PACKAGE INSERT- READ INSTRUCTIONS BEFORE USE

Rapid One-step Quantitative Detection of Ferritin

in human blood

IVD 8 ºC – 30 ºC Σ 25

REF

Cat # NSFE-QN-25

INTENDED USE

Test4Fe is a rapid immunoassay for the quantitative detection of ferritin levels in human blood.

This product is meant for professional use only. This assay provides only a preliminary screening test result. The performance characteristics of this assay have not been established in a pediatric population.

PRINCIPLE

Test4Fe is based on the sandwich assay. Anti-Ferritin monoclonal antibody conjugated gold nanoparticles are immobilized on conjugate pad. The second antibody is coated onto the nitrocellulose membrane. When sample is introduced, first antibody conjugated to gold nanoparticles binds to ferritin in the sample and ferritin-antibody-gold complex moves to test line where second antibody will capture the complex and a red colored test line appears. The intensity of the colored test line is directly proportional to the concentration of ferritin in blood/serum. A control line is present in the test window to work as procedural control.

MATERIALS PROVIDED

Each package contains:

1. 25 Test4Fe individually packed test devices
2. 25 blood lancets
3. 25 transfer pipettes
4. 1 Buffer Vial containing Chase Buffer (5.0 mL)
5. 1 Package Insert and 1 RFID card

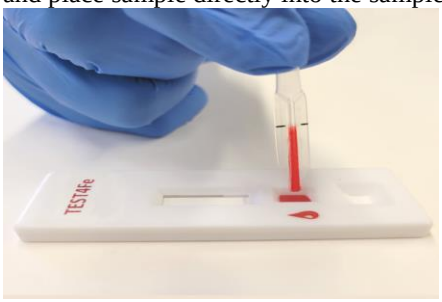
MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or clock
- Cube reader

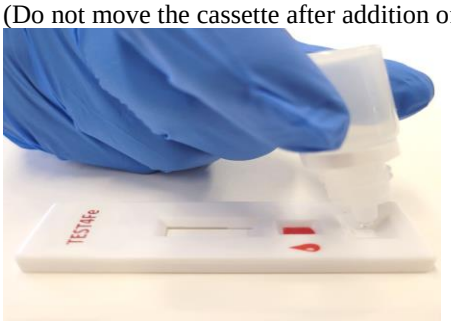
PROCEDURE

1. Remove the cassette from sealed pouch and place it on a hard flat surface with the view window facing up

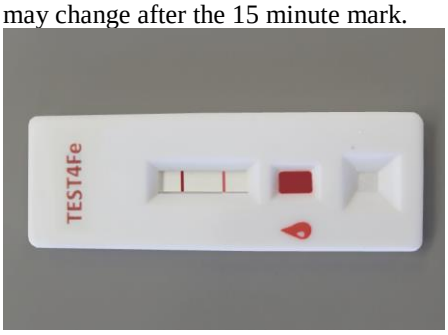
2. Draw a drop of blood by using lancet. Touch the blood drop with the tip of the provided sample pipette (do not press the bulb) and collect 10 µl of blood sample, and place sample directly into the sample well.



3. Add 2 full drops of Chase Buffer into the buffer well (Do not move the cassette after addition of buffer).



4. Let cassette sit for 15 minutes and immediately read your results by Cube reader as shown below. Results may change after the 15 minute mark.



TEST RESULTS AND REPORT

1. Place the adapter on top of the test cassette.
2. Place the cube reader on top of the adapter correctly.
3. Press the black button on reader, it will display ON.
4. Press the button again and display will read “RFID”.
5. Place the Lot Specific RFID card on the cube reader with each lot to upload the calibration data.
6. Following a beep signal, “TEST” is displayed.
7. Press the black button, it will display RUN.
8. The results will scroll horizontally on the display screen in ng/ml. Note the results.
9. The reader will switch off automatically after 50 seconds.

PERFORMANCE CHARACTERISTICS:

Sensitivity: The sensitivity was determined based on 20 measurements of individual ferritin-free samples, calculated by subtracting 3 times of standard deviation from the mean. The sensitivity is 20 ng/mL.

Detection Range: The Detection range of Test4Fe is from 20ng/mL to 400 ng/mL.

Spiking Studies: Low ferritin sample was spiked with Ferritin and estimated with Test4Fe. Percentage recovery was between 93 and 111%.

Accuracy: The accuracy of test was determined using 20 blood samples in comparison with ELISA assay. The comparison result showed a correlation coefficient of 96.4%.

Precision: Precision measurements were performed to evaluate repeatability. Precision studies were conducted using the samples that had low, mid and high Ferritin values. Each sample was tested twice over a period of five days. Precision was found to be less than 10% CV at all the three levels tested.

The inter-assay variation was calculated as 8.3 % by assaying the test samples over a period of fourteen days, and intra assay variation was found to be 5.6% by assaying 10 replicates on the same day.

Specificity: No interference and cross reactivity was observed with added high concentrations of Vitamin A, Vitamin D, bilirubin, triglycerides and cholesterol.

PRECAUTIONS

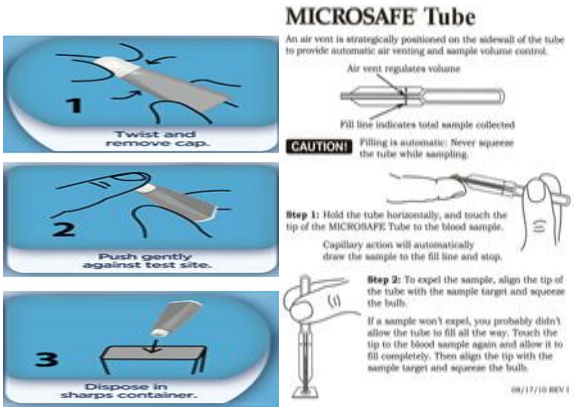
For *in vitro* diagnostic use only.

1. Reagents and device must be at room temp. (8 ºC – 30 ºC).
2. Do not use if test device packaging is open or damaged.
3. Do not use the product beyond expiration date. Handle all specimens as potentially infectious.
4. Read test results at 15 minutes as required. Results may deteriorate and may not be consistent after 15 minutes.

STORAGE AND STABILITY

The test device should be stored at 8 °C – 30 °C and will be stable until the expiration date. The product is humidity sensitive and should be used immediately after being open.

INSTRUCTIONS TO USE LANCET & BLOOD TRANSFER PIPETTE:



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INSTRUCTIONS FOR USING CUBE READER (*CE*) WITH Test4Fe

1. After the test is completed, put the Test4Fe cassette in the correct orientation into the adapter.
2. Put the Cube reader on the adapter so that it fits on the square space properly.

3. Turn on the cube reader by pressing the black button. After a brief period of self-testing, during which the reader shows WAIT, the reader will show ON. Press the black button.

4. The reader will show RFID**. Place the Lot Specific RFID card on top of the Cube Reader**. An audible signal will indicate successful reading of the RFID card. The Cube Reader will show TEST. At this point, press the black button again.

5. The reader will display RUN and the ferritin concentration in the sample will be shown in ng/mL. The result will scroll horizontally in the display.
6. The Cube Reader will shut down automatically in 50 seconds.