

Iron Deficiency Anemia (IDA) Early Screening and Diagnosis

Certified by TÜV / MHRA / NMPA

Serum Ferritin Test Kit (SF) Semi-Quantitative Self-Testing

21 Years Top Supplier to Global RDT Manufacturers & End Users
Leading-Edge Technology in the IVD Industry



Uncut Sheet



Rapid Test

2024 VERSION

Contact NewScen Team :

Add : No. 65, 6th Street, Tianjin TEDA, 300457, Tianjin, P.R.China

Web : www.newscenestestkit.com (Uncut Sheet)

Web : www.newscenbiotech.com (Rapid Test)

Email : export@newscen.com

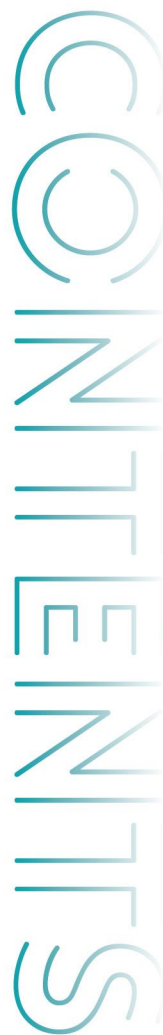


Women and Children's Health



Serum Ferritin

Early Detection and Early Treatment of Iron Deficiency for the Maternal, Newborn and Children.



COMPANY PROFILE

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SERUM FERRITIN TEST KIT (SF)

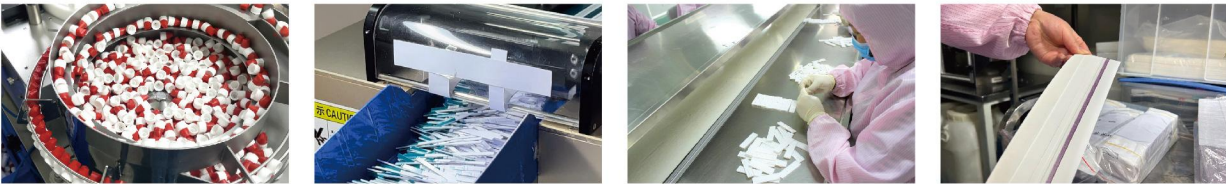
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Company Profile



Export Product Category

Infectious Disease Test	HIV HCV
Iron Deficiency Test	★ SF (Bestselling since launched in 2009)
Tropical Disease Test	
Hormone Test	HCG LH FSH
Drug of Abuse Test	
Tumor Marker Test	FOB
Respiratory Disease Test	
Cardiac Marker Test	
Inflammatory Marker Test	
Renal Injury Marker Test	



Manufacturer

NewScen Coast Bio-Pharmaceutical Co., Ltd. (NEWSCEN)

Company History

Founded in 2003, 21 Years Experience in the IVD Industry

Site of Headquarter

Based in Tianjin, the Largest Port City in North China

Management System

ISO 9001: 2015 , ISO 13485: 2016

Global Market

90+ Countries and Regions Globally

Public Procurement (Million-plus Orders)

Italy-HCV

Germany-PSA

Indonesia/Singapore/Malaysia/South Africa-HIV



Milestone

NewScen has created a series of number ones and leaded the trend of technology development in the past two decades in the IVD industry.

✓ **Rapid Test** ✓ **Equipment** ✓ **System** ✓ **Platform**

- **2002** Achievement of 1st National New Drug Certificate for HIV 1+2 Rapid Test (CLASS II)
- **2008** Technology Breakthrough and 1st Application of Double Antigen Sandwich Method for HCV Early Detection in CHINA
- **2010** Invention of 1st Rapid Immuno Assay Reader (Open System with Universal Compatibility)
- **2012** Production and Promotion of Quantitative Rapid Test (Colloidal Gold Method)
- **2014** Establishment of 1st MI-POCT System Based on Internet+ Technology
- **2016** Technology Transfer of Immunofluorescence Microfluidics Technique (Precision Diagnosis)
- **2017** NEEQ Listed (Stock Name : NewScen Biotech Stock Code : 872334)
- **2019** Establishment of 1st Automatic, Intelligent Immunofluorescence Microfluidics Platform in CHINA
- **2020** Global Registration of Medical Devices : COVID-19 Series (Ag, IgG/IgM) of CE Certificates and in Australia (TGA), Brazil (ANVISA), Dominica, etc.
- **2021** Global Registration of Medical Devices : COVID-19 Series (NAb) of CE Certificates and in Vietnam, etc.
- **2022** Global Registration of Medical Devices : HIV in Thailand, CE Certificates of 18 Products, NMPA Certificate of Reader, etc.
- **2023** TJ Pharmaceutical Group & DRT Group Had Become Major Shareholders of NewScen

Shareholders & Co-founders of NewScen



NewScen has been controlled by the Tianjin Pharmaceutical Group and DaRenTang Group in 2022.

