

FERRITIN ASSAY

Anemia
Marker

Diazyme's Ferritin Assay is a cost effective latex enhanced immunoturbidimetric reagent system that demonstrates outstanding sensitivity, precision and on-board stability. The test provides liquid stable reagent, calibrator and controls and is directly traceable to WHO international standards. For added convenience the Ferritin test offers a wide range of instrument parameters for facilitating and simplifying implementation in the laboratory.

DIAZYME FERRITIN ASSAY ADVANTAGES

- Improves laboratory efficiency and workflow
- Fast test results (under 10 minutes)
- Wide range of instrument parameters available for facilitating and simplifying implementation
- Liquid stable format that requires no reagent preparation, saving time and reducing sample handling

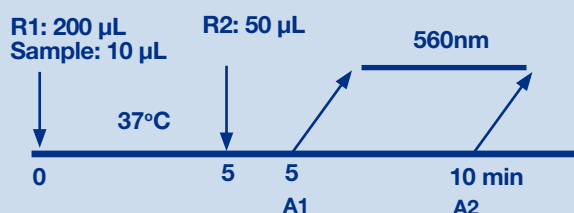
REGULATORY STATUS

510(k) Cleared; EU:  

ASSAY SPECIFICATIONS

Method	Latex Enhanced Immunoturbidimetric Assay
Sample Type	Serum Plasma - K ₂ EDTA - Li-heparin
Sample Volume	10 µL
Linearity	13 - 1000 ng/mL
Correlation	Deming Regression: N = 91 R ² = 0.9964 Slope = 0.996 y Intercept = -4.162
LOB LOD LOQ	Intra-Assay %CV: 1.2% - 4.1% Inter-Assay %CV: 0% - 4.9% Total % CV: 2.3% - 9.5%
LOB LOD LOQ	6.0 ng/mL 9.2 ng/mL 13.0 ng/mL

Ferritin Assay Procedure



For Diazyme Sales inquiries please contact
sales@diazyme.com

For Diazyme Technical Support please call
858.455.4768 or email support@diazyme.com

ASSAY PRECISION

The precision of the Diazyme Ferritin Assay was evaluated according to CLSI EP5-A2 guideline. In the study, 2 levels of serum based controls containing 112.8 and 318.2 ng/mL of ferritin, and four serum sample containing approximately 35.8, 247.7, 616.2 and 855.2 ng/mL of ferritin, respectively, were tested with 2 runs per day in duplicates over 20 working days. Results were calculated using the EP Evaluator software precision statistic template and summarized in the following table:

Sample	Mean	Within-Run CV(%)	Between Run CV(%)	Between Day CV(%)	Total CV(%)
Control 1	112.8	1.2	1.2	5.0	5.3
Control 2	318.2	1.7	0	3.1	3.5
Serum 1	35.8	4.1	4.9	7.7	9.5
Serum 2	247.7	1.3	0	2.8	3.1
Serum 3	616.2	1.4	1.0	3.6	4.0
Serum 4	855.2	1.2	0	2.0	2.3

Two very low serum samples containing ferritin concentrations of 15.7 ng/mL and 23.4 ng/mL ferritin were tested with 2 runs per day in duplicates over 20 working days on Hitachi 917 according to CLSI EP5-A2 guideline. Results were calculated using the EP Evaluator software precision statistic template and summarized in the following table:

Sample	Mean	Within-Run CV(%)	Between Run CV(%)	Between Day CV(%)	Total CV(%)
Serum 5	15.72	7.2	4.2	3.7	9.1
Serum 6	23.86	4.2	3.1	1.5	5.5

DIAZYME LABORATORIES, INC.

12889 Gregg Court, Poway, CA 92064 USA
PO Box 85608, San Diego, CA 92186 USA
Tel: +1-858-455-4768 +1-888-DIAZYME
www.diazyme.com sales@diazyme.com

DIAZYME EUROPE GMBH

Zum Windkanal 21, 01109 Dresden, Germany
Tel: +49-351-886-3300 Fax: +49-351-886-3366
sales@diazyme.de

SHANGHAI DIAZYME CO., LTD.

Building 8, 3879 Dongchuan Road
Minhang District, Shanghai, 200245
Tel: +86-21-54843802 Fax: +86-21-51320663
www.lanyuanbio.com service@lanyuanbio.com