MHS

Qualitative Test For Detection of Hemoglobins A, S And C For Sickle Cell Disorders

MicroScreen Sickle Cell Test

Product code	Pack Size
M003-C0001	25 Tests
M003-C0002	40 Tests
Read this pack insert thoroughly before use	

Intended Use

MicroScreen Sickle Cell Test is an In-vitro diagnostics Immunochromatographic assay kit for the qualitative detection of Hemoglobin variants Type-A, Type-S and Type-C using finger prick capillary and/or venous whole blood specimens. The test is intended for use by the trained competent person and healthcare professionals as an aid to the diagnosis in either laboratory or point of care settings. Also suitable for Neonatal/Newborn screening.

Introduction

Sickle Cell disease (SCD) is an Inherited red blood cell disorder. The most common type is known as sickle cell anemia (Type-S), Often causes red blood cells to become sickle-shaped through the presence of the abnormal hemoglobin S variant, The more rigid sickle shaped blood cell may have difficulty passing through small blood vessels, blocking the normal blood flow, damaging tissues, and ultimately leading to many of the complications of Sickle Cell Disease.

Additionally, red blood cells containing mostly hemoglobin S live only about 16 days compared to 120 days for normal red blood cells.

Several types of Sickle Cell conditions exist, with the most common being Sickle Cell Trait (HbAS), Sickle Cell Disease (HbSS), Sickle-Hb C Disease (HbSC), and Sickle-HbC Trait (HbAC). Early diagnosis (preferably as a newborn) of Sickle Cell Disease is important to initiate life saving health care therapies such as penicillin prophylaxis, vaccination against pneumococcus bacteria, folic acid supplementation, pain management medications. blood transfusions and hydroxyurea, the sickle cell trait is not a type of disease; with sickle cell trait, a child receives the sickle cell gene mutation from only one parent. In this case, the child doesn't get the disease, but can pass the defective gene on to future generations. Sickle cell disease is a serious and lifelong health condition, although treatment can help manage many of the symptoms, harmful complications are possible in extreme conditions (increased atmospheric pressure, high altitudes, low oxygen levels, intense athletic competition or dehydration). The carriers of Sickle Cell Trait should be identified to be overcautious of such complications as well as for genetic professional counseling and also for family planning.

Principle

MicroScreen Sickle Cell test is a lateral flow immunoassay kit for visual and qualitative determination of Hemoglobin variants, hemoglobin A (HbA), Hemoglobin S (HbS) and Hemoglobin C (HbC) from whole bloods specimens.

Monoclonal anti hemoglobin A, S and C antibodies are coated as capture on the test line region. If hemoglobin variants are present in the specimen, the test sample bind to monoclonal anti-hemoglobins coupled with colloidal gold, The antigen-antibody complex moves along the membrane and gets captured by anti-Hemoglobin and will appear irrespective of the sample status. The presence of hemoglobin variants A, S and C will be indicated by a reddish colour line in that region. The control band is used for procedural control and should always appear if the test protocol and test procedure is performed correctly The intensity of control band has nothing to do with intensity of test band,

Reagents and Materials Provided

Kit Contents	M003-C0001	M003-C0002
Each pouch containing 1 test device, 1 desiccant	25	40
Pre-filled buffer Tube with nozzle	25	40
Specimen transfer devices	25	40
Alcohol Swab	25	40
Lancet/Safety Lancet	25	40
Package Insert	1	1
Extraction tube stand	1	1

• Materials Required But Not Provided

1. Timer
2. Protective gloves
3. Specimen and test waste container
4. Cotton wool

Storage and Stability

All reagents are ready to use as supplied. Store unopened test devices at 2-30°C, If stored at 2-8°C, test device has to be brought to room temperature before opening the pouch. In case, the dessicant pouch changes colour from blue to light pink or colourless, the device should not be used. The unopened test device is stable up to the expiration date printed on the sealed pouch. **Do not freeze the kit or expose the kit over 30°C.**

