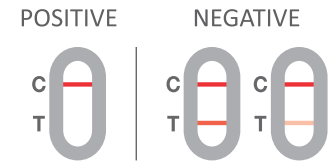


berkeleyhealth IRON FER

Self-test for the detection of ferritin levels in whole blood samples



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0483



IRON STORAGE & FERRITIN

Iron is an essential metal for our bodies and is crucial for transporting oxygen in the blood, for cell multiplication and to build the structure of tissues and organs. However, in excessively high levels it is toxic for the body. For this reason, every one of us has a system for taking up iron from the external environment (e.g. via a diet rich in iron-containing foods) and storing it in cells in a way that is not excessive (and therefore not toxic). Ferritin is the protein responsible for this storage function. The level of ferritin is an excellent indicator of the amount of iron available to the body. Low levels of this protein in the blood are an indication of depleted iron stores, a condition that precedes the development of anaemia. A decrease can be caused by pregnancy, haemorrhages, alterations in iron uptake.

WHO ARE THE INTENDED USERS

Everyone over the puberty age (≈ 15 years). Before normal levels are higher than the decision value of the cut-off level of this test.

WHY - BENEFITS

Checking the normality of the Ferritin value is a useful tool for verifying the iron deficiency anaemia.

TEST PRINCIPLE

IRON FER TEST is an immunochromatographic assay which detects the protein Ferritin thanks to special monoclonal gold-conjugate antibodies embedded to test strip.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
30 ng/mL	85.9%	100%	96.6%

Performance data obtained by clinical study with 120 participants enrolled. Biokit Quantex Ferritin has been utilized as reference method.

CONTENT:

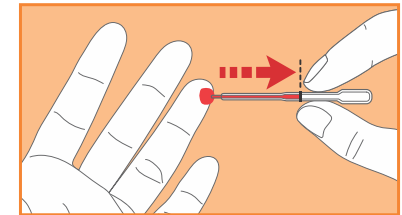
1 sealed aluminium pouch containing: 1 test device and 1 desiccant bag; 1 transparent plastic bag containing a pipette for blood collecting; 1 vial with dropper containing the diluent; 2 sterile lancets for blood sampling; 1 alcohol swab and 1 instructions for use leaflet.

CLINICAL EVIDENCES

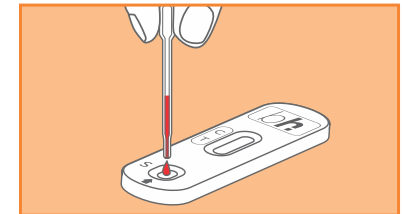
1. Wick M, Pingerra W, Lehmann P, Iron metabolism: diagnosis and therapy of anemias, 5th ed, Vienna, New York: Springer Verlag, 2003; p. 151.
2. Worwood M. The laboratory assessment of iron status – an update. Clin Chim Acta 1997; 259: 3-23.
3. Kaltwasser JP, Werner E. Diagnosis and clinical evaluation of iron overload. Baillieres Clin Haematol 1989; 2; 363-89.
4. Baynes RD, Cook JD. Current issues in iron deficiency. Curr Opin Hematol 1996; 3:145-9.
5. Lee MH, Means RT Jr. Extremely elevated serum ferritin levels in a university hospital: associated diseases and clinical significance. Am J Med 1996; 98: 566-71.

HOW TO USE IT

1) Take a blood sample after pricking the finger.



2) Deposit the sample into the specimen well of the cassette.



3) Add 2 drops into the well and wait 5 minutes before reading the result.

