sysmex | Lighting the way with diagnostics

HemoTypeSC™

Universal screening for sickle cell disease and sickle cell trait

www.sysmex-europe.com

Do you know your shape?

Sickle cell disease (SCD) is a genetic condition that is present at birth. It is inherited when a child receives two sickle cell genes – one from each parent.

50 – 90 % of all babies born with SCD will die before 5 years of age[1]. The HemoTypeSC™ screening test for sickle cell disease is possible from birth. Let's do it now and save our children!

- ✔ **10-minute test**
- ✔ **Compact and portable**
- ✔ **Clinically accurate**

Epidemiology

Sickle cell disease is common throughout much of sub-Saharan Africa, affecting up to 3 % of births in some parts of the continent[2].

(Adapted from reference 2)

[1] Obiageli E Nnodu, Alayo Sopekan, Uche Nnebe-Agumadu, Chinatu Ohiaeri, Adeyemi Adeniran, Grace Shedul, Hezekiah A Isa, Olumide Owolabi, Reuben I Chianumba, Yohanna Tanko, Juliet H Iyobosa, Adekunle D Adekile, Olufunmilayo I Olapade, Frédéric B Piel
[2] Grosse SD, Odame I, Atrash HK, Amendah DD, Piel FB,Williams TN. Sickle cell disease in Africa: a neglected cause of early childhood mortality. Am J Prev Med 2011; 41 (suppl 4): S398–405.
[3] Adegoke SA, Kuteyi EA. Psychosocial burden of sickle cell disease on the family, Nigeria. Afr J Prim Health Care Fam Med. 2012;4(1):380. Published 2012 Apr 24. doi:10.4102/phcfm.v4i1.380
[4] Steele, et al. Am J Hematol. 2018 Oct 5. doi: 10.1002/ajh.25305
[5] Quinn, et al. Br J Hematol. 2016 Nov; 175(4):724-73

Burden of disease

Sickle cell disease (SCD) is the most common genetic disorder amongst Africans and poses significant psychosocial burden on the sufferers, the caregivers and their families [3].

Poor quality of life

- Frequent severe pain
- Disability and reduced opportunity for normal play and social interaction
- Childhood survivors have poor school outcomes due to frequent absenteeism

Economic hardship

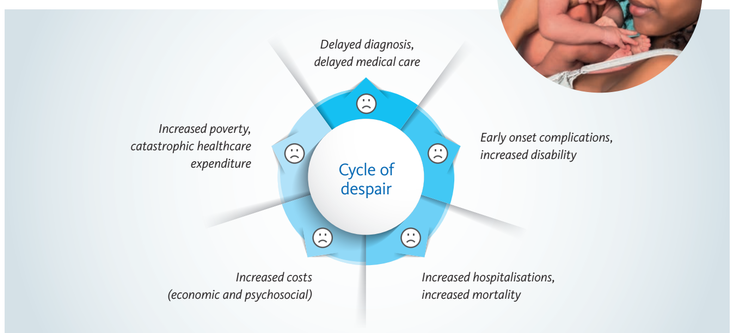
- High out-of-pocket costs (hunger, neglect of other children, malnutrition, reduced productivity)
- Caregiving demands (lost business/work days with reduction in income or high unemployment rates, exacerbating the poverty cycle)
- Caregivers lose between 1 to 48 days per affected child per year
- ~ 20 % of families take out loans to pay for SCD healthcare
- Forced to sell assets to cover costs

Negative psychological impact

- Depression, chronic unhappiness, spiritual distress, despair and suicide (caregivers and childhood survivors)
- Impacts on medical management and self care

(Table adapted from reference 3)

Current situation



Early screening can break the cycle of despair

Clinically accurate

In multiple clinical studies, HemoTypeSC™ has exhibited > 99 % clinical accuracy, including 100 % sensitivity and 100 % specificity for sickle cell anaemia [4-5]. This accuracy was achieved in adults, children, and newborns.

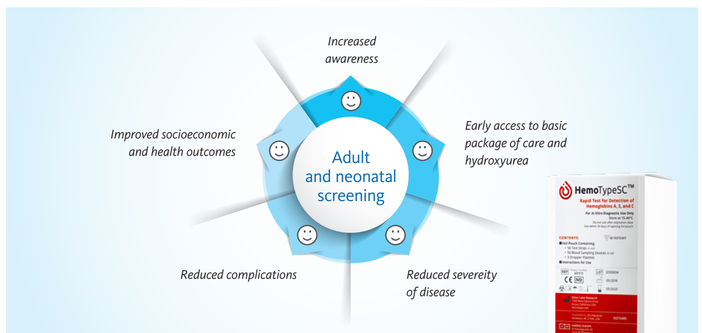
Reliable for neonatal and adults screening

Results are not affected by foetal haemoglobin. Execution very simple – only 1 – 2 µL capillary blood needed (can be used even for very premature babies). For adults, to prevent some complications and for premarital screening.

