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**SICKLE CELL SOLUBILITY CONTROLS**  
**PRODUCT NO: NCS-1**

**INTENDED USE:**

**FOR IN VITRO DIAGNOSTIC USE.** For use as positive and negative controls in testing for the presence or absence of hemoglobin S (Hb S) in the Nova Century Scientific Sickle Cell Solubility Test or other sickle cell solubility (tube) test.

**PRINCIPLE:**

In the sickle cell solubility test, erythrocytes are lysed by saponin and the released hemoglobin is reduced by dithionite in a phosphate buffer. Reduced Hb S is characterized by its lack solubility in the phosphate buffer and by the formation of nematic liquid crystals (tactoid), so that in the presence of Hb S or the two other non-S sickling hemoglobin, the system becomes and remains turbid. Electrophoresis confirmation is required for conclusive identification.

**MATERIALS PROVIDED:**

Two vials NCS A/S Heterozygous POSITIVE CONTROL, 0.5mL  
Two vials NCS A/A Homozygous NEGATIVE CONTROL, 0.5mL  
Two vials NCS DILUENT, 1.5mL-deionized water

**REAGENT PREPARATION:**

Add 0.5mL of the diluent provided to the contents of each vial of control and recap tightly. Allow to stand for 20 minutes, then mix thoroughly and vortex lightly. Allow the controls to stand in the refrigerator at 2-8°C for 24 hours prior to its utilization. Refrigerate and store immediately at 2-8°C after using.

**REAGENT STORAGE AND STABILITY:**

Stable in the original package for 24 months after the date of manufacture when stored at 2-8°C. Reconstituted Nova Century Scientific controls are stable for 60 days after reconstitution when stored at 2-8°C.

**PROCEDURE:**

Reconstituted Nova Century Scientific controls A/S and A/A when used in the sickle cell solubility test are treated the same as patient samples. Use Nova Century Scientific A/S and A/A control in accordance with the directions accompanying the sickle cell solubility test used.

**EXPECTED RESULTS:**

When instructions for storage and use of this product are followed the A/S and the A/A controls will perform as described throughout the dated period. During the solubility test, Hb S will result in a turbid and opaque suspension, while the more soluble hemoglobin (A/A) will form a clear transparent to slightly turbid solution. Sickle Cell control A/S indicates the presence of Hb S while Sickle Cell control A/A indicates the absence of Hb S.

**PRECAUTIONS AND WARNINGS:**

Source material from which this product was derived was found to be non-reactive for HBsAB and HTLV III antibody when tested with FDA approved commercial reagents. No known test method can offer assurance that products derived from human blood will transmit hepatitis or Aids. Therefore, blood derived products from humans should be handled with appropriate care. If contact is made with eyes flush with copious amounts of water and consult a physician.

**PROCEDURE LIMITATIONS:**

Sample volume for the Nova Century Scientific A/S and A/A controls may vary according to the sickle cell solubility test system used. Erroneous results may occur if improper mixing is used, controls are used beyond stated expiration date, or hemoglobin other than Hb S or Hb A may be present. Nova Century Scientific A/S and A/A controls are not to be used as a substitute for electrophoresis controls. Electrophoretic confirmation of all suspected specimens is required for conclusive identification.

**WARRANTY:**

This product is warranted to perform as described in the Nova Century Scientific labeling and literature. Nova Century Scientific Inc. disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event shall Nova Century Scientific Inc. be liable for any consequential damages arising out of the aforesaid expressed warranty.

**REFERENCES:**

1. Naibandian R.M. et. Al. Ditionite Tube Test: A Rapid Inexpensive Technique for the Detection of Hemoglobin S and non S Sickling Hemoglobin. Clin. Chem. 17:1028, 1971.
2. "Directory of Hemoglobin Variants", Hemoglobin Information Center, Medical College of Georgia, Augusta, Georgia 30912.