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Confirmatory Typing of Donor RBC Units

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document will provide policies and procedures related to confirmatory testing of donor red blood cells (RBCs).

II. DEFINITIONS/ACRONYMS:

A. RBC: Red Blood Cell

B. Donor sample: For the purpose of this procedure, it is a segment removed from the original RBC unit.

C. Designee: Lead Medical Technologist or other staff member that have been given temporary authority to make departmental decisions in the absence of the Blood Bank Supervisor.

D. NT: Not tested

III. POLICIES:

A. Processing RBCs

1. All RBCs must be processed into inventory as described in Transfusion Medicine policy, Receiving Components from Outside Source except for RBCs received from one of the other Blood Banks in our health care system.
2. Confirmatory testing must be performed on these units before the units can be made available for transfusion. This testing can be done by manual tube method or by automated method on

the Ortho Vision™.

3. The technologist who performs/loads confirmatory testing should be the same technologist who obtains the segment for confirmatory testing. **Reminder**: In addition to the segment(s) used for confirmatory typing, two (2) additional segments should be saved for each RBC.
4. Donor units must not be labeled with ABO Confirmation tags or placed into available inventory until confirmatory testing is complete.

B. Labeling of Samples used for Confirmatory Testing

1. Manual Tube Testing
    a. All test tubes used for manual confirmatory testing must be properly labeled.
    b. A segment from each unit will be placed in a test tube that is labeled with the full donor number. A sticker from the back of the unit may be used for this purpose.
    c. Each additional test tube for confirmatory testing (as described in the Procedure section of this document) must also be labeled. A sticker from the back of the unit may be used for this purpose, or these tubes may be labeled with the last 3 numbers of the full donor number.
2. Ortho Vision™ Testing
    a. The Ortho Vision™ automatically scans barcodes. Test Tubes should be labeled with a barcoded donor number sticker from the back of donor Unit.

C. Required Confirmatory Testing

1. RBC units labeled as Rh positive by the blood supplier must be tested by a forward typing for ABO; Rh(D) testing is not required.
    a. The Ortho Vision™ RTDP test profile is configured to use the MTS™ A/B gel cards for this testing.
2. RBC units labeled as Rh negative by the blood supplier must be tested by a forward typing for ABO and Rh(D).
    a. The Ortho Vision™ RTDN test profile is configured to use the MTS™ A/B/D gel cards for this testing.

IV. SPECIMEN COLLECTION AND HANDLING:

A. The specimen consists of packed RBCs obtained from an integrally attached segment acquired from each donor unit. The segments are placed in a test tube that is labeled with the donor unit number in accordance with the labeling policy above.

V. REAGENTS:

A. Manual Tube Reagents
    1. Ortho Bioclone Anti-A
    2. Ortho Bioclone Anti-B,

3. Ortho Bioclone Anti-D
4. 7% BSA

B. Ortho Vision Reagents
    1. MTS™A/B/D Monoclonal Grouping Cards
    2. MTS™ A/B Monoclonal Grouping Card
    3. MTS™ Diluent 2 Plus

VI. EQUIPMENT:

A. Lighted viewing mirror
B. Table top centrifuge
C. Ortho Vision™ Analyzer

VII. SUPPLIES:

A. 10 x 75mm or 12 x 75mm test tubes
B. Disposable Pipettes
C. Scissors or segment splitters
D. Gauze
E. Blood Bank Saline
F. ABO Confirmation Tags

VIII. QUALITY CONTROL (QC):

A. Quality Control must be tested and pass in order to release confirmatory test results.
B. Daily quality control of ABO and Rh(D) tube testing is performed as described in site specific Transfusion Medicine policies, *Quality Control of Blood Bank Reagents* and documented in the Blood Bank computer system or on paper per site procedure.
C. Daily quality control (QC) of the gel cards used in automated ABO and Rh(D) testing is performed on the ORTHO VISION™ as described in Transfusion Medicine policy, ORTHO VISION™ Analyzer QC. This QC is documented in the Blood Bank computer system or on paper per site procedure.

IX. PROCEDURE:

A. Confirmatory Typing by the Tube Method

1. After delivering the RBCs in the computer, build a worksheet in the Blood Bank computer.
    1. Each unit must be scanned into the computer when building a worksheet in the computer to perform confirmatory testing. The quantity and donor numbers of the units on the worksheet must match the quantity and donor numbers of units for

which the technologist is performing confirmatory testing.