- Tianjin Pharmaceutical Group is listed in "Top 100 Pharmaceutical Companies in China"
- As a leading high-tech company in the IVD industry, NewScen is highly ranked in the business line of Device and Diagnosis within the entire group business framework.

Factory Tour



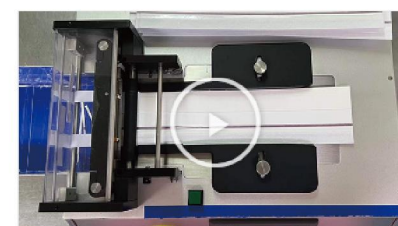
Display of Workshop



Components Preparations



Uncut Sheet Assembling



Uncut Sheet Cutting



Cassette Format Processing



Foil Pouch Sealing



External Packing



QC Inspection of Finished Product



Warehousing for Shipping

Please scan the QR code here for NewScen factory tour.



For our colloidal gold workshop

Production Capacity: 5,000,000 pcs / Day



R & D Capacity

R & D Team, Experience, Achievement

The NewScen R & D team always keep a close pace with the development trend and cutting-edge technology of POCT industry by means of attending various well-known domestic and international exhibitions or professional academic seminars, organizing new product launch conferences. All of these market-oriented research events or business development campaigns contribute greatly to the global vision of NewScen R & D team and has been bringing the efficacy of our intelligent manufacturing process to a sustainable growth in return, and win us the trustfulness of our clients globally and the precious opportunities of long-term cooperations.

20+

Core Members of

R & D Team

60+

NMPA Medical Device

Registration Certificates

40+

CE Certificates

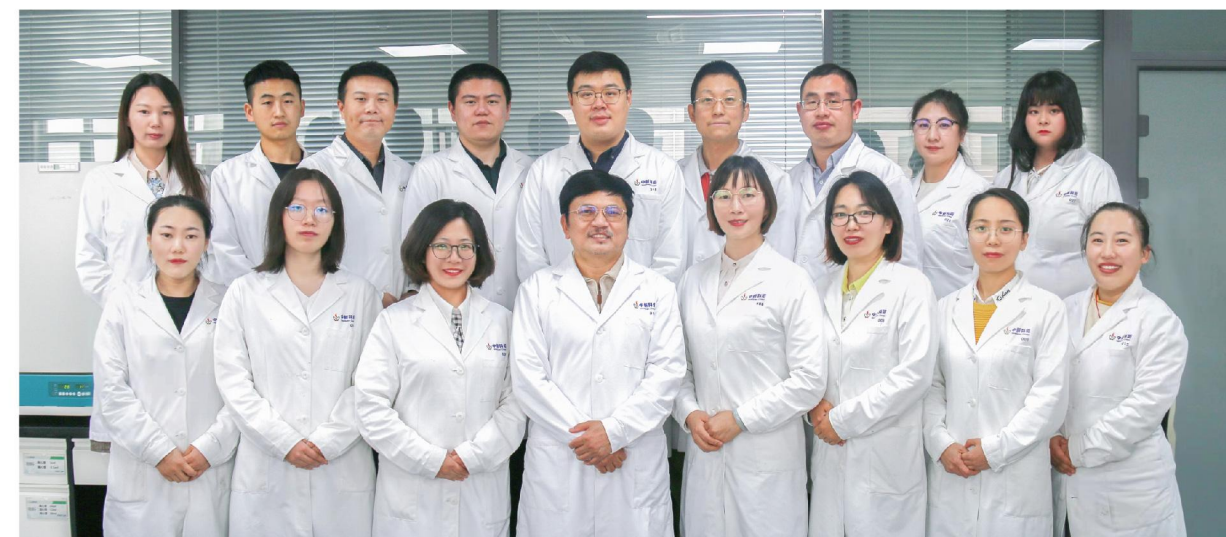
(CE 0123, etc.)

