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Ferritin Test Card

For Whole Blood, serum and Plasma

REF

Catalog No.R11-410

EXPLANATION OF THE TEST

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

The FERRITIN Test is a highly sensitive immunoassay for semi quantitative determination of human ferritin in whole blood, serum or plasma. This test is intended for professional use as an aid in the diagnosis of iron deficiency anaemia. The sensitivity of the test is 10 ng/ml.

MATERIALS PROVIDED

The FERRITIN test kit contains the following items to perform the test:

1. FERRITIN test device.
2. One blood specimen collection droppers.
3. Instructions.

PRECAUSIONS

The FERRITIN test kit should be stored at room temperature 4-30°C (40-86°F). The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date.

Specimen Collection and Storage

Whole Blood specimen collection: Collect an anti-coagulated blood sample (sodium heparin or lithium heparin). Whole blood samples must be tested within 24 hours of drawing.

SPECIMEN COLLECTION AND STORAGE

1. Centrifuge whole blood to get plasma/serum specimen.
2. If specimens are not immediately tested they should be refrigerated at 2-8 °C. For storage periods greater than three days, freezing is recommended. The specimens should be brought to room temperature prior to use.
3. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

WARNINGS

1. For professional use only.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
7. Do not use the test kit if the pouch is damaged or the seal is broken.
8. 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.
9. Decontaminate and dispose of all specimens, reaction kits, lancet needle and potentially contaminated materials, as if they were infectious wastes, in a biohazard container.
10. Do not use the kit after the expiration date.

PROCEDURE

1. Remove the test disk from the foil pouch, and place it on a flat, dry surface. Note: Once the test disk is removed from the pouch, it should be used as soon as possible.
2. Obtain specimen
3. Transfer specimen into the dropper.
4. Add 2 to 3 drops of specimen into the specimen well of the test. (Figure 1)
5. As the test begins to work, you will see purple color dyes move across the Result Window in the center of the test disk.
6. Interpret test results at 10 to 15 minutes. Do not interpret test results after 15 minutes.

Figure 1

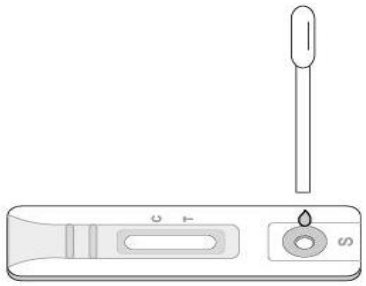
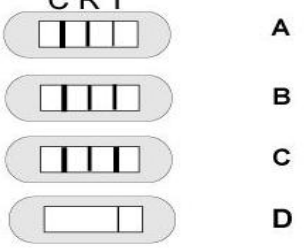


Figure 2



C:Control, R: Reference, T: Test

INTERPRETATION OF THE TEST

Ferritin concentration of about 10 ng/ml: The "T" band is visible but, it's intensity is weaker than both the "R" and "C" bands indicating that Ferritin level is 10 ng/m as in part (a) of Figure 2.

Ferritin concentration of 50 ng/ml: The intensity of the "T" band is similar to the "R " band and less than the "C" band indicating that Ferritin level is 50 ng/ml in part (b) of Figure 2.

Ferritin concentration greater than 100 ng/ml: The intensity of the "T' band is darker than the "R " band and is similar to the "C line" indicating that Ferritin level is 100 ng/ml in part (c) of Figure 2.

Invalid: If after performing the test, no "R" and/or "C" color bands 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 (part d of Figure 2).

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. Some specimens with a high rheumatoid factor concentration may yield a nonspecific positive result.

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.

LIMITATIONS OF THE TEST

Although the IMMUNOSPEC FERRITIN Test is very accurate in detecting FERRITIN, 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.

REFERENCES

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2. 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.

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PIR11-410
Revision date: 9-15-2008