Precautions

1. For *in-vitro* diagnostics and professional use only.
2. Allow all reagents and sample(s) to attain room temperature (15°C to 30°C) before use.
3. Test Device is sensitive to humidity; hence use the Test Device immediately once pouch is opened.
4. Do not use the kit contents beyond the expiry date.
5. Do not touch the nitrocellulose part of the device. Finger print or scratch on nitrocellulose membrane may give erroneous results.
6. Test Devices and buffers of different lot must not be mixed and used.
7. Do not re-use accessories like specimen transfer device for testing purpose.
8. Perform the test by using kit's buffers. Performing the test with any other buffer is not valid.
9. Follow the assay procedure and storage instructions strictly.
   Deviation will lead to erroneous results.
10. Do not use haemolysed or lipemic specimen for testing. Use sufficient volume of sample for testing.
11. Do not re-use the Test Devices and pipette tips from the procedure; this may lead to aberrant results.
12. Do not pipette reagents by mouth and do not smoke, eat or drink while handling specimens and performing a test.
13. Avoid contact of reagents with eyes and skin,
14. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed. Avoid reusing of gloves or use of washed gloves.
15. Handle sample(s) and used materials as if it is capable of transmitting infection.
16. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective material. All remnants of sample(s), used materials, pipette tips etc. should be disposed in suitable biohazard container. Materials should be autoclaved at 121°C for 30 minutes or dipped in 10% hypochlorite solution for 30 minutes prior to disposal.
17. Clean up spills thoroughly using an appropriate disinfectant.

Specimen Required

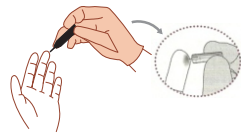
- Capillary blood or venous blood with the following anticoagulants: EDTA

Specimen Collection and Handling

A. Venous Whole Blood Collection by venipuncture

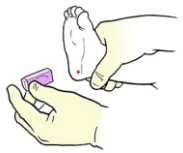
1. Using venipuncture, draw whole blood into the collection tube (containing anticoagulants including EDTA)
2. Whole blood specimens should be tested as soon as possible after collection. If whole blood specimens cannot be tested immediately, it must be refrigerated at 2-8°c and tested within 3 days of collection.
3. Do not use a blood specimen stored for more than 3 days(72 hrs); it can cause a nonspecific reaction.
4. Bring blood specimens to room temperature (15-30°C) prior to use.

B. Capillary Whole Blood Collection through finger prick



1. Clean the area to be lanced with an alcohol swab.
2. Squeeze the fingertip then prick the lateral side of the finger with the sterile lancet provided.
   Immediately, safely dispose of the lancet.
3. Wipe away the first drop of blood with cotton wool.
4. Using a specimen transfer device, take 5µL whole blood and transfer on pre-filled buffer tube.
5. The specimen collected must be used immediately. The specimen collected cannot be stored.

C. Capillary Whole Blood Collection through Heel prick

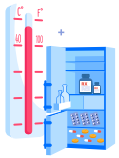


1. Obtained the blood sample from medial and lateral portions of planter surface of the heel.

2. Prewarm the foot for 5 minutes to enhance blood flow. Immobilize the foot in a dependent position, cleanse with antiseptic and allow to dry.
3. Safely puncture the skin with the lancet.
4. Wipe away the first drop of blood with cotton wool.
5. Using a specimen transfer device, take 5µL of whole blood and transfer on pre-filled buffer tube.
6. The specimen collected must be used immediately. The specimen collected cannot be stored

Test Procedure

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.

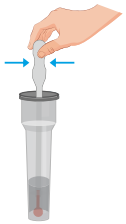


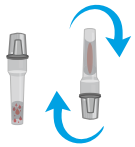
2. When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface,

3. Take Whole Blood sample upto the marking (5 µL) on specimen transfer device,

4. Peel-off the Aluminium seal from the pre-filled buffer tube.

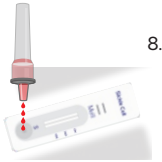
5. Immerse the Sampler tip into the tube. Dispense the specimen into the buffer. Take care in opening the Pre-filled buffer, as it contains a pre-measured volume of buffer. Dispose off used specimen transfer device as a bio-hazard waste.





6. Secure the nozzle with cap on top of the buffer tube and Gently invert the buffer tube **3-4 times** for proper mixing.

