The Blood Connection
1099 Bracken Road
Piedmont, SC 29673

# Process Description

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| Title: | Autologous Unit Management: Non-conforming Test Results |
| Document Number | 9733PD08 |
| Scope: | DS (Special Donations Coordinator or Designee), TS, HS |
| Related procedures or processes | 9733Fa: Reactive/Positive Autologous Units Reporting Form<br>9733Fb: Non-conforming Autologous Unit Notification Form<br>6225P: Labeling A Component<br>6232P: Shipping A Product<br>4411P: Final Labeling of Autologous and/or Directed Whole Blood or RBCs<br>4213P: Shipment of Autologous Units<br>4208F: Shipment Information for Imported Products<br>4914P: Hold and Release from Hold/Discard of Blood Products |
| References: | Current AABB Technical Manual and Standards, FDA memorandums regarding autologous donation, and 21 CFR 606 – 610. |
| Prepared by: | Tracy Bridges, MLT (ASCP)<br>Director of Technical Services |

**Purpose:** The process defines the processing of autologous units through the manufacturing process. (Autologous donor care and management are not addressed in this process description.)

**Application:**
Special Donations: Physician's office contact and donor management
Testing Laboratory: Testing and quarantining procedures
Hospital Services: Labeling, shipping, transfusion facility notification

**Process:**

## I. Autologous Testing

Autologous units are tested for the following: anti-HCV, anti-HTLV I/II, HBsAg, anti-HBcore, anti-HIV-1,2, HIV-1 RNA (NAT), HCV RNA (NAT), WNV (NAT), HBV (NAT), Chagas Disease and syphilis. Units with conforming test results are shipped to transfusion facilities where they are transfused back to the autologous donor/patient. Units with non-conforming test results require further action. (See sections II -IV).

## II. Units with Non-Conforming Test Results

Units with non-conforming test results are placed on hold by HS in accordance with SOPs 4914PD. The units are identified as bio-hazardous by the application of a biohazard label to the unit. This label is applied by the testing laboratory when the unit is deemed non-conforming as a result of laboratory testing. The unit remains in the quarantine location until it is approved for labeling (see sections III and IV). If unit is not approved for labeling, it will be discarded.

For each unit deemed as non-conforming, the testing laboratory generates a *Reactive/Positive Autologous Unit Reporting Form: 9733Fa/current version* and routes to Special Donations. This form identifies the reactive/positive test(s) and is used by Special Donations to notify the ordering physician of the non-conforming autologous unit.

## III. Ordering Physician Notification / Release

Federal guidelines require blood centers to notify ordering physicians when autologous donors are reactive for infectious disease markers. Special Donations routes the *Reactive/Positive Autologous Unit Reporting Form: 9733Fa/current version* to the ordering physician when the report is received from the testing laboratory. The ordering physician must sign and return the release form before the unit can be labeled and subsequently shipped to the indicated transfusion facility. When the signed release form is returned, Special Donations routes the completed reporting form to Hospital Services for labeling and distribution.

## IV. Labeling and Shipping

Upon receiving the completed *Reactive/Positive Autologous Unit Reporting Form: 9733Fa/current version* (bearing the physician's signature), Hospital Services labels the unit in accordance with SOPs 6225P and 4411P. **The Labeling tech must remove the Biohazard label applied by TS** upon successful completion of the labeling. (The full-face label will indicate that the unit is for Autologous Use Only and is Biohazardous). The labeler will also place the Intended Recipient Label on the unit (see 4411P/current version). The reactive unit is placed in the *labeled-available autologous quarantine* area. The unit remains in the area until it is shipped to the appropriate transfusion facility.

The form *Non-Conforming Autologous Unit Notification: 9733Fb/current version* is completed by Hospital Services and included in the shipment for each non-conforming autologous unit. The unit is shipped in accordance with SOPs 6232P and 4213P.

When the unit is shipped, the *Reactive/Positive Autologous Unit Reporting Form: 9733Fa/current version* is routed back to Special Donations indicating that the unit has been shipped.

