



Division of Cellular Therapy

DOCUMENT NUMBER: ABMT-GEN-019 FRM3**DOCUMENT TITLE:**

Unacceptable Supply and Corrective Action Log FRM3

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ABMT-GEN-019 FRM3
Unacceptable Supply Corrective Action Log FRM3
(To be completed by Receiver)

Complete all the information below when receiving unacceptable inventory

Date	Initial	Supply Name	Lot Number	Description of Problem	Corrective Action	Apheresis Coordinator/ designee Initials/Date	CQP Initial/ Date

ABMT-GEN-019 FRM3

Unacceptable Supply Corrective Action Log FRM3

(To be completed by Receiver)

Complete all the information below when receiving unacceptable inventory

INSTRUCTIONS

Notify Apheresis Coordinator/designee upon discovery

Field	Requirements
Date	Record date that supplies were found unacceptable.
Initials	Initials of person filling in log.
Supply Name	Record name of unacceptable supply.
Lot Number	Record lot number of unacceptable supply.
Description of Problem	Describe why the supply is unacceptable.
Corrective Action (with help from Apheresis Coordinator/designee)	Record the corrective action taken (supply discarded, returned to manufacturer, etc.).
Apheresis Coordinator/designee Initials	Inform the Apheresis Coordinator/designee of the unacceptable supply so they can review problem and assist with corrective action. At completion, the Apheresis Coordinator/designee will initial.
CQP Initials	The Clinical Quality Program (CQP) personnel will review the unacceptable supply, verify corrective action, and initial and sign at completions.

Signature Manifest**Document Number:** ABMT-GEN-019 FRM3**Revision:** 07**Title:** Unacceptable Supply and Corrective Action Log FRM3**Effective Date:** 08 May 2025

All dates and times are in Eastern Time.

ABMT-GEN-019 FRM3 Unacceptable Supply and Corrective Action Log**Author**

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Document Release

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