DIAGNOSTIC KIT FOR DETERMINATION OF TRANSFERRIN CONCENTRATION

OS – TRANSFERRIN

INTRODUCTION

Transferrin (siderophilin) is a glycoprotein synthesised in the liver. Transferrin is the major plasma transport protein for iron. Its concentration correlates with the total iron-binding capacity (TIBC). Evaluation plasma/serum transferrin levels is useful for the differential diagnosis of anaemia and for monitoring its treatment. Causes of decreased synthesis and low plasma levels may be chronic liver disease and malnutrition. High levels of transferrin occur in pregnancy and during estrogen administration.

METHOD PRINCIPLE

Transferrin present in a sample form with the specific antibody an immunological complex. The increase of turbidity after the addition of antiserum measured spectrophotometrically is proportional to transferrin concentration in the sample.

REAGENTS

Package	
1-Reagent	1 x 40.5 ml
2-Reagent	1 x 12.5 ml

Buffer (1-Reagent) stored at 2-25°C and antiserum (2-Reagent) stored at 2-8°C are stable until expiry date printed on the package. Store closed. Protect from light and avoid contamination!

Concentrations in the test

Imidazole buffer (pH 7.0); PEG; sodium chloride; anti human transferrin antiserum; HEPES buffer (pH 7.4); stabilizers.

Warnings and notes

- Products for in vitro diagnostic use only.
- The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Products from human source have been tested for HBsAg and antibodies to HIV and HCV and found to be non-reactive. However this material should be handled as thought capable of transmitting infectious disease.
- Products contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN

Serum or plasma.

Concentration of transferrin in serum is stable up to 43 days at -20°C. Nevertheless it is recommended to perform the assay with freshly collected samples!

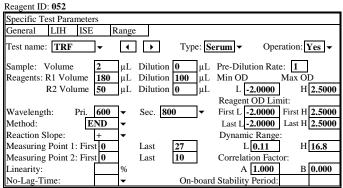
PROCEDURE

These reagents may be used in automatic analysers Olympus AU400/AU640.

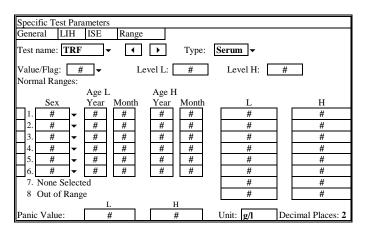
1-Reagent and 2-Reagent are ready to use.

For reagent blank 0.9% NaCl is recommended.

APPLICATION







Calibration Specific General ISE	;					
Test name: TRF ▼						
Calibration Type:	Calibration Type: 6AB ▼ Formula: Spline ▼ Counts: 1 Process: CONC ▼					
Cal.	No. OI	O CONC	Factor/OD-L	Factor/OD-H		
Point 1: #	E	**	-2.0000	2.5000		
Point 2: #	!	*	-2.0000	2.5000		
Point 3: #	!	*	-2.0000	2.5000		
Point 4: #	ŀ	*	-2.0000	2.5000		
Point 5: #	ŀ	*	-2.0000	2.5000		
Point 6: #	ŀ	*	-2.0000	2.5000		
Point 7:						
1-Point Cal.Point: with CONC-0 Slope Check: None ← Advanced Calibration: # ▼						
MB Type Factor: Calibration Stability Period:						

User defined

* Calibrator value

** Saline should be used as calibrator 1

REFERENCE VALUES⁶

newborns	1.30 – 2.75 g/l
children (3 months – 16 years)	2.03 – 3.60 g/l
adults F	2.50 – 3.80 g/l
М	2.15 – 3.65 g/l
M	2.15 – 3.65 g/l

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY IMMUNO-CONTROL III (Cat. No 4-291) with each batch of samples.

For the calibration of automatic analysers systems the CORMAY IMMUNO-MULTICAL (Cat. No 4-287).

The calibration curve should be prepared every 4 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analysers Olympus AU400, Cobas Mira and Hitachi 911. Results may vary if a different instrument is used.

Analytical range: 0.006 g/l – 8 g/l.

Specificity / Interferences

Haemoglobin up to 0.26 g/dl, bilirubin up to 29.5 mg/dl, triglycerides up to 2000 mg/dl, heparin up to 0.5 g/l, sodium fluoride up to 4 g/l, EDTA up to 5 g/l, sodium citrate up to 5 g/l do not interfere with the test.

Precision

Repeatability (run to run)	Mean	SD	CV
n = 10	[mg/dl]	[mg/dl]	[%]
level 1	167.2	2.1	1.3
level 2	242.2	2.6	1.1
level 3	300.9	2.2	0.7
level 4	399.9	4.0	1.0

Reproducibility (day to day)	Mean	SD	CV
n = 10	[mg/dl]	[mg/dl]	[%]
level 1	161.6	6.2	3.8
level 2	232.7	6.7	2.9
level 3	289.1	6.8	2.4
level 4	389.3	11.4	2.9

Method comparison

A comparison between CORMAY reagent (y) and commercially available assay (x) using 21 samples gave following results: y = 0.9927 x - 0.1898 g/l;

R = 0.9960

(R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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MANUFACTURER

PZ CORMAY S.A.

22 Wiosenna Street, 05-092 Łomianki, POLAND tel.: +48 (0) 22 751 79 10 fax: +48 (0) 22 751 79 14 <u>http://www.cormay.pl</u>

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