10 minute test

This test uses monoclonal antibodies to directly detect haemoglobins A, S, and C. Results are available at the point-of-care in about ten minutes. It is low-cost and extremely portable. The test does not require any instrumentation.

Ideal situation with HemoTypeSC™



HemoTypeSC™ test procedure

HemoTypeSC™ kit – included items

Procedure

Please read these instructions thoroughly before beginning to test samples.

1. Using dropper pipette, add six drops of water (approximately 250 microliters) 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 (1–2 microliters). Touch the white pad of the blood sampling device to blood sample, until the white pad absorbs the blood droplet. In case of using whole blood: Do not immerse the blood sampling device into the tube of blood. **Ensure that the entire white pad has turned red.**

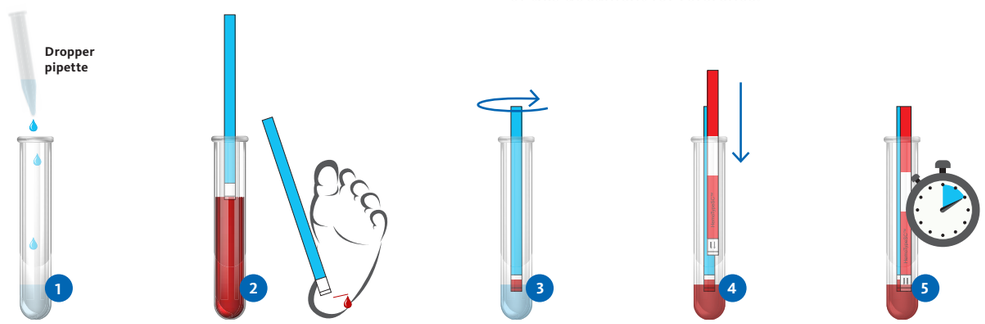
3. Insert blood sampling device into test vial water and swirl to mix.

   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 colour.
   c) Leave blood sampling device inside the test vial 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 reverse side of this document for reference.



How to interpret HemoTypeSC™ results?

Reading results

Red lines may appear at each of three haemoglobin variant-specific locations (HbA, HbS and HbC), and a control location. If no control line appears, the test is invalid and should be repeated.

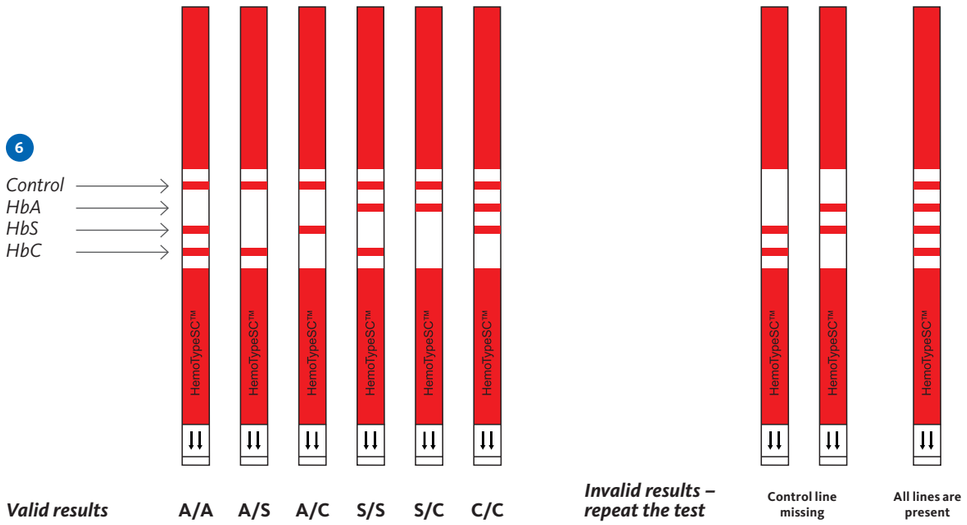
Important

If test result is unclear, repeat the entire procedure starting with step 1.

Refer to IFU on HemoTypeSC™ test strip vial if unsure whether or not a test line is present. The control line will appear if the test procedure has been correctly performed. Recent blood transfusion may impact the results and should be considered during result interpretation.

Compare the HemoTypeSC™ test strip to the chart to obtain test result

Missing line(s) = Presence of haemoglobin
Visible line(s) = Absence of haemoglobin



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