

INTENDED USE

For the Quantitative determination of Ferritin in serum
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	CONT
TFN 25T	1 x 7.5 ML
TFN 50T	1 x 15 ML

CLINICAL SIGNIFICANCE

This product is used to determine the level of ferritin in serum and plasma. Ferritin is a spherical, hollow iron storage protein that stores about 450,000 iron atoms. Ferritin is mainly distributed in liver and spleen, and participates in detoxification and storage. The content of ferritin in serum is very small, but the dynamic change of its value reflects the storage of iron in the body. The determination of serum FER concentration is very useful for the diagnosis, treatment and prognosis of iron metabolism abnormalities such as anemia and iron excess, liver diseases, etc.

PRINCIPLE

Iron antigen + latex coated ferritin antibody → The turbidity of insoluble complexes was measured at 570 nm, and the ferritin content of samples could be calculated by calibration.

KIT CONTENT

Reagent	25 tests/kit	50 tests/kit	Major ingredients
Reaction buffer (R1 reagent)	1x5.5 ml	1x11 ml	Phosphate Reaction buffer
Ferritin latex combo (R2 reagent)	1x2 ml	1x4 ml	Latex particles coated with anti-human human FER Antibody
Cuvette & Bead	25 no's	50 no's	/
Specification	1 copy	1 copy	/
Magnetic card	1 piece	1 piece	/

SAFETY PRECAUTIONS AND WARNINGS

- For in vitro diagnostic use only.
- DO NOT pipette by mouth. Avoid contact with skin and eyes. If spilt, thoroughly, wash affected areas with water. For further information, consult the Ferritin Reagent Material Safety Data Sheet.
- Reagent contains Sodium Azide as a preservative. This may react with copper or lead plumbing to form explosive metal azides. Upon disposal, flush with large amounts of water to prevent azide build up.
- Do not use the reagent after the expiration date printed on the kit.
- 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 the calibrator cautiously as potentially infectious material.

SAMPLE COLLECTION AND PRESERVATION

Fresh serum : Stable for 7 days at 2-8°C or 3 months at -20°C.
Samples with presence of fibrin should be centrifuged before testing.
Do not use highly hemolysed or lipemic sample.

REAGENT STABILITY

All the component of the kit are stable until the expiry date on the label when stored tightly closed at 2-8°C and contaminants prevented during there use, Do not use expired reagents.

ASSAY PROCEDURE

1.THE REAGENT DOSE DISPENSING IN THE CUVETTE

Reagent	Dose
Reaction Buffer (R1 Reagent)	220µl
Sample	10 µl
Mix and incubate for 4 minutes at 37°C in incubator slot (A,B,C,D).	
Ferritin antibody latex combo (R2 Reagent)	80 µl

2. OPERATING STEP

- When starting it shows "Read card", Put the corresponding lot magnetic card in the reader slot, reading the card correctly, the screening displays the reagent name and lot number, the instrument status indication light is working (yellow-green). Please check carefully.
- After confirm the lot number, dispense 220µl reaction buffer (R1) to a colorimetric cuvette and 10µl sample and mixing sticker. Do not produce bubbles when dispensing the sample. Mix and incubate for 4 minutes at 37°C in incubator slot (A,B,C,D).
- Put the colorimetric cuvette in the detection well, gently press the cuvette until it contacts the bottom. The status indication light will be off when the analyzer detects the colorimetric cuvette successfully.
- When the analyzer shows "Add [R2]", dispense 80µl Ferritin antibody latex combo (R2) in the cuvette. The analyzer will mix automatically and start to detect, it shows: "Testing..." it shows the result automatically and record the value.
- After detecting, move the cuvette. The status indication light will be working (yellow- green). Return to step (2) to detect next sample.
- If moving the cuvette out in the process of detecting, the screen shows "Give up testing".
- If the result shows >1000 ng/ml, may use Normal saline to dilute the sample 1:5 (add 400µl Normal saline in 100µl sample), input dilution multiply 5, the analyser can calculate the sample concentration automatically.

LINEARITY

The method is linear to a concentration of 20 -1000 ng/ml.

If the concentration exceeds this value, the sample should be diluted 1:5 with 0.9% saline solution and re-assayed.

REFERENCE INTERVAL

Male 20-250ng/ml;

Female 20-200ng/ml

According to the distribution range of 95% of normal people.

It is suggested that each laboratory verify this reference range or establish its own reference range.

QUALITY CONTROL

To ensure adequate quality control, Normal and abnormal control with assayed values should be run as unknown samples.

INTERFERENCES

Hemoglobin 10 g/dL, Bilirubin 20 mg/dL and Lipemia 10 g/dL do not interfere.
Other substances may interfere.

BIBLIOGRAPHY

- Cook, J.D., Lipschitz,D.A., Laughton, M.B.B., Miles, E.M. & Finch, C.A: Serum Ferritin as a measure of iron stores in normal subjects.
- Walters,G.O., Miller, F.M & Wormwood, M.: Serum Ferritin Concentration on and iron stores in normal subjects. J. Clin.Pathol. 26:770-, 1973.