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FMH RapidScreen Lot to Lot Comparison

Document Type: Procedure

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I. PURPOSE AND OBJECTIVE:

This document provides policies and instructions for the Blood Bank staff to perform the fetal cell screen (FCS) test kit lot to lot comparison using the FMH RapidScreen kit that is provided by Immucor/ Gamma®.

II. PRINCIPLE:

Clinical laboratory reagents are exposed to many variables including changes in temperature during transportation and various storage conditions. The verification by parallel testing of new lot numbers with lot numbers currently in use is performed to ensure no clinically significant differences in results are obtained. Verification by parallel testing is required by CAP and is part of good laboratory practice. This procedure outlines parallel testing requirements for the Immucor® FMH RapidScreen test kits including frequency and acceptance criteria of results.

III. POLICIES:

Parallel testing is required each time a new lot number is put into use. Test results should match between the lot number currently in use (current lot) and the new lot. Any discrepancies must be documented and investigated.

IV. EQUIPMENT & REAGENTS:

A. Test tubes, 10 x 75 mm or 12 x 75 mm
B. Disposable pipettes

C. Microscope
D. Microscope slides
E. Isotonic saline, preferably phosphate-buffered saline (approximately 15 mM, pH 6.5 – 7.5) Note: washing manually or using the automated cell washer is acceptable.
F. Timer
G. Centrifuge
H. FMH RapidScreen Kit (lot number currently in use)
I. FMH RapidScreen Kit (new lot number)

V. PROCEDURE:

1. Before you begin, bring all reagents to room temperature before use.
2. Label four test tubes to identify the following:
    a. NL Pos (New Lot Positive Control)
    b. NL Neg (New Lot Negative Control)
    c. CL Pos (Current Lot Positive Control)
    d. CL Neg (Current Lot Negative Control)
3. Add 1 drop of the positive control to the correspondingly labeled tube.
4. Add 1 drop of the negative control to the correspondingly labeled tube.
5. Add 1 drop of the new lot of the FMH RapidScreen Anti-D reagent to the current lot positive control (CL POS) and to the current lot negative control (CL NEG).
6. Add 1 drop of the current lot of the FMH RapidScreen Anti-D reagent to the new lot positive control (NL POS) and to the new lot negative control (NL NEG).
7. Mix well and incubate the FMH RapidScreen test for 5 (±1) minutes at room temperature (18°C - 30°C).
8. Wash the RBCs 4 times (if using 12 x 75mm test tubes) or 6 times (if using 10 x 75mm test tubes).
    a. The RBCs may be washed using the automated cell washer or washed manually.
    b. Decant completely between washes and after the last wash.
    c. Resuspend the RBCs thoroughly when adding saline for the next wash.
9. To the FMH RapidScreen dry cell button obtained after washing, add 1 drop of new lot indicator cells to the current lot positive control (CL POS) and to the current lot negative control (CL Neg).
10. To the FMH RapidScreen dry cell button obtained after washing, add 1 drop of current lot indicator cells to the new lot positive control (NL POS) and to the new lot negative control (NL Neg).
11. Mix each tube well by shaking.
12. Centrifuge immediately at 3400 RPM at the posted calibration time for the centrifuge.

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13. Resuspend the RBC button.
14. Decant onto a microscope slide and examine 5 fields under low power magnification.
15. Determine the number of mixed-field agglutinates observed in the 5 fields.
16. Results should be interpreted immediately upon completion of the test.
17. Compare results. Record all results on the Transfusion Medicine form, *FMH Lot to Lot Comparison Form*.

VI. INTERPRETATIONS:

A. **Positive Test:** After examining 5 low-power fields, if 5 or more agglutinates of RBCs are observed, the test should be interpreted as positive.

B. **Negative Test:** After examining 5 low-power fields, if 4 or fewer clumps of agglutinated RBCs are observed the test should be interpreted as negative.

C. Controls of the new lot should match results of the old lot. The controls must give expected results or must be repeated.

VII. LIMITATIONS:

A. False-positive results may occur if the washing procedure is inadequate.

B. The reactivity of the red cells may tend to diminish over the dating period.

C. Marked hemolysis or darkening of the cells are indication of product deterioration.

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VIII. NOTES:

A. All testing profiles may not be validated and/or in use at every Beaumont location for all methods. Only testing and methods that have been implemented and properly quality controlled in each individual Beaumont Health Blood Bank shall be performed at that location.

B. All requests for Fetal Screens at Beaumont Taylor will be referred to Beaumont Dearborn for testing.

IX. REFERENCES:

1. Package insert for the FMH RapidScreen, Immucor/Gamma®, revised March 2017.
2. AABB, *Technical Manual*, current edition.
3. AABB, *Standards for Blood Banks and Transfusion Services*, current edition.
4. College of American Pathologists, *Transfusion Medicine Checklist*, current edition.

Attachments

FMH Lot to Lot Comparison Form

Approval Signatures

Step Description	Approver	Date
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	Jeremy Powers: Chief, Pathology	6/14/2022
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