

Liquid Reagents – ready to use

FERRITIN

2 Reagents

Diagnostic reagent for the quantitative in vitro determination of Ferritin in human serum by turbidimetric immunoassay

REF

Cont.

A06551 1 x 10 ml Ferritin Latex Reagent
2 x 25 ml Ferritin Buffer

Additionally offered:

A06560 5 x 1 ml Ferritin Calibrator 5 level series
A00610 1 x 1 ml Ferritin Control High
A00821 1 x 5 ml Ferritin Control High
A00570 1 x 1 ml Ferritin Control Low
A00820 1 x 5 ml Ferritin Control Low
A00590 1 x 1 ml Protein Control
A00800 1 x 5 ml Protein Control
A08591 1 x 1 ml Protein Control Low
A08823 1 x 5 ml Protein Control Low

GENERAL INFORMATION

Method: Immunoturbidimetric
Reaction: Nonlinear, endpoint
Wavelength: 600 nm
Assay Temperature: 18 – 37°C
Sample: Serum
Measuring Range: approx. 0–500 ng/ml
Sensitivity: 4 ng/ml (Hitachi 911)
Hook effect: no risk
Procedure: Manual and Automated

Manual Test Procedure Tests/kit*
without Sample Dilution 50

Automated Test Procedure: Please ask for applications

REAGENT COMPOSITION

Ferritin Latex Reagent	FINAL CONC.
Solution of suspended latex microparticles sensitized with duck anti-ferritin IgY (Δ Fc)	variabel
Sodium azide	0.095 %
Ferritin Buffer	
Phosphate Buffer	2,9%
Sodium azide	0.095 %

REAGENT PREPARATION

The reagents are ready for use.

REAGENT STABILITY AND STORAGE

Conditions: protect from light
Close immediately after use

Stability: at 2 - 8°C up to the expiration date
at 18 - 25°C 1 month

Do not freeze!

SAMPLE STABILITY AND STORAGE

Stability: at 2 - 8°C 48 hours
at - 20°C 3 months

Freeze only once!

INTERFERING SUBSTANCES

No interference up to:

Hemoglobin	1000 mg/dl
Bilirubin	20 mg/dl
Triglycerides	2500 mg/dl
EDTA	5 mg/ml
Heparin	50 mg/dl
Sodium Citrate	1000 mg/dl

MANUAL TEST PROCEDURE

Test Procedure without Sample Dilution:

Samples/ Controls: Ready to use
Calibration curve: Use the Ferritin Calibrator 5 level series.
Use Use 0.9% saline as zero point.

Pipette into test tubes	Calibrators	Samples/Controls
Buffer	1000 μ l	1000 μ l
Cal./Ctrls/Samples	80 μ l	80 μ l
Mix. Read A1 of calibrators and samples/controls at 600 nm. Then add:		
Latex Reagent	200 μ l	200 μ l
Mix. Incubate 5 minutes at assay temperature. Read A2 of calibrators and samples/controls at 600 nm. Calculate: $\Delta A = (A2 - A1)$		

CALCULATION

Calculate and plot $\Delta A = (A2 - A1)$ of the calibrators versus assigned concentration values on a linear-linear graph paper. Calculate ΔA optical densities of samples and control(s) and read values in ng/ml on the reference curve. Samples yielding absorbances above highest calibrator should be retested after further dilution.

REFERENCE RANGE**

Men: 15 – 300 ng/ml
Women: 10 – 200 ng/ml

** It is recommended that each laboratory establishes its own normal range.

TEST PRINCIPLE

The assay of Ferritin is based on turbidimetric measurement. Turbidity is caused by the formation of antigen – antibody insoluble immuno complexes.

DIAGNOSTIC IMPLICATIONS

The plasma Ferritin concentration declines very early in the development of iron deficiency. On the other hand, a large number of chronic diseases result in increased serum Ferritin concentrations. These diseases include chronic infections, chronic inflammatory disorders such as rheumatoid arthritis or renal disease, Gaucher's disease, and numerous types of malignancies, especially lymphomas, leukaemia's, breast cancer and neuroblastoma. Increase in plasma Ferritin concentration also occurs in viral hepatitis or following toxic liver injury as a result of release of Ferritin from damaged liver cells. Plasma Ferritin concentration is also increased with increases of iron stores, as seen in patients with hemosiderosis or hemochromatosis. Besides the use of Ferritin as an iron metabolism parameter, Ferritin as also gained importance as a tumour marker for therapeutic drug monitoring and follow-up.

