silver lake research

HemoTypeSC™

Investigational Use Only

Product # HT301RUO
IFU v. 02162018

INSTRUCTIONS FOR USE

HemoTypeSC™ is a rapid test kit for the determination of hemoglobin (Hb) type in whole blood. This test is a competitive lateral flow assay incorporating monoclonal antibodies for detection of hemoglobin A, hemoglobin S, and hemoglobin C. HemoTypeSC™ provides point-of-care detection of the following hemoglobin phenotypes: HbAA (normal), HbSS & HbSC (sickle cell disease), HbCC (hemoglobin C disease), and HbAS & HbAC (carrier, or trait).

- HemoTypeSC™ does not detect fetal hemoglobin, and results are not affected by fetal hemoglobin.
- Phenotype HbS/β_0-Thalassemia will produce the same HemoTypeSC™ result as HbSS.
- Other hemoglobin variants (e.g. HbD or HbE) will produce the same HemoTypeSC™ result as HbA.

Observe biohazard safety procedures when handling human blood samples and disposing of used materials. Do not reuse any test strips or blood sampling devices.

The HemoTypeSC™ Test Kit Includes:

1. One Foil Pouch containing the following:
   a. One Vial of 50 Test Strips – single-use, disposable
   b. One Vial of 50 Blood Sampling Devices – single-use, disposable
   c. One Bag of Three Dropper Pipettes – reusable
   d. One Instructions for Use Sheet

Materials Not Provided:

1. Water – use drinking water or tap water
2. Timer
3. * Lancing Device and Lancets
4. * Test Vials (1.5 mL tubes or vials of similar size may be used)
5. * Rack for holding Test Vials
** Available as part of the HemoTypeSC™ Accessory Pack*

Storage/Shelf-Life: Store HemoTypeSC™ at room temperature. Test Strip Vial and Blood Sampling Device Vial are provided in a sealed Foil Pouch. The Expiration Date of the unopened pouch is printed on the pouch. Do not use any test components after the expiration date.

IMPORTANT: Use all Test Strips and Blood Sampling Devices within 30 days of opening the Foil Pouch.

PROCEDURE (WHOLE BLOOD):

Please read these instructions thoroughly before beginning to test samples.

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 below the blue cover 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.**

3. Insert Blood Sampling Device into Test Vial and swirl to mix.

a) **Sufficient swirling is essential** for blood to be properly transferred into Test Vial.

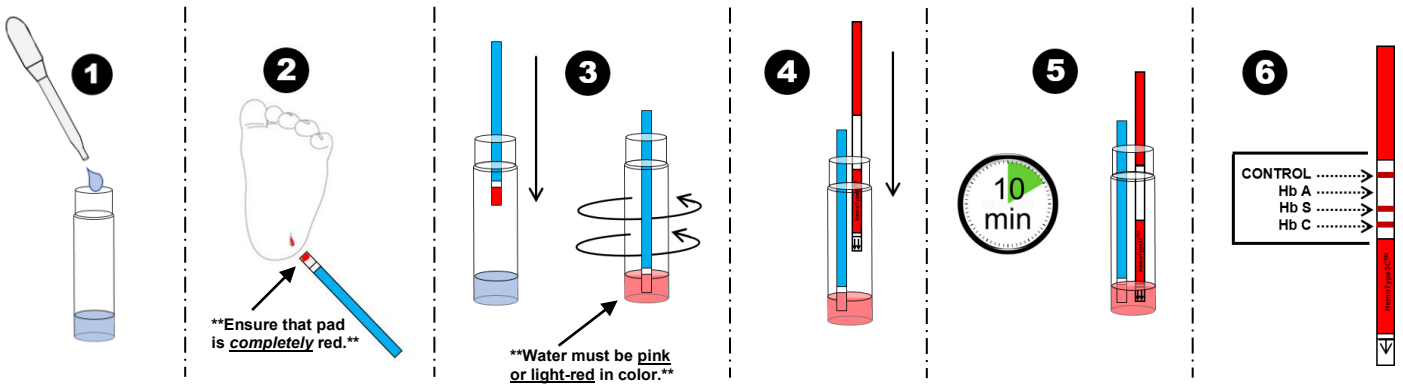
b) Check visually to ensure that water has become **pink or light-red** in color.

c) Leave Blood Sampling Device inside the Test Vial water after swirling.

