

SICKLE-TEST RAPID SCREEN FOR HbS

IVD For In-Vitro diagnostic and professional use only

15°C 30°C
Store at 15-30°C

INTENDED USE

Atlas sickle test kit is a qualitative solubility test for Sickle Haemoglobin the test can be performed in two ways:

1. A screening test to detect sickle haemoglobin (HbS).
2. A centrifugation test to confirm results.

INTRODUCTION

Sickle cell disease (also called sickle cell anaemia) is an inherited blood disorder that affects red blood cells. The sickle cell gene causes the body to produce abnormal haemoglobin. In sickle cell disease, the haemoglobin clumps together, causing red blood cells to become stiff and develop a C-shaped ("sickle") form. These sickled red blood cells can block blood vessels, reducing blood flow in many parts of the body. This process results in tissue and organ damage.

Each red blood cell contains about 280 million haemoglobin molecules. Haemoglobin is the most important component of red blood cells. It is composed of protein (globulin) and a molecule (haeme), which binds to iron.

In the lungs, the haeme component takes up oxygen and releases carbon dioxide. The red blood cells carry the oxygen to the body's tissues, where the haemoglobin releases the oxygen in exchange for carbon dioxide, and the cycle repeats. The oxygen is essential for all cells in the body to function.

Sickle cell disease reduces or denies adequate oxygen to many parts of the body. This contributes to the severe pain experienced as a sickle cell crisis and both short- and long-term organ damage.

MATERIALS

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- Reagent A (Buffer).
- Reagent B (Reducing agent).
- Negative control (Optional).
- Positive control (Optional).

PREPARATION OF THE WORKING SOLUTION

Bring 1 bottle of Reagent 'A' and 1 vial Reagent 'B' up to Room Temperature. Add Reagent 'B' to Reagent 'A' and mix well for 5 minutes. **Record date on bottle.**

Once the working reagent prepared for the first time leave the bottle standing for 15 minutes before use.

PROCEDURE:

Sickle Cell Screening Test Procedure:

1. Using the solution prepared as above, place 2 ml quantities into the required number of 75 x 12mm tubes.
2. Using whole anti coagulated blood (EDTA), add (20 µl) to each tube. Mix well and **stand for 5 minutes**. Hold against viewer or 1cm away for best results.

To confirm the test result:

Centrifuge reaction tubes for 5 minutes at 1000 RCF.

Note: Always use known positive and negative controls.

RESULTS

1. SCREENING TEST:

- Negative (Absence of S Haemoglobin): Clear Hemolyzed red solution (lines on the viewer should be seen).
- Positive (Presence of S Haemoglobin): turbid red solution (Completely absence of the lines on the viewer).

2. CONFIRMING RESULT (by centrifugation):

- Positive: Yellowish-Pink or Straw solution with dark red band on the top.
- Negative: Red hemolyzed solution with grayish band on the top.

NOTES

1. The working solution should be kept refrigerated and will remain stable for up to 2 weeks. Allow the reagent to reach to room temperature before use.
2. ANAEMIC SAMPLES Adjust haematocrit to approximately 50% by removal of plasma. Do not add double volume of sample.
3. False Positives may be caused by abnormal plasma protein or when patients are receiving parental nutrition.
4. False Negatives may be found if old or outdated reagents are used, or the blood of small children under the age of 6 months if the proportion of HbS is less than 20%, or following Blood transfusion in severe anaemia.

STORAGE AND STABILITY

- The reagents should be stored at 15-30°C.
- Never Freeze or expose to elevated temperature.
- The reagent is stable until the expiry date stated on the product label. Do not use the reagents past the expiry date

PRECAUTIONS AND LIMITATIONS

- The reagents are intended for in vitro diagnostic use only.
- Do not use reagents if it is turbid or contain particles as this may indicate reagent deterioration or contamination.

- Protective clothing should be worn when handling the reagents.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.
- Wash hands and the test table top with water and soap once the testing is done.
- Hemolyzed blood sample should not be used for testing.
- The test should be performed at room temperature in a well lit area with very good visibility.
- Failure to follow the procedure in this package insert may give false results or safety hazard.
- Close the vial tightly after each test.
- The reagent is considered toxic, so do not drink or eat beside it.

REFERENCES

















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	Catalogue Number		Temperature limit
	<i>In Vitro</i> diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry