SickleScreen® Sickle Hemoglobin Screening Kit or SickleScreen Control Set

I. Intended Use

Pacific Hemostasis SickleScreen Sickle Hemoglobin Screening Kit and SickleScreen Control Set is intended for use in screening for sickle cell disease and sickle cell trait. SickleScreen Controls can be used with providers based on differential suitability of reconstituted hemoglobin, or with enzyme immunoassay specific for hemoglobin S.

II. Summary and Principles

Sickle cell disease is a chronic hemolytic anemia seen in individuals homozygous for the hemoglobin S gene (SS). In these individuals, Hemoglobin S occurs normally as a part of the total hemoglobin. When Hemoglobin S is reduced to deoxyhemoglobin S, a common lesion found in sickle cell disease, the red blood cells become rigid and cannot flow through small blood vessels.

Rationale

This test is not considered hazardous by the 2012 OSHA HazCom Standard (20 CFR 1910.1200)

III. Reagents

A. Reaction Vials (32 determinations): Prefilled with sodium hydrosulfite. Store at room temperature (10-30°C). Do not expose to light for excessive periods. Best stored as supplied in kit. Use within 3 months of kit expiration.

IV. Procedure

1. Place the Reagent Controls into a tube reading rack. Add 4 mL of Phosphate Buffer/Sodium Hydrosulfite to each test tube with reconstituted controls within 4 hours.

2. Add 0.5 mL of Sodium Hydrosulfite to each test tube. Let stand undisturbed for 30 minutes then vortex to mix.

3. The reaction is complete when a reaction line is visible in the test tube.

4. Read the test tubes using a tube reader.

V. Calculation

VI. Results

A. Positive Control: Lyophilized hemoglobin A/S. Store at 2-8°C. Reconstitute with 0.3 mL Phosphate Buffer: 0.5 mL vial: 4 mL of Phosphate Buffer as supplied. Use reconstituted controls within 4 hours.

B. Negative Control: Reconstituted hemoglobin A/S. Store at 2-8°C. Reconstitute with 0.3 mL Phosphate Buffer: 0.5 mL vial: 4 mL of Phosphate Buffer as supplied. Use reconstituted controls within 4 hours.

VII. Limitations

A. Severe anemia can cause false negatives. If the total hemoglobin is ≤ 2 g/dL, the sample volume to 100 µL.

B. Patients with multiple myeloma, cryoglobulinemia, and other cryoprecipitable diseases 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 a month of age.

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

E. Some sickle cell variants such as Hemoglobin C Harlem or C Town may give a positive reaction.

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

VIII. Performance Characteristics

A. Will identify all sickling hemoglobins seen in sickle cell disease, sickle cell trait, or Hb S variants.

B. Will identify Patients with sickling hemoglobin.

C. Will identify Hb S variants.

D. Will identify Hemoglobin C Harlem or C Town.

E. Will identify Hb S membrane instability.

F. Will identify Patients with sickling hemoglobin.

G. Will identify Hb S variants.

H. Will identify Hemoglobin C Harlem or C Town.

I. Will identify Hb S membrane instability.

J. Will identify Patients with sickling hemoglobin.

K. Will identify Hemoglobin C Harlem or C Town.

L. Will identify Hb S variants.

M. Will identify Patients with sickling hemoglobin.

N. Will identify Hb S variants.

O. Will identify Hemoglobin C Harlem or C Town.

P. Will identify Hb S membrane instability.

Q. Will identify Patients with sickling hemoglobin.