7. Remove the Nozzle cap from the Nozzle.



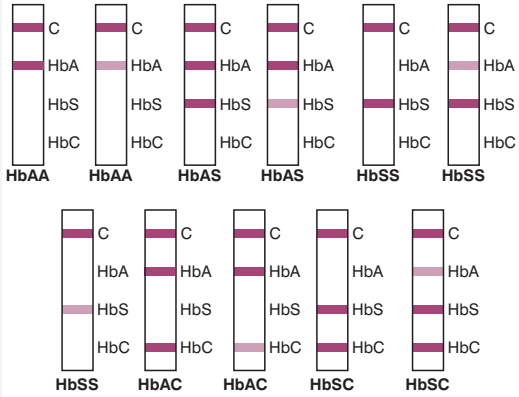
8. Add four drops of the Buffer-sample mixture to the Sample well(S) of the test device

9. Interpret the test results at 10 minutes. Do not read the results after 10 minutes.

Interpretation of Results

• Expected results are as follows

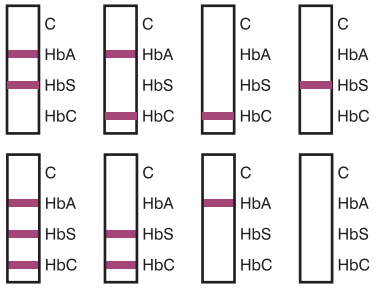
A total of four detection lines are possible, with the control (C) line appearing when sample has been flowed through the Test Device. The presence of hemoglobin variants A, S, and C greater than the limit of detection will be indicated by a reddish purple line in that region. The diagram below demonstrates the expected results of hemoglobin variants that the provider may encounter



Note: In some cases of sickle cell diseases, a faint band for HbA may appear indicating presence of HbA along with HbS, however, band intensity of HbS is always significantly stronger then for HbA.

• Invalid Result

If no Control(C) band is developed, the assay is invalid regardless of colour development on 'HbA','HbS' and 'HbC' bands as indicated below. Repeat the assay with a new device.



• Disposal

Discard the test device immediately after reading the results. Add few drops of disinfectant on the device and items used for the handling of Whole blood. Dispose all the items as per the standard QC norms.

Performance Characteristics

MicroScreen Sickle Cell Test has been tested using an in-house panel of positive and negative clinical samples. The result shows that MicroScreen Sickle Cell Test is suitable for screening of Sickle cell disorder. Based on the following evaluation:

	SS	AS	SC	AC	AA	Total
Clinical SS	100	0	0	0	0	100
Clinical AS	0	100	0	0	0	100
Clinical SC	0	0	25	0	0	25
Clinical AC	0	0	0	20	0	20
Clinical AA	0	0	0	0	100	100
Total	100	100	25	20	25	125
Specificity	>99%	>99%	>99%	>99%	>99%	>99%
Sensitivity	>99%	>99%	>99%	>99%	>99%	>99%

Limitations of the Test

1. As with all diagnostic tests, the test result must always be co-related with clinical findings.
2. A negative result can occur if the quantity of the analyte of interest present in the specimen is below the detection limits of the assay or the analyte of interest that are detected are not present during the stage of disease in which a sample is collected.
3. Repeat the test in case of very faint band or if have any doubt for test band.
4. Other clinically available tests should be used if questionable results are obtained.
5. Performance of MicroScreen Sickle cell test has not been established for sickle cell patients with beta-thalassemia.
6. If a recent blood transfusion was performed on a sickle cell patient, a weak band may be observed in the HbA test line along with the HbS test line.

REFERENCES

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• Product disclaimer

Every precaution has been taken to ensure the diagnostic ability and accuracy of this product. The product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by environmental factors and / or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

• Warning

The manufacturers and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether negative, in the use of this product.

Symbols used on Diagnostics Labels

REF	Catalogue number	LOT	Batch code
	Manufacturer		Use-by date
	Date of manufacture		Keep Dry
	Temperature limit		Caution
	Consult *instructions for use*		*Do not re-use*
	Keep away from sunlight	UDI	Unique Device Identifier
Σ	Contains sufficient for <*n*> tests		
IVD	In vitro diagnostic *medical device*		
	Do not use if package is damaged and consult *instructions for use*		

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