EnCore Biomedicals

EnSure SICKLE CELL TEST

Rapid Diagnostics Test for Sickle Cell Test

Store at 2°c to 30°c

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, C and S using fingerstick or venipuncture whole blood samples. User will be a clinical professional such as a doctor, physician assistant, nurse, clinical or medical assistant, or laboratory technician.

SUMMARY

Sickle Cell Disease, an inherited blood disorder, often causes red blood cells to become sickle-shaped through the presence of the abnormal hemoglobin S variant. 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. 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) and Sickle Cell Disease (HbCC). Early diagnosis (preferably as a newborn) of Sickle Cell Disease is important to initiate life saving health maintenance therapies such as penicillin prophylaxis, vaccination against pneumococcus bacteria, folic acid supplementation, pain management mediations, blood transfusions, and hydroxyurea. While Sickle Cell Trait is not a type of disease, harmful complications are possible in extreme environments (increased atmospheric pressure, high altitudes, low oxygen levels, intense athletic competition, or dehydration). Carriers o f Sickle Cell Trait should be identified to be cautious of such situations as well as for genetic counseling and family planning.

PRINCIPLE OF THE ASSAY

The Sickle Cell Rapid test kit is a rapid, qualitative lateral flow immunoassay kit for the identification of sickle cell disorder of hemoglobins A, C and S. A small amount of blood, ten microliters (10 μL) is taken by fingerstick or venipuncture using the provided sample collection dropper. The Sample 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 by lysate addition dropper of the Sickle Cell card test. The treated sample flows through the test cassette for 10 minutes before the result is read. The sample will interact with antibody-conjugated and travel to the capture zones. A total of four detection lines are possible, with the control line appearing when sample has been flowed through the card test. The presence of hemoglobin variants A, C and S will be indicated by a red line in that region.

PACKAGE CONTAINS

1. Each Pouch contents: Test Cassette, Desiccant
2. Sample Collection Dropper
3. Lysate addition dropper
4. Pre-filled extraction tubes
5. 1 Instruction for use

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer
2. Disposable gloves
3. Lancets
4. Alcohol wipes

WARNINGS AND PRECAUTIONS

1. Only for in vitro diagnostic use for human whole blood sample.
2. Handle specimens in accordance to the OSHA Standard on Blood borne Pathogens.
3. Wear protective gloves, clothing, and eyewear.
4. Wash hands thoroughly after handling specimens.
5. Do not use Sickle Cell card test, Pre-Filled extraction tube, or any kit component beyond the indicated expiration date.
6. Dispose of all used or damaged Sickle Cell card tests, Pre-Filled extraction tube, or other kit component as bio hazardous materials.
7. Do not disassemble Sickle Cell card tests, which contain dry-loaded reagents that may be bio hazardous, allergenic, and/or toxic.
8. 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.
9. Grossly hemolytic, lipidic, or turbid specimens should be avoided for optimal results.
10. Specimens should be free of visible aggregates and other particulate matter.
11. Heterophilic Antibody Interference: some individuals have antibodies to mouse, goat, rabbit, or other heterophilic proteins; interferences may occur.
12. 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 pouch until ready for use.
- When stored/transported properly, Sickle Cell card tests and 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 – 8°c can be tested with Sickle Cell Card Test.
- Fingerstick or samples collected with the provided Sample collection dropper should be used immediately upon collection

TEST PROCEDURE

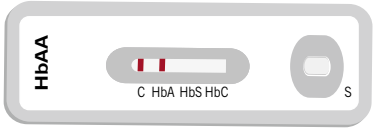
Do not open pouch until ready to use. Prep necessary materials: Sickle Cell card test pre-Filled extraction tube and label them with patient ID.

1. Obtain 10 μL (2 drop) of fingerstick blood specimen with the help of sample collection dropper.
2. Open Pre-Filled extraction tubes and insert the 10 μL sample into the pre-Filled extraction tube.
   Take care in opening the pre-Filled extraction tube, as it contains a premeasured volume of extraction buffer.
3. Tightly close the cap of extraction tube. Invert the extraction tube, mix few times and allow it to incubate for 20-30 mins at room temperature for complete treatment of the specimen with buffer.
4. With the help of lysate addition dropper (Approx. 60-70 μL) provided, immediately dispense 2-3 drops of specimen into the Sickle Cell test.
5. Remove any air bubbles in the dropper.
   Test on a level surface at room temperature.
6. Read the results 10 minutes.
   Do Not read the results after 15 minutes.

INTERPRETATION OF RESULTS

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, C and S greater than the limit-of-detection will be indicated by a red line in that region. The diagram below demonstrates the expected results of hemoglobin variants that the provider may encounter

HbAA POSITIVE: A distinct colored lines appear at control region 'C' and test region "HbA".



