

Instructions for Use

HemoTypeSC™ is a rapid test kit for the determination of hemoglobin type in whole blood. This is a competitive lateral flow assay incorporating monoclonal antibodies for detection of hemoglobin A, hemoglobin S, and hemoglobin C.

HemoTypeSC™ provides point-of-care determination of hemoglobin phenotypes Hb AA (normal), Hb SS and Hb SC (sickle cell disease), Hb CC (hemoglobin C disease), and Hb AS and Hb AC (carrier or trait).

HemoTypeSC™ does not detect – and results are not affected by – fetal hemoglobin. Therefore, this test is ideal for newborn screening.

For Investigational Use Only. Store all items at room temperature. Observe biohazard safety procedures when handling human blood samples and disposing of used materials.

The HemoTypeSC™ Test Kit Includes:

1. Test Strip – single-use, disposable (50-Pack)
2. Blood Sampling Device – single-use, disposable (50-Pack)
3. Dropper Pipette – reusable (three provided per 50-Pack)

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

Exposure: Close test strip vial immediately after taking out strip(s) for use and keep closed.

Storage: This test kit should be stored at 1 – 50 °C.

Shelf-Life: 18 months unopened.

PROCEDURE (WHOLE BLOOD):

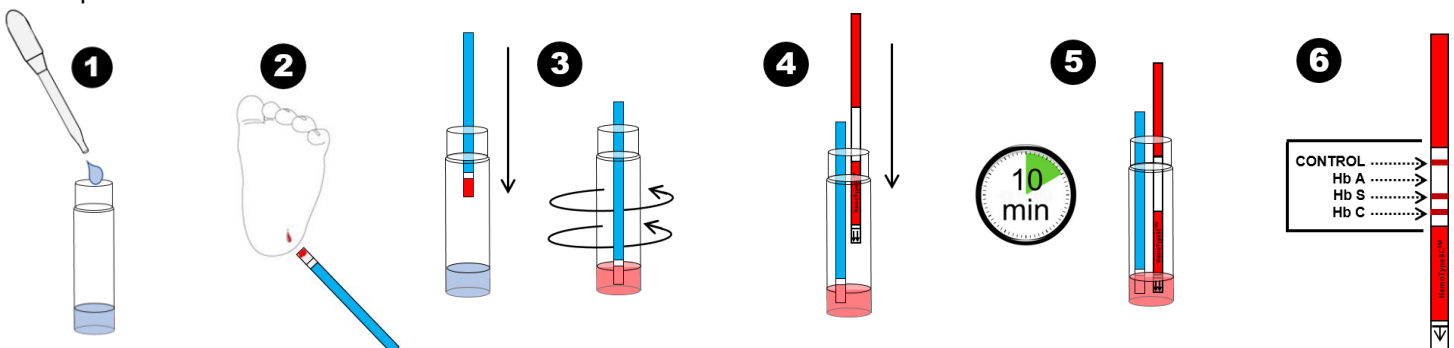
Please read these instructions thoroughly before beginning to test samples.

1. Using Dropper Pipette, add six (6) drops of water to Test Vial. Place Test Vial in a compatible rack. 1.5-mL test tubes may also be used.
2. Obtain blood sample – a small drop is sufficient (approximately one microliter). Touch the white pad below the blue cover of the Blood Sampling Device to blood sample, until the white pad absorbs blood droplet.
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.

NOTE:

Instead of using Blood Sampling Device, 1 µL of whole blood may be combined and mixed with 250 µL water in Test Vial by pipetting.

4. Insert HemoTypeSC™ Test Strip into Test Vial with arrows pointing **DOWN**. Wait 10 minutes.
5. Take HemoTypeSC™ Test Strip out of the Test Vial and read results.



PROCEDURE (DRIED BLOOD SPOTS):

The HemoTypeSC™ procedure using dried blood spots (DBS) is essentially the same as with whole blood. The DBS should be the **same size as the circles below** and must be **completely soaked red** with blood:

Before blood soaking: ○

After blood soaking: ●

- 1) Soak DBS with whole blood.
- 2) Cut out DBS at the **same size as the above circle** and submerge in water inside Test Vial.
- 3) Incubate for 10 minutes.
- 4) Insert HemoTypeSC™ Test Strip and incubate for 10 minutes.
- 5) Take HemoTypeSC™ Test Strip out of Test Vial and read result.

READING RESULTS:

Red lines may appear at each of three hemoglobin variant-specific locations (Hb A, Hb S, & Hb C) and a control location.

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

This test is different from many other rapid tests (e.g. malaria, TB, HIV, pregnancy), because for HemoTypeSC™:

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

For Example:

1) If the Hb S line is absent, but the Hb A and Hb C lines are clearly visible, then the sample is positive for Hb S (Type Hb SS).

2) If the Hb A and Hb S lines are both absent but the line for Hb C is clearly visible, then the sample is positive for Hb A and Hb S (Type Hb AS).

Compare the HemoTypeSC™ Test Strip to the chart below to obtain test result

HemoTypeSC™ Results Chart

[Missing Band(s) = Positive Hemoglobin(s)]

