

Calibration

None

Quality Control

Positive and Negative Controls are included in each Color Slide® II Mononucleosis Test kit. Store the controls in the refrigerator at 2°-8°C. **DO NOT FREEZE**. The controls are stable until the expiration date stated on the bottle label.

Cross-check a brand new reagent lot against the previous lot of reagent by running a previous positive patient sample and a previous negative patient sample with the new lot of reagents and record on the QC sheet. Should the patient results not agree with the previous results, investigate and notify the specialists or the supervisor. In addition, cross-check a new shipment of a current lot by verifying that QC is acceptable. The new kit should be cross-checked as soon as possible after it is received.

The positive and negative patient samples used for cross-checking should be aliquotted into bullets and frozen at or below -20°C. Label aliquots with a 6 month stability. When the positive reactivity has diminished, a new positive sample should be saved and aliquotted.

Controls should be tested each time the kit is removed from the refrigerator for patient testing. If aberrant quality control results are noted, patient results should not be reported.

Refer to the Clinical Chemistry Quality Control Procedure #3000.T for laboratory quality control policy and corrective action.

Procedure

Preliminary Preparation and Notes

1. Allow reagents to equilibrate to room temperature prior to use (approximately 30 minutes). If samples have been refrigerated, allow specimens to equilibrate to room temperature too.
2. For new unopened kits, replace the caps on Reagent A and Reagent B with the bottle droppers provided.
3. Determine the number of test circles required (one circle for each patient specimen or control to be tested). Tear the test card along perforations to remove the test circles needed. Save extra test circles for future testing.
4. Create worksheet, "**SC MONO**".
5. Pipettes and reagent droppers should always be held vertically when delivering drops. To ensure accuracy of test results, dispense free-falling drops of reagents and specimens to each test circle; otherwise, test accuracy may be compromised due to imprecise volume. A vertical drop is 30 µL, while a drop at a 45° angle is 50 µL.



Free-falling drop

6. Use of pipettes: Squeeze the bulb of the pipette and insert into the specimen. Release the pressure on the bulb to draw serum into the pipette channel. To dispense one drop of specimen, gently squeeze the pipette while holding it **vertically** over the test card. Use a separate pipette for each specimen. When handling pipettes, avoid touching the pipette tip.
7. Before aspirating the Reagents (A and B) with the dropper, clear the dropper channel by squeezing the dropper bulb. Gently mix the Reagents by inversion to **THOROUGHLY** resuspend the cells and antigen.
8. To avoid cross contamination, do not interchange the liquid reagent bottle droppers. Do not exchange contents of kits. The components of each kit have been calibrated to give proper sensitivity and reactivity.

