Ferritin FS*

Diagnostic reagent for quantitative in vitro determination of ferritin in serum or plasma on photometric systems

Order Information

Cat. No.	Kit size						
1 7059 99 10 930	R1	3 x	20 mL	+	R2	3 x	10 mL
1 7059 99 10 935	R1	1 x	20 mL	+	R2	1 x	10 mL
1 7059 99 90 309	R1	3 x	20 mL	+	R2	3 x	10 mL
1 7050 99 10 058		4 x	1 mL	TruCal Ferritin:			
	Calibrator set with 4 different levels						

Summary [1-4]

Ferritin is an iron storage protein consisting of 24 subunits forming a hollow sphere in which up to 4000 iron atoms can be enclosed. Iron-loaded ferritin represents the primary source of reserve iron of each cell and of the entire organism readily available for hemoglobin synthesis. Variations in serum ferritin generally are closely related to changes in tissue ferritin. Measurement of serum ferritin concentration gives a quantitative determination of the mobilizable storage iron. Thus, a decreased ferritin level indicates tissue iron depletion and is particularly useful in the early detection of iron deficiency anemia, which is the most common deficiency disorder in the industrialized world. Increased serum ferritin concentrations can be suggestive of iron overload in conjunction with iron storage disorders like hereditary or acquired hemochromatosis. They can also be used to evaluate clinical conditions not related to iron storage including chronic liver disease, infections, inflammation and malignancy.

Method

Particle enhanced immunoturbidimetric test

Principle

Determination of the concentration of ferritin by photometric measurement of antigen-antibody-reaction of latex-particles coated with antibodies to ferritin with ferritin present in the sample.

Reagents

Components and Concentrations

R1:	Glycine	pH 8.3	170 mmol/L
	NaCl		100 mmol/L
	Bovine serum albumin		5 g/L
R2:	Latex particles coated with anti ferritin antibody		0.7 g/L
	Glycine	pH 7.3	170 mmol/L
	NaCl		100 mmol/L

Storage Instructions and Reagent Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

Warnings and Precautions

1. The reagents contain sodium azide (0.9 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Reagent 1 contains biological material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
3. In very rare cases, samples of patients with gammopathy might give falsified results [8].
4. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
5. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum or plasma (EDTA, Heparin, citrate)

Stability [5]:			
	7 days	at	20 – 25°C
	7 days	at	4 – 8°C
	1 year		–20°C

Only freeze once!
Discard contaminated sera!

Assay Procedure for Analyzers

Application sheets for automated systems are available on request.

Basic parameters for Hitachi 911

Wavelength	800 / 570 nm (bichromatic)
Temperature	37°C
Measurement	2-Point Test (Fixed Time Kinetics)
Sample/calibrator	8 µL
Reagent 1	160 µL
Reagent 2	80 µL
Addition Reagent 2	Cycle 15 (275 s)
Absorbance 1	Cycle 18 (335 s)
Absorbance 2	Cycle 31 (590 s)
Calibration	Spline function

Note: For manual procedures, the volumes of sample, calibrator and reagents have to be calculated appropriately and the timing has to be kept exactly.

Calculation

The ferritin concentration of unknown samples is derived from a calibration curve using an appropriate mathematical model such as logit/Log or spline. The calibration curve is obtained with four calibrators at different levels and NaCl solution (9 g/L) for determination of the zero value.
Stability of calibration: 25 days.

Calibrators and Controls

For the calibration of automated photometric systems, DiaSys TruCal Ferritin calibrator set is recommended. Calibrator values have been made traceable to the WHO 4th International Standard for Ferritin, NIBSC 19/118. DiaSys TruLab Protein control should be assayed for internal quality. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruLab Protein 1	5 9500 99 10 046	3 x 1 mL
TruLab Protein 2	5 9510 99 10 046	3 x 1 mL

Performance Characteristics

Measuring Range

The test has been developed to determine ferritin concentrations within a measuring range from 5 – 1000 µg/L, at least up to the concentration of the highest calibrator. When values exceed this range samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Prozone Limit

No prozone effect was observed up to ferritin values of 30000 µg/L.

Specificity/Interferences

Due to its antibodies, DiaSys Ferritin FS is specific for human ferritin. No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 60 mg/dL and hemoglobin up to 1000 mg/dL. Lipemic interference was less than 10% up to 1400 mg/dL triglycerides at a ferritin concentration of 180 µg/L and up to 600 mg/dL triglycerides at a ferritin concentration of 50 µg/L. The photometric measuring range of some instruments may be exceeded by highly lipemic samples containing high levels of ferritin. For further information on interfering substances, refer to Young DS [7].

Sensitivity/Limit of Detection

The lower limit of detection is 5 µg/L.

Precision

Intra-assay precision (n=21)	Mean [µg/L]	SD [µg/L]	CV [%]
Sample 1	15.0	0.60	3.98
Sample 2	100	0.68	0.68
Sample 3	430	0.83	0.19

Inter-assay precision (single calibration) (n=40)	Mean [µg/L]	SD [µg/L]	CV [%]
Sample 1	16.5	0.87	5.31
Sample 2	105	1.60	1.52
Sample 3	429	3.52	0.82

Method Comparison

A comparison of DiaSys Ferritin FS (y) to a commercially available immunoturbidimetric test (x) using 105 samples gave following results:
y = 1.006 x + 2.193 µg/L; r = 0.999

A comparison of DiaSys Ferritin FS (y) to a commercially available nephelometric test (x) using 62 samples gave following results:
y = 1.008 x -5.856 µg/L; r = 0.988

Reference Range [1]

Children	4 months – 16 years	15 – 150 µg/L
Adults	Women < 50 years	15 – 150 µg/L
	Women > 50 years	Approximation to the reference range for men
	Men	30 – 400 µg/L

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Wick M, Pingerra W, Lehmann P, Iron metabolism: diagnosis and therapy of anemias, 5th ed, Vienna, New York: Springer Verlag, 2003; p. 151.
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3. Kaltwasser JP, Werner E. Diagnosis and clinical evaluation of iron overload. Baillieres Clin Haematol 1989;2;363-89.
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5. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 28-9.
6. Lee MH, Means RT Jr. Extremely elevated serum ferritin levels in a university hospital: associated diseases and clinical significance. Am J Med 1996;98:566-71.
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Manufacturer

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