CE IVD

FRENOVO

Sickle Cell Screen Rapid Test Kit
Instructions For Use

PRODUCT NAME

FRENOVO Sickle Cell Screen Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

FRENOVO Sickle Cell Screen rapid test is lateral flow immuno-chromatographic qualitative assay to aid in rapid diagnosis of sickle cell disorder of hemoglobin A, S and C using whole blood sample (Capillary or finger prick or venipuncture)to screen individuals of any age (zero to forty), including newborns.This In-vitro diagnostic test intended to be used by healthcare professionals.

INTRODUCTION

Sickle cell disease is an inherited blood disorder.It is marked by flawed hemoglobin. That's the protein in red blood cells that carries oxygen to the tissues of the body. So, sickle cell disease interferes with the delivery of oxygen to the tissues. SCD is a genetic condition that is present at birth. It is inherited when a child receives two genes-one from each parent that code for abnormal hemoglobin.
Normal red blood cells can live up to 120 days.But,sickle cells only live for about 10 to 20 days.The sickled cells also damage the spleen.This puts you are at greater risk for infections.
There are several types of SCD.The specific type of SCD a person has depends on the genes they inherited from their parents.People with SCD inherit genes that contain instructions,or code,for abnormal hemoglobin.
People who have this form of SCD inherit two genes, one from each parent,that code for hemoglobin"S."Hemoglobin S is an abnormal form of hemoglobin that causes the red cells to become rigid,and sickle shaped.This is commonly called sickle cell anemia and is usually the most severe form of the disease.
People who have this form of SCD inherit a hemoglobin "S" gene from one parent and a gene for a different type of abnormal hemoglobin called"C"from the other parent.This is usually a milder form of SCD.
People who have sickle cell trait(SCT) inherit a hemoglobin"S"gene from one parent and a normal gene (one that codes for hemoglobin"A") from the other parent.People with SCT usually do not have any of the signs of the disease.However,in rare cases, a person with SCT may develop health problems. Additionally,people who have SCT can pass the abnormal hemoglobin "S" gene on to their children.

PRINCIPLE

FRENOVO Sickle Screen Rapid test is a double antibody lateral flow chromato-graphic immunoassay.The test cassette consists of 1)a nitrocellulose membrane strip containing a test line (HA, HS and HC) pre-coated with monoclonal antibodies and a control line (C line) pre-coated with Goat anti Mouse IgG.2) Conjugate pad containing monoclonal antibodies to sickle cell conjugated with colloidal gold.When an adequate volume of test specimen applied to the sample well of the test cassette,the specimen migrates by capillary action across the cassette.Hemoglobin variant A,S and C,if present in the specimen, will bind to the antibody and will form the complex with coated and conjugated antibodies.The immune-complex migrates on the membrane,when it reaches the test line; it will be captured by pre-coated antibodies and forms a visible Pink / Purple band. The control line is a procedural control should appear always.

KIT COMPONENTS

Each kit contains:

1. Test Devices: 20 pieces test devices individually pouched (with desiccant).
2. 5ul dropper: 20 pieces .
3. Extraction Tubes (with Caps): 20 pieces filled 1.5ml extraction solution.
4. Package insert: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Sterile Lancet and Alcohol pad
- Disposable gloves and/or protective clothing
- Micro-pipette

STORAGE AND STABILITY

Store kit between 2-30℃ till the expiration date indicated on the aluminum pouch.DO NOT FREEZE.
Ensure that the test device is brought to room temperature before testing.

SPECIMEN COLLECTION AND HANDLING

Use fresh Whole blood fortesting.
• Capillary Blood:To use fresh blood from finger prick/puncture,cleanse the finger using sterile swab allow it to dry. With the help of lancet puncture the skin and collect blood in sample dispenser.
• Venous Blood:Collect the whole blood in a blood collection tube/container having EDTA or sodium Citrate as anticoagulant.

PRECAUTION

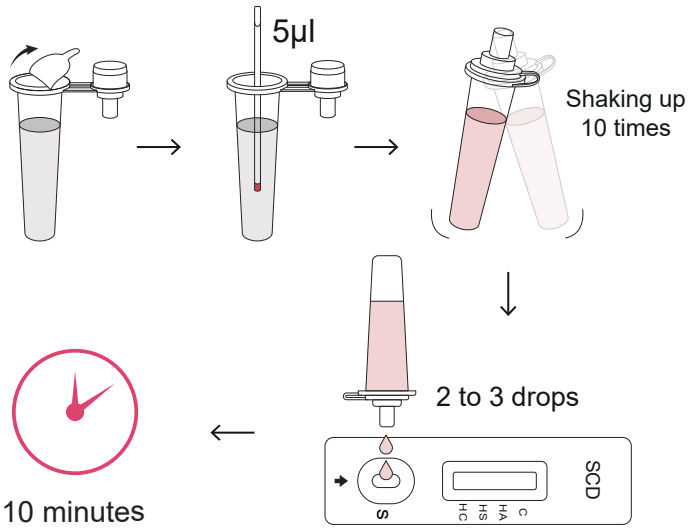
Whole blood specimen should be used for testing immediately or shall be stored at 2-8℃ for up to 72 hours (3 days).Do not use blood specimen stored for more than 3 days,it can cause a non-specific reaction.Do not freeze whole blood specimen.

