CORMAY FERRITIN

DIAGNOSTIC KIT FOR DETERMINATION OF FERRITIN CONCENTRATION

Kit name	Kit size	Cat. No
CORMAY FERRITIN	1 x 75 ml	6-303

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 50 ml
2-Reagent	1 x 25 ml

Reagent preparation and stability

The reagents are ready to use.

The reagents are stable up to the kit expiry date printed on the package when stored at 2-10°C. Protect from light!

Concentrations in the test

suspension of latex particles sensitized with anti-ferritin (rabbit) antibodies (pH 7.3)	0.10 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.

ADDITIONAL EQUIPMENT

- automated clinical chemistry analyser capable of accommodating two-reagent assays;
- general laboratory equipment;

SPECIMEN

Serum or plasma.

After blood has clotted thoroughly, the sample is centrifuged and the serum is separated from blood cells and fibrins.

It is recommended to perform the assay with freshly collected samples. 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.

Samples which contain an excessive amount of ferritin should be diluted with physiological saline and re-tested.

PROCEDURE

wavelength	572 nm
temperature	37°C

These reagents may be used in automatic analysers according to their service manual. These reagents may be used directly in HITACHI 911/912 analysers. Applications for analysers are available on request.

REFERENCE VALUES

serum, plasma	µg/l
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, after lot change, as required. The standard solutions should be measured at least twice.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using an automatic analyser HITACHI 917. Results may vary if a different instrument is used.

- **Analytical range:** 10 – 1000 ng/ml.
- **Antigen excess:** up to 30000 ng/ml.
- **Specificity / Interferences**
  Haemoglobin up to 500 mg/dl, bilirubin up to 30 mg/dl, RF up to 560 U/ml, intralipid up to 5% do not interfere with the test.
- **Precision**

Repeatability (within run) n = 21	Mean [ng/ml]	SD [ng/ml]	CV [%]
level 1	15.0	0.50	3.31
level 2	104.2	0.81	0.78
level 3	411.3	2.87	0.70

Reproducibility (run to run) n = 20	Mean [ng/ml]	SD [ng/ml]	CV [%]
level 1	13.5	0.83	6.13
level 2	102.9	2.66	2.59
level 3	407.0	4.52	1.11

- **Method comparison**

A comparison between CORMAY reagent (y) and commercially available assay (x) using 98 samples gave following results:

y = 1.02x + 2.6 ng/ml;

R= 0.994 (R - correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Kaplan L.A., Pesce A. J.,: Clinical Chemistry, 3rd ed. St Louis, Mosby, 701 (1996).

Date of issue: 02. 2005.

MANUFACTURER

P.Z. CORMAY
ul. Rapackiego 19, 20-150 Lublin, POLAND
P.O. Box 122, 20-954 Lublin 2
tel.: +48 (0) 81 749 44 00
fax: +48 (0) 81 749 44 34
http://www.pzcormay.pl

02/05/02/05