FERRITIN ASSAY

Dual Vial Liquid Stable

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) for a rapid turnaround time
- Wide range of instrument parameters available for facilitating and simplifying implementation
- Liquid stable format requires no reagent preparation, saving time and reducing sample handling

REGULATORY STATUS

510(k) Cleared CE

AVAILABLE INSTRUMENT SPECIFIC PACKAGING

- **Roche**
  - Hitachi

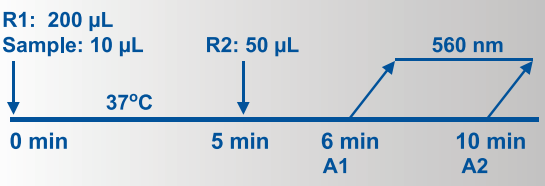
FERRITIN ASSAY
Dual Vial Liquid Stable

DIAZYME

ASSAY SPECIFICATIONS

Method	Latex Enhanced Immunoturbidimetric Assay
Sample Type & Volume	• Serum • Plasma - K_2EDTA - Li-heparin Sample Volume 10 µL
Method Correlation	Deming Regression: N = 91 y-intercept = -4.162 Slope = 0.996 R^2 = 0.9964
Linear Range	13 to 1000 ng/mL
LOB ***LOD*** ***LOQ***	6.0 ng/mL 9.2 ng/mL 13.0 ng/mL
Calibration Levels	4-Point Calibration
Reagent On-Board Stability	Opened: Stable for 4 weeks on board Hitachi 917

*Ferritin Assay Procedure**



***Analyzer Dependent**

Parameter questions for Ferritin Assay should be addressed to Diazyme technical support. Please call 858.455.4768 or email support@diazyme.com

1. Aisen, P., and Listowsky, I. 1980. Iron transport and storage proteins. Annual Review of Biochemistry. 49, 357–393.
2. Lipschitz, DA., Cook, JD. and Finche, CA. 1974. A clinical evaluation of serum Ferritin as an index of iron stores. The New England Journal of Medicine. 290:1213-1216
3. Wu, Alan H. B. Tietz Clinical Guide to Laboratory Tests Fourth Edition Page 392-394
4. Fischbach FT, Dunning MB III, eds. (2009). Manual of Laboratory and Diagnostic Tests, 8th ed. Philadelphia: Lippincott Williams and Wilkins.
5. Charles Moore, Jr, Michelle Ormseth, Howard Fuchs, Causes and Significance of Markedly Elevated Serum Ferritin Levels in an Academic Medical Center J Clin Rheumatol. 2013;19(6):324-328.

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:

	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:

	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%

ASSAY INTERFERENCE

To determine the level of interference from the substances present in serum, the Diazyme Ferritin Assay was used to test three serum samples with "low", "medium" and "high" Ferritin concentrations spiked with various concentrations of substances following Clinical and Laboratory Standards Institute EP7-A2. The following substances do not interfere with this assay at the levels tested (less than 10% bias):

Triglyceride:	1000 mg/dL	Ibuprofen:	2425 µM
Ascorbic Acid:	176 mg/dL	Levodopa:	1.3 mM
Bilirubin:	40 mg/dL	Methyldopa:	71 µM
Bilirubin Conjugated:	40 mg/dL	Metronidazole:	701 µM
Hemoglobin:	500 mg/dL	Rifampicin:	78.1 µM
Rheumatoid Factor:	200 IU/mL	Theophylline:	222 µM
Heparin:	3000 IU/L	Phenylbutazone:	650 µM
N-acetylcysteine:	17.6 mM	Valproic Acid:	3.5 mM
Acetylsalicylic Acid:	2.78 mM	Deferasiron:	1.0 mM
Ampicillin:	152 µM	Methotrexate:	2.0 mM
Dobesilate:	33.3 µg/ml	Prednisone:	0.5 mM
Na2-Cefoxitin:	1549 µM		

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