

ASI Sickle Cell Test

RAPID · SIMPLE · CONVENIENT · RELIABLE

Sickle Cell is a hereditary disease, occurring mostly in individuals of African, Mediterranean and Caribbean descent for which abnormal hemoglobin (Hb-S) causes red blood cells (erythrocytes) to become sickle-shaped, fragile and nonfunctional, leading to chronic anemia.

INTENDED USE

The ASI Sickle Cell Test is intended to be used as an aid in the qualitative detection of hemoglobin S (Hb-S) in anticoagulated whole blood.

FEATURES

- Simple and economical to use
- Easy to interpret
- Contains a reagent to distinguish between hemoglobin (Hb-S) and (Hb-C)
- Turbidity line test
- Detects both homozygous (S/S) and heterozygous (A/S) sickle cell
- Room temperature storage
- Kit does not include controls
- Working Sickle Cell Buffer is stable for 30 days
- Up to 18 month shelf life (from date of manufacture)
- The test does not distinguish between sickle cell disease (HbS/S) and sickle cell trait (HbS/A)
- This test is not recommended for use on newborns under 3 months of age

SENSITIVITY & SPECIFICITY

Sensitivity: >99%

Specificity: >99%

Test Kit Size	ASI Part No.
25 Test	200025
100 Test	200100

CPT Code 85660

510(k)-K960947

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