

## Ferritin FS\*

Diagnostic reagent for quantitative in vitro determination of ferritin in serum or plasma on BioMajesty JCA-BM6010/C

### Order Information

Cat. No. 1 7059 99 10 964

R1: 6 x 100 tests

R2: 6 x 100 tests

### 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 present in the sample.

### Reagents

#### Components and Concentrations

<b>R1:</b>	Glycine	pH 8.3	170 mmol/L
	NaCl		100 mmol/L
	Bovine serum albumin		5 g/L
<b>R2:</b>	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

- The reagents contain sodium azide (0.9 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 1 contains biological material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
- In very rare cases, samples of patients with gammopathy might give falsified results.
- 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.
- For professional use only!

#### Waste Management

Please refer to local legal requirements.

#### Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent trays.

#### Specimen

Serum or plasma (EDTA, Heparin, citrate)

Stability [1]:

7 days at 20 – 25°C

7 days at 4 – 8°C

1 year at –20°C

Only freeze once! Discard contaminated specimens.

#### Calibrators and Controls

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

	Cat. No.	Kit size
TruCal Ferritin (4 Levels)	1 7050 99 10 058	4 x 1 mL
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 up to 1000 µg/L (2247 pmol/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 rerun function).	
Limit of detection**	5 µg/L (11.2 pmol/L) ferritin
No prozone effect up to 30000 µg/L (67410 pmol/L) ferritin	
On-board stability	12 weeks
Calibration stability	12 weeks

<b>Interferences &lt; 10% by</b>
<b>Ascorbate</b> up to 50 mg/dL
<b>Bilirubin</b> (conjugated and unconjugated) up to 30 mg/dL
<b>Hemoglobin</b> up to 500 mg/dL
<b>Lipemia</b> (triglycerides) up to 400 mg/dL (Ferritin conc. 61 µg/L)
<b>Lipemia</b> (triglycerides) up to 800 mg/dL (Ferritin conc. 199 µg/L)
For further information on interfering substances, refer to Young DS [7].

Precision			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [µg/L]	15.2	103	394
Mean [pmol/L]	34.2	231	885
Coefficient of variance [%]	5.73	0.88	0.75
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [µg/L]	76.6	109	527
Mean [pmol/L]	172	244	1185
Coefficient of variance [%]	3.19	2.14	1.63

Method comparison (n=97)	
Test x	DiaSys Ferritin FS (Hitachi 917)
Test y	DiaSys Ferritin FS (BioMajesty JCA 6010/C)
Slope	0.957
Intercept	0.724 µg/L (1.63 pmol/L)
Coefficient of correlation	0.9995

\*\* lowest measurable concentration which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

#### Conversion factor

Ferritin [µg/L] = Ferritin [ng/mL]

#### Reference Range [2]

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

- Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1<sup>st</sup> ed. Darmstadt: GIT Verlag; 2001; p. 28-9.
- 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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- Kaltwasser JP, Werner E. Diagnosis and clinical evaluation of iron overload. Baillieres Clin Haematol 1989; 2; 363-89.
- Baynes RD, Cook JD. Current issues in iron deficiency. Curr Opin Hematol 1996; 3:145-9.
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#### Manufacturer



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## Ferritin FS

Chemistry code 10 705

### 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.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	40
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	4.0
Sample vol (U)	4.0
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	FERR
Digits	1
M-wave L.	571
S-wave.L	****
Analy.mthd.	IMA
Calc.mthd.	MSTD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	Serum	Urine
Reac. sample vol.	4.0	4.0
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

Endpoint Method	
Re.absorb (u)	9.999
Re.absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.l	0
M-DET.P.m	22
M-DET.P.n	29
S-DET.P.p	0
S-DET.P.r	0
Check D.P.l.	22
Limit value	0.003
Variance	30
Reac.type	Inc

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Prozone	
Prozone form	Prozone formula
Prozone limit	0.034
Prozone judge	Upper limit
Judge limit	0.003
M-DET.P.m	23
M-DET.P.n	23
S-DET.P.p	22
S-DET.P.r	22

MULTI-STD Setting								
Formula	Spline	Axis Conv	No conv					
Blank	Blank any value	Points	5					
	FV	Reac. smp. vol.	Dil. method	Dil. smp. vol.	Diluent vol.	Diluent pos.	STD H	STD L
BLK	#	4.0	No dil	0	0	0	9.999	-9.999
1	#	4.0	No dil	0	0	0	9.999	-9.999
2	#	4.0	No dil	0	0	0	9.999	-9.999
3	#	4.0	No dil	0	0	0	9.999	-9.999
4	#	4.0	No dil	0	0	0	9.999	-9.999

IMA Setting					
	Blank (u)	Blank (d)	Sample (u)	Sample (d)	Prozone value
Calibrator Set	4	0	4	0	4
D.P. set l	22	22	22	3	22
D.P. set m	0	0	23	23	23
Factor d	1.50	0.20	0.95	0.00	1.05
Automatic setting	Not do	Not do	Not do	Not do	Do

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