



**Transfusion Medicine Quality Manual
Standard Operating Procedure for
Sickle Cell Screening Test
For Donor Units**



1.0 Policy Statements

- 1.1 Physician/Designate shall, whenever possible, notify the transfusion medicine laboratory when there is a diagnosis of sickle cell disease (SCD).
- 1.2 Red cells selected for transfusion shall be negative when tested for hemoglobin S whenever possible. (SICKLEDEX®).
- 1.3 Sickle trait blood should not be transfused to a patient with SCD.
- 1.4 Physician/Designate shall be consulted if the red blood cells for transfusion are not screened for Hemoglobin S.

Note: Follow facility policy for emergency release of red blood cells if testing is not complete and patient requires immediate transfusion.

2.0 Linkages

Product information for SICKLEDEX®: available at:

http://www.streck.com/resources%5CHematology%5CSICKLEDEX%5C02_Product_Information%5C02_Paper_SICKLEDEX_-_Screening_Test_Guidelines.pdf

3.0 Scope

- 3.1 All Transfusion Medicine Laboratory Technologists.
- 3.2 All Physicians who prescribe transfusions.

4.0 General Information

- 4.1 In emergency situations, blood may be transfused to SCD patients prior to sickle cell testing (SICKLEDEX®).
- 4.2 The SICKLEDEX® test is a qualitative screening procedure and does not differentiate between SCD and sickle cell trait.

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5.0 Process

5.1 Quality Control

- 5.1.1 All reagents shall be used and controlled according to the manufacturer's written instructions.
- 5.1.2 The results of the visual inspection, reagent lot number, expiry date, date of the inspection and the individual performing the inspection shall be documented.
- 5.1.3 The expiry date shall be checked on each reagent used. Do not use reagents beyond expiry date.

5.2 Procedure

5.2.1 Working Solubility Buffer Preparation

- 5.2.1.1 Bring buffer and reagent powder to room temperature.
- 5.2.1.2 Add the contents of one vial of SICKLEDEX® Reagent Powder to one bottle of SICKLEDEX® Solubility Buffer.
- 5.2.1.3 Place a white dispenser cap on the working solubility buffer and dissolve the reagent powder completely with vigorous agitation.
- 5.2.1.4 Record the reconstitution date on the bottle.
- 5.2.1.5 Store tightly capped at 2°C to 10°C when not in use. Reconstituted buffer must be used within 45 days.

5.2.2 Sickle Cell Screen Procedure

- 5.2.2.1 Bring all reagents, controls and segments to be tested to room temperature.
- 5.2.2.2 Label test tubes with positive control, negative control and donor unit number.
- 5.2.2.3 Dispense 2.0mL of working SICKLEDEX® Solubility Buffer into the labelled test tubes.
- 5.2.2.4 Mix controls as follows:

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- 5.2.2.4.1 Hold vial horizontally between the palms of the hands and roll the vial back and forth for 20 to 30 seconds.
- 5.2.2.4.2 Mix by rapid inversion to ensure cells are suspended. (Vials stored for an extended period of time may require extra mixing.)
- 5.2.2.4.3 Gently invert 8 to 10 times before testing.
- 5.2.2.5 Add 20 microliters of whole blood or 10 microliters of packed red cells to the donor test tube and 1 drop of respective control to control labelled test tubes (1 drop of Sickle-Chex control is equal to 20 microliters).
- 5.2.2.6 Mix the contents of the test tube by swirling the tube several times.
- 5.2.2.7 Place the test tube in the test tube rack.
- 5.2.2.8 Allow to stand at room temperature for 6 minutes to 60 minutes.
- 5.2.2.9 Observe the sample for turbidity.
Positive test: a cloudy, turbid suspension - the ruled lines **will not** be visible through the vial.
Negative test: virtually transparent suspension - the ruled lines **will** be visible through the vial.
- 5.2.2.10 If controls are valid, record and report results.

5.3 Guidelines

Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014: Retrieved from:

<http://www.nhlbi.nih.gov/health-pro/guidelines/sickle-cell-disease-guidelines>

5.4 Materials

5.4.1 Reagents:

5.4.1.1 SICKLEDEX® Solubility Buffer

5.4.1.2 SICKLEDEX® Reagent Powder

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5.4.2 Supplies:

- 5.4.2.1 Test tubes (12x75mm)
- 5.4.2.2 Test tube rack (paperboard or rack with lines)
- 5.4.2.3 20 microL precision pipette with disposable tips or 20 microL micropipettes

5.4.3 Equipment:

- 5.4.3.1 Interval timer

5.4.4 Controls:

- 5.4.4.1 Positive and negative Sickle-Chex® hemoglobin quality control samples

5.4.5 Specimen

- 5.4.5.1 Blood bank segments containing whole blood; or
- 5.4.5.2 Packed cells with additive solutions

6.0 Acronyms

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| SCD | Sickle cell disease |
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7.0 Definitions

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| Sickle cell disease | Sickle cell disease (SCD) is caused by inherited mutations involving the beta globin gene that result in the formation of an abnormal hemoglobin (hemoglobin S). Red blood cells, which contain a predominance of hemoglobin S, undergo shape change when low oxygen concentrations cause polymerization of the sickle hemoglobin. The damaged red blood cells become rigid and inflexible, occluding blood vessels and inducing tissue ischemia, pain, and organ damage. This process is accompanied by an inflammatory response and shortened red blood cell survival. These alterations may result in a wide variety of clinical manifestations |
| Sickle cell trait | A usually asymptomatic blood condition in which some red blood cells tend to sickle but usually not enough to produce anemia and which occurs in individuals (especially those of African or Mediterranean descent) who are heterozygous for the gene controlling hemoglobin S. |

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| Hemoglobin S | Abnormal hemoglobin that occurs in the red blood cells in sickle-cell anemia and sickle-cell trait. |
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8.0 Records Management

- 8.1 The recipient transfusion data file in the transfusion service laboratory shall be retained indefinitely.
- 8.2 All transfusion records in the recipient's medical chart shall be retained in accordance with health care facility's retention policy for medical records.
- 8.3 Quality control of blood components, blood products, reagents and equipment shall be retained for 5 years.
- 8.4 Date and time of specimen collection and phlebotomist's identification shall be retained for 1 year.
- 8.5 Request form for serologic tests shall be retained for one month.
- 8.6 Documentation of staff training and competency must be kept for a minimum of ten years.

9.0 Key Words

Sickle cell, SICKLEDEX®

10.0 Supporting Documents

10.1 Process Flow/Algorithm (NA)

10.2 Tables/Charts(NA)

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