Cat. No 9-446

DIAGNOSTIC KIT FOR DETERMINATION OF FERRITIN CONCENTRATION

OS – FERRITIN

INTRODUCTION
Ferritin is an iron-containing protein with a molecular weight of approximately 450 kD. It is found mainly in the human liver and spleen, where its function is to eliminate and store iron in the body, and is also found in small amounts in human serum. This amount varies according to the movement of iron in the body, and hepatitis and malignant tumors, may be seen to increase due to cell destruction or tumor cell production, independent of iron reserves. Consequently, the measurement of ferritin is considered to be useful in the diagnosis, treatment, assessment of disease progression, and postoperative prognosis for such disease conditions.

METHOD PRINCIPLE
When an antigen-antibody reaction occurs between ferritin in a sample and anti-ferritin antibody which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change (572 nm), with the magnitude of the change being proportional to the quantity of ferritin in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of know concentration.

REAGENTS
Package

1-Reagent	1 x 35 ml
2-Reagent	1 x 19 ml

The reagents when stored at 2-10°C are stable up to expiry date printed on the package. The reagents are stable for 10 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Concentrations in the test

suspension of latex particles sensitized with anti-ferritin (rabbit) antibodies (pH 7.3)	0.07 w/v%
glycine buffer solution (pH 8.3)	

Warnings and notes
- Product for in vitro diagnostic use only.
- After measurements are taken, reagent bottles should capped and kept at 2-10°C. Care should be taken not to interchange the caps of reagent bottles.
- Reagents with different lot numbers should not be interchanged or mixed.
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN
Serum.
If the test cannot be done immediately, the sample should be placed in a tightly sealable container and stored at -20°C. Repeated freezing and thawing should be avoided.
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: **050**

Specific Test Parameters
General | LIH | ISE | Range

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

Sample:	Volume	8	µL	Dilution	0	µL	Pre-Dilution Rate:	1	
Reagents:	R1 Volume	160	µL	Dilution	0	µL	Min OD		Max OD
	R2 Volume	80	µL	Dilution	0	µL	L -2.0000	H	2.5000
							Reagent OD Limit:		
Wavelength:	Pri.	660		Sec.	None		First L -2.0000	First H	2.5000
Method:		RATE					Last L -2.0000	Last H	2.5000
Reaction Slope:		+					Dynamic Range:		
Measuring Point 1:	First	12		Last	19		L	H	
Measuring Point 2:	First			Last			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: **FERRITIN** 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						#	#

Panic Value: L # H # Unit: **ng/ml** Decimal Places: **2**

Calibration Specific
General | ISE

Test name: **FERRITIN** Type: **Serum**

Calibration Type: **5AB** 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:					
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]

serum	ng/ml
male	20 – 250
female	10 – 120

It is recommended for each laboratory to establish its own reference ranges for local population. Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

QUALITY CONTROL
For internal quality control it is recommended to use the CORMAY IMMUNO-CONTROL II (Cat. No 4-290) with each batch of samples.
For the calibration of automatic analysers systems the CORMAY FERRITIN CALBRATORS kit (Cat. No 4-491) is recommended. Renewed calibration is recommended: after 1 month when using the reagent on the analyser, 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 analyser HITACHI 917. Results may vary if a different instrument is used.

- **Analytical range:** 10 – 1000 ng/ml.

For higher concentrations dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

- **Specificity / Interferences**

Haemoglobin up to 0.98 g/dl, bilirubin up to 62 mg/dl, RF up to 520 IU/ml, triglycerides up to 500 mg/dl do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 21	Mean [ng/ml]	SD [ng/ml]	CV [%]
level 1	14.90	0.60	4.0
level 2	100.00	0.65	0.6
level 3	431.05	2.20	0.5
Reproducibility (day to day) n = 21	Mean [ng/ml]	SD [ng/ml]	CV [%]
level 1	16.47	0.87	5.31
level 2	105.18	1.60	1.52
level 3	428.71	3.52	0.82

- **Method comparison**

A comparison between CORMAY reagent (y) and commercially available assay (x) using 77 samples gave following results:
y = 1.085 x - 2.93 ng/ml;
R = 0.994 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

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