2. It is unacceptable to click “F5-Mark All” when building the worksheet; each unit must be scanned onto the worksheet.

2. Obtain a segment from each unit and place the segment in a test tube labeled with the full donor number. A barcode label from the back of the unit may be used for this purpose. This tube will be used to make the cell suspension.
3. Label all additional test tubes with a small donor number sticker from the back of the RBC or by writing the last 3 digits of the donor number on the test tube.
    a. For Rh positive units, label 2 additional test tubes, as “A” and “B.”
    b. For Rh negative units, label 3 additional test tubes, as “A” and “B” and “D.”
4. Make a 2-4% suspension of the donor RBCs in the tube prepared from step 2. Refer to Transfusion Medicine policy, Making a Test Red Cell Suspension.
5. Add 1 drop of the appropriate reagent typing sera and then add 1 drop of the donor RBC suspension to each of the correspondingly labeled tubes. For example:
    a. Combine 1 drop of Anti-A and 1 drop of the RBC suspension to the “A” tube.
    b. Combine 1 drop of Anti-B and 1 drop of the RBC suspension to the “B” tube.
    c. Combine 1 drop of Anti-D and 1 drop of the RBC suspension to the “D” tube (if applicable).
    d. For AB positive RBC units, it is not necessary to perform testing with the 7 % BSA bovine albumin control.
6. Agitate all tubes to mix and then centrifuge.
7. Gently re-suspend the cell buttons. Read, grade, and record the test reactions in the Blood Bank computer. Refer to Transfusion Medicine policy, Reading, Grading and Recording Test Reactions.
8. Interpret the ABO and Rh test results. If the ABO or Rh test results do not match the ABO and Rh on the label, place the unit in quarantine.
    a. Notify the Blood Bank Supervisor or Lead Medical Technologist.
    b. Submit a variance.
    c. Do NOT place the unit into available inventory.
9. Label the units with the ABO confirmatory tags and place them on the available inventory shelf (based on ABO, Rh, expiration date, antigens, attributes, etc.).
    a. Do not label the RBCs with confirmatory tags If the ABO or Rh test results do not match the ABO and Rh on the label. This discrepancy must be investigated and resolved before labeling with a confirmatory tag.

B. Confirmatory Typing by the Ortho Vision™

1. Obtain a segment from the donor unit to be tested.
2. Label a test tube with a large barcode label from the donor unit.

3. Using Blood Bank scissors, cut the top and the bottom off the segment and fully empty the segment into the tube.
    a. Do not use the segment device to obtain blood from the segment as it can cause hemolysis.
    b. The Ortho Vision™ requires 7mm of donor sample in the test tube for processing. Filling the curvature at the bottom of test tube should yield a sufficient volume of packed cells for testing. If one segment does not give enough sample for 7 mm, add additional segments until the 7 mm volume is reached.
    c. If desired the tube may also be centrifuged in the table top centrifuge to pack cells before loading.
4. Place the samples onto the load station, using the provided handles on the rack.
    a. If the Unit Barcodes do not read once loaded, the unit must be assigned to a position by scanning the barcode with the hand-held barcode reader.
    b. If the blood confirmation orders do not automatically upload once loaded, confirm products were scanned into the Blood Bank Computer system to qualify for a worklist.
    Note: The Ortho Vision™ does not allow for the testing of related apheresis simulataneously on the Vision.
    c. If order interfaces are not available create an order for Rh positive units by selecting the RTDP test code for Rh positive units by selecting the RTDP test code for Rh positive units or RTDN test code for Rh negative units respectively.
5. When testing is complete, result in the Blood Bank computer system. Refer to Transfusion Medicine policy, Routine Testing on the Ortho Vision Analyzer.
6. Interpret the ABO and Rh test results. If the ABO or Rh test results do not match the ABO and Rh on the label, place the unit in quarantine.
    a. Notify the Blood Bank Supervisor or Lead Medical Technologist.
    b. Submit a variance.
    c. Do NOT place the unit into available inventory.
7. Label the units with the ABO confirmatory tags and place them on the available inventory shelf (based on ABO, Rh, expiration date, antigens, attributes, etc.).
    a. Do not label the RBCs with ABO confirmatory tags If the ABO or Rh test results do not match the ABO and Rh on the label. This discrepancy must be investigated and resolved before labeling with a confirmatory tag.

X. CALCULATIONS AND INTERPRETATIONS:

A.

Observed Reactions			
Anti-A	**Anti-B**	**Anti-D**	**Interpretation**
0	0	0	O Negative
0	0	NT	O

3+ or 4+	0	0	A Negative
3+ or 4+	0	NT	A
0	3+ or 4+	0	B Negative
0	3+ or 4+	NT	B
3+ or 4+	3+ or 4+	0	AB Negative
3+ or 4+	3+ or 4+	NT	AB

If a valid interpretation cannot be made based on the observed graded reactions, then additional investigation is required. Place the unit in quarantine and submit an internal variance. Unresolved discrepancies will be reported to the collecting facility and must be resolved before issue of the blood for transfusion.

XI. REFERENCES:

1. AABB, *Standards for Blood Banks and Transfusion Services*, current edition.
2. AABB, *Technical Manua*l, current edition.
3. College of American Pathologists, *Transfusion Medicine Checklist*, current edition.

Approval Signatures

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