute the samples 1+1 with NaCl-solution (9 g/l). Multiply result by 2.

Prozone Effect
No effect up to 2000 mg/dl.

Specificity / Interferences
Greiner transferrin is specific on human transferrin. No interference with ascorbic acid up to 30 mg/dl, bilirubine up to 60 mg/dl, hemoglobin up to 1000 mg/dl, lipämia up to 2000 mg/dl triglycerides, and no effect with RF up to 1700 IU/ml.

Sensitivity / Detection Limit
Lower Detection Limit = 3 mg/dl

Imprecision
(Ref.: NCCLS = National Committee of Clinical Laboratory Standards)

<table>
<thead>
<tr>
<th></th>
<th>n = 40</th>
<th>Mean [mg/dl]</th>
<th>SD [mg/dl]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>222</td>
<td>5.29</td>
<td>2.38</td>
<td></td>
</tr>
<tr>
<td>Sample 2</td>
<td>394</td>
<td>7.25</td>
<td>1.84</td>
<td></td>
</tr>
<tr>
<td>Sample 3</td>
<td>543</td>
<td>9.08</td>
<td>1.67</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>n = 40</th>
<th>Mean [mg/dl]</th>
<th>SD [mg/dl]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>222</td>
<td>0.91</td>
<td>0.41</td>
<td></td>
</tr>
<tr>
<td>Sample 2</td>
<td>394</td>
<td>0.93</td>
<td>0.24</td>
<td></td>
</tr>
<tr>
<td>Sample 3</td>
<td>543</td>
<td>7.45</td>
<td>1.37</td>
<td></td>
</tr>
</tbody>
</table>

Method Comparison
A comparison of Greiner (y) with an established immunoturbidimetric test (x) using 70 samples gave following results:
y = 0.98 x - 0.93 mg/dl; r = 0.993.

A comparison of Greiner (y) with an established nephelometric test (x) using 71 samples gave following results:
y = 1.10 x - 16.6 mg/dl; r = 0.974.

Normal Range
200 – 360 mg/dl (2.0 – 3.6 g/l)

Literature

SYMBOLS USED

For in vitro diagnostic medical use

Batch Code

Use by

Temperature limitation