

HemoTypeSC™

In Vitro Diagnostic Use Only

INSTRUCTIONS FOR USE

HemoTypeSC™ is a rapid test kit intended to determine the presence of hemoglobin A, S and C in whole blood. The kit is intended for *in vitro* diagnostic use by health professionals. This test is a competitive lateral flow immunoassay incorporating monoclonal antibodies for determination of the presence of hemoglobins A, S, and C. HemoTypeSC™ provides rapid detection of hemoglobin phenotypes HbAA, HbSS, HbSC, HbCC, HbAS, and HbAC.



- HemoTypeSC™ results are not affected by fetal hemoglobin.
- Phenotype HbS/β₀-thalassemia will produce the same HemoTypeSC™ result as HbSS.
- Other hemoglobin variants (e.g., HbD and HbE) will produce the same HemoTypeSC™ result as HbA.

Observe applicable biohazard safety procedures when handling Test Strips and human blood. Do not reuse any test strips or blood sampling devices. Some immobilized Test Strip reagents are derived from human sources - refer to local and national guidelines for biohazard safety handling procedures.



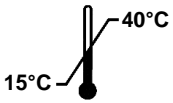
The HemoTypeSC™ Test Kit Includes:

1. Foil Pouch containing the following:
 - a. Vial of 50 single-use Test Strips
 - b. Vial of 50 single-use Blood Sampling Devices – vial may contain extra
 - c. Three reusable Dropper Pipettes
2. Instructions for Use

Materials Not Provided:

1. Water – use drinking water, **NOT** saline solutions
 2. Timer
 3. * Lancing Device and Lancets
 4. * Test Vials (1.5 - 5 mL tubes or vials may be used)
 5. * Rack for holding Test Vials
- * Available as part of the HemoTypeSC™ Accessory Pack

50 Tests/kit



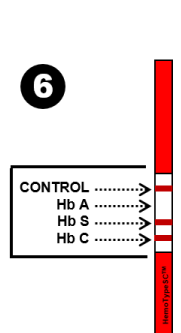
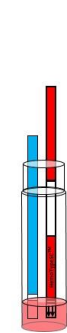
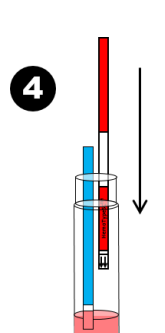
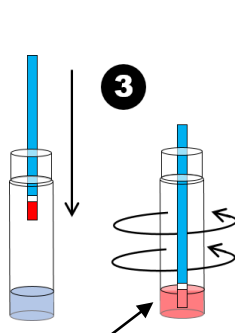
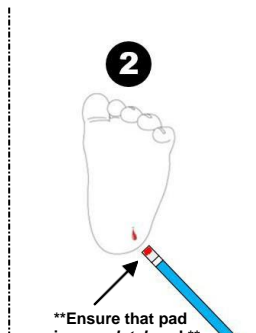
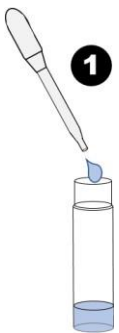
Storage: Store at 15-40°C and away from moisture. Test Strip Vial, Blood Sampling Device Vial, and Dropper Pipettes are provided in a sealed Foil Pouch, reject if seal is broken upon receipt. The Expiration Date of the unopened pouch is printed on the pouch. Do not use any components after the expiration date.

IMPORTANT: Use or discard all Test Strips, Blood Sampling Devices, and Dropper Pipettes within 30 days of opening the Foil Pouch.



PROCEDURE:

<ol style="list-style-type: none"> 1. Using Dropper Pipette, add six (6) drops of water to Test Vial. Place Test Vial in a compatible rack. 2. Open Vial of Blood Sampling Devices, remove one Blood Sampling Device, and reclose Vial. Obtain blood sample – a small drop is sufficient (1 to 2 microliters). Touch the white pad of the Blood Sampling Device to blood sample, until the white pad absorbs the blood droplet. Ensure that the entire white pad has turned red. 	<ol style="list-style-type: none"> 3. Insert Blood Sampling Device into Test Vial water and swirl to mix. <ol style="list-style-type: none"> a) Sufficient swirling is essential for blood to be properly transferred into Test Vial. b) Check visually to ensure that water has become pink or light-red in color. c) Leave Blood Sampling Device in the Test Vial after swirling. 	<ol style="list-style-type: none"> 4. Open Vial of Test Strips, remove one Test Strip, and reclose Vial. Insert HemoTypeSC™ Test Strip into Test Vial with arrows pointing DOWN. 5. Wait 10 minutes. 6. Take HemoTypeSC™ Test Strip out of the Test Vial and read results. Compare Test Strip to Results Chart on reverse side of this document for reference.
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READING RESULTS:

Red lines may appear at each of three hemoglobin variant-specific locations (HbA, HbS, & HbC), and a control location.