PERFORMANCE CHARACTERISTICS

SENSITIVITY

4 ng/ml (Hitachi 911)

ACCURACY

Controls were assayed in duplicate for Ferritin to verify proper assay recovery

Control	Assigned Value (ng/ml)	Measured Value (ng/ml)
DIALAB Control Low	72.4 (61.5 – 83.3)	70.17
DIALAB Control High	243.6 (207 – 280)	229.34
DADE BEHRING Ctrl	113 (90 – 136)	129.08
CLINIQA Control 1	45.2 (38.4 – 52.0)	49.37
CLINIQA Control 2	158 (134 – 182)	145.69
CLINIQA Control 3	287 (244 – 330)	343.47
BIORAD Control 1	41 (33 – 49)	41.58
BIORAD Control 2	220 (176 – 264)	212.56
ProteoGol 1	93.4 (79.0 – 107)	95.26
ProteoGol 2	188 (135 – 241)	186.81
ProteoGol 3	281 (239 – 323)	297.21

PRECISION

Intra –Assay Precision

3 serum samples with a low, medium and high concentration of Ferritin were consecutively measured 20 times.

Expected Value	n	Mean	S.D.	C.V.
Low	20	16.27	0.78	4.81
Medium	20	41.15	1.44	3.50
High	20	215.03	2.07	0.97

Inter-Assay Precision

Ferritin was measured in 3 sera at regularly time intervals during 2 weeks. Sera were stored at 4°C.

Sample	n	Mean	S.D.	C.V.
Low	15	16.01	0.77	4.83
Medium	15	74.32	1.86	2.50
High	15	226.70	4.50	1.99

METHOD COMPARISON

A comparison with Roche gave the following results:
 $y = 1.2373x - 2.5882$; $r = 0.9773$

QUALITY CONTROL

All commercially available Control sera with Ferritin values measured by this method may be used.

REF

Cont.

A00610	1 x 1 ml Ferritin Control High
A00821	1 x 5 ml Ferritin Control High
A00570	1 x 1 ml Ferritin Control Low
A00820	1 x 5 ml Ferritin Control Low
A00590	1 x 1 ml Protein Control
A00800	1 x 5 ml Protein Control
A08591	1 x 1 ml Protein Control Low
A08823	1 x 5 ml Protein Control Low

CALIBRATION

The assay requires the use of Ferritin Calibrators. We recommend:

REF

Cont.

A06560

5 x 1 ml Ferritin Calibrator 5 level series

AUTOMATION

Applications for automated systems.

WARNINGS AND PRECAUTIONS

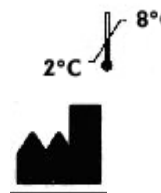
1. The Ferritin reagents are intended for in vitro diagnostic use only.
2. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion.
3. Each donor unit used in the preparation of the standards and controls was found to be negative for the presence of HIV antibodies, as well as for Hepatitis B surface antigen, using a method approved by the FDA.

WASTE MANAGEMENT

Please refer to local requirements.

REFERENCES

1. Lipzchitz DA, Cook JD, Finch CA. A clinical evaluation of serum ferritin as an index of iron stores. N Engl J Med. 1974; 290(22): 1213-1216
2. Worwood M. Ferritin in human tissues and serum. Clin Heamatol. 1982; 11(2): 275-307
3. Worwood M. Serum ferritin. Clin Sci(Lond)1986; 70(3): 215-220
4. Warr GW, Magor KE, Higgins DA. IgY: clues to the origins of modern antibodies. Immunology Today 1995; 16: 92-8.



IVD



DIALAB Produktion und Vertrieb von chemisch – technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
 A – 2351 Wiener Neudorf Austria
 IZ-NÖ Süd , Hondastrasse, Objekt M55
 Phone: ++43 (0) 2236 660910-0
 Fax: ++43 (0) 2236 660910-30 E-Mail: office@dialab.at