LordsMed Sickle Cell Hb S, Hb A and Hb C Rapid test

Catalog No.	Pack Size	Specimen Type
SKCLMR01	25 Test Device	WholeBlood
SKCLMR02	50 Test Device	WholeBlood

INTENDED USE

LordsMed sickle cell test is a lateral flow chromatographic qualitative immunoassay to aid in the rapid diagnosis of sickle cell disorders of hemoglobin A, S, and C using fingerstick or venipuncture whole blood samples. It is intended for professional use.

PRINCIPLE

LordsMed Sickle cell rapid test is a rapid, qualitative lateral flow immunoassay kit for the identification of sickle cell disorder of hemoglobins A, S, and C. A small amount of blood, ten microliters (10µl), 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 test device. The treated sample flows through the test cassette for 10 minutes before the result is read. The sample will interact with antibody-conjugated colorimetric detector nanoparticles 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 device. The presence of hemoglobin variants A, S, and C will be indicated by a red line in that region.

MATERIALS PROVIDED

1. Sickle cell test cassettes
2. Blood sample collection droppers (10 µl)
3. Lysate addition droppers (25 µl)
4. Pre-filled extraction tubes
5. Lancets
6. Alcohol wipes
7. Package insert

MATERIALS NEEDED BUT NOT PROVIDED

1. Gloves
2. Timer

STORAGE AND STABILITY

1. Store sealed Sickle cell test device and pre-filled extraction tube at 2 °C – 30 °C. Do not freeze (0 °C or lower) Sickle cell test device and pre-filled extraction tube.
2. Do not remove the Sickle cell test device from sealed pouch until ready for use.
3. When stored/transported properly, Sickle cell test device and pre-filled extraction tube are stable until the marked expiration date.

PRECAUTION

1. Only for in vitro diagnostic use for human whole blood sample.
2 Handle specimens in accordance to the OSHA Standard on Bloodborne Pathogens.
3. Wear protective gloves, clothing, and eyewear.
4. Wash hands thoroughly after handling specimens.
5. Do not use Sickle cell cartridge, pretreatment Module, or any kit component beyond the indicated expiration date.
6. Dispose of all used or damaged Sickle cell cartridges, pretreatment modules, or other kit component as biohazardous materials.
7. Do not disassemble Sickle cell cartridges, which contain dry-loaded reagents that may be biohazardous, allergenic, and/or toxic.
8. Do not use Sickle cell cartridge, pretreatment Module, 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. Pretreatment Modules from one lot should not be used with tests from a different lot.

SPECIMEN COLLECTION

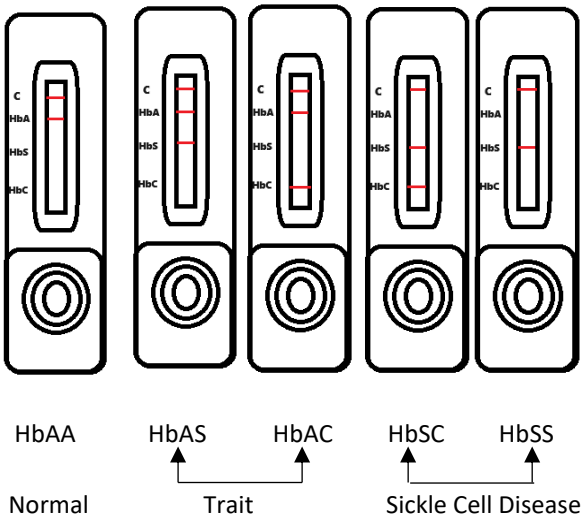
1. Follow instructions detailed in this package insert as well as the specimen collection tube (with EDTA anticoagulant) manufacturer instructions for venipuncture specimens. Samples stored in specimen collection tube with EDTA anticoagulant for 1 week after collection at 2°C – 45°C can be tested with Sickle cell device.
2. Fingerstick or samples collected with the provided sample collection dropper should be used immediately upon collection.
3. Do not use a blood specimen stored for more than 3 days (72 hrs).

PROCEDURE

1. Do not open pouch until ready to use. Prep necessary materials: Sickle cell test device, pre filled extraction tube and label them with patient ID.
2. Obtain 10 µL (1 drop) of fingerstick blood specimen with the help of sample collection dropper provided. For intravenous sampling follow standard laboratory protocols.
3. Open pre-filled extraction tubes and insert the 10 µL sample into it. Take care in opening the pre-filled extraction tube, as it contains a premeasured volume of extraction buffer.
4. Tightly close the cap of extraction tube. Invert the extraction tube, mix few times for complete treatment of the specimen with buffer.
5. With the help of lysate addition dropper provided, immediately dispense 2-3 drops of specimen into sickle cell test device.
6. 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.

TEST INTERPRETATION (REFER TO FIGURE)

A total of four detection lines are possible, with the control line appearing when sample has been flowed through the device. The presence of hemoglobin variants A, S, and C 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.



PERFORMANCE CHARACTERISTICS

As per ICMR- National Institute of Immunohematology–Mumbai & ICMR CRMCH Chandrapur.

Sensitivity	Specificity
100 %	100 %

LIMITATION

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

BIBLOGRAPHY

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

REF	Catalog No		Attention Caution
LOT	Batch No.		Instruction for use
	Manufacturing Date	IVD	*In-vitro* Diagnostics
	Expiry Date		Storage temperature
	Manufacturer	Σ	No. of Tests

Lord's Mark Industries Ltd., Plot No. A71, Royal Ind. Hub, Poman, Kaman-Bhiwandi Road, Taluka -Vasai, Palghar- 401208, Maharashtra (India). Customer Care No.: 8425982321. Email: ivdcare@lordsmark.com; Website:www.lordsmed.com