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 next page for reference.



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PROCEDURE (DRIED BLOOD SPOTS):

HemoTypeSC™ can be adapted for use with dried blood spots (DBS). The DBS should be cut to be the **same size as the circles below** and must be **completely red** with blood:

Before blood spotting: ◯ After blood spotting: ●

1. Using Dropper Pipette, add six (6) drops of water to Test Vial. Place Test Vial in a compatible rack.
2. Cut out DBS to be the **same size as the above circles** and completely submerge under the water inside the Test Vial.
3. Wait 10 minutes.
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 below for reference.

READING RESULTS:

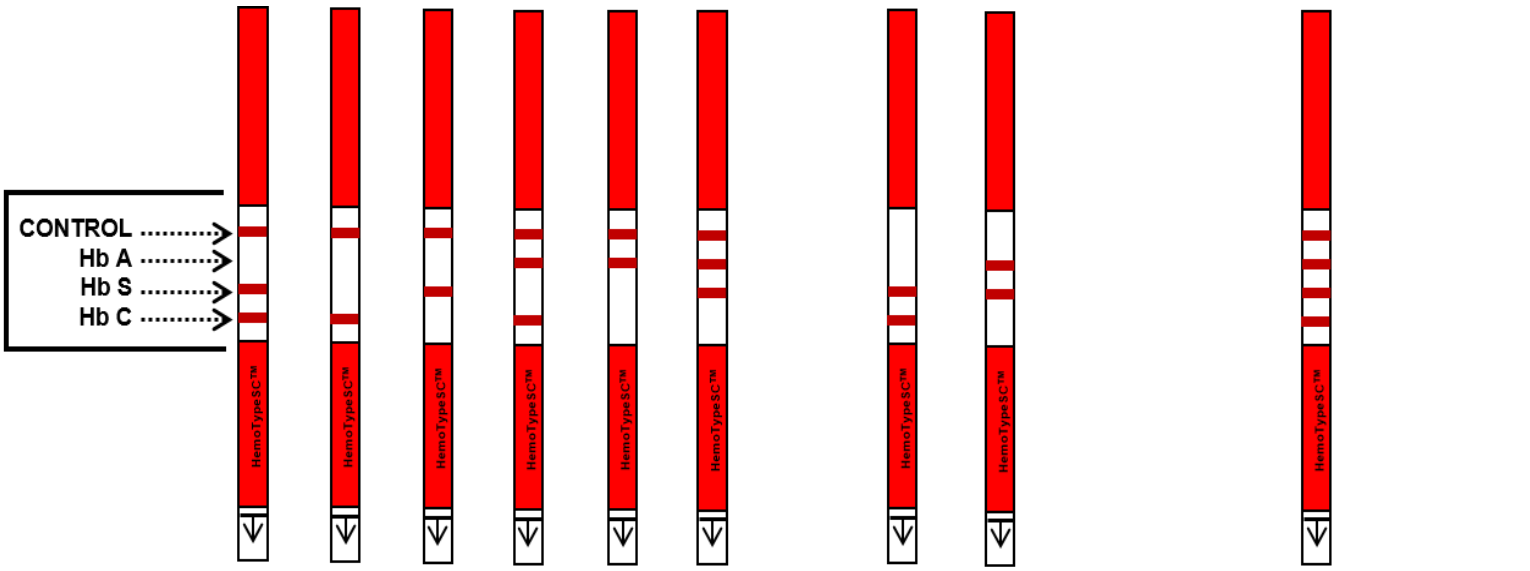
Red lines may appear at each of three hemoglobin variant-specific locations (HbA, HbS, & HbC), and a control location.

- If no control line appears, the test is invalid and should be repeated.

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

Compare the HemoTypeSC™ Test Strip to the Chart below to Obtain Test Result

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



RESULT: A/A	A/S	A/C	S/S	S/C	C/C	Not Valid (Control line missing) REPEAT THE TEST	Not Valid (Inadequate blood transferred to Test Vial, or thalassemia) REPEAT THE TEST

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