



Division of Cellular Therapy

DOCUMENT NUMBER: ABMT-GEN-019 FRM2**DOCUMENT TITLE:**

Package Insert Review Log FRM2

DOCUMENT NOTES:**Document Information****Revision:** 05**Vault:** ABMT-General-rel**Status:** Release**Document Type:** ABMT**Date Information****Creation Date:** 21 Apr 2022**Release Date:** 08 May 2025**Effective Date:** 08 May 2025**Expiration Date:****Control Information****Author:** MSR68**Owner:** MC363**Previous Number:** ABMT-GEN-019 FRM2 Rev 0 **Change Number:** APBMT-CCR-267

ABMT-GEN-019 FRM2
Package Insert Review Log FRM2
(To be completed by Receiver)

Complete all the information below when receiving inventory

Supply/Reagent: _____ Manufacturer: _____

Completed by Apheresis Nurse					Completed by Apheresis Coordinator/designee					Completed by CQP	
Date Received	Version Date/ Number	Version Date/Number Change?		Apheresis Coordinator/ designee Notified?	Initials/ Date	Procedure Change / Training Required?		Change Control Request Number	Changes Implemented?		Initials/ Date
		Yes	No			Yes	No		N/A	Yes	
								<input type="checkbox"/> N/A			
								<input type="checkbox"/> N/A			
								<input type="checkbox"/> N/A			
								<input type="checkbox"/> N/A			
								<input type="checkbox"/> N/A			
								<input type="checkbox"/> N/A			
								<input type="checkbox"/> N/A			
								<input type="checkbox"/> N/A			

ABMT-GEN-019 FRM2

Package Insert Review Log FRM2

(To be completed by Receiver)

Complete all the information below when receiving inventory

Field	Requirements
Completed by Apheresis Nurse	
Supply/Reagent	Record Supply/Reagent
Manufacturer	Record Manufacturer of Supply/Reagent
Date Received	Record receipt date of supply and package insert.
Version Date/Number	Record version date and/or number of package insert (PI).
Version Date/Number Change? Yes or No	Check ✓ Yes if PI is new, or version date and/or number have changed. Check ✓ No if no change in PI.
Apheresis Coordinator/designee Notified? N/A or Yes	Check ✓ N/A if no change in PI. If PI is new, or it has changed, notify Supervisor, check ✓ Yes and hold supply in quarantine.
Initials/ Date	Record initials and date.
Completed by Apheresis Coordinator/Designee	
Procedure Change/Training Required? Yes or No	Check ✓ Yes or No as applicable, if procedure change and/or training are required.
Change Control Request Number	Record Change Control Request (CCR) Number. Check ✓ N/A if CCR is not required.
Changes Implemented? N/A or Yes	Check ✓ Yes once change is implemented and applicable training is initiated. Check ✓ N/A if change is not required.
Initials/ Date	Record initials and date after completion of PI review.
Completed by CQP	
Initials/Date	Responsible Clinical Quality Program (CQP) personnel record initials and dates after Apheresis Coordinator/designee confirms required change and/or training are implemented.

Signature Manifest**Document Number:** ABMT-GEN-019 FRM2**Revision:** 05**Title:** Package Insert Review Log FRM2**Effective Date:** 08 May 2025

All dates and times are in Eastern Time.

ABMT-GEN-019 FRM2 Package Insert Review Log**Author**

Name/Signature	Title	Date	Meaning/Reason
Melissa Ritt (MSR68)	GMP, Quality Assurance Associate I	21 Apr 2025, 11:29:07 AM	Approved

Management

Name/Signature	Title	Date	Meaning/Reason
Jennifer Frith (JLF29)		22 Apr 2025, 04:47:46 PM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Stefanie Sarantopoulos (SS595)	Professor of Medicine	22 Apr 2025, 06:02:36 PM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Bing Shen (BS76)	Associate Director, Quality Assurance	23 Apr 2025, 01:11:26 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Amy McKoy (ACM93)	Document Control Specialist	24 Apr 2025, 10:11:29 AM	Approved