Sickle Cell Rapid Test Kit

Intended Use

The Sickle Cell Rapid test kit is a lateral flow chromatographic qualitative immunoassay to aid in the rapid diagnosis of sickle cell disorders of hemoglobins A and S using fingerstick or venipuncture whole blood samples. User will be a clinical professional such as a doctor, physician assistant, nurse, clinicalor medical assistant, or laboratory technician.

Summary

Sickle Cell Disease, an inherited blood disorder, often causes red blood cells to become sickle-shaped through the presenceof the abnormal hemoglobin S variant. 1. The more rigid sickle-shaped blood 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. 2.Additionally, red blood cells containing mostly hemoglobin S live only about 16 days compared to 120 days for normal red blood cells. 3. Several types of Sickle Cell conditions exist, with the most common being Sickle Cell Trait (HbAS), Sickle Cell Disease (HbSS). Early diagnosis (preferably as a newborn) of Sickle Cell Disease is important to initiate lifesaving health maintenance therapies such as penicillin prophylaxis, vaccination against pneumococcus bacteria, folic acid supplementation, pain management mediations, blood transfusions, and hydroxyurea. 4. While Sickle Cell Trait is not a type of disease,harmful complications are possible in extreme environments (increased atmospheric pressure, high altitudes, low oxygenlevels, intense athletic competition, or dehydration). 5.Carriersof Sickle Cell Trait should be identified to be cautious of such situations as well as for genetic counseling and family planning.

Test Principle

The Sickle Cell Rapid test kit is a rapid, qualitative lateral flow immunoassay kit for the identification of sickle cell disorder of hemoglobins A and S. A small amount of blood is taken by fingerstick or venipuncture using the provided Capillary Sampler. The Sampler is placed into the buffer loaded pre-Filled extraction tube to release hemoglobin by lysing erythrocytes. 2-3 drops of the treated sample are dropped from the pre-Filled extraction tube and added to the sample inlet of the Sickle Cell card test. The treated sample flows through the test cassette for 10 minutes before the resultis read. The sample will interact with antibody-conjugated colorimetric detector nanoparticles and travel to the capture zones. A total of three detection lines are possible, with the control line appearing when sample has been flowed through the card test. The presence of hemoglobin variants A and S will be indicated by a red line in that region.

Contents of the Kit

One Sickle Cell test kit contains:

• Test Cassettes • Blood Sample Collection Droppers • Lysate Addition Droppers • Pre-filled Extraction Tubes • Lancets • Alcohol wipes • Package Insert

Materials not provided but required:

Gloves | Timer

Warnings and Precautions

- Only for in vitro diagnostic use for human whole blood sample.
- Handle specimens in accordance to the OSHA Standard on Blood borne Pathogens.
- Wear protective gloves, clothing, and eyewear.
- Wash hands thoroughly after handling specimens.
- Do not use Sickle Cell card test, Pre-Filled extraction tube, or any kit component beyond the indicated expiration date.
- Dispose of all used or damaged Sickle Cell card tests,Pre-Filled extraction tube, or other kit component as bio hazardous materials.
- Do not disassemble Sickle Cell card tests, which contain dry-loaded reagents that may be bio hazardous, allergenic, and/or toxic.
- Do not use Sickle Cell card test, Pre-Filled extraction tube, or any other kit components if the pouch is damaged or the seal is broken.
- Grossly hemolytic, lipidic, or turbid specimens should be avoided for optimal results.
- Specimens should be free of visible aggregates and other particulate matter.
- Heterophilic Antibody Interference: some individuals have antibodies to mouse, goat, rabbit, or other heterophilic proteins; interferences may occur.
- Pre-Filled extraction tube from one lot should not be used with tests from a different lot.

Storage Instructions

- Store sealed Sickle Cell card tests and pre-Filled extraction tube at 2°C – 30°C. Do not freeze (0°C or lower)Sickle Cell card tests and pre-Filled extraction tube Do not remove the Sickle Cell card test from sealed pouchuntil ready for use.
- When stored/transported properly, Sickle Cell card testsand pre-Filled extraction tube are stable until the marked expiration date.

Specimen Collection and Preparation

- Follow instructions detailed in this package insert as well as the specimen collection tube (with EDTA anticoagulant) manufacturer instructions for venipuncture specimens. Samples stored in specimen collection tube with EDTA anticoagulant for 1 week after collection at 2°C – 30°C canbe tested with Sickle Cell Card Test.
- Fingerstick or samples collected with the provided

Capillary Samplers should be used immediately upon collection.

- **Do not use a blood specimen stored for more than 3 days (72 hrs). Appropriate blood storage is needed.**

Test Procedure

Do not open pouch until ready to use. Prep necessary materials: Sickle Cell card test | pre-Filled extraction tube and label them with patient ID.

1. Aspirate finger prick blood till the bulb marking using sample collection dropper and transfer it to pre-filled extraction tube
   For intravenous sampling follow standard laboratory protocols.



