

Ferritin SR*

Diagnostic reagent for quantitative in vitro determination of ferritin in serum or plasma on DiaSys respons[®]920

Order Information

Cat. No. 1 7245 99 10 921

4 twin containers for 80 determinations each

Cat. No. 1 7245 99 10 926

2 twin containers for 80 determinations each

Method

Particle enhanced immunoturbidimetric test

Principle

Determination of the ferritin concentration by photometric measurement of antigen-antibody-reaction of latex-particles coated with anti-ferritin with ferritin present in the sample (agglutination).

Reagents

Components and Concentrations

R1: Tris Buffer pH 7.2 120 mmol/L
R2: Latex particles coated with rabbit antibodies against human ferritin

Storage Instructions and Reagent Stability

Unopened reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions

1. Reagent 1: Warning. H319 Causes serious eye irritation. H335 May cause respiratory irritation. P264 Wash hands and face thoroughly after handling. P280 Wear protective gloves/protective clothing/eye protection/face protection. P304+P340 If inhaled: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P308+P313 IF exposed or concerned: Get medical advice/attention. P403+P233 Store in a well-ventilated place. Keep container tightly closed.
2. Reagent 1 contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
3. Reagents contain biological material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
4. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons[®]920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
5. Samples containing heterophilic antibodies can cause falsely elevated results.
6. In very rare cases, samples of patients with gammopathy might give falsified results [8].
7. 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.
8. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents need to be mixed via inversion 5 – 10 times before being placed into the reagent rotor and the mixing must be repeated on a weekly basis.

Specimen

Serum or plasma (EDTA, heparin)

Stability [1]:

7 days at 20 – 25°C
7 days at 2 – 8°C
1 year at –20°C

Discard contaminated specimens. Do not use hemolytic samples. Freeze only once.

Calibrators and Controls

DiaSys TruCal Ferritin SR calibrator set is recommended for calibration. The assigned calibrator values have been made traceable to the WHO International Standard Ferritin, NIBSC 94/572. For internal quality control DiaSys TruLab Protein controls should be assayed. Each laboratory should establish corrective actions in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal Ferritin SR (5 Levels)	1 7240 99 10 059	5 x 1 mL
TruLab Protein Level 1	5 9500 99 10 046	3 x 1 mL
TruLab Protein Level 2	5 9510 99 10 046	3 x 1 mL

Performance Characteristics

Measuring range up to 440 µg/L ferritin, at least up to the concentration of the highest calibrator (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use the rerun function).	
Limit of detection**	3 µg/L ferritin
No prozone effect up to 125000 µg/L ferritin	
On-board stability	4 weeks
Calibration stability	2 weeks

Interfering substance	Interferences < 10%	Ferritin [µg/L]
Hemoglobin	up to 100 mg/dL	39.0
	up to 450 mg/dL	218
Bilirubin, conjugated	up to 65 mg/dL	30.2
	up to 65 mg/dL	147
Bilirubin, unconjugated	up to 70 mg/dL	30.0
	up to 70 mg/dL	145
Lipemia (triglycerides)	up to 900 mg/dL	27.5
	up to 750 mg/dL	139

For further information on interfering substances refer to Young DS [2].

Precision			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [µg/L]	45.9	92.3	216
Coefficient of variation [%]	2.15	2.38	2.07
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [µg/L]	47.6	263	382
Coefficient of variation [%]	3.00	2.45	1.37

Method comparison (n= 80)	
Test x	Competitor Ferritin (Hitachi 917)
Test y	DiaSys Ferritin SR (respons [®] 920)
Slope	0.894
Intercept	0.367 µg/L
Coefficient of correlation	0.996

** according to NCCLS document EP17-A, vol. 24, no. 34

Reference Range [3]

Children	4 months – 16 years	15 – 150 µg/L
	Men	30 – 400 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. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 28-9.
2. Young D.S. Effects of Drugs on Clinical Laboratory Tests. 5th. ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press, 2000.
3. Wick M, Pingerra W, Lehmann P, Iron metabolism: diagnosis and therapy of anemias, 5th ed, Vienna, New York: Springer Verlag, 2003; p. 151.
4. Worwood M. The laboratory assessment of iron status – an update. Clin Chim Acta 1997; 259: 3-23.
5. Kaltwasser JP, Werner E. Diagnosis and clinical evaluation of iron overload. Baillieres Clin Haematol 1989; 2; 363-89.
6. Baynes RD, Cook JD. Current issues in iron deficiency. Curr Opin Hematol 1996; 3:145-9.
7. 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.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.



Manufacturer

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Ferritin SR

Applikation for serum and plasma

Test Details		Test Volumes		Reference Ranges	
Test	: FERR			Auto Rerun	<input type="checkbox"/>
Report Name	: Ferritin			Online Calibration	<input type="checkbox"/>
Unit	: µg/L	Decimal Places	: 2	Cuvette Wash	<input type="checkbox"/>
Wavelength-Primary	: 700	Secondary	: 0	Total Reagents	: 2
Assay Type	: 2-Point	Curve Type	: Cubic Spline	Reagent R1	: FERR R1
M1 Start	: 19	M1 End	: 19	Reagent R2	: FERR R2
M2 Start	: 36	M2 End	: 36	Consumables/Calibrators:	
Sample Replicates	: 1	Standard Replicates	: 3	Blank	: 0
Control Replicates	: 1	Control Interval	: 0	Calibrator 1	: **
Reaction Direction	: Increasing	React. Abs. Limit	: *	Calibrator 2	: **
Prozone Limit %	: 97	Prozone Check	: Lower	Calibrator 3	: **
Linearity Limit %	: 0	Delta Abs. / Min.	: 0.00	Calibrator 4	: **
Technical Minimum	: *	Technical Maximum	: *	Calibrator 5	: **
Y = aX + b	a = 1.00	b =	0.00		

*Technical limits are automatically defined by the software via the upper and lower calibrator level.

** Enter calibrator value.

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