Ferritin Rapid Test Kit (Serum/Plasma/Whole blood)

INTENDED USE:
The Ferritin Rapid Test Kit is an immunochromatographic assay designed for the rapid detection of ferritin in human serum, plasma or whole blood samples
For professional / self and in-vitro diagnostic use only.

ORDER INFORMATION

REF	Cont.
PFER 01	01 Test
PFER 05	05 Tests
PFER 10	10 Tests
PFER 25	25 Tests
PFER 50	50 Tests

CLINICAL SIGNIFICANCE:
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 ferritin concentration is very useful for the diagnosis, treatment and prognosis of iron metabolism abnormalities such as anemia and iron excess, liver diseases, etc.

PRINCIPLE:
The Ferritin Rapid Test Kit utilizes immunochromatographic technology to detect ferritin in human serum, plasma, or whole blood. It is intended for determining the iron storage status in the body and assisting in the diagnosis of anemia-related diseases. The detection zone of the nitrocellulose membrane in this test kit is coated with anti-ferritin monoclonal antibodies. The end of the test strip has immobilized gold particles conjugated with anti-ferritin monoclonal antibodies, forming a colored complex. Sufficient ferritin in the sample reacts with the gold conjugate and migrates through capillary action on the membrane to react with the immobilized antibodies in the detection zone, resulting in the appearance of a colored line. The control line (C line) serves as an internal control, and its appearance indicates that the sample contains a sufficient volume and the reaction system is functioning properly.

COMPONENTS:

1. Individually foiled Test device with desiccant
2. Assay buffer
3. Sample dropper (25 µl sampling device)
4. Instruction for use
5. Color Chart
6. Lancet
7. Alcohol swab

STORAGE AND STABILITY:

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed aluminum pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test device/strip, if the pouch is damaged or seal is broken.

PRECAUTIONS

1. Wear protective gloves while handling specimens wash thoroughly afterwards.
2. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
3. Do not mix reagents from different lot.
4. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
5. Follow the testing procedure exactly as mention in the insert.

LIMITATIONS:

1. The Ferritin Rapid Test Kit is for in vitro diagnostic use only. Results should be interpreted in conjunction with other clinical and laboratory findings.
2. The test may provide false-positive or false-negative results. Confirmatory testing should be conducted if necessary.
3. Interference from substances such as rheumatoid factor, heterophilic antibodies, or lipemic or hemolyzed specimens may affect the test performance.
4. This test is optimized for human serum or plasma samples. Other sample types or interference may affect the results.

SPECIMEN COLLECTION AND PREPARATION:

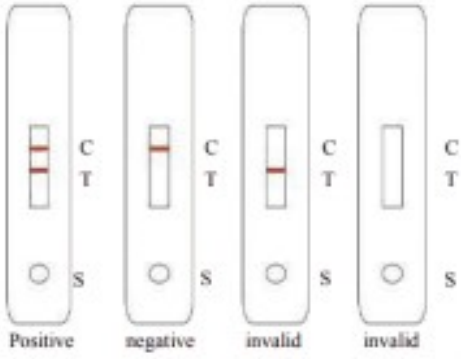
1. Collect a fresh serum or plasma or whole blood sample using standard laboratory procedures.
2. Remove any particulate matter or precipitate by centrifugation before testing if required.
3. Avoid hemolysis, as it may interfere with the test results.
4. **Serum (S):** Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
5. **Plasma (P):** Collect the whole blood into a collection tube (containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.
6. **Whole Blood (WB):** Use Blood samples collected by venipuncture into a collection tube containing EDTA, citrate or heparin. Alternately, collect the whole blood by lancing devices. WB can be delivered by pipette or sample dropper directly to the test card.

TEST PROCEDURE:

1. Bring the test device, sample buffer, and specimens to room temperature (15-30°C) before use.
2. Open the pouch and place the test device on a clean and flat surface.
3. Dispense 1 drop (approximately 25µL) of the serum, plasma or whole blood sample into the sample well of the test device using the sample dropper provided.
4. Dispense 1 drop (approximately 40µL) of the sample buffer into the sample well of test device.
5. Start the timer and wait for the colored bands to appear.
6. Read the test results within 15 minutes. Do not interpret the results after 20 minutes.

INTERPRETATION OF RESULTS:

Positive: TWO distinct red bands appear, one in the test region (T) and the second one in the control region (C). This indicates the presence of ferritin in the sample.
Negative: Only ONE red band appears in the control region (C). No band appears in the test region(T), suggesting the absence of ferritin.
Invalid: If no red band appears in the control region (C), the test is invalid. Repeat the test with a new device.



Quality Control

Internal procedural controls are included in the test individually. A colored line appearing in control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

PERFORMANCE CHARACTERISTICS

The Ferritin Rapid Test Kit has been evaluated with competitor kit.A total of 185 samples (serum/plasma/whole blood) were tested.

Ferritin	
Sensitivity	98.9 %
Specificity	98.8 %

Note: The Ferritin Rapid Test Kit has a lower limit of detection of 10ng/mL. The product has been studied and tested after 60 days at room temperature and 45°C.

INTERFERING SUBSTANCES

The following compounds have also been tested using the Ferritin Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed in the following compounds up till the concentrations mentioned Albumin: 20mg/ml, Bilirubin: 20 µg/ml, Hemoglobin: 15mg/ml, Glucose: 20mg/ml, Uric acid: 200µg/ml, Lipids: 20mg/ml, Ascorbic acid: 200mg/dL, Caffeine: 20mg/ml.

BIBLIOGRAPHY

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3. Wang J, Pantopoulos K. Regulation of cellular iron metabolism. Biochem J. 2011 Mar 15;434(3):365-81. doi: 10.1042/BJ20101825. PMID: 21348856; PMCID: PMC3048577.
4. Wang W, Knovich MA, Coffman LG, Torti FM, Torti SV. Serum ferritin: Past, present and future. Biochim Biophys Acta. 2010 Aug;1800(8):760-9. doi: 10.1016/j.bbagen.2010.03.011. Epub 2010 Mar 19. PMID: 20304033; PMCID: PMC2893236.

GLOSSARY OF SYMBOL

	Consult Instruction for Use
REF	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

India office
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