INTENDED USE
Sicklevue is a qualitative screening solubility test for the detection of hemoglobin S in blood samples.

SUMMARY
Hemoglobin S (Hb S) differs from the normal Hemoglobin 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 such as hypoxia during anesthesia, flight in poorly pressurized airplanes, severe pneumonia, they can experience a sickle cell crisis.

KIT CONTENTS
- Phosphate Buffer Solution: A concentrated, ready to use phosphate buffer solution containing 2 ml pipettes, Micropipette (100 µl), test tubes, test tube rack, stop watch, laboratory centrifuge.

REAGENT STORAGE AND STABILITY
Store the reagents at 2-8°C. DO NOT FREEZE. Do not expose to light for excessive periods. Best stored as supplied in the kit. The shelf life of the reagents is as per the expiry date mentioned on the Sio HbS Solubility Test carton.

PRINCIPLE
Sbio HbS Solubility Test 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 hemoglobin is then reduced by sodium dithionite in a concentrated phosphate buffer.

In the presence of Sodium Dithionite, HbS precipitates causing turbidity of the reaction mixture. Under the same conditions, Hb A, as well as most other hemoglobins, are soluble. When subjected to a centrifugal force the precipitated hemoglobin (Hb S) forms a red precipitate on top layer leaving the lower solution clear and colourless. The soluble hemoglobin (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 hemoglobin gives a red precipitate ring on top layer with a light red to pink colour lower solution.

NOTE
1. Reagent for laboratory use only.
2. Do not pipette by mouth.
3. The reagent does not 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 exposure to extreme temperatures.
5. Use reagent of same lot numbers. Do not interchange reagent of different lot numbers.

SAMPLE COLLECTION AND PREPARATION
No special preparation of the patient is necessary prior to specimen collection by approved techniques. Collect whole blood in EDTA, Heparin, Sodium Citrate or ACD anticoagulant. Though fresh blood samples are preferable, the sample can be stored at 2-8°C for up to 24 hours, in case of delay in testing.

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.

ADDITIONAL MATERIAL REQUIRED BUT NOT PROVIDED

TEST PROCEDURE
Bring all reagents and samples to room temperature before use.
1. Use the required number of reaction tubes, as the number of samples to be tested.
2. Label the reaction tubes appropriately and set on a test tube rack.
3. Add 2 ml of the solubility test reagent to each of the reaction tubes, using the pipette.
4. With the help of a micropipette, add 100 µl of whole blood sample.
5. Vortex or mix for 10 - 15 seconds.
6. Allow to stand for 15 minutes.
7. Centrifuge the reaction tubes at 1200 g for 5 minutes in a laboratory centrifuge.
8. Allow the centrifuge to stop without braking and carefully remove the reaction tubes without disturbing the contents.
9. Centrifuge the tube if lower layer is not clear for another 5 minutes.
10. Observe the pattern formed in the reaction tubes.

INTERPRETATION OF RESULTS

<table>
<thead>
<tr>
<th>Type</th>
<th>Lower Layer</th>
<th>Upper Layer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hb-AA (Normal)</td>
<td>Clear and dark red in colour</td>
<td>Grey precipitate</td>
</tr>
<tr>
<td>Hb-AS (Sickle Cell Trait)</td>
<td>Clear and light red to pink in colour</td>
<td>Red precipitate</td>
</tr>
<tr>
<td>Hb-SS (Sickle Cell Anemia)</td>
<td>Clear and colourless</td>
<td>Red precipitate</td>
</tr>
</tbody>
</table>

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, cryoglobulinemia and cancer could lead to false positive results.

Sbio HbS Solubility Test
Solubility test for detection of Hemoglobin S

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other dysglobulnemias may give false positive results. (3) It is recommended that the performance of reagents should be verified with known positive and negative results. (4) 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 SBIo Hb/S Solubility Test have yielded good correlation with hemoglobin 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**