Record of Product Recall/Withdrawal Form: 5200PDFc02

To be completed by QA for the recall or withdrawal of a component.

Select the appropriate action by placing a (√) check mark or (x) in the provided space.

_____ Recall **_____ Withdrawal**

Document a detailed description of the reason for the recall or withdrawal. If the withdrawal is due to a subsequent positive test, the positive test must be indicated.

Reason:_____

_____

- *Record who is initiating the recall/withdrawal and the date in the provided space.*
- *Record the component being recalled/withdrawn.*
- *Record the ABO/Rh of the unit, collection date, date shipped, facility that received the unit being recalled/withdrawn, and if applicable the box number and bill of lading number .* ***Note: Box numbers and bill of lading numbers may be required when recovered plasma for further manufacturing is involved. This information can be obtained by reviewing shipping records.***
- *If the withdrawal is due to a subsequent positive test, record the date of positive test and date of last negative test in the provided spaces.*

Recall/Withdrawal initiated by: _____ **Date:** _____

Product:_____ **Donation No.:**_____ **ABO/Rh:** _____
(product code)

Collected on: ____/___ /____ **Date shipped:**___ /___ /____ **To:**_____
Receiving Facility

Box No.:_____ **Bill of Lading No:**_____

Date of positive test: _____ **Date of last negative test:**_____
(mm/dd/yy) *(mm/dd/yy)*

- *Immediately notify receiving facility of the recall/withdrawal.*
- *Document who the information is given to, the date and time the information is given to the receiving facility, and who is giving the information to the receiving facility.*
- *Request from the receiving facility the current disposition of the component. Record this information in the Product Disposition section with a (√) check mark or (x) in the appropriate space.*

Information given to:_____ **Date:**_____/_____/_____ **Time:**_____

By:_____

Product Disposition:

_____transfused, Date ____ /_____/____Adverse Reaction?_____**
_____returned to TBC *(date: mm/dd/yy)*_____
_____expired/destroyed
_____retained by facility
_____other, explain: _____

Comments:_____

*** If adverse reaction is reported, attach a brief description.*