FERRITIN TEST
004A715

ulti med Ferritin Test
For Fingerstick Whole Blood Specimens

INTRODUCTION

A ferritin immunological test system is a device that consists of the reagents used to measure the concentration of ferritin (an iron-storing protein) in whole blood by immunochemical techniques. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism, such as haemochromatosis (iron overload) and iron deficiency anaemia.

INTENDED USE

The ulti med FRT Test is a highly sensitive immunoassay for semiquantitative determination of human ferritin in whole blood. This test is intended for professional use as an aid in the diagnosis of diseases like iron deficiency anaemia. The sensitivity of the test is 10 ng/ml.

MATERIALS PROVIDED

- FRT test cassettes
- disposable sample droppers
- 1 package insert

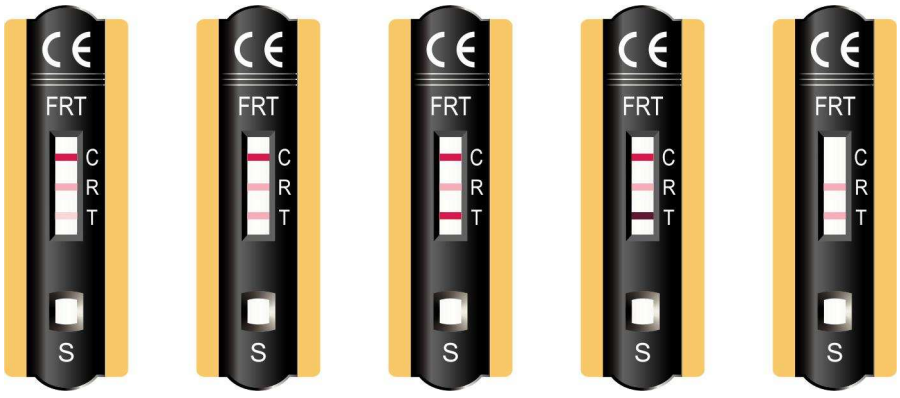
MATERIALS REQUIRED, BUT NOT PROVIDED

- Stop watch
- Alcohol pads
- Lancets
- Band aid

PROCEDURE OF THE TEST

1. Remove the test cassette from the foil pouch, and place it on a flat, dry and clean surface.
   Note: Once the test cassette is removed from the pouch, it should be used as soon as possible.
2. Clean the second or third finger by rubbing it with an alcohol pad.
3. Collect blood from the patient's finger. Massage near the puncture site to obtain blood flow.
4. Add 150 µl of blood (6 drops) into the Sample Well (S). Before adding the next drop, the previous one should be fully absorbed.
5. As the test begins to work, you will see a purple coloured front move across the Result Window in the centre of the test cassette.
6. Interpret test results at 10 minutes. Do not interpret test results after more than 15 minutes.

Caution: The above interpretation time is based on reading the test results at room temperature of 15 to 30°C. If your room temperature is significantly lower than 15°C, then the interpretation time should be properly increased.



< 10 ng/ml **50 ng/ml** **100 ng/ml** **> 100 ng/ml** **invalid**

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INTERPRETATION OF THE TEST

Ferritin concentration of less than 10 ng/ml: The intensity of the “T” line is weaker than both the “R” and “C” lines indicating that ferritin level is less than 10 ng/ml.

Ferritin concentration of 50 ng/ml: The intensity of the “T” line is similar to the “R “ line and less than the “C” line indicating that ferritin level is 50 ng/ml.

Ferritin concentration of 100 ng/ml: The intensity of the “T’ line is darker than the “R “ line and is similar to the “C line” indicating that ferritin level is 100 ng/ml.

Ferritin concentration greater than 100 ng/ml: The intensity of the “T” line is darker than both the “R” and the “C” lines indicating that ferritin level is greater than 100 ng/ml.

Invalid: If after performing the test, no “R” and/or “C” lines are visible within the Result Window, the result is considered invalid. Some causes of invalid results are not following the directions correctly or the test may have deteriorated beyond the expiration date.

Note: A positive result will not change once it has been established at 15 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after 15 minutes. Interpreting test results after 15 minutes, the sensitivity of the test will be higher than 10 ng/ml. Some specimens with a high rheumatoid factor concentration may yield a non-specific positive result.

LIMITATIONS

Although the ulti med FRT Test is very accurate in detecting FRT, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained.
As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

WARNINGS

- The same lancet needle should be used for one person only and should not be shared with another person, because the used needle is a biohazard.
- Decontaminate and dispose of all specimens, reaction kits, lancet needle and potentially contaminated materials, as if they were infectious wastes, in a biohazard container.
- Do not use the kit after the expiration date.
- For in vitro diagnostic use only.
- Do not use test, if pouch is torn or damaged.

REFERENCES

- Bothwell TH, Charlton RW, and Motulsky AG, “Hemochromatosis”, The Metabolic Basis of Inherited Disease, 6th ed, Scriver CR, Beaudet AL, Sly WS, et al, eds, New York, NY: McGraw-Hill Inc, 1989,1433-62.
- Stacy DL and Ha P, “Serum ferritin measurement and the degree of agreement using four techniques,” Am J Clin Pathol, 1992, 98(5):511-5.

	Manufacturer		Contents sufficient for <n> tests
IVD	For in vitro diagnostic use only	LOT	Lot. no.
	For single use only		Use by
	Read instructions for use		Store at

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January
2009/K