I. Intended Use
Pacific Hemostasis SickleScreen™ Sickle Hemoglobin Screening Kit or SickleScreen Control Set is intended for use in screening for sickle cell disease and sickle cell trait. SickleScreen Controls can be used with protocols based on differential solubility of reduced hemoglobin, or with enzyme immunoassays specific for hemoglobin S.

II. Summary and Principles
Sickle cell disease is a chronic heritable anomaly seen in individuals heterozygous for the hemoglobin S gene (A/S). In these individuals, Hemoglobin S is unstable and forms 70% of the total hemoglobin. When Hemoglobin S is reduced to deoxyhemoglobin, it forms filamentous tactoids that cause red blood cells of these individuals to “sickle”. Repeated cessation of blood flow in small arteries can lead to sickle cell crises in various tissues.

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 anemia, sickle cell disease is a major problem for pregnant women.

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

III. Materials


B. Sodium Hydrosulfite Powder Vials: (30 determination kit) Store at room temperature (10-30°C). Do not expose to light for excessive periods. Best stored as supplied in kit.

C. Phosphate Buffer Vials: (30 determination kit) Store at room temperature (10-30°C). Do not expose to light for excessive periods. Best stored as supplied in kit.

D. Label one test tube for each patient and control. Use prefilled Reaction Vials for 30 det. kit

E. Use uncapped vials within 12 hours.

F. A reconstitution solution is supplied in kit. Use uncapped vials within 12 hours.

IV. Procedure

A. Bring all reagents and samples to room temperature.

B. Run a known positive and negative control with each group of samples.

C. Label one test tube for each patient and control. Use prefilled Reaction Vials for 30 det kit.

D. Reconstitution Fluid: Store at room temperature.

E. Use uncapped vials within 12 hours.

F. Label one test tube for each patient and control. Use prefilled Reaction Vials for 30 det kit.

G. Sodium hydrosulfite powder, when exposed to light for excessive periods, may cause false positives. Wash patient red blood cells in physiologic saline to minimize these problems.

H. Controls have been tested by an FDA licensed method and found non-reactive for HbsAg. Standard (29 C FR 1910.1200)

I. Controls are recom mended to avoid deposits in metal piping in which explosive conditions may develop.

J. Each unit of source material used in the preparation of Positive and Negative Controls has been tested by an FDA licensed method and found non-reactive for hemoglobin A2, M, C, F, C/E, S, and T.

K. Controls are recom mended to avoid deposits in metal piping in which explosive conditions may develop.

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

V. Negative

A. 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.

Positive

A. If sickling hemoglobin is present the solution will be cloudy to white. The lines on the Tube Reading Rack will be easily seen through the tube contents.

Weakly Positive

A. If sickling hemoglobin is present the solution will be cloudy to white. The lines on the Tube Reading Rack will be easily seen through the tube contents.

B. Any positive or questionable results should be further evaluated with hemoglobin electrophoresis.

VI. Results

A. For in vitro diagnostic use.

B. A reaction in 12 x 75 test tubes and plug stoppers (120 det. kit)

C. Distilled water with sodium azide is supplied in kit. Normal Hemoglobin A and most other hemoglobin remain in solution under these conditions. Both sickle cell disease and sickle cell trait can be detected with this procedure.

D. This test is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

E. Use uncapped vials within 12 hours.

F. Sodium hydrosulfite powder, when exposed to light for excessive periods, may cause false positives. Wash patient red blood cells in physiologic saline to minimize these problems.

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VII. Limitations

A. Severe anemia can cause false negatives. If the total hemoglobin is < 2 g/dl, the sample volume should be increased to 100 µL.

B. Patients with many myelomas, cryoglobulinemia, and other fibrinogen-like molecules 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 the test for infants under 1 month of age.

D. Recent transfusion can cause false positive or false negative results.

E. Some sickle cell variants such as Hemoglobin C-Trenkalian or G-Steinmetz may give a positive reaction.

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 results.

VIII. Performance Characteristics

A. Twenty samples analyzed by hemoglobin electrophoresis, ten were confirm ed A/A (> 80%), ten were confirm ed A/S (55-80% Hemoglobin S). All tested using the SickleScreen Kit, all samples were correctly reported as negative. All A/S samples were correctly reported as positive. Two A/A samples were tested.

B. Controls are recom mended to avoid deposits in metal piping in which explosive conditions may develop.

C. Each reaction in tube vials for 120 det./kit. Add 4 ml Sodium Hydrosulfite to a test tube.

D. Add 50 µL white blood cell to control. Cap and shake vigorously immediately after adding the whole blood or control into each tube.

E. Incubate in Tube Reading rack in room temperature for 10-30 minutes.

F. Do not report patient results if the positive control appears negative.