NEWSCEN
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CE 0123 IVD SF-B-29300101000 REF Version: A/3 Revision Date: 02/07/2022

Serum Ferritin Test Kit (SF)

INTENDED USE

Serum Ferritin Test Kit (SF) is a single use, rapid immunoassay for semi-quantitative detection of ferritin in human finger blood to aid in diagnosis of anemia. It is intended for use by the lay users. Serum Ferritin is a protein that stores iron, which measures the diagnosis of iron metabolism and is an indicator of early iron deficiency. The lower iron elements in the body cause hemoglobin to decrease. If the early diagnosis of iron deficiency, anemia can be avoided.

PRINCIPLE

Antibodies to SF are precoated onto membrane as a capture reagent on the test zone. During the test, specimen is allowed to react with the colloidal gold particles, which have been labeled with antibodies to SF. If SF is present, a red colored line will develop on the membrane in proportion to the amount of SF present in the specimen. To serve as a procedural control, red colored line in the control zone will always appear regardless of the presence of SF.

COMPONENTS

REAGENTS AND MATERIALS PROVIDED

Each kit contains:

2. Each pouch contains one cassette with one desiccant bag
3. One bottle of diluent buffer
4. Disposable plastic dropper
5. Instruction for use
6. Color card
7. Sterile lancet
8. Alcohol pad
9. Capillary tube

Table 1 Manufacturer information of purchased components

Sterile lancet	CE0123 CERTIFICATE No. G2 072777 0009 Rev.01	Ningbo Medsun Medical Co., Ltd. No.55 Jinxi Road, Zhenhai 315221 Ningbo People's Republic of China	Shanghai International Holding Corp. GmbH（Europe） Eiffestraβe 80 20537 Hamburg, GERMANY
Alcohol pad	CE0123 CERTIFICATE No. G2S 103710 0002 Rev.00	Jiangsu Sunclean Medical Co., Ltd. No. 11 Fenghuang South Road, Hutang Town, Wujin District, 213162 Changzhou City, Jiangsu Province, People's Republic of China	MedPath GmbH Mies-van-der-Rohe-Strasse 8 80807 Munich, Germany

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer or stopwatch

WARNING AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use if pouch has been perforated.
4. Do not reuse the test devices. Discard it in the dustbin after single use.
5. Always interpret the results under good light conditions to avoid misreading of the results.
6. If desiccant bag is not present in the pouch, DO NOT USE the test.
7. Always add accurate volume of specimen by following the instruction.
8. The test is not intended to be used for diagnosing diseases associated with elevated Ferritin levels.
9. The test does not substitute relevant prevention programs for pregnant women.
10. Different batch of product components cannot be mixed.

STORAGE

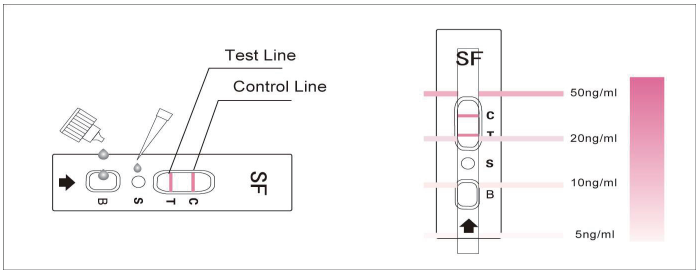
Serum Ferritin Test Kit (SF) should be stored at room temperature (4-30°C, do not freeze) for 24 months from the date of manufacture. Keep the test cassette in sealed pouch until use. Once you have taken the test cassette out of the pouch, perform the test as early as possible (within 1 hour) to avoid test cassette from becoming moist.

SAMPLE COLLECTION AND TEST PREPARATION

1. Clean the area to be lanced with an alcohol swab.
2. Squeeze the end of the fingertip and pierce it with a sterile lancet.
3. Use capillary tube to obtain finger blood to the marked line, about 20μL fresh blood.

EXAMINATION PROCEDURE

1. Place the test cassette on a non-absorbent flat surface. Before opening, allow the test cassette to reach room temperature. Use it immediately after opening.
2. Squeeze the end of the fingertip and pierce it with provided lancet.
3. Use capillary tube to obtain finger blood to marked line, about 20μL fresh blood. The capillary blood sample has to be transferred immediately to the Sample well.
4. Put all blood samples of capillary tube into S well, after all blood completely absorbed, add 1~2 drops (50-80μL) of buffer into B well. Observe the result in 15~20 minutes. Compare the color of the test line (T) with the color card to determine the test results. More than 20 minutes to determine the results are invalid.



INTERPRETATION OF RESULTS

1. If only one red line appears in the control zone(C), or the color intensity of test line is lower than or equal to line of 5ng/mL on the color card, it indicates the concentration of ferritin is lower than 5ng/mL. If the color intensity of test line

is between 5~50ng/mL, compare with the color card to get a semi-quantitative result. If the color intensity of test line is higher than 50ng/mL line, it indicates the concentration of ferritin is higher than 50ng/mL.
2. The ferritin content in the tested samples is less than or equal to 20ng/mL, indicating that the tested subjects may have insufficient iron storage in their bodies. Greater than 20ng/mL suggests that the iron reserves in the subjects may be normal.
3. If no red line appears in the control zone(C), the test is invalid. Discard the test and repeat with new specimen and new cassette/strip.

Built-In Control

Serum Ferritin Test Kit (SF) has a built in procedural control that demonstrates assay validity. A red line appearing adjacent to the control zone (C) indicates that the test runs correctly.

LIMITATION

1. The test is intended for semi-quantitative detection of ferritin.
2. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
3. When it is used for the monitoring of an existing disease, the patient should only adapt the treatment if he has received the appropriate training to do so.

PERFORMANCE CHARACTERISTICS

Analysis sensitivity: 5ng/mL

Analysis Specificity: Have no cross-react with AFP 400ng/mL, 200mg/mL albumin, sample diluent.

The test range: 0~50ng/mL, compare to the color chat to get a semi-quantitative result;≥50ng/mL, compare to the color card to get a qualitative result.

Interference Testing

The following substances were added in blood samples. None of the substances at concentration tested interfered in the assay.

Table 1 Interference substances

Heparin	20-30IU/mL
EDTA	1.5g/L
Sodium citrate	10.9mmol/L
Sodium azide	0.2%

Clinical Study

A total of 220 specimens were detection by the kit and reference reagent. The results are summarized in the Table 2 below.

Table 2 Results of Performance

NewScen	Reference reagent		Total
	≤20ng/mL	> 20ng/mL	
≤20ng/mL	45	1	46
> 20ng/mL	2	172	174
Total	47	173	220

Sensitivity=95.74%;
Specificity= 99.42%;
Total coincidence rate=98.64%.

REFERENCE

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INDEX OF SYMBOLS

	Do not re-use
REF	Catalogue number
IVD	For In Vitro Diagnostic medical device
	Use by date
	Date of manufacture
4°C 30°C	Temperature limitation
	Consult instructions for use
EC REP	Authorized Representative in the European Community
LOT	Batch code
Σ n	Contains sufficient for < n > tests
CE 0123	CE Mark
	Manufacturer

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