

Pacific Hemostasis® SickleScreen® Sickling Hemoglobin Screening Kit

SickleScreen Control Set

Intended Use

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.

Summary and Principles

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

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 detect-

For in vitro diagnostic use.

Reaction Vials (30 determination kit): Prefilled with sodium hydrosulfite. Store at room temperature (15-30°C). Do not expose to light for excessive periods. Best stored as supplied in kit. Use uncapped vials within 12 hours.

Tap the Reaction Vials lightly to break up any clumps and to bring all powder to the bottom of the tube. Do not use Reaction Vials that have clumped, wet-appearing powder. Uncap Reaction Vials and place in Tube Reading Rack. Add approximately 4 mL of Phosphate Buffer to each Reaction Vial. Mix well. Use reconstituted Reaction Vials within 4 hours.

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





Hazard Symbol: Exclamation Mark, Flame Signal Word: Danger

H302 Harmful if swallowed H251 Self-Heating; May catch fire

Precautionary Statements - Prevention

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

Precautionary Statements - Response Ingestion

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse

Precautionary Statements - Storage

Maintain air gap between stacks/pallets Store bulk masses greater than 1 kg/ 2.22 lbs at temperatures not exceeding .?3 °C/ .?4 °F

Store away from other materials

Precautionary Statements - Disposal Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)

Not applicable

Unknown Toxicity 0% of the mixture consists of ingredient(s) of unknown toxicity

Other information

Harmful to aquatic life with long lasting effects

Interactions with Other Chemicals

No information available

See Safety Data Sheets for additional information

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

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910 1200)

Precautionary Statements - Prevention Obtain special instructions before use Precautionary Statements - Response

Precautionary Statements - Storage

Precautionary Statements - Disposal

Hazards not otherwise classified (HNOC)

Not applicable

27.836% of the mixture consists of ingredient(s) of unknown toxicity

Other information

May cause slight eye irritation Interactions with Other Chemicals

No information available

See Safety Data Sheets for additional information.

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

Warning: Phosphate Buffer and Reconstitution Fluid contain sodium azide. Sodium azide under acid conditions yields hydrazoic acid, an extremely toxic compound. Dilute with running water before discarding, and then flush with large volumes of water. These precautions are recommended to avoid deposits in metal piping in which explosive conditions may devel-

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

Precautionary Statements - Prevention

Obtain special instructions before use

Precautionary Statements - Response

Precautionary Statements - Storage

Precautionary Statements - Disposal

Hazards not otherwise classified (HNOC)

Unknown Toxicity

27.836% of the mixture consists of ingredient(s) of unknown toxicity Other information

May cause slight eye irritation

Interactions with Other Chemicals No information available

See Safety Data Sheets for additional information

- 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.
- 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.

Caution: 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 HBsAg and negative for antibodies to HIV and HCV. However, no known test method can offer complete assurance that products derived from human blood will not transmit hepatitis. AIDS, or other infectious diseases. This product, like all materials of human origin, should be handled as potentially infectious biological material.

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

Precautionary Statements - Prevention

Obtain special instructions before use

Precautionary Statements - Response

Precautionary Statements - Storage

Precautionary Statements - Disposal

Hazards not otherwise classified (HNOC)

Not applicable

Unknown Toxicity

99.985% of the mixture consists of ingredient(s) of unknown toxicity Other information

May cause slight eye irritation

Interactions with Other Chemicals

No information available See Safety Data Sheets for additional information.

Lack of vacuum (lyophilized controls), unexpected results, or reagent color variations could indicate product deterioration

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 (30 determinations):

Phosphate Buffer: 1 x 125 mL vial with dispensing cap

Reaction Vials: 30 vials prefilled with sodium hydrosulfite powder

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

Materials Required, But Not Provided:

Negative Control: 4 x 0.5 mL vials

Reconstitution Fluid: 2 x 4 mL vials

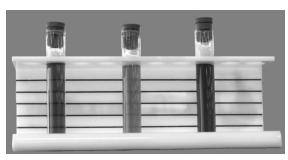
Tube reading rack

Clear 12 x 75 test tubes and plug stoppers (120 det. kit)

50 µL pipet

Controls are not provided with the SickleScreen Kit. They must be ordered separately.

- Bring all reagents and samples to room temperature.
- Run a known positive and negative control with each group of samples.
- Run a positive control with each newly opened tray of tubes.
- Label one test tube for each patient and control. Use prefilled Reaction Vials for 30 det. kit and 12 x 75 test tubes for 120 det. kit. Place in Tube Reading Rack.
- In the 30 det/kit, add 4 mL Phosphate Buffer to the prefilled reaction vial and mix well. In the 120 det/kit, add 4 mL Sodium Hydrosulfite to a test tube.
- Add 50 µL of whole blood or control. Cap and shake vigorously immediately after adding the whole blood or control to each tube.
- Incubate in Tube Reading Rack at room temperature for 10-20 minutes Do not report patient results if the positive control appears negative



Positive Negative Weakly Positive

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 soley 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.

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

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

ORDERING INFORMATION

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

Nalbandian, R.M., Nichols, B.M., Camp Jr., F.R., Lusher, J.M., Conte, N.F., Henry, R.L., and

Cat. No. Description 100250 SickleScreen Kit SickleScreen Kit 503021 Tube Reading Rack 100251 SickleScreen Control Set

References

Wolf, P.L. 1971. Clin Chem 17:1028.

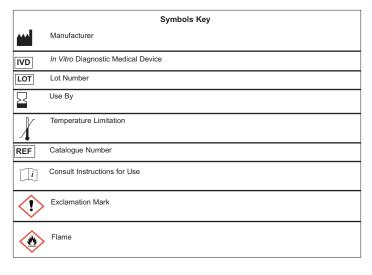
Itano, H.A. 1953. Arch Biochem Biophys 47:148.

Contents 30 determinations 120 determinations One 10-place rack Positive: 4 x 0.5 mL Negative: 4 x 0.5 mL Reconstitution Fluid: 2 x 4 mL

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Fisher Diagnostics (FD) warrants to the purchaser only that FD products will perform as described on their labeling and product literature. Purchaser must determine the suitability of FD products for their specific applications. FD's sole obligation will be, at its option, to either replace a non-conforming or defective product, or return the purchase price. FD DISCLAIMS ALL OTHER WAR-RANTIES, EXPRESSED OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR ANY PARTICULAR PURPOSE. Neither FD nor its affiliates shall, in any event, be liable for incidental or consequential loss or damage.

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