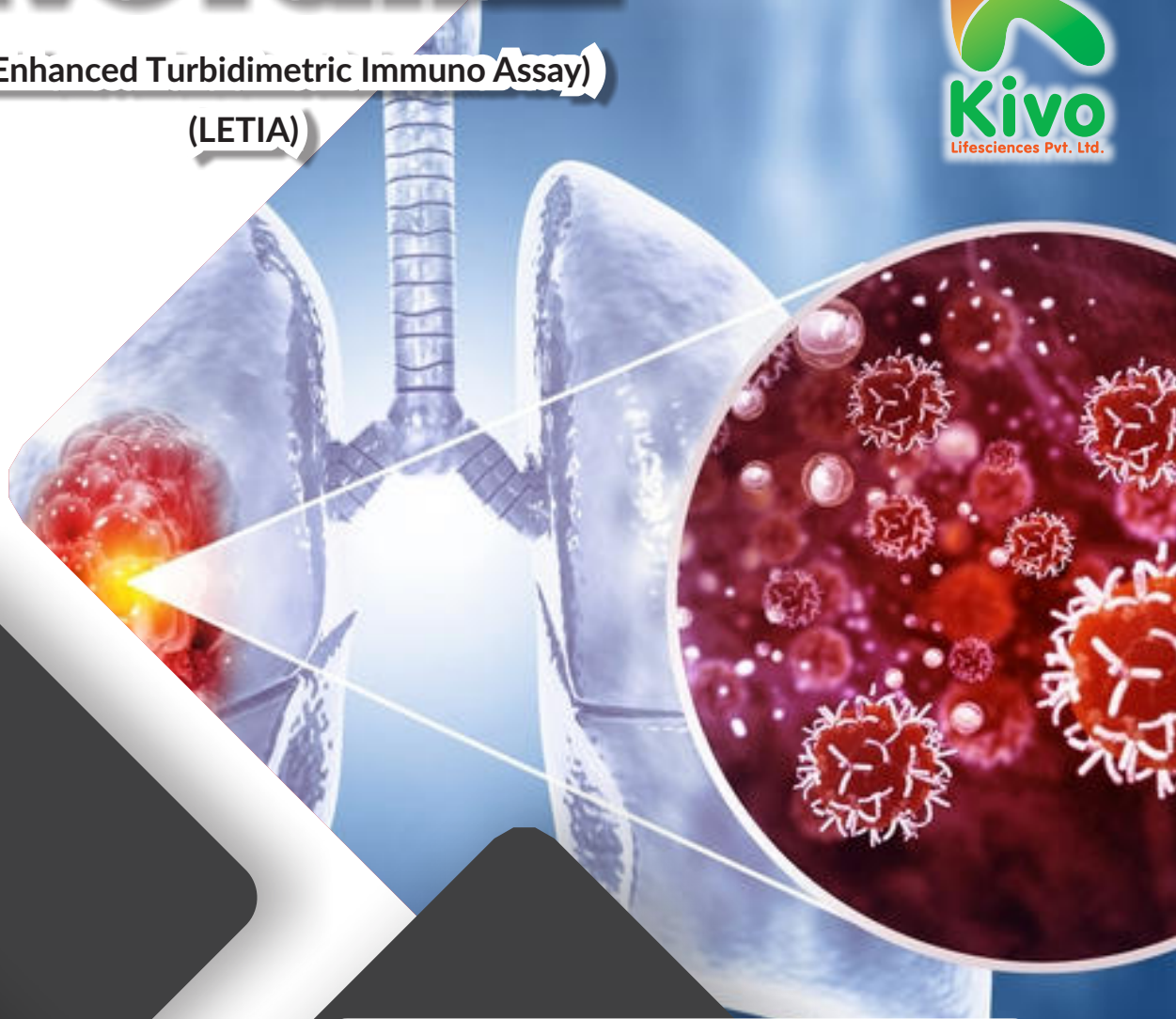


KIVO Ferritin

(Latex Enhanced Turbidimetric Immuno Assay)

(LETIA)



Features:

- Latex Enhanced Turbidimetric Immuno Assay (LETIA)
- Liquid Stable Two Reagents
- 5 level Calibrators provided
- 2 Level Controls provided (Optional)
- Measuring wavelength 630 nms (600-630)
- 8 Minutes test procedure (10 Sec+480 Sec)
- Linearity: 1000 ng/mL
- Adaptable to Semi and Fully auto analyzers

KIVO Ferritin



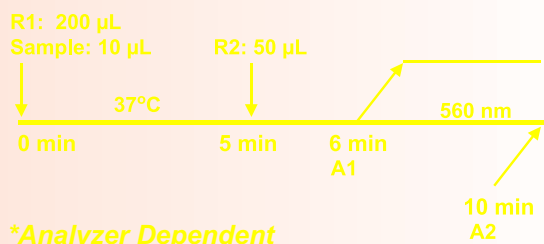
Assay Specifications:

(Latex Enhanced Turbidimetric Immuno Assay)

(LETIA)

Method	Latex Enhanced Immunoturbidimetric Assay
Sample Type & Volume	<ul style="list-style-type: none"> • Serum • Plasma - K₂EDTA - Li-heparin <p>Sample Volume 10 µL</p>
Method Correlation	<p>Deming Regression: N = 91 y-intercept = - 4.162 Slope = 0.996 R² = 0.9964</p>
Linear Range	13 to 1000 ng/mL
LOB	6.0 ng/mL
LOD	9.2 ng/mL
LOQ	13.0 ng/mL
Calibration Levels	4-Point Calibration
Reagent On-Board Stability	<p>Opened: Stable for 4 weeks on board Hitachi 917</p>

Ferritin Assay Procedure*



Parameter questions for Ferritin Assay should be addressed to Pariksha technical support. Please call +91 70757 06709 or email support@parikshbio.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 HighQ 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 HighQ 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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