100+

Independent Intellectual

Property Rights

Chief Scientist from **U.S.** - Dr. Tony Lee
Co-founder of the NewScen company in 2003
Inventor of the 1st 3-line HIV, HCV, SF RDT in China



Certificates

101 Independent Intellectual Property Rights

61 NMPA Medical Device Certificates

Class III * 11 Class II * 46 Class I * 4

41 CE Certificates

LIST A * 1 Self-Testing * 5 Others * 35



★ Certifications by International Authorities



★ Authorized Invention Patent Certificates



Factory Certification

The following is the qualification certificate of our factory:
NewScen Coast Bio-Pharmaceutical Co., Ltd.



- Certificate: EN ISO 13485 : 2016
- Issue Date: 2022/09/20
- Expiry Date: 2025/10/20
- Issued By: TÜV
- Report No.: SH22107301



- Certificate: ISO 9001 : 2015
- Issue Date: 2022/11/10
- Expiry Date: 2025/11/24
- Issued By: TÜV
- Report No.: SH22107301

Product Certification

We can provide the following product certifications to all of our global partner customers.



- Products: HCG, LH, FSH, FOB, SF, HIV, HCV
- Certificate: CE
- Issue Date: 2022/05/02
- Issued By: TÜV
- Method: Lateral Flow Assay (Immunochromatography Assay)



Model(s):

Human Chorionic Gonadotropin (hCG) tests
(Pregnancy tests)
Luteinizing Hormone (LH) tests
(Ovulation tests)
Follicle Stimulating Hormone (FSH) tests
(Menopause tests)
One-Step Fecal Occult Blood (FOB) Diagnostic Kit
Serum Ferritin Test Kit (SF)
HIV(1+2) Antibody Rapid Test
HCV Antibody Rapid Test

MHRA

- **Products:** PCT, CRP, AFP, CEA, cTnI, D-Dimer, mAlb, TSH, HCG, LH, FSH, SF, FOB, HIV, HCV
- **Certificate:** CE
- **Issue Date:** 2022/04/28
- **Expiry Date:** Indefinite
- **Issued By:** MHRA
- **Method:** Lateral Flow Assay (Immunochromatography Assay)

REG
Medicines & Healthcare products
Regulatory Agency

**Medicine & Healthcare products
Regulatory Agency**
11 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
+44(0) 20 300 9000
reg@ma.hk.gov.hk

Wellness Ltd
Estate of the RMA, NW Business Complex
1 Birchington Road
Dover, Northern Ireland
BT18 7JH
Northern Ireland, United Kingdom

23 April 2023

Dear Yui Cuddy

We are pleased to confirm that the application to register or update an existing registration for the following
medicament, which you submitted on 23 April 2023 has been received.

Application reference: 2023M083506559

Maintainer organisation: Wellspan Care Bio-Pharmaceutical Co., Ltd.
Address:
No. 48, 4th Street,
Tianjin TEDA,
Tianjin
300457
China

Maintainer contact registration status: Registered

Date(s):

ECrep (IVDD ListA 30829&65847)

A88

Medicines & Healthcare products
Regulatory Agency

Mobilisation & Mobilisation products
Regulatory Agency

31 South Colonnade
Croydon Road
London
CR9 4PU
United Kingdom

+44(0) 20 300 4602
per@mhpra.gov.uk

Wellking Ltd
Patterson House, VII, Western Complex,
1 Shepherdess Road
Derry, Northern Ireland
BT47 8HJ
Northern Ireland, United Kingdom

23 April 2012

Dear Edward Wang

We are pleased to confirm that the application to register as sponsor or existing registration for the following medicinal product, which you submitted on 23 April 2012 has been received.

Application reference: 2012M4308E00002

Manufacturer organisation: NewKoon Carb Bio-Pharmaceutical Co., Ltd.
Address:
No. 48, 4th Street,
Taiping TADA,
Tianjin
300070
China

