Cat. No 9-451

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
Reagent ID: **052**

Specific Test Parameters
General | LIH | ISE | Range

Test name: **TRF** Type: **Serum** Operation: **Yes**

Sample: Volume	2	µL	Dilution	0	µL	Pre-Dilution Rate:	1	
Reagents: R1 Volume	180	µL	Dilution	100	µL	Min OD		Max OD
R2 Volume	50	µL	Dilution	0	µL	L	-2.0000	H 2.5000
						Reagent OD Limit:		
Wavelength: Pri.	600		Sec.	800		First L	-2.0000	First H 2.5000
Method:	END					Last L	-2.0000	Last H 2.5000
Reaction Slope:	+					Dynamic Range:		
Measuring Point 1: First	0		Last	27		L	0.11	H 16.8
Measuring Point 2: First	0		Last	10		Correlation Factor:		
Linearity:		%				A	1.000	B 0.000
No-Lag-Time:						On-board Stability Period:		

Specific Test Parameters
General | LIH | ISE | Range

Test name: **TRF** Type: **Serum**

Value/Flag: # Level L: # Level H: #

Normal Ranges:

	Sex	Age L Year	Age L Month	Age H Year	Age H Month	L	H
1.	#	#	#	#	#	#	#
2.	#	#	#	#	#	#	#
3.	#	#	#	#	#	#	#
4.	#	#	#	#	#	#	#
5.	#	#	#	#	#	#	#
6.	#	#	#	#	#	#	#
7. None Selected						#	#
8 Out of Range						#	#

	L	H		
Panic Value:	#	#	Unit: **g/l**	Decimal Places: **2**

Calibration Specific
General | ISE

Test name: **TRF** Type: **Serum**

Calibration Type: **6AB** Formula: **Spline** Counts: **1** Process: **CONC**

	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	#		**	-2.0000	2.5000
Point 2:	#		*	-2.0000	2.5000
Point 3:	#		*	-2.0000	2.5000
Point 4:	#		*	-2.0000	2.5000
Point 5:	#		*	-2.0000	2.5000
Point 6:	#		*	-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 VALUES [6]

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
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) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
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) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
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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Date of issue: 05. 2016.

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05/16/05/16