137 mm x 218 mm

CE

SICKLEVUE®

Modified assay. Read packinsert before use.

SOLUBILITY TEST FOR DETECTION OF HAEMOGLOBIN S

INTENDED USE

SICKLEVUE® is a qualitative screening solubility test for the detection of haemoglobin S in blood samples.

SUMMARY

Haemoglobin S (Hb S) differs from the normal Haemoglobin A (Hb A) by a single amino acid mutation at position 6 of the beta chain; wherein glutamic acid is replaced by valine. During low oxygen conditions, the red blood cell morphology may range from mild elongation to irreversible elongated tactoid. This elongated filamentous tactoid formation results in the typical 'sickle' appearance of the red blood cell.

Individuals with sickle cell anemia (homozygous S/S) may have early mortality with vascular occlusions of multiple organ systems, severe hemolytic anemia and hypoxia. Individuals with sickle cell trait (heterozygous A/S) are usually asymptomatic. However, under certain conditions of reduced oxygen tension such as hypoxia during anaesthesia, flight in poorly pressurized airplanes, severe pneumonia, they can experience a sickle cell crisis.

PRESENTATION

REF	**M-810020**
Σ	**20 Test**
R1	**2 x 20 mL**
R2	**2 vials**
Empty Reaction tubes	**20 nos**
Result reading stand	**1 no.**
Reagent dropper	**2 nos**
Sample Dropper	**20 nos**
Rubber Teat	**2 nos**
Pack insert	**1 no.**

REAGENT

a) R1 **:** Solubility Buffer (Phosphate buffer solution contains red cell lysing reagent with stabilizers and preservatives)
B) R2 **:** Solubility Reagent Powder (Sodium Dithionite)

PRINCIPLE

SICKLEVUE® Solubility Test for detection of Haemoglobin S is based on the solubility difference between Hb S and Hb A in concentrated phosphate buffer solution. Red blood cells under test are lysed by a powerful hemolytic agent and the released haemoglobin is then reduced by sodium dithionite in a concentrated phosphate buffer. In the presence of Sodium Dithionite, Hb S precipitates causing turbidity of the reaction mixture. Under the same conditions, Hb A, as well as most other haemoglobins, are soluble. When subjected to a centrifugal force the precipitated haemoglobin (Hb S) forms a red precipitate on top layer leaving the lower solution clear and colourless. The soluble haemoglobin (Hb A) gives a clear red lower solution with a grey precipitate on the top layer and most HbAS which contains both precipitated and soluble haemoglobin gives a red precipitate ring on top layer with a light red to pink colour lower solution.

NOTES

(1) Reagent for laboratory use only. (2) Do not pipette by mouth. (3) Solubility Test Reagent contain preservatives. Aseptic conditions should be followed to avoid contamination. However as a powerful hemolytic agent is included in the composition, avoid contact with skin or mucosa. Wash hands after use. (4) The reagent can be damaged due to microbial contamination or on exposure to extreme temperatures. (5) Use reagent of same lot numbers. Do not interchange reagent of different lot numbers.

REAGENT STORAGE AND STABILITY

Store the reagents at 2°C-30°C. Do not expose to light for excessive periods. The shelf life of the unopened reagents is as per the expiry date mentioned on reagent vial label. **After reconstitution the Working reagent (R1) is stable for 1 month at 2°C-8°C and 3 days at 22°C-25°C** (do not freeze it). Please refer the working reagent preparation instructions **in REAGENT PREPARATION.**

ADDITIONAL MATERIAL REQUIRED BUT NOT PROVIDED

Micropipette (100 µL), test tubes, test tube rack, stop watch, laboratory centrifuge (if required).

REAGENT PREPARATION

Bring the reagents to Room temperature prior to testing.
(a) To prepare 20 mL **working reagent** take one vial of Solubility buffer **(R1)** and one vial Solubility reagent powder **(R2).**

(b) Add 1mL of solubility buffer from R1 vial into R2 vial and gently swirl the R2 vial to mix the content well. Transfer the entire content of R2 vial to R1 vial. Gently mix the R1 vial and allow it to stand for 10 minutes. Label the date of reconstitution on the R1 vial and the reagent is now ready to use. After reconstitution store the R1 reagent at 2°C-8°C (Do not freeze or expose to light). (d) Mix the working reagent (R1) thoroughly before use.

