

Dade® Sickle-Sol™ Test

Qualitative solubility test
for the identification of sickling hemoglobin

Summary and Principle

Mendelian inheritance allows S hemoglobin to manifest itself in two manners: (1) as the homozygous condition (S/S) known as sickle cell disease, and (2) as the heterozygous condition where the sickle hemoglobin is present with other hemoglobins, such as hemoglobin A, hemoglobin C, or hemoglobin D, etc.^{1,2}

Lowered oxygen tension plays a vital role in the pathologic character of hemoglobin S, for without this state of reduced oxygen, the S hemoglobin would not form sickle-shaped tactoids.²⁻⁴

Solubility tests differentiate between sickling and non-sickling hemoglobin but do not identify the hemoglobin type. Hemoglobin types can be further differentiated by electrophoresis. However, some hemoglobins having identical electrophoretic mobilities may be differentiated by solubility properties. To determine the hemoglobin type, both solubility tests and electrophoresis are necessary.

Sickle-Sol™ Test is a rapid solubility tube test employing the properties of reduced hemoglobin S. Some other hemoglobins known to give the same positive reaction as hemoglobin S are hemoglobins C (Harlem), C (Georgetown), and Memphis/S.

Reagents

| Cat. No. | Product | Pkg. |
|----------|-----------------------------------------------------------|----------|
| B4585-1 | Sickle-Sol™ Test | 100 test |
| B4585-5 | Sickle-Sol™ Test | 12 test |
| B4585-10 | Sickle-Trol™ Sickle Cell Hematology Controls, A/A and A/S | 2 x 5 mL |

Sickle-Sol™ Buffer: 2.3M phosphate buffer. Store at 2-8°C.

Sickle-Sol™ Reagent Powder: sodium hydrosulfite and saponin.

Store at 2-8°C.

Working Reagent:

- Bring buffer and reagent powder to room temperature before mixing.
- Add one vial of reagent powder to a bottle of buffer and agitate **immediately** until the powder has completely dissolved. Foaming can be expected.
- Record date of solution preparation on bottle label. **Reagent must be used or discarded within 30 days.**
- Keep tightly capped and store at 2-8°C when not in use.
- Bring working reagent to room temperature before using.

For in vitro diagnostic use

Specimen Collection and Preparation

Use anticoagulated whole blood. If blood is used immediately, sufficient sample may be obtained by a finger or heel puncture. Never use a clotted specimen.

If the hematocrit is less than 15%, double the amount of blood sample in the test procedure. If hematocrit is low and specimen appears to have turbid plasma, centrifuge sample and adjust hematocrit to greater than 15% to avoid false positive test results.

Procedure

Materials Provided

- Sickle-Sol™ Buffer
- Sickle-Sol™ Reagent Powder
- Lined card
- Test tubes (12 x 75 mm) (included in 12-test package only)
- Micropipets (20 µL, disposable) (included in 12-test package only)

Materials Required but Not Provided:

Sickle-Trol™ Sickling Hemoglobin Controls A/A and A/S (available separately from Siemens Healthcare Diagnostics Inc.).

Procedure Outline

- Add 20 µL of blood sample to 2.0 mL working reagent in 12 x 75 mm test tube. Mix.
- Incubate 5 minutes at room temperature.
- Observe for turbidity by holding the test tube one inch in front of lined card. When folding the card 90° (right angle) on the perforated line the two black dots indicate the right distance.

Quality Control

Good laboratory procedure dictates the routine use of controls. Using the separate Sickle-Trol™ Sickling Hemoglobin Controls A/S and A/A will provide assurance that the Sickle-Sol™ test system is functioning properly.

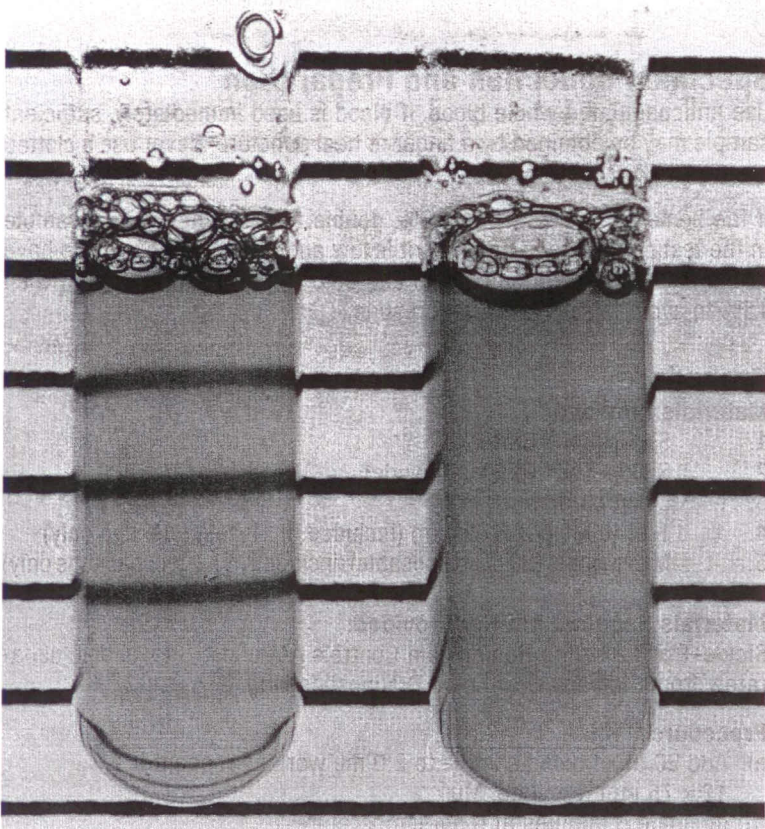
Results:

Positive test - lines on card **cannot** be seen through the test solution as noted below.

Negative test - lines on card **can** be seen through the test solution as noted below.

Left side: Negative test

Right side: Positive test



After turbidity readings have been made, all tests with **questionable results** should be centrifuged at approximately 1000 rpm for three minutes. **Do not use brake.** Results should be determined as noted below.

Positive test - yellow to light pink solution with red material at the air-liquid interface.

Negative test - dark pink to red solution with varying amounts of white to pinkish material at the air-liquid interface.

Limitations of Procedure^{5,6}

Solubility tests differentiate between sickling and non-sickling hemoglobin. This procedure does not quantitate the amount of sickling and/or non-sickling hemoglobin; therefore, it does not differentiate the heterozygous from the homozygous condition. Hemoglobin types must be further differentiated by electrophoresis or other methods. However, some hemoglobins having identical electrophoretic mobilities may be differentiated by solubility properties.

False negative reactions may be obtained by inadequate quantities of hemoglobin from anemic patients. Quantities of hemoglobin S may also be too small to detect in infants and possibly following transfusions.

False positive reactions may be caused by a polycythemic specimen which provides too much hemoglobin to reagent ratio. Dysglobulinemias can also cause false positives.

Specific Performance Characteristics

When used as outlined under **Procedure**, Sickle-Sol™ Test will yield the results described.

Bibliography

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5. Murayama, Ph.D., M.; Nalbandian, M.D., R. M. Sickle cell hemoglobin molecule to man. Boston: Little, Brown and Company; 1973: 81-85.
6. Davidsohn, D.D., I.; Henry, M.D., J. B. Clinical diagnosis by laboratory methods. 15 ed. Philadelphia: W.B. Saunders Company; 1974:206-208,218.

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