

Quantitative determination of Ferritin IVD

Store 2 - 8°C.

PRINCIPLE OF THE METHOD

This test is a quantitative test for the measurement of ferritin in human serum. The human serum reacts upon colloidal gold coated with a mixture of monoclonal antibodies to ferritin. In the presence of ferritin, the particles agglutinate, which induces a red shift in the visible spectrum of the colloid. This induces an increase in optical density which is proportional to the ferritin concentration in the sample.

CLINICAL SIGNIFICANCE

Ferritin is a protein which binds and stores iron, it is the major iron storage compound and it is synthesized by the liver. Serum ferritin is believed to reflect reliably the concentration of cellular ferritin. Pathological iron overload (hemochromatosis) may be either primary (i.e. idiopathic or familiar) or secondary (acquired) as a consequence of alcoholism, thalassemia or repeated transfusion. The diagnosis can be made by documenting elevation of serum ferritin levels in conjunction with increases in serum iron levels. Iron deficiency is one of the most prevalent disorders of humans, assay of serum ferritin concentration is a high sensitive and reliable means of demonstration of this disorder.

REAGENTS

R1	Tris buffer, pH 8, sodium azide <1 g/L, PEG, detergents
R2	Mixture of monoclonal antibodies against human ferritin (+/- 20 µg/mL) coated on colloidal gold particles suspended in borate buffer, stabilizers and sodium azide (<1 g/L)
Optional	Ref.: ACC16-030 Ferritin control.

PRECAUTIONS

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.

CALIBRATION

The sensitivity of the assay has been standardized against the Ferritin international standard NIBSC code 94/572.

ADDITIONAL EQUIPMENT

- Pipette 100 - 1000 µL
- Pipette 10 - 100 µL
- Cuvettes and microstirrers

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C and contamination are prevented during their use. Do not use reagents after the expiration date.

Reagent deterioration: Presence of particles and turbidity. Do not freeze.

SAMPLES

Fresh serum or plasma. Stable 7 days at 2-8°C or 3 months at -20°C. The samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipemic samples.

TEST PARAMETER

Filter: set filter on position A
Reading time: 300 seconds

PROCEDURE

1. Pipette into an appropriate number of cuvettes:

kind of reagent	µL
R1	375
Sample or control	30

2. Incubate the cuvettes in positions 1-4 for 1 minute
3. Transfer each cuvette in the reading channel and, when requested on the display, add 75 µL of R2
4. Read the result which will appear automatically on the reader's display after 300 sec.

QUALITY CONTROL

Control Sera are recommended to monitor the performance of manual and automated assay procedures. Electa Lab Ferritin Control (Ref.: ACC16-030) is available.

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

REFERENCE VALUES

Men: 20 - 250 ng/mL.

Women: 10 - 120 ng/mL.

Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

1. Assay detection range: Up to 300 ng/mL, under the described assay conditions. Samples with higher concentrations, should be diluted 1/5 in NaCl 9 g/L and re-tested again.
2. Detection limit: Values less than 10 ng/mL give non-reproducible results.
3. Precision:

Mean (mg/L)	Intra-assay (n = 10)			Inter-assay (n = 10)		
	31	97	220	31	97	220
SD	3.7	2.1	2.3	3.9	6.8	16.7
CV	11.6	2.2	1.09	12.6	7.0	7.6

INTERFERENCES

Bilirubin (20 mg/dL), hemoglobin (10 g/L), and rheumatoid factors (600 IU/mL), do not interfere. Lipemia (≥ 2.5 g/L), interferes. Other substances may interfere⁶.

NOTES

Prepare the cuvette containing R1 and sample or control just before to test them. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

BIBLIOGRAPHY

1. Lipschitz, DA et al. The new England Journal of Medicine 1974; 20: 1213 - 1216
2. Enguix A et al. Quimica Clinica 1996; 15(6): 416-419
3. Tamura T et al. Obstetrics & Gynecology 1996; 87: 360 - 365
4. Waktors GO et al. J Clin Pathol Nutr 1974; 27: 681-687
5. Susan J et al. Clinical Chemistry 1997; 43(9): 1582-1587
6. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

PACKAGING

Ref: ACC16-021

Cont.	: 1 x 50 mL R1
	: 1 x 5 mL R2