Manufacturer registration status: Registered

DOCSID:5

ECrep (IVDDother COVID IgG) 64839

No.	Product name	GMST code	Modul	CE class
1	Human Prolactin(hP) quantitative rapid test kit (colloidal gold)	58305	cassette	IVDD others
2	reactive prothrombin (CRP) quantitative rapid test kit (colloidal gold)	58305	cassette	IVDD others
3	Alpha (fetoprotein) (AFP) quantitative rapid test kit (colloidal gold)	63961	cassette	IVDD others
4	Carcino-embryonic Antigen quantitative rapid test kit (colloidal gold)	54657	cassette	IVDD others
5	Cardiac Troponin-I (TnI) quantitative rapid test kit (colloidal gold)	61295	cassette	IVDD others
6	25-OH vitamin D quantitative rapid test kit (colloidal gold)	47343	cassette	IVDD others
7	Urea microalbumin (mAb) quantitative rapid test kit (colloidal gold)	66374	cassette	IVDD others
8	Human Thyroid Stimulating Hormone (TSH) quantitative rapid test kit (colloidal gold)	60471	cassette	IVDD others
9	Human Chorionic Gonadotropin (HCG) tests (Pregnancy tests)	54312	microdisc, strip, midstream	IVDD self-testing
10	Luteinizing Hormone (LH) tests (Ovulation tests)	65974	microdisc, strip, midstream	IVDD self-testing
11	Follicle Stimulating Hormone (FSH) tests (Menopausal tests)	65941	microdisc, strip	IVDD self-testing
12	Serum Ferritin/Total Iron (Sf)	61367	cassette, strip	IVDD self-testing
13	Diagnosis Rapid Occult Blood (POB)	65665	cassette, strip	IVDD self-testing
14	Neovision HIV 1/2 Antibody Rapid Test	61647	cassette	IVDD others
15	Neovision HIV Antibody Rapid Test	30629	cassette	IVDD class A
16	Novoson 10 IgG/anti Microfluidic Chip	64889	cartridge	IVDD others
17	COVID-19 IgG/anti Rapid test Cassette	64736	cassette	IVDD others

NewScen List

NMPA

- **Products:** HIV, HCV, TP, TB, HPAG, HPAb, FOB, SF
- **Certificate:** NMPA
- **Issue Date:** HIV 2024/04/08, HCV 2021/01/12, TP 2020/07/01, TB 2024/04/08, HPAG/HPAb 2022/06/29, FOB/SF 2022/06/19
- **Expiry Date:** HIV 2029/04/07, HCV 2026/01/11, TP 2025/06/30, TB 2029/04/07, HPAG/HPAb 2027/06/28, FOB/SF 2027/06/18
- **Issued By:** NMPA
- **Method:** Lateral Flow Assay (Immunochromatography Assay)

[illegible]HCV NMPA
2021-2026

中华人民共和国	
医疗器械注册证(体外诊断试剂)	
注册人名称	上海爱康生物科技有限公司
注册人住所	天津经济技术开发区南大街44号
生产地址	天津经济技术开发区南大街44号
代理人住所	/
产品名称	每瓶独立包装快速检测试剂(“试纸条”)
规格型号	1.名称(中文): 试纸条(中文); 试纸条(英文): 试纸条(英文); 2.规格: 试纸条(中文): 试纸条(中文); 试纸条(英文): 试纸条(英文); 3.规格: 试纸条(中文): 试纸条(中文); 试纸条(英文): 试纸条(英文); 4.规格: 试纸条(中文): 试纸条(中文); 试纸条(英文): 试纸条(英文);
主要组成成分	1.试剂组成: 主要成分为快速检测试剂(“试纸条”)和检测试剂。 2.试剂组成: 主要成分为快速检测试剂(“试纸条”)和检测试剂。 3.试剂组成: 主要成分为快速检测试剂(“试纸条”)和检测试剂。 4.试剂组成: 主要成分为快速检测试剂(“试纸条”)和检测试剂。
销售渠道	产品通过指定经销商进行销售, 在各级医疗机构均有销售。
附件	产品说明书、说明书。
产品注册有效期	4-30℃避光保存, 有效期12个月。
其他内容	/
备注	C

注册日期: 2018年12月14日

注册有效期至: 2023年12月14日

TP NMPA
2020-2025[illegible]TB NMPA
2024-2029[illegible]HPAb NMPA
2022-2027[illegible]FOB NMPA
2022-2027[illegible]SF B NMPA
2022-2027

