TBC Notification to a Consignee of an Unsuitable Component

Two Classifications of Notifications:

A. **Recall:** A product recall occurs when a product(s) is discovered to have been unsuitable for release but was distributed due to an error/accident in the manufacturing process.

   Examples of a Recall:

   1. Incomplete donor record
   2. Error in donor sample identification
   3. Acceptance of an unsuitable donor
   4. Labeling error
   5. Testing deficiencies

B. **Market Withdrawal:** A Market Withdrawal occurs when a product was suitable for release following manufacture but is later discovered to be unsuitable.

   Examples of a Market Withdrawal:

   1. Post donation illness/information
   2. Post transfusion reaction or infection
   3. Any existing in-date products from a previous donation of a donor whose current donation has a repeatedly reactive HBsAg, HBc, HCV, HIV 1/2, HTLV I/II, positive NAT testing (HCV, HIV, HBV, WNV, Zika), positive bacterial testing, or Chagas testing.

Process of Notification :

- Record of Product Recall/Withdrawal Form (5200PDFc) is generated by TBC QA.
- TBC QA notifies transfusion facility via phone call. TBC QA will request and record the current product disposition and any adverse reactions documented in the patient file if transfused.
- TBC QA sends this form (5200PDFc) and a cover letter (5200PDFd) to the transfusion facility for verification and acknowledgement. The transfusion facility is directed to return 5200PDFd to TBC QA.

Note:

- Notification of a subsequent positive test to the transfusion facility must occur within 72 hours of the knowledge of the positive test.
- If a withdrawal is initiated and is due to a subsequent positive test, the withdrawal form is held until confirmation/supplemental testing is complete. This additional testing information is recorded on the form and then sent to the transfusion facility.

- Notification report of subsequent history of Zika Virus in the past 4 weeks will require withdrawal of any in-date transfusible component. If informed through TBC withdrawal process, it is advised the transfusion service inform the transfusion recipient's physician of record regarding the potential need for monitoring the recipient for a possible Zika Virus infection.