Sickle SCAN®

HEMATOLOGY

Instructions For Use

Intended Use |

The Sickle SCAN® test is a lateral flow chromatographic qualitative immunoassay to aid in the rapid diagnosis of sickle cell disorders of hemoglobins A, S, and C 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.[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), Sickle-Hb C Disease (HbSC), and Sickle-Hb C Trait (HbAC). 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.[3,4] 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).[5] Carriers of Sickle Cell Trait should be identified to be cautious of such situations as well as for genetic counseling and family planning.[6]

Test Principle |

The *Sickle SCAN* test kit 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, five microliters, is taken by fingerstick or venipuncture using the provided Capillary Sampler. The Sampler is placed into the buffer loaded PreTreatment Module to release hemoglobin by lysing erythrocytes. Five drops of the treated sample are dropped from the PreTreatment Module and added to the sample inlet of the *Sickle SCAN* cartridge. The treated sample flows through the test cartridge for 5 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 (Ctrl) line appearing when sample has been flowed through the cartridge. The presence of hemoglobin variants A, S, and C will be indicated by a blue line in that region.

Contents of the Kit |

One *Sickle SCAN* test kit contains:
20 *Sickle SCAN* cartridges | 22 Capillary Sampler
20 PreTreatment Modules (w/ buffer) | 1 Package Insert

One *Sickle SCAN* cartridge contains:
- Dried reagents with stabilizers
- Monoclonal anti-HbA, HbS, HbC capture antibodies
- Monoclonal IgG (anti-host animal) capture antibodies
- Monoclonal IgG (anti-hemoglobin) antibodies conjugated to dyed nanoparticles

Materials not provided but required:
Lancet | Alcohol wipes | 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 Bloodborne Pathogens.[7]
- Wear protective gloves, clothing, and eyewear.
- Wash hands thoroughly after handling specimens.
- Do not use *Sickle SCAN* cartridge, PreTreatment Module, or any kit component beyond the indicated expiration date.
- Dispose of all used or damaged *Sickle SCAN* cartridges, PreTreatment Modules, or other kit component as biohazardous materials.
- Do not disassemble *Sickle SCAN* cartridges, which contain dry-loaded reagents that may be biohazardous, allergenic, and/or toxic.
- Do not use *Sickle SCAN* cartridge, PreTreatment Module, 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.[8,9]
- PreTreatment Modules from one lot should not be used with tests from a different lot.

Storage Instructions |

- Store sealed *Sickle SCAN* cartridges and modules at 2°C – 45°C or 35°F – 113°F. Do not freeze (0°C or lower) *Sickle SCAN* cartridges and modules.
- Do not remove the *Sickle SCAN* cartridge from sealed pouch until ready for use.
- When stored/transported properly, *Sickle SCAN* cartridges and modules 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 – 45°C can be tested with *Sickle SCAN*.
- Fingerstick or samples collected with the provided Capillary Samplers should be used immediately upon collection.

Test Procedure |

Do not open pouch until ready to use. Prep necessary materials: *Sickle SCAN* cartridge | PreTreatment Module | Capillary Sampler (5 µL volume)
- Label PreTreatment Module and Test cartridge with patient ID.

1 | Obtain a fingerstick specimen using standard laboratory protocols. Using Capillary Sampler, obtain 5 µL of fingerstick blood specimen.
- Take care to draw sample by capillary action; do not squeeze dispensing bulb.
- For intravenous sampling follow standard laboratory protocols.

2 | Open PreTreatment Module and immerse the Sampler tip into the Module. Dispense the specimen into the buffer.
- Take care in opening the PreTreatment Module, as it contains a premeasured volume of extraction buffer.

3 | Replace and tightly screw the two-piece cap onto the Module. Invert the Module and mix 3 times, allowing complete treatment of the specimen with buffer.

4 | Remove colored cap of the PreTreatment Module. Immediately dispense 5 drops into the *Sickle SCAN* cartridge.
- Remove any air bubbles in the dropper.
- Test on a level surface at room temperature.

5 | Allow test to run for 5 minutes. Read the results of the *Sickle SCAN* by viewing the detection window.
- Test results that have run over 10 minutes are invalid.

Display of Results/Expected Values |

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

HbAA HbAS HbSS HbAC HbSC

Internal Quality Control Procedure |

Each *Sickle SCAN* test device has a built-in control. A dark-blue colored line in the detection window at the Control line can 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 BioMedomics for technical support.

External Quality Control Procedure |

- Good laboratory practice recommends the use of external positive and negative controls to ensure the function of the test reagents and to evaluate the user ability to properly perform a test. It is recommended that external controls be performed with each new lot or shipment of *Sickle SCAN*. If the controls do not perform as expected, review the instructions and repeat the test. Consult the laboratory director before performing patient tests and reporting results.
- *Sickle SCAN* performance can be evaluated using *Sickle SCAN* Controls (negative, positive) available from BioMedomics. Follow instructions included in *Sickle SCAN* Controls package for preparation, use, storage, and determination of appropriate values. Frequency of external control testing should be determined by your laboratory director and according to your laboratory standard quality control protocols. Upon confirmation of the expected results, the kit is ready to use with patient specimens.
- The negative control will yield an affirmative result (dark blue line) for the control (Ctrl) line only, when the test has been performed correctly and the test device is properly functioning. The positive control will produce affirmative results (blue lines) for test (HbA, HbS, HbC) and control (Ctrl) lines when the test has been performed correctly and the test device is functioning properly.
- The use of negative and positive controls from other commercial kits has not been established in the *Sickle SCAN*.

Limitations |

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

Performance Characteristics |

Method Comparison | *Sickle SCAN* was compared to hemoglobin electrophoresis using guidelines outlined in CLSI document EP15-A2-IR. Patient samples (n = 290) were collected and measured in duplicate on both systems.

Sickle SCAN performance compared to hemoglobin electrophoresis based diagnosis.

	SS	AS	SC	AC	AA	Total
Clinical SS	95	0	95	95	95	95
Clinical AS	0	89	0	0	0	89
Clinical SC	0	0	53	0	0	53
Clinical AC	0	0	0	8	0	8
Clinical AA	0	0	0	0	45	45
Total	95	89	53	8	45	290
Specificity	>99%	>99%	>99%	>99%	>99%	>99%
Sensitivity	>99%	>99%	>99%	>99%	>99%	>99%

Detection Limit | The *Sickle SCAN* limit of detection for hemoglobins A, S, and C is determined to be <10%, <10%, and <10%, respectively.

Interferences | *Sickle SCAN* 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.

BioMedomics

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Do Not Reuse

Manufacturer

Expiration Date

EC REP Authorized Represntative in Europe

LOT Batch Code

IVD In Vitro Diagnostic Medical Device

REF Catalog Number

45°C 2°C Storage Temperature Range

See Instructions For Use

Σ Contains <n> tests

CE Mark

Consult Instructions

Pre-Treatment Module

Capillary Sampler

Sickle SCAN Cassette

Quick Start Guide

References

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