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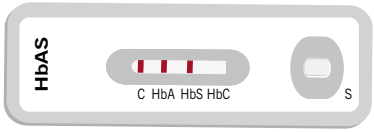
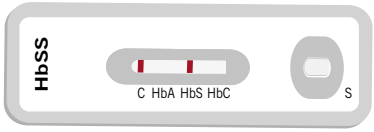
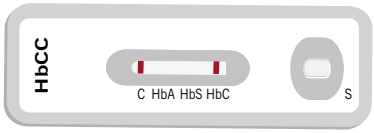
HbAS POSITIVE: A distinct colored lines appear at control region 'C', test region "HbA" & test region "HbS".



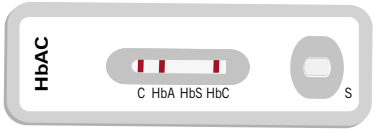
HbSS POSITIVE: A distinct colored lines appear at control region 'C' and test region "HbS".



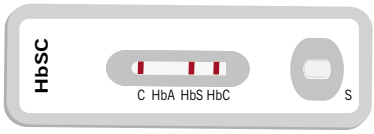
HbCC POSITIVE: A distinct colored lines appear at control region 'C' and test region "HbC".



HbAC POSITIVE: A distinct colored lines appear at control region 'C' , test region "HbA" & test region "HbC" .



HbSC POSITIVE: A distinct colored lines appear at control region 'C' , test region "HbS" & test region "HbC" .



PERFORMANCE CHARACTERISTICS

Internal Evaluation

In an in-house study, total 190 samples were evaluated for sensitivity and specificity. We found the relative sensitivity was 98.90 % (i. e. 90/91) and the relative specificity was 99% (i. e. 99/100). The results are summarized in the following table:

Sample	Total no. of samples tested	Rapid Sickle cell test		Sensitivity	Specificity
		Positive	Negative		
Sickle cell HbAA	15	15	0	98.90%	
Sickle cell HbAS	15	15	0		
Sickle cell HbSS	15	15	0		
Sickle cell HbCC	15	14	1		
Sickle cell HbAC	15	15	0		
Sickle cell HbSC	15	15	0		
Negative sickle cell samples	100	1	99		99%

LIMITATIONS

Performance of Sickle Cell has not been established for sickle cell patients with beta-thalassemia.

DISCLAIMER

The all precaution shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results. This test provides presumptive diagnosis of Sickle cell infection. A confirmed Sickle cell infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

REFERENCES

- 1. K Gosh et al., Guidelines for screening, diagnosis and management of hemoglobinopathies. Indian J Hum Genet. 2014 101-119.
- 2. M Murayama., Structure of sickle cell hemoglobin and molecular mechanism of the sickling phenomenon. Clin Chem. 1967 578-588.
- 3. BP Yawn et al., Management of sickle cell disease: summary of the 2014 evidence-based report by expert panel members. JAMA 2014, 1033-1048.
- 4. EP Vichinsky and BH Lubin., Sickle cell anemia and related hemoglobinopathies. Pediatr Clin North Am. 1980, 429-447.
- 5. SC Davies and PE Hewitt., Sickle cell disease. Br J Hosp Med. 1984, 440-444.
- 6. MH Steinberg., Review: the sickle hemoglobinopathies—genetic analyses of common phenocopies and new molecular approaches to treatment. Am J Med Sci. 1984, 169-174.
- 7. Chao, E.L.; Henshaw, J.L., Occupational Safety and Health Administration: Model Plans and Programs for the OSHA Blood borne Pathogens and Hazard Communications Standards. OSHA 3186-06R, 2003.
- 8. RW Schroff et al., Human Anti-Murine Immunoglobulin Responses in Patients Receiving Monoclonal Antibody Therapy. Cancer Res 1985, 879-885.
- 9. LM Boscato and MC Stuart., Heterophilic Antibodies: A Problem for All Immunoassays. Clin Chem 1988, 27.

SYMBOL KEY

IVD	In Vitro Diagnostic Use	2°C 30°C	Temperature limitation
	Manufacturer	2	Single Use
	Manufacturing Date	Σ	Number of tests in the pack
	Expiry Date		Do not use if pouch or kit damaged
LOT	Lot Number	i	Read package insert before use

Manufacturer By **ENCORE BIOMEDICALS PVT. LTD.**
R-548, 3rd floor, TTC Industrial Area, Rabale, Navi Mumbai - 400701.
Mob.: +91 91368 84688
Email ID : support@encorebiomedicals.com