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Lot-to-Lot Comparison for Sickle-Dex and FMH Kit

I. PURPOSE

To describe the procedure for performing Lot to Lot comparison of Sickle-Dex and Fetal Maternal Hemorrhage Kit (FMH Kit).

II. SCOPE

This SOP applies to:

- FMH RapidScreen kits
- Hemoglobin S screening kits

III. EXCEPTIONS

This SOP does not apply to Blood Bank bench and automation instruments, including antisera, reagent red cells, and potentiating media. Lot to Lot comparisons for these reagents are accomplished via day of use QC.

IV. DEFINITIONS

Lot-to-Lot Comparison: The comparison of testing results with new lots of lab reagents which are received as a kit (multiple reagents for the testing), to the lot currently in use to ensure that testing results are comparable.

V. POLICY STATEMENTS

A. All new lots or new shipments of FMH RapidScreen and Sickledex must have an acceptable lot-to-lot comparison before being placed into use.

B. Per CAP requirements: If there are multiple components of a reagent kits (example: FMH and SickleDex), the Blood Bank will only use components of reagent kits only within the kit lot received. The only deviation to this practice would be if specified by the manufacturer that the kit components may be used interchangeably.

VI. PRINCIPLE/BACKGROUND

CAP Standards for New Reagent Lot Confirmation of Acceptability requires that new reagent lots and shipments must be checked against previous reagent lots or with suitable reference material before or concurrently with being placed into service.

- For Fetal Bleed Screen and Hemoglobin S, which are qualitative tests, the minimum required testing is retesting of one positive and one negative sample against the new reagent lot.
- The CAP checklist allows for positive and negative patient samples tested on a previous lot, previously tested proficiency testing materials, and external QC materials tested on the previous lot.

VII. MATERIALS

Fetal Bleed Screen:

1. One kit from a new lot or shipment of FMH RapidScreen
2. One kit from the previous lot or shipment of FMH RapidScreen Hemoglobin S:

1. One kit from a new lot or shipment of Sickledex.
2. In-use lot of Sickle-Chex (positive and negative control) that has been tested with the previous lot/ shipment of Sickledex.

NOTE: If the previous lot/shipment of FMH RapidScreen or Sickle-Chex is not available, notify management. Management will develop a planned deviation using one of the alternative acceptable methods stated in the Principle/Background section.

VIII. SPECIMEN REQUIREMENTS

None

IX. PROCEDURE

1. Receive new lots/shipments of FMH RapidScreen and Sickledex reagents following Reagent/Supplies Inspection & Receiving. NOTE: For new lot numbers, do not mark these reagents as "Okay to Use," until Lot-to-Lot Comparison Worksheet (below) is completed.
2. Initiate Form Lot to Lot Comparison Worksheet:
    1. Check the box indicating if the lot-to-lot comparison is being performed on the FMH Rapidscreen or Sickledex.
    2. Document the date of testing.
    3. Document the lot number and expiration of the new reagents being tested
    4. Document the lot number and expiration of the *previously tested* QC material. **NOTE:** For the FMH Rapidscreen, ***do not use*** the QC material that comes in the same kit as the new reagents. The QC material must come from the current lot-in- use.
    5. Document tech initials.
3. Perform Quality Control testing following the SOP/package insert for the test system.
4. Document QC results on Form Lot to Lot Comparison Worksheet.
5. Compare the observed results with the expected results:
    1. If the observed and expected results match, circle A (Acceptable).
    2. If the observed and expected results do not match, circle U (Unacceptable) and notify a supervisor.
6. Give the completed Form BBQC-F046 to a supervisor for review and retention.
7. When lot-to-lot comparison is complete and acceptable, document in the Remarks column of the Reagent Receiving Log that the lot is **OK to use.**

X. APPENDICES/ATTACHMENTS/FORMS/ LABELS

Lot to Lot Comparison Worksheet

XI. REFERENCES

N/A

POLICY #:

BBQC-046