Special Hematology/ 103 SICKLESCREEN TEST

Copy of version 1.0 (approved and current)

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Comments for version 1.0
Initial version

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Periodic review	Lab Director	4/2/2024	1.0	Ali Mousa Ramadan MD	
Periodic review	Medical Pathologist	3/22/2024	1.0	Lekidule Taddesse-Heath	
Approval	Lab Director	8/15/2021	1.0	Ali Mousa Ramadan	
Approval	Laboratory Operations Manager	8/13/2021	1.0	Wendell McMillan	
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Version History

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1.0	Approved and Current	Initial version	7/22/2021	8/15/2021	Indefinite

HOWARD UNIVERSITY HOSPITAL
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE

STANDARD OPERATING POLICY AND PROCEDURE MANUAL

Special Hematology/103 **SickleScreen test**

PURPOSE:

Pacific Hemostasis SickleScreen Sickling Hemoglobin Screening Kit and SickleScreen Control Set are intended for use in screening for sickle cell disease and sickle cell trait. SickleScreen Controls can be used with procedures based on differential solubility of reduced hemoglobin, or with enzyme immunoassays specific for Hemoglobin S

PRINCIPLE:

Sickle cell disease is a chronic hemolytic anemia seen in individuals homozygous for the Hemoglobin S gene (S/S). In these individuals, Hemoglobin S constitutes 70-99% of the total hemoglobin. When Hemoglobin S is reduced to deoxyhemoglobin1, it forms filamentous tactoids that cause red blood cells of these individuals to "sickle". Repeated vascular occlusion in sickle cell anemia can lead to accumulated damage in a variety of organs, including kidney, heart, lung, and eyes. Heterozygous (A/S) individuals are carriers of the sickle cell trait and have up to 50% Hemoglobin S. While they are usually asymptomatic, these patients should be identified for genetic counseling purposes. Under conditions of reduced oxygen pressure, such as anesthesia, flight in poorly pressurized airplanes, and severe pneumonia, sickle cell syndrome may occur. The SickleScreen Kit is a modified Nalbandian2 procedure based upon differential solubility. Red blood cells are lysed by a surfactant. The released hemoglobin is reduced by sodium hydrosulfite. Reduced Hemoglobin S is insoluble and forms a turbid suspension in concentrated phosphate solutions3. Normal Hemoglobin A and most other hemoglobins remain in solution under these conditions. Both sickle cell disease and sickle cell trait can be detected with this procedure.

REAGENTS:

For in vitro diagnostic use.

A. Sodium Hydrosulfite Powder Vials: (120 determination kit):

- Store at room temperature (15-30°C).

- Do not expose to light for excessive periods. Best stored as supplied in kit.
- Pour the entire contents of one Sodium hydrosulfite vial into one bottle of Phosphate Buffer. Powder must be dry and free flowing. Mix well and let stand 15 minutes to dissolve.
- Store combined Phosphate Buffer/Sodium hydrosulfite tightly capped at 2-8°C.
- Use within 28 days of reconstitution. One bottle is sufficient for 30 tests.

Precautionary Statements

- Wash face, hands and any exposed skin thoroughly after handling
- Do not eat, drink or smoke when using this product
- Keep cool. Protect from sunlight
- Wear protective gloves/protective clothing/eye protection/face protection

B. Phosphate Buffer: A concentrated solution containing surfactant, with 0.02% Sodium azide as a preservative. Store at room temperature (15-30°C).

C. Reconstitution Fluid: Deionized water with sodium azide as a preservative. Store at 2-8°C.

D. Positive Control: Lyophilized hemoglobin A/S. Store at 2-8°C. Reconstitute with 0.5 mL Reconstitution Fluid. Let stand undisturbed for 30 minutes then vortex to mix. Reconstituted control is stable for 21 days at 2-8°C.

E. Negative Control: Lyophilized hemoglobin A/A. Store at 2-8°C. Reconstitute with 0.5 mL Reconstitution Fluid. Let stand undisturbed for 30 minutes then vortex to mix. Reconstituted control is stable for 21 days at 2-8°C

See Safety Data Sheets for additional information https://portables.thermoscientific.com/safety-data-sheets.