Product Certification

RIOMAVIX

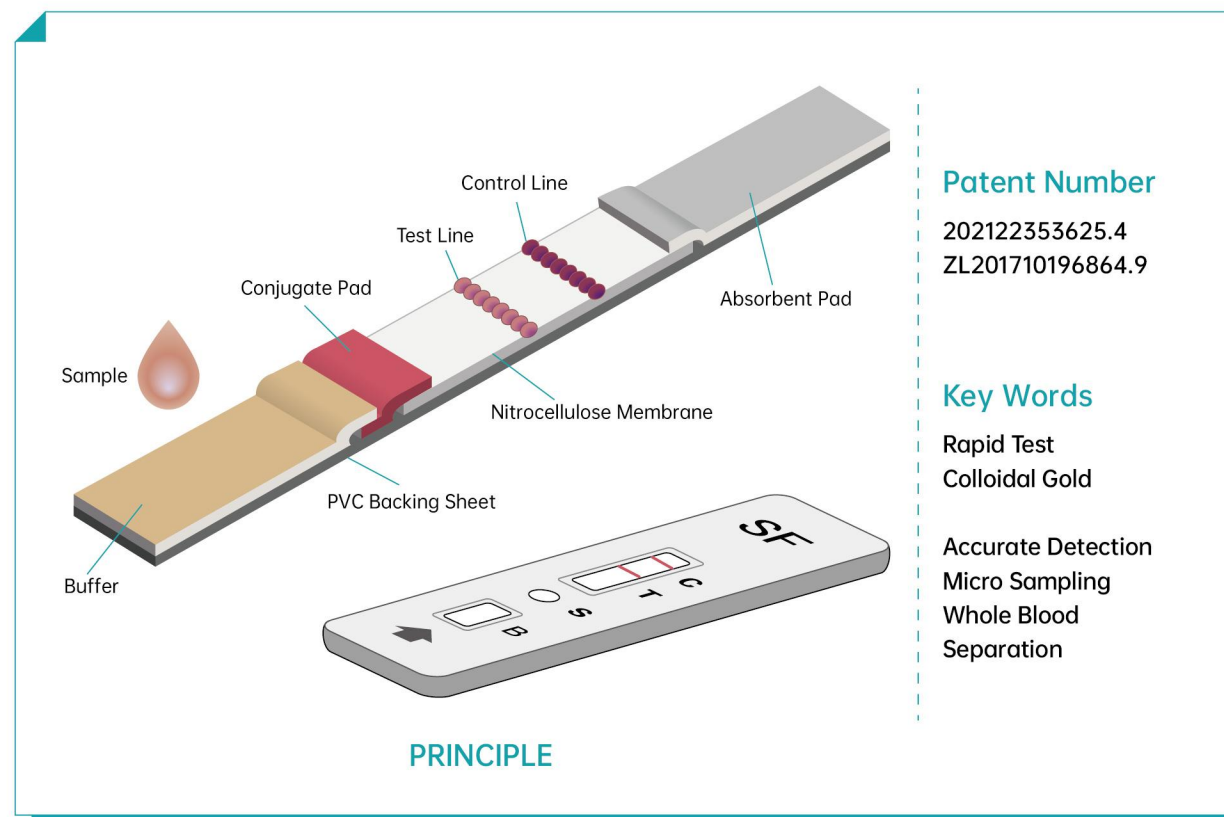
- Products:** MDT, CHIK IgG/IgM, ZIKA IgG/IgM, ZIKA NS1Ag, DEN IgG/IgM, DEN NS1 Ag, MAR Pf/Pan, HPAb, HPAG, TB, TF, TP
- Certificate:** CE
- Issue Date:** 2022/03/08
- Issued By:** RIOMAVIX
- Expiry Date:** Indefinite
- Method:** Lateral Flow Assay (Immunochromatography Assay)



Serum Ferritin Test Kit (SF)

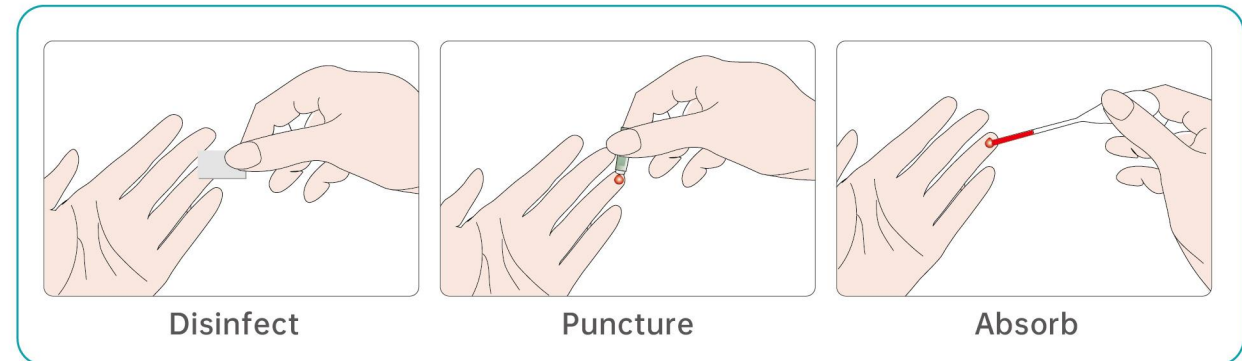
Summary

- ★ **INTENDED USE :**
Early Diagnosis of Iron Deficiency (LFA)
- ★ **PRINCIPLE :**
Double Antibody Sandwich Method
- ★ **PATENTS :**
Seperate Sample & Buffer Well

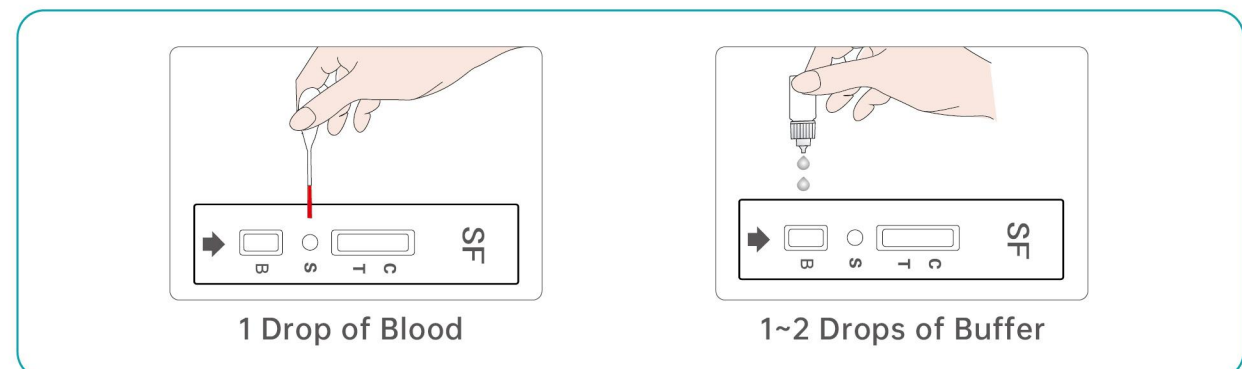


Procedures

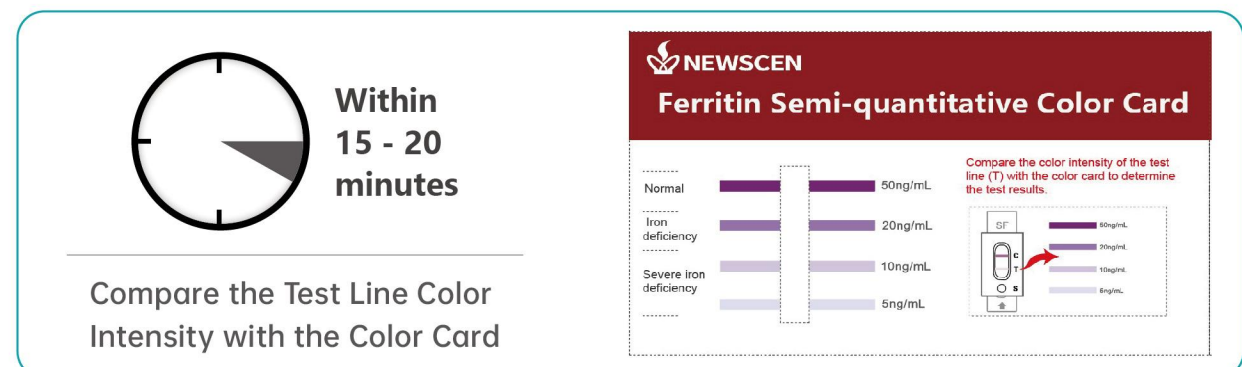
I. SAMPLE COLLECTION



II. TEST PROCEDURE



III. RESULT INTERPRETATION



Tips : For patients with their test results indicating iron deficiency (20ng/mL - 10ng/mL) and severe iron deficiency (10ng/mL - 5ng/mL or even lower than 5ng/mL), the iron supplementation therapy under medical supervision followed by continuous efficacy monitoring with Serum Ferritin Test Kit (SF) is recommended.

