
Title: Autologous Unit Management: Non-conforming Test Results

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
Testing Laboratory: Testing and communicating hold request to HS
Hospital Services: Labeling, shipping, transfusion facility notification

Process:

A. Autologous Testing

Autologous units are tested for the following: anti-HCV, anti-HTLV I/II, HBsAg, anti-HBcore, anti-HIV-1,2 (and group O), 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 B-E).

B. Units with Non-Conforming Test Results

Units with non-conforming test results are placed on hold by HS in accordance with PD.BP.4914/current version. The units are identified as bio-hazardous by the application of a biohazard label to the unit. This label is applied by HS when the unit is deemed non-conforming as a result of laboratory testing (this information is transmitted to HS for HOLD). The unit remains in the quarantine location until it is approved for labeling (see sections C and D). If unit is not approved for labeling, it is discarded.

For each unit deemed as non-conforming, the testing laboratory generates a *Reactive/Positive Autologous Unit Reporting Form: F.CW.9733a/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.

C. Ordering Physician Notification / Release

Federal guidelines require blood centers to notify ordering physicians when autologous donors are reactive for infectious disease markers. A designated member of Special Donations routes the *Reactive/Positive Autologous Unit Reporting Form: F.CW.9733a/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 faxes a copy of the signed reporting form to the Donor Testing laboratory. Special donations retains the original.

D. Labeling and Shipping

Upon receiving the completed *Reactive/Positive Autologous Unit Reporting Form: F.CW.9733a/current version* (bearing the physician's signature), the donor testing lab completes the product recommendation section of the electronic hold form and routes the copy of the *Reactive/Positive Autologous Unit Reporting Form: F.CW.9733a/current version* to Hospital Services. Hospital Services performs the requested action. If physician requests release of the unit, Hospital Services labels the unit in accordance with SOP.IT.6225/current version and SOP.BP.4411/current version. **The Labeling tech must remove the Biohazard label previously applied** 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 SOP.BP.4411/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: F.CW.9733b/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 SOP.IT.6232/current version and SOP.BP.4213/current version.

When the unit is shipped, the *Reactive/Positive Autologous Unit Reporting Form: F.CW.9733a/current version* is routed back to donor services indicating that the unit has been shipped.

E. 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: F.BP.4208/current version* for the particular unit.