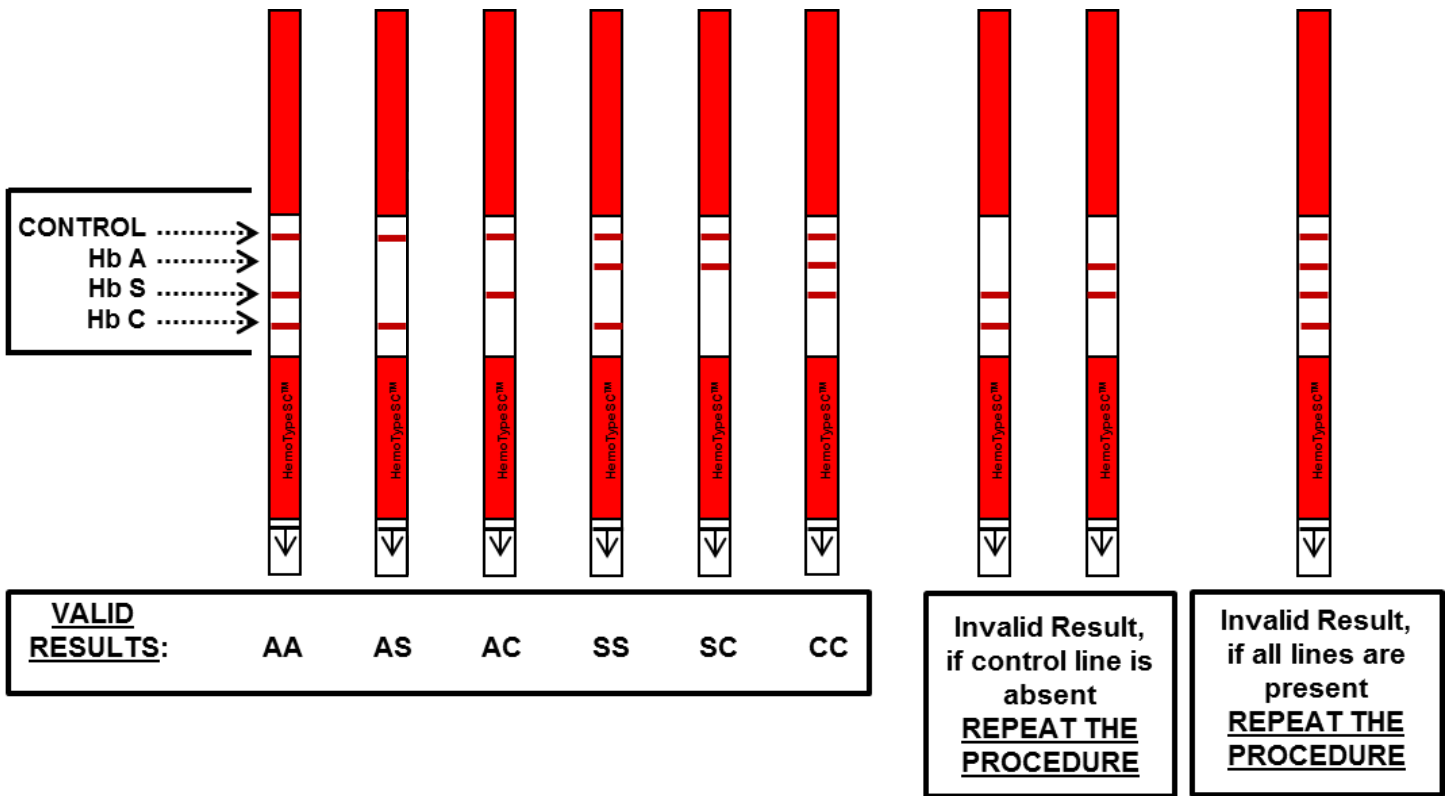
- The **PRESENCE** of a line indicates the **ABSENCE** of the hemoglobin variant.
- The **ABSENCE** of a line indicates the **PRESENCE** of the hemoglobin variant.



Compare the HemoTypeSC™ Test Strip to the Chart below

[Absent Line(s) = Hemoglobin(s) Are Present in the Blood]

[If control line is absent, result is invalid]



IMPORTANT: If test result is unclear or invalid, repeat the entire procedure starting with Step #1.



Manufactured By:

 Silver Lake Research Corporation
 1300 West Optical Drive
 Azusa, California, USA
Hemotype.com

Assembled By:

 EG Industries
 Asheboro, NC 27205, USA
ISO 13485

Authorized Representative:

EC	REP
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