respons®910

Ferritin SR*

Diagnostic reagent for quantitative in vitro determination of ferritin in serum or plasma on DiaSys respons®910

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 antibodies 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 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. The reagents contain sodium azide (< 0.1%) 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 laboratory practice.
4. Samples containing heterophilic antibodies can cause falsely elevated results.
5. In very rare cases, samples of patients with gammopathy might give falsified results [8].
6. 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.
7. 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, citrate)

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

For calibration DiaSys TruCal Ferritin SR calibrator set is recommended. 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 500 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 blank**	6 µg/L ferritin
No prozone effect up to 125000 µg/L ferritin	
On-board stability	3 weeks
Calibration stability	1 weeks

Interfering substance	**Interferences < 10%**	**Ferritin [µg/L]**
Hemoglobin	up to 350 mg/dL	44.1
	up to 450 mg/dL	196
Bilirubin, conjugated	up to 65 mg/dL	43.5
	up to 65 mg/dL	207
Bilirubin, unconjugated	up to 70 mg/dL	43.6
	up to 70 mg/dL	199
Lipemia (triglycerides)	up to 1000 mg/dL	36.2
	up to 1100 mg/dL	150
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]	41.5	146	211
Coefficient of variance [%]	4.60	2.62	2.28
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg/L]	49.5	270	394
Coefficient of variance [%]	5.32	3.85	3.49

Method comparison (n= 82)	
Test x	Competitor Ferritin (Hitachi 917)
Test y	DiaSys Ferritin SR (respons®910)
Slope	0.901
Intercept	4.75 µg/L
Coefficient of correlation	0.990

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

Reference Range [3]

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. 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. Clin Chem Lab Med 2007; 45(9):1240-1243.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
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respons®910

Ferritin SR

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	FERR
Shortcut:	
Reagent barcode reference:	709
Host reference:	709

Technic	
Type:	Fixed time kinetic
First reagent:[µL]	120
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	120
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	800
Secondary wavelength:[nm]	
Polychromatic factor:	
1 st reading time [min:sec]	04:48
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	6.0000
Concentration technical limits-Upper	500.0000
SERUM	
Normal volume [µL]	18.0
Normal dilution (factor)	1
Below normal volume [µL]	27.0
Below normal dilution (factor)	1
Above normal volume [µL]	9.0
Above normal dilution (factor)	1
URINE	
Normal volume [µL]	18.0
Normal dilution (factor)	1
Below normal volume [µL]	27.0
Below normal dilution (factor)	1
Above normal volume [µL]	9.0
Above normal dilution (factor)	1
PLASMA	
Normal volume [µL]	18.0
Normal dilution (factor)	1
Below normal volume [µL]	27.0
Below normal dilution (factor)	1
Above normal volume [µL]	9.0
Above normal dilution (factor)	1
CSF	
Normal volume [µL]	18.0
Normal dilution (factor)	1
Below normal volume[µL]	27.0
Below normal dilution (factor)	1
Above normal volume [µL]	9.0
Above normal dilution (factor)	1
Whole blood	
Normal volume [µL]	18.0
Normal dilution (factor)	1
Below normal volume[µL]	27.0
Below normal dilution (factor)	1
Above normal volume [µL]	9.0
Above normal dilution (factor)	1

Results	
Decimals	2
Units	µg/L
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	Male
Age	
SERUM	>=30.00 <=400.00
URINE	
PLASMA	>=30.00 <=400.00
CSF	
Whole blood	
Gender	Female
Age	< 50 a
SERUM	>=15.00 <=150.00
URINE	
PLASMA	>=15.00 <=150.00
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*
	Max delta abs.
Cal. 1	0.0100
Cal. 2	0.0100
Cal. 3	0.0100
Cal. 4	0.0100
Cal. 5	0.0100
Cal. 6	0.0150
Drift limit [%]	5.00

Calculations	
Model	Cubic Spline
Degree	

* Enter calibrator value