SAMPLE COLLECTION AND PREPARATION

No special preparation of the patient is necessary prior to specimen collection by approved techniques.

a. Collect whole blood in EDTA, Heparin, Sodium Citrate or ACD anticoagulant. Though fresh blood samples are preferable; the sample can be stored at 2°C-8° C for up to 24 hours, in case of delay in testing.
b. Prick the finger (preferably ring finger) with the help of lancet. Press the finger till blood oozes out freely. Wipe off the initial blood drop. Using the sample dropper (provided with the kit) collect one drop for the test and immediately add to the labeled **SICKLEVUE**® reaction tube already filled with 2 mL working reagent.

SAMPLE WASTE AND DISPOSAL

This product requires the handling of human specimens. Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents. Disposal by incineration is recommended.

TEST PROCEDURE

Bring all reagents and samples to room temperature before use.

Screening Method

1. Use the required number of **SICKLEVUE**® reaction tubes, as the number of samples to be tested.
2. Label the **SICKLEVUE**® reaction tubes appropriately and set on the results reading stand.
3. Add 2 mL of the working reagent (R1) to each **SICKLEVUE**® reaction tube (up to the 2 mL mark).
4. With the help of a sample dropper, add 1 drop (20 µL) of whole blood sample.
5. Mix well and allow to stand for 10 minutes.
6. To read the test results, place the **SICKLEVUE**® reaction tubes into the slots of the Result Reading stand provided.
7. Read the turbidity in the **SICKLEVUE**® reaction tubes by holding the result reading stand against a dim illumination and viewing the black lines printed on the background of the result reading stand, through the solution in the **SICKLEVUE**® reaction tube.

Differentiation Method

To differentiate between Sickle cell Trait (Hb AS) and Sickle cell Anemia (Hb SS).

1. If positive results are obtained during the screening method take a fresh **SICKLEVUE**® reaction tube and repeat the test procedure as in Screening Method with 100 µL of whole blood sample.
2. Mix for 10-15 seconds and allow to stand for 10 minutes.
3. Centrifuge the reaction tube at 1200 rpm for 5 minutes in a laboratory centrifuge.
4. Allow the centrifuge to stop without breaking and carefully remove the test tubes without disturbing the contents.
5. Centrifuge the tube if lower layer is not clear for another 5 minutes.
6. Observe the pattern formed in the **SICKLEVUE**® reaction tubes.

INTERPRETATION OF RESULTS

Screening Method

1. A turbid solution (black lines on the background of result reading stand are barely visible or cannot be seen) indicates a **POSITIVE TEST** for sickle cell heamoglobinopathies.
2. A clear solution (black lines on the background of result reading stand are clearly visible) indicates a **NEGATIVE TEST** result.

Differentiation Method

Type	Lower Layer	Upper Layer
Hb-AA (Normal)	Clear and dark red in colour	Grey precipitate
Hb-AS (Sickle Cell Trait)	Clear and light red to pink in colour	Red precipitate
Hb-SS (Sickle Cell Anemia)	Clear and colourless	Red precipitate

QUALITY CONTROL

Good laboratory practice is recommended for the use of control material along with the test samples to ensure proper performance of the test kit.

REMARKS

1. All positive results should be confirmed on electrophoresis.
2. Blood samples from patients with multiple myeloma, cryglobulinemia and other dysglobulnemias may give false positive results.

3. Severe anemia can cause false negative results. If the hemoglobin concentration is 8 g/dL or less, the sample volume for testing should be doubled to 40 µL in screening method.
4. False negative may occur in infants under six months of age due to high levels of Hemoglobin F.
5. It is recommended that the performance of reagents should be verified with known positive and negative results.
6. As with all diagnostic tests, the results of the test should be correlated with clinical findings to arrive at the final diagnosis.

PERFORMANCE CHARACTERISTICS

Evaluation of **SICKLEVUE® Solubility Test for detection of Haemoglobin S** have yielded good correlation with haemoglobin electrophoresis techniques.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. Practical Haematology, Sir John Dacie, Eighth Edition, 1995.
2. Clinical Diagnosis and Management, J.B Henry, 7th Edition, 1998.
3. Diagnostic Haematology by B. F. Rodak, 1995.
4. Clinical Laboratory Diagnostics; Edited by Lothar Thomas, 1st Edition.
5. Standardization in detection of Abnormal Haemoglobins, R.M. Schmidt *et al.,* JAMA, Vol 225, No.: 10., Sept 3, 1973.
6. Data on File: Tulip Diagnostics (P) Ltd.

SYMBOL KEYS

Temperature Limit	Manufacturer	LOT Batch Code	EC REP Authorised Representative	Date of Manufacture	This way up	R1 Solubility Buffer	R2 Solubility Reagent Powder
REF Catalogue Number	Consult Instructions for use	Use-by Date	IVD *In vitro* Diagnostic Medical Device	Σ Contains sufficient for <n> tests		ERT Empty Reaction Tubes	

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