Performance

Clinical Consistency

Clinical Report (NMPA)

- Sensitivity :**
95.74%
- Specificity :**
99.42%
- Total Accuracy :**
98.64%



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

ELISA (220 Samples)

Consistency with CLIA (ROCHE)

- Sensitivity :**
100.00%
- Specificity :**
100.00%
- Total Accuracy :**
100.00%

NewScen	Roche		Total
	≤20ng/mL	>20ng/mL	
≤20ng/mL	15	0	15
>20ng/mL	0	78	78
Total	15	78	93

CLIA (93 Samples)



Hospital Application

Hospital Clinical Applications and References

As an important indicator of early detection, treatment and effect monitoring of iron deficiency and anemia, serum ferritin has been widely recommended and applied in the maternal and child health care system. It is of great significance in understanding the iron reserve status of pregnant women and infants, evaluating the risk factors for iron deficiency in time, providing reasonable guidance for iron supplementation, improving iron nutrition status, ensuring maternal and infant health and promoting optimal fertility.

A total of 9,312 specimens of infants, children and pregnant women from 11 hospitals in Anhui, Chongqing, Yunnan, Tianjin, Jilin and Shanxi were tested by Serum Ferritin Test Kit (SF). It has been concluded by a series of hospital clinical applications and papers that as a simple, feasible, reliable, and fast POCT rapid test, Serum Ferritin Test Kit (SF) of colloidal gold method from NewScen meets the requirements of clinical tests with good performance and efficiency of iron deficiency diagnosis in infants, children and pregnant women.

Hospital	Population	Samples (n)	Reference
Hefei Maternal and Child Health Center	Children aged 6 months to 7 years old	2,095	Study on the status of anemia and iron deficiency among children aged 6 months to 7 years old in rural areas in Hefei
Maanshan Institute of Maternal and Child Health	Fully breastfed infants aged 6 months	1,473	Analysis of iron deficiency and its influential factors of fully breastfed infants aged 6 months
Chongqing Health Center for Women and Children Children's Hospital of Chongqing Medical University	Children aged 2 to 5 years old	100	Evaluation of performance of colloidal gold method on detecting blood ferritin and the value of blood ferritin in iron deficiency anemia in children
Yunnan Provincial Maternal and Child Health Care Hospital Nuijiang State Maternal and Child Health Care Hospital Gongshan County Maternal and Child Health Care Hospital	6 to 24 months old infants from Yunnan Drung minority area	120	Investigation of anemia of 6~24 months old infants among Drung ethnic minority in Yunnan province
Tianjin Dongli District Jinzhong Street Community Health Service Center	Infants under 2 years old	2,016	Analysis of the status of iron deficiency among 2016 infants and children under the age of 2 years old in Tianjin
Tianjin Binhai New Area Hujiayuan Street Community Health Service Center	Pregnant women of average age 27.31 ± 4.7 years old	1,675	Analysis of the iron deficiency anemia detection index among the pregnant women in a certain community in Tianjin Binhai New Area
Jilin Women and Children Health Hospital	Infants and children under 5 years old	1,664	The application of Serum Ferritin Test Kit (SF) in the screening for iron deficiency in infants and children
Baoji Women and Children Health Hospital	Pregnant women aged 24 to 33 years old	169	Analysis of the red blood cell related parameters and serum ferritin determination of second trimester pregnant women
11 hospitals (Anhui, Chongqing, Yunnan, Tianjin, Jilin, Shanxi)	Infants, children, pregnant women	9,312	8 references (published on authoritative magazines and journals)

Method Comparison

Lateral Flow Assay : Serum Ferritin Test Kit (SF)

✓ Affordable ✓ Approachable ✓ Fast & Accurate ✓ Stable & Convenient

Item	ELISA	CLIA	Immunofluorescence	Lateral Flow Assay
Testing Time	Long Time	Long Time	15 Minutes	15 Minutes
User Operation	Complicated	Complicated	Easy	Easy
Equipment	ELISA Reader	CLIA Analyzer	Fluorescence Immunoassay Analyzer	No Equipment Required Visual Interpretation with Color Card
Sample	Serum	Serum	Whole Blood	Whole Blood (Fingertip)
Transportation	Cold Chain	Cold Chain	Room Temperature	Room Temperature
Cost	Very Expensive	Expensive	Relative Cheap	Cheap
Shelf Life	8 - 12 Months	8 - 12 Months	12 Months	24 Months

Internal Quality Control

Repeatability

LOT	GOD										Intra Lot CV (%)	Inter Lot CV (%)
202203184	2.11	1.94	2.13	2.22	2.06	2.01	1.98	1.85	2.20	1.92	6.03%	6.30%
202208052	2.00	2.22	2.23	1.99	2.22	2.13	2.06	1.98	1.92	2.21	5.71%	
202302273	1.87	1.87	2.11	2.04	2.17	1.92	1.93	1.91	2.00	2.06	5.25%	
202304103	1.96	1.87	1.97	1.93	2.25	2.08	2.25	1.90	2.10	1.88	7.13%	
202307181	1.92	2.26	2.00	2.22	2.16	2.08	2.28	1.96	2.22	2.12	6.05%	