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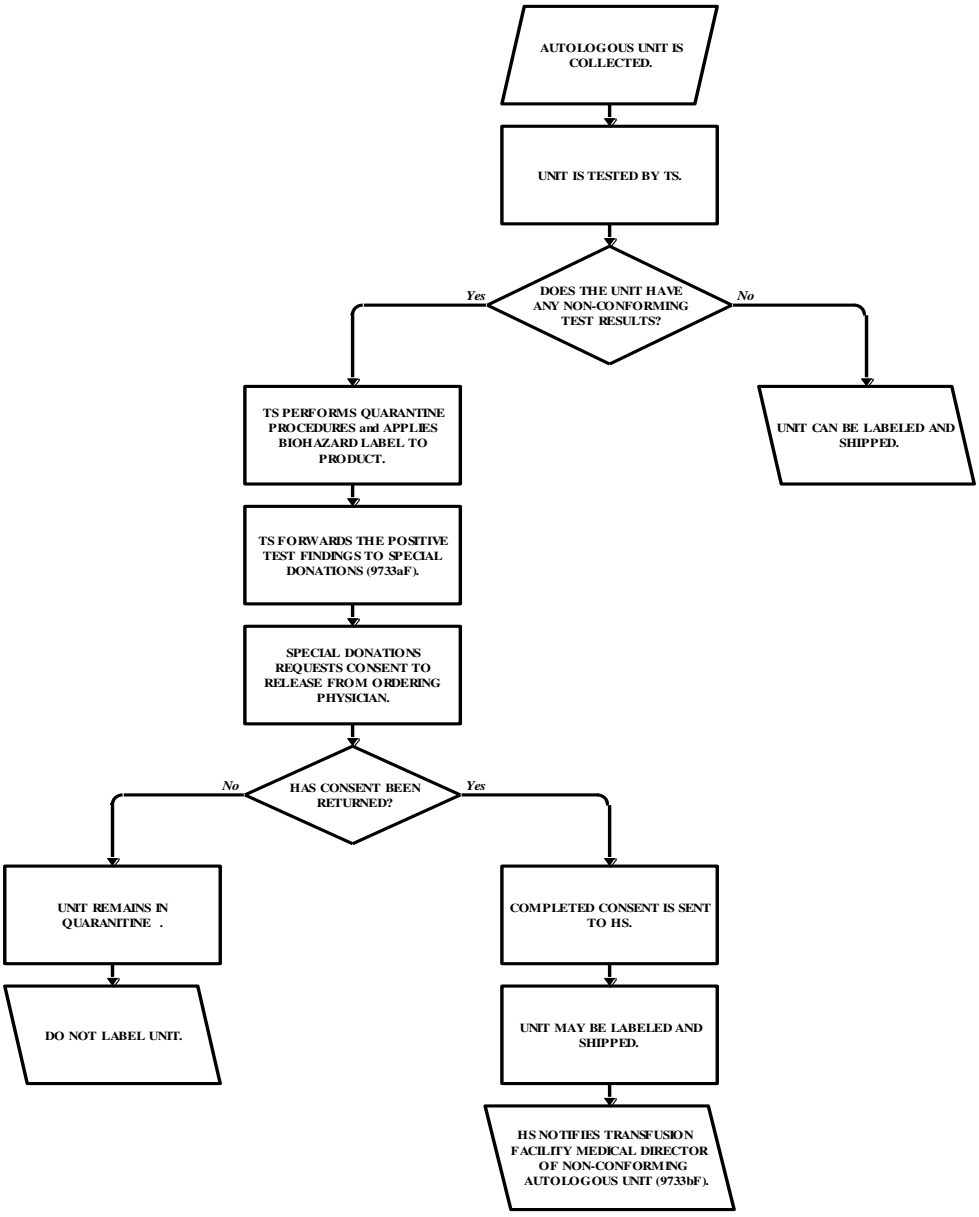

## V. Reactive/Positive Autologous Units Collected at Facilities other than The Blood Connection

If a Reactive/Positive autologous unit is received at The Blood Connection that was collected at an outside facility for transfusion at a hospital serviced by TBC, permission for shipment must be obtained from the receiving hospital prior to delivery to that hospital. Hospital Services staff will notify the hospital and document the date/time of the call, the transfusion facility staff member who gave permission for the shipment, and the TBC staff member who called the transfusion facility. This information is documented on the *Shipment Information for Imported Products: 4208F/current version* for the particular unit.