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Sample Collection:

Collect whole blood in EDTA, Heparin, Sodium citrate, or ACD anticoagulant. Samples can be stored at 2-8°C for up to 2 weeks before testing

Procedure:

Materials provided:

- Pacific Hemostasis SickleScreen Kit (120 determinations):
- Phosphate Buffer: 4 x 125 mL vials with dispensing caps
- Sodium Hydrosulfite Powder: 4 x 5.7 gram vials
- Pacific Hemostasis SickleScreen Control Set:
  - Positive Control: 4 x 0.5 mL vials
  - Negative Control: 4 x 0.5 mL vials
  - Reconstitution Fluid: 2 x 4 mL vials

Materials Required, But Not Provided:

- Tube reading rack
- Clear 12 x 75 test tubes and plug stoppers (120 det. kit)
- 50 µL pipet

1. Bring all reagents and samples to room temperature.
2. Run a known positive and negative control with each group of samples.
3. Run a positive control with each newly opened tray of tubes.
4. Label one test tube for each patient and control. Use 12 x 75 test tubes. Place in Tube Reading Rack.
5. Add 4 mL Sodium Hydrosulfite to a test tube.
6. Add 50 µL of whole blood or control. Cap and shake vigorously immediately after adding the whole blood or control to each tube.

7. Incubate in Tube Reading Rack at room temperature for 10-20 minutes.
8. Do not report patient results if the positive control appears negative.

Results:

Negative: If no sickling hemoglobin is present the solution will be clear to slightly cloudy. The lines on the Tube Reading Rack will be easily seen through the tube contents.

Weakly Positive: The differentiation between weakly positive samples and negative samples solely depends on subjective evaluation. Some will describe a sample giving a slightly cloudy solution with the lines on the Tube Reading Rack visible as very faint lines as positive whereas others describe it as negative. All positive or questionable results should be further evaluated with hemoglobin electrophoresis.

Positive: If Hemoglobin S or any other sickling hemoglobin is present the solution will be turbid. The lines on the Tube Reading Rack will not be clearly visible when viewed through tube contents. All positive or questionable results should be further evaluated with hemoglobin electrophoresis.

Limitations:

A. Severe anemia can cause false negatives. If the total hemoglobin is < 8 g/dL, double the sample volume to 100 µL.
B. Patients with multiple myeloma, cryoglobulinemia, and other dysglobulinemias may give false positives. Wash patient red blood cells in physiologic saline to minimize these problems.
C. Elevated levels of Hemoglobin F can cause false negative results. Do not use this test for infants under 6 months of age.
D. Recent transfusion can cause false positive or false negative results.
E. Some rare hemoglobin variants such as Hemoglobin C Harlem or C Georgetown may give a positive reaction.

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F. This test is a screening procedure only. All positive or questionable results should be further evaluated with hemoglobin electrophoresis.

G. Sodium hydrosulfite powder, when exposed to light for excessive periods, may cause false negative reactions

Performance Characteristics:

Of twenty samples analyzed by hemoglobin electrophoresis, ten were confirmed A/A (> 95% Hemoglobin A). The remaining 10 were confirmed A/S (37-46% Hemoglobin S). When tested using the SickleScreen Kit, all A/A samples were correctly reported as negative. All A/S samples were correctly reported as positive. Multiple kit lots were used.

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References:

1. Lange, R.D., Minnich, V., and Moore, C.V. 1951. J Lab Clin Med 37:389.

2. Nalbandian, R.M., Nichols, B.M., Camp Jr., F.R., Lusher, J.M., Conte, N.F., Henry, R.L., and Wolf, P.L. 1971. Clin Chem 17:1028.

3. Itano, H.A. 1953. Arch Biochem Biophys 47:148.

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Replaces Core Lab/ Hematology/105/2018/2. Approval and revision of documentation maintained electronically