* GOD : Color Intensity of Test Line (T) * LoD : 5ng/mL (Limit of Detection)

Stability

Days	GOD										Average Value	Deviation (%)
0	1.93	2.05	1.98	2.03	2.03	2.15	2.16	2.02	2.09	2.15	2.059	—
10	1.88	2.02	1.89	2.1	2.02	2.12	1.92	2.05	2.1	1.89	1.999	-4.45%
20	1.93	1.97	1.86	2.01	1.89	2.03	1.81	2.08	1.88	2.13	1.959	-6.04%
30	1.88	1.88	1.93	1.84	1.86	1.9	1.9	2.17	1.94	2.11	1.941	-6.46%

45°C Accelerated Aging Testing (0D, 10D, 20D, 30D)

* High Precision ✓

CV < 10%

Rapid Immuno Assay Reader
(Quantitative)

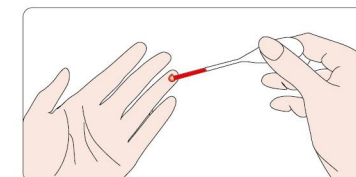
* High Stability ✓

Deviation < 10%

Advantages

Micro Sampling (Whole Blood)

- Finger Prick Sample
1 Drop (20 μ L)



✓ Safe ✓ Fast
✓ Accurate ✓ Easy

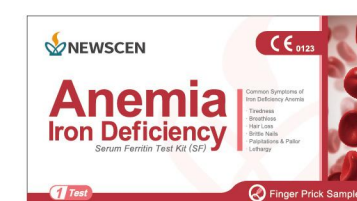
Consistency (Whole Blood V.S. Serum)

- Sensitivity : 90.32%
- Specificity : 100.00%
- Total Accuracy : 94.00%

Serum	Whole blood		Total
	≤ 20ng/mL	> 20ng/mL	
≤ 20ng/mL	28	0	28
> 20ng/mL	3	19	22
Total	31	19	50

CONSISTENT (50 Samples)

Components



1 Test / Kit



1 × Foil Pouch with Test Cassette and Desiccant

1 × Disposable Plastic Dropper with
1 × Capillary Tube



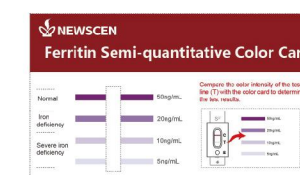
1 × Diluent Buffer



1 × Sterile Lancet



1 × Alcohol Pad



1 × Color Card



1 × Instruction for Use

Product	Ref. No.	Pack Size
Serum Ferritin Test Kit (SF)	SF-B-29304004000	40 Tests / Kit
	SF-B-29300101000	1 Test / Kit

Storage : 4°C - 30°C Shelf Life : 24 Months

Cases

Projects and Channels

Serum Ferritin Test Kit (SF)

National and Regional Project of Eliminating Anemia in Infants and Children Selected Product

► NATIONAL PROJECTS



All-China Women's Federation
National Health Commission of the
People's Republic of China
China Children and Teenagers' Fund



► REGIONAL PROJECTS



Maternal and Children Health Care System
Official Documents (Shanghai, Jilin, Jiangxi)



► NEW CHANNELS



Combination of Medication and Diagnosis ; E-commerce Platform



Cooperations

► NEW PRODUCT RESEARCH AND DEVELOPMENT

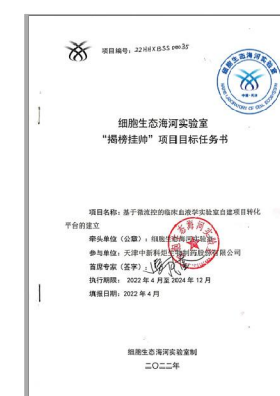
* NewScen R & D Team

Fully integrate domestic & global platforms from research and development to clinical practice, registration.

* Hepcidin

(Biomarker of iron Inflammatory anemia and immune anemia)
Joint development of test kit for iron metabolism diseases

Deep Cooperation for New Product Launch (with Top Ranking Labs and Hospitals)



Hematology Hospital of the
Chinese Academy of Medical Sciences



Tianjin Highest Level Scientific
Research and Innovation Base

* The largest specialized hospital
for hematology in China

* The central laboratory has dual
certifications of CNAS and ISO15189