TEST PROCEDURE

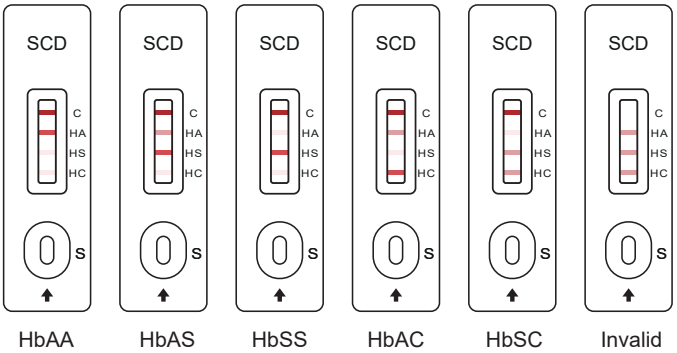
Allow the test device, specimen, extraction solution to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the sealed foil pouch and use it as soon as possible. Place the test device on a clean and level surface. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Place the extraction tube on the work station and tear the aluminum film.
3. Take 5µl of whole blood sample into the extraction tube and mix sample by Shaking up 10 times.
4. Dispense 2 to 3 drops(approximately 60~80µl) of mixed sample buffer to sample well of the test cassette.
5. Wait for the colored line(s)to appear. The test result should be read at 10 minutes. Do not interpret the result after 15 minutes.

DESCRIPTION OF TEST PROCEDURE



INTERPRETATION OF THE TEST



HbAA: Two distinct red/purple lines appear, one in the control region (C)and another in the HA region, with no band or a very faint band at the HS and HC lines. This result indicates the presence of HBAA, which is considered normal hemoglobin.

HbAS: Three red/purple lines appear, one in the control region (C),another in the HA region, and a third in the HS region, with no band or a very faint band at the HC line. This result indicates the presence of HBAS, which is associated with the sickle cell trait.

HbSS: Two distinct red/purple lines appear, one in the control region (C) and another in the HS region, with no band or a very faint band at the HA and HC lines. This result indicates the presence of HBSS, which is associated with sickle cell disease.

HbAC: Three red/purple lines appear, one in the control region (C), another in the HA region, and a third in the HC region, with no band or a very faint band at the HS line. This result indicates the presence of HBAC, which is associated with the sickle cell trait.

HbSC: Three red/purple lines appear, one in the control region (C), another in the HS region,and a third in the HC region, with no band or a very faint band at the HA line. This result indicates the presence of HBSC, which is associated with a different type of sickle cell trait.

Invalid: If the control band fails to appear within the result window, the result is considered invalid. This could be due to various reasons, such as improper test procedure or deterioration of the test kit. In such cases, it is recommended to retest the specimen.

LIMITATIONS OF THE TEST

1. FRENOVO Sickle Cell Screen Rapid Test is for in vitro diagnostic use only.This test should be used for the detection of hemoglobin A, S and C in whole blood specimens only.Neither the quantitative value nor the rate of increase in hemoglobin A, S and C concentration can be determined by this qualitative test.
2. FRENOVO Sickle Cell Screen Rapid Test will only Indicate the presence of hemoglobin S and C in the specimen and should not be used as the sole criterion for the diagnosis of Sickle cell disease.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of beta-thalassemia.

PRECAUTION & WARNINGS:

1. For in vitro diagnostic use only.
2. Do not reuse.
3. Do not use if the pouch seal or its packaging is compromised.
4. Do not use after the expiration date shown on the pouch.
5. Do not mix and interchange different specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.
7. Wash hands thoroughly after finishing the tests.
8. Do not eat, drink or smoke in the area where the specimens or kits are being handle clean up spills thoroughly with appropriate disinfectants.
9. It is recommended that all specimens of human origin should be handled as recommended for any potentially infectious human serum or blood specimen in the centers for Disease Control/national institute of Health Manual "Biosafety in Microbiological and Biomedical Laboratories",1984

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity
Clinical study was performed to compare the results obtained by The kit and Microscopy. The results indicated that The kit has a high sensitivity and specificity as summarized below:

SCD clinical study		Microscopy		
FRENOVO Sickle Cell Screen Rapid Test	Results	Positive	Negative	Negative
	Positive	54	8	62
	Negative	1	318	319
Total Results		55	326	381

SCD Clinical Study Summary Results:
Clinical sensitivity =98.18% (95%CI*90.28%～99.75%)
Clinical specificity = 97.55% (95%CI*95.22%～98.93%)
Accuracy=97.64% (95%CI*95.56%～98.91%)

SCT clinical study		Microscopy		
FRENOVO Sickle Cell Screen Rapid Test	Results	Positive	Negative	Negative
	Positive	85	8	93
	Negative	0	318	318
Total Results		85	326	411

SCT Clinical Study Summary Results:
Clinical sensitivity >99.00% (95%CI*96.54%～100.0%)
Clinical specificity = 97.55% (95%CI*95.22%～98.93%)
Accuracy=98.05% (95%CI*96.20%～99.16%)

Interference Substances
The following potential interfering substances were added to negative and positive specimens. None of the substances at the concentration tested interfered in the assay.

Substance	Tested Concentration
Hemoglobin	6 mg/ml
Bilirubin	0.4 mg/ml
Triglycerides	15 mg/ml
Cholesterol	4 mg/ml
Human Anti-mouse Antibody (HAMA)	100 IU /ml
Rheumatoid Factor	1500 IU/ml
Antinuclear Antibody (ANA)	100 IU/mL
Acetaminophen	20 mg/dL
Caffeine	20 mg/dL
Acetylsalicylic Acid	20 mg/dL
Gentisic Acid	20 mg/dL
Ascorbic Acid	2 g/dL
Albumin	2 g/dL
Creatin	200 mg/dL
Bilirubin	1g/dL
Oxalic Acid	60 mg/dL

Cross Reaction
FRENOVO Sickle Cell Screen Rapid Test has been tested by HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, Syphilis, HIV, HCV, H. Pylori, MONO, CMV, Rubella, HSV and TOXO positive specimens. The results showed no cross-reactivity.

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use, Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2°C 30°C	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
CE	CE mark		Biological risks

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INSTRUCTION APPROVAL AND REVISION DATE

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