

FERRITIN (TURBI-LATEX) (3+1)

Turbi-latex reagent for in-vitro diagnostic determination of Ferritin present in human serum.

REF: BS.1/FER1.050.0050

50 tests

REF: BS.1/FER1.100.0100

100 tests

CLINICAL SIGNIFICANCE

Serum ferritin concentration usually reflects body iron stores and is considered one of the most reliable indicators of iron status of patients. Whereas low serum concentrations of ferritin are always indicative of an iron deficiency, elevated concentrations can occur for variety of reasons. Thus, although elevated concentrations often indicate an excessive iron intake, they are also caused by liver disease, chronic inflammation and malignancies. Pregnant women, blood donors, hemodialysis patients, adolescents and children are groups particularly at risk.

METHOD PRINCIPLE

BioScien Ferritin latex particles coated with specific anti-human ferritin are agglutinated when mixed with samples containing ferritin. The agglutination causes an absorbance change, dependent upon the ferritin contents of the sample that can be quantified by comparison from a calibrator of known ferritin concentration.

REAGENT COMPOSITION

Reagents:	Composition
R1: BUFFER REAGENT	Glycine buffer 170 mM, PH 8.2.
R2: LATEX REAGENT	Latex particles coated with anti human ferritin, PH 8.2.
CALIBRATOR	Ferritin concentration is stated on the vial label.

Both reagents contain Sodium azide as a preservative.

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person. Do not ingest or inhale as reagent contains sodium azide which is classified as dangerous substance for environment.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.

S56: dispose of this material and its container at hazardous or special waste collection point.

S57: use appropriate container to avoid environmental contamination.

S61: avoid release in environment.

For further information, refer to the FERRITIN reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

BioScien FERRITIN reagent is stable until expiration date stated on label when properly stored in an upright position and refrigerated at 2-8°C (do not freeze).

Working reagent: Swirl the latex vial gently before use. Prepare the necessary amount as follows: 300 µl Buffer Reagent + 100 µl Latex Reagent.

Deterioration

The **BioScien** FERRITIN reagent can be damaged due to Presence of particles and turbidity.

SPECIMEN COLLECTION AND PRESERVATION

Fresh serum. Stable 7 days at 2 - 8 °C or 3 months at -20 °C. Any additional clotting or precipitation, which occurs due to the freeze/thaw cycle, should be removed by centrifugation prior to assay.

Very lipemic specimens, or turbid frozen specimens after thawing, must be clarified before the assay by high-speed centrifugation (15 min at approx. 15.000 rpm).

SYSTEM PARAMETERS

Wavelength	540 nm (530 – 550 nm)
Optical path	1 cm
Assay type	Turbidimetric
Temperature	37 °C

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes
- Centrifuge
- Stop watch
- Variable Micropipettes
- Automatic analyzer

ASSAY PROCEDURE

1. Bring the reagents to room temperature.
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

R1: Buffer Diluent	300 µl
R2: Latex Reagent	100 µl
Calibrator or Sample	45 µl

4. Mix and read the absorbance after 5 sec. (A1) and after 5 minutes (A2) of the sample addition.

CALCULATION

$A2-A1) \text{ sample} \times \text{Calibrator concentration} = \mu\text{g/L Ferritin}$

(A2-A1) calibrator

QUALITY CONTROL

Control sera are recommended to monitor the performance of manual and automated assay procedures.

Each laboratory should establish its own quality control scheme and corrective actions if controls do not meet the acceptable tolerances.

For more information please contact **BioScien** technical support.

PERFORMANCE CHARACTERISTICS

Precision	Within run (Repeatability)		Run to run (Reproducibility)	
	Normal level	High level	Normal level	High level
n	80	80	80	80
Mean µg/L	33.4	289.8	33.4	289.8
SD.	1.7	2.4	2.1	7.5
CV. %	5.1	0.8	6.3	2.6

Measuring range: up to 550 µg/L.

Samples with higher values should be diluted 1/5 in NaCl 9 g/L and retested. The upper linearity limit increases as the sample volume and the sensitivity decrease.

Detection limit: 5.04 µg/L

Quantification limit: values under 6.6 µg/L may give non-reproducible results.

Prozone effect: No prozone effect was detected up to 9000 µg/L.

INTERFERING SUBSTANCES

Bilirubin (10 mg/dL) and hemoglobin (5 g/L), and rheumatoid factors (750 IU/mL), do not interfere. Lipids (≥ 2.5 g/L) do interfere. Other substances may interfere.

LIMITATIONS OF PROCEDURE

1. The results of this test **should not** be used as a single diagnostic tool to make a clinical diagnosis. Instead, the test results must be evaluated together with other clinical findings and observed symptoms to aid in the final diagnosis.
2. Temperature of the reagents and specimens is critical to test outcome.
3. Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV and antibody to HIV (1/2). However handle cautiously as potentially infectious.
4. Do not use damaged or leaking reagents.
5. After usage the antigen suspension should be immediately recapped and replaced at 2-8 C.

EXPECTED VALUES

Men: 30 – 220 µg/L

Women: 20 – 110 µg/L

Each laboratory should establish its own reference range.

REFERENCES

1. Wick M, Pinnggera W, Lehmann P. Ferritin in iron metabolism. Diagnosis of anemias. 2nd ed. Springer-Verlag. Wien 1994.
2. Rodriguez Perez J et al. Revista Clinica Española 1980; 156 (1): 39-43
3. Milman N et al. Eur J Haematol 1994; 53: 16-20.
4. Young DS. Effects of drugs on clinical laboratory test, 5th ed. AACC Press, 1999.

SYMBOLS IN PRODUCT LABELLING			
	For in-vitro diagnostic use		Number of <n> test in the pack
	Batch Code/Lot number		Caution
	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		



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