Cat. No 7-330

ACCENT 300

ACCENT-300 FERRITIN

DIAGNOSTIC KIT FOR DETERMINATION OF FERRITIN CONCENTRATION

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 40 ml
2-Reagent	1 x 18.3 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 or plasma (Na-EDTA, K-EDTA, Na-Heparin, Li-Heparin).
After blood has clotted thoroughly, the sample is centrifuged and the serum is separated from blood cells and fibrins.
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 analyser ACCENT-300.
1-Reagent and 2-Reagent are ready to use.
For reagent blank 0.9% NaCl is recommended.

APPLICATION

Parameters

No.	47	Prim.Wave.	578
Test	FERRI	Sec.Wave.	
Method	Endpoint	Sample Vol.	3
Direction	Ascend	R1 Vol.	225
Unit	ng/ml	R2 Vol.	100
Decimals	0	Line. Limit	
Incubation	20	Antigen Check	v
Reaction	2 | 40	Substrat	0
R1 Blank		**Mix. R Blank**	
Lower	0	Lower	10
Upper	0	Upper	900
Response		**Linearity**	
Lower	-2.5	Lower	0
Upper	2.5	Upper	0
Sample Vol.	45	Full Name	FERRI
Dilution	5	Print No.	47

Calibration

Rule	Logistic 5P
K Factor	0
Replicates	1
Interval	0
Sensitivity	0
Correlation	0
Difference	2.5
Blank Response	0 | 2.5
Coefficient Difference	0
Non-linear SD	0

REFERENCE VALUES [6]

serum, plasma	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. As a 0 calibrator 0.9% NaCl should be used.
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 an automatic analyser Accent-300 and Hitachi 917. Results may vary if a different instrument is used.

- **Sensitivity:** 10 ng/ml.
- **Linearity:** up to 900 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 0.5 g/dl, bilirubin up to 30 mg/dl, RF up to 500 IU/ml, trigliceridies up to 500 mg/dl do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 20	Mean [ng/ml]	SD [ng/ml]	CV [%]
level 1	101.25	6.56	6.48
level 2	371.30	8.90	2.40

Reproducibility (day to day) n = 21	Mean [ng/ml]	SD [ng/ml]	CV [%]
level 1	16.49	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 ferritin values determined at Accent-300 (y) and at Hitachi 912 (x) using 23 samples gave following results:
y = 0.996 x + 2.9466 ng/ml;
R = 0.9988 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

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