Blood Sample Collection Dropper

Take care in opening the pre-Filled extraction tube, as it contains a premeasured volume of extraction buffer.

2. Tightly close the cap of extraction tube. Invert the extraction tube, **mix few times** for complete treatment of the specimen with buffer.

3. With the help of lysate addition dropper provided, **immediately dispense 3 drops (75µl)** of specimen into the Sickle Cell card test.



Lysate Addition Dropper

Remove any air bubbles in the dropper.
Test on a level surface at room temperature.

4. Allow test to run for 10 minutes. Read the results of the Sickle Cell by viewing the detection window.
   Test results that have run over 15 minutes are invalid.

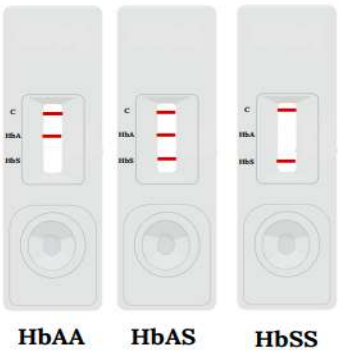
Display of Results/Expected Values

A total of three detection lines are possible, with the control line appearing when sample has been flowed throughthe card test. The presence of hemoglobin variants A and S greater than the limit-of-detection will be indicated by ared line in that region. The diagram below demonstrates the expected results of hemoglobin variants that the provider may encounter.

Internal Quality Control Procedure

Each Sickle Cell test device has a built-in control. A dark- red colored line in the detection window at the Control linecan be considered an internal positive procedural control. The Control line will appear if the test procedure has been correctly performed. If the Control line does not appear, the test is invalid and a new test must be performed. If the problem persists, please contact your local vendor or Paramcare for technical support.

INTERPRETATION OF RESULTS



1) **Normal (HbAA):** Two distinct red lines appear. The control line (c) and HbA (Normal Hemoglobin) line are visible on the test cassette. This indicates the presence of Normal Hemoglobin in specimen.

2) **Sickle Cell Trait (HbAS)**: The control line (c), HbA line (Normal Hemoglobin) and HbS line (Sickle Hemoglobin) are visible on the test cassette.

3) **Sickle Cell Disease (HbSS):** The control line (c) and HbS (Sickle Hemoglobin) line are visible on the test cassette.

Limitations

This test is not used for detection of beta-thalassemia.

Performance Characteristics

Patient samples (n = 100) were collected and characterized using HPLC analysis and solubility test and were then used for assessment of our kit. All known samples were characterized as HbAS, HbSS and HbAA.

	SS	AS	AA	Total
Clinical SS	10	0	0	10
Clinical AS	0	10	0	10
Clinical AA	0	0	80	80
Total	10	10	80	100
Specificity	>99%	>99%	>99%	>99%
Sensitivity	>99%	>99%	>99%	>99%

Sickle Cell performance compared to hemoglobin electrophoresis based diagnosis.

Interferences Sickle Cell demonstrates ≤10% interference with the following substances at the concentrations indicated: Protein (Albumin) 50 mg/mL, Bilirubin 2.5 µg/mL, Triglycerides 2.5 mg/mL, Hydroxyurea 75 µg/mL, and Penicillin 500 µg/mL.

References

K Gosh et al., Guidelines for screening, diagnosis and management of hemoglobinopathies. Indian J Hum Genet. 2014 101-119.

M Murayama., Structure of sickle cell hemoglobin and molecular mechanism of the sickling phenomenon. Clin Chem. 1967 578-588.

BP Yawn et al., Management of sickle cell disease: summary of the 2014 evidence-based report by expert panel members. JAMA 2014, 1033-1048.

- EP Vichinsky and BH Lubin., Sickle cell anemia and related hemoglobinopathies. Pediatr Clin North Am. 1980, 429-447.
- SC Davies and PE Hewitt., Sickle cell disease. Br J Hosp Med. 1984, 440-444.
- MH Steinberg., Review: the sickle hemoglobinopathies—genetic analyses of common phenocopies and new molecular approaches to treatment. Am J Med Sci. 1984, 169-174.
- Chao, E.L.; Henshaw, J.L., Occupational Safety and Health Administration: Model Plans and Programs for the OSHA Bloodborne Pathogens and Hazard Communications Standards. OSHA 3186-06R, 2003.
- RW Schroff et al., Human Anti-Murine Immunoglobulin Responses in Patients Receiving Monoclonal Antibody Therapy. Cancer Res 1985, 879-885.
- LM Boscato and MC Stuart., Heterophilic Antibodies: A Problem for All Immunoassays. Clin Chem 1988, 27.

GLOSSARY OF SYMBOL

	Consult Instruction for Use
REF	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

India office
BIOBOON BIOTECH INDIA LLP
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2nd floor, Above D'mart shopping mall
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