

Sickle QC

HEMATOLOGY CONTROLS

CONTROL

LOT SC0525

2025-11-05

Expected Values:

	LEVEL 1 LOT	LEVEL 2 LOT
Method	SC0525-1	SC0525-2
Solubility	Negative	Positive

INTENDED USE

Sickle QC is intended to be used as a sickle cell control in testing for the presence of Hemoglobin S in solubility tests.

SUMMARY AND PRINCIPLE

It is an established laboratory practice to use a stable control to monitor the performance of diagnostic tests. This control is composed of stable materials that provide a means of monitoring the presence of sickling hemoglobins in solubility tests. It is sampled in the same manner as a patient specimen.

REAGENTS

Sickle QC is an *in vitro* diagnostic reagent composed of human erythrocytes suspended in a plasma-like fluid with preservatives.



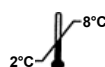
PRECAUTION

Sickle QC is intended for *in vitro* diagnostic use only by trained personnel.



WARNING:

POTENTIALLY BIOHAZARDOUS MATERIAL. For *in vitro* diagnostic use. Each human donor/unit used in the preparation of this product has been tested by a FDA licensed method/test and found to be negative or non-reactive for the presence of HBsAg, Anti-HCV, NAT testing for HIV-1, HCV (RNA) and HIV-1/2. Each unit is also negative by a serological test for Syphilis (RPR or STS). Because no test method can offer complete assurance that infectious agents are absent, this material should be handled as potentially infectious. When handling or disposing of vials follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (OSHA 29 CFR Part 1910.1030) or other equivalent biosafety procedures.



STABILITY AND STORAGE

Store Sickle QC upright at 2 - 8° C (35 - 46 F) when not in use. **Protect tubes from overheating and freezing.** Unopened tubes are stable through the expiration date. Opened tubes are stable for 100 days, provided they are handled properly.

INDICATIONS OF DETERIORATION

After mixing, product should be similar in appearance to fresh whole blood. In unmixed tubes, the supernatant fluid is expected to be dark in color; this is normal and does not indicate deterioration. Unacceptable results may indicate deterioration. **Do not use the product if deterioration is suspected.**



INSTRUCTIONS FOR USE

1. Remove vials from the refrigerator and allow to warm to room temperature (15 - 30°C or 59 - 86°F) for 15 minutes before mixing.
2. To mix, hold a vial horizontally between the palms of the hands. **Do not pre-mix on a mechanical mixer.**
 - a) Roll the vial back and forth for 20 - 30 seconds; occasionally invert the vial. Mix vigorously, but do not shake.
 - b) Continue to mix in this manner until the red cells are completely suspended. Vials stored for a long time may require extra mixing.
 - c) Gently invert the vial 8 - 10 times immediately before sampling.
3. Analyze the sample as instructed in the reagent test kit instructions.
4. After sampling:
 - a) Clean residual material from the cap and vial rim with a lint-free tissue. Replace the cap tightly.
 - b) Return vials to refrigerator within 30 minutes of use.

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LIMITATIONS

The performance of this product is assured only if it is properly stored and used as described in this insert. Incomplete mixing of a vial prior to use invalidates both the sample withdrawn and any remaining material in the vial.

EXPECTED RESULTS

Sickle QC is designed to be handled in the same manner as a patient specimen. Analyze the sample as instructed in the reagent test kit. The positive control will appear as a cloudy turbid suspension as described in the reagent test kit instructions for use. The negative control will appear as a nearly transparent solution as described in the reagent test kit instructions for use.

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

For assistance in resolving control recovery problems, please call Technical Service at (800) 523-3395. For additional information on R&D Systems, Inc. hematology controls and calibrators, or to place an order, call Customer Service at (800) 428-4246.

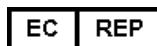
QUALITY CONTROL PROGRAM

For information on CBC-Monitor, our Inter-Laboratory Quality Control Program, call (800) 523-3395 ext. 4435.



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