



PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

DOCUMENT NUMBER: PBMT-EQUIP-003 FRM2

DOCUMENT TITLE:

Package Insert Review Log FRM2

DOCUMENT NOTES:

Document Information

Revision: 01

Vault: PBMT-Equipment-rel

Status: Release

Document Type: Equipment

Date Information

Creation Date: 20 Mar 2019

Release Date: 01 Apr 2019

Effective Date: 01 Apr 2019

Expiration Date:

Control Information

Author: MC363

Owner: MC363

Previous Number: None

Change Number: PBMT-CCR-240

PBMT-EQUIP-003 FRM2 PACKAGE INSERT REVIEW LOG

Supply/Reagent: _____

Manufacturer: _____

Completed by Apheresis Nurse						Completed by Supervisor						Completed by QA	
Date Received	Version Date/Number	Version Date/Number Change?		Supervisor Notified		Initials/Date	Procedure Change / Training Required?		Change Control Request Number	Changes Implemented		Initials/Date	Initials/Date
		Yes	No	N/A	Yes		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				

PBMT-EQUIP-003 FRM2 PACKAGE INSERT REVIEW LOG

Note: All package inserts must be reviewed upon receipt and recorded on this log. Prepare one form per supply. Package inserts will be filed in the Supply Notebook.

Field	Requirements
Completed by Apheresis Nurse	
Date Received	Receipt date of supply and package insert.
Version Date/Number	Record version date and/or number of package insert.
Version Date/Number Change? Yes or No	Check <input checked="" type="checkbox"/> Yes if package insert is new, or version date and/or number have changed. Check <input checked="" type="checkbox"/> No if no change in package insert.
Supervisor Notified N/A or Yes	Check <input checked="" type="checkbox"/> N/A if no change in package insert. If package insert is new, or it has changed, notify Supervisor, check <input checked="" type="checkbox"/> Yes and hold supply in quarantine.
Initials/ Date	Record initials and date.
Completed by Supervisor	
Procedure Change/Training Required? Yes or No	Check <input checked="" type="checkbox"/> Yes or No as applicable, if procedure change and/or training are required.
Change Control Request Number	Record Change Control Request (CCR) Number. Check <input checked="" type="checkbox"/> N/A if CCR is not required.
Changes Implemented N/A or Yes	Check <input checked="" type="checkbox"/> Yes once change is implemented and applicable training is initiated. Check <input checked="" type="checkbox"/> N/A if change is not required.
Initials/ Date	Record initials and date after completion of PI review.
Completed by QA	
Initials/Date	Responsible QA personnel record initials and dates after Supervisor confirms required change and/or training are implemented.

Signature Manifest**Document Number:** PBMT-EQUIP-003 FRM2**Revision:** 01**Title:** Package Insert Review Log FRM2

All dates and times are in Eastern Time.

PBMT-EQUIP-003 FRM2 Package Insert Review Log**Author**

Name/Signature	Title	Date	Meaning/Reason
Mary Beth Christen (MC363)		21 Mar 2019, 10:29:09 AM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		21 Mar 2019, 11:16:32 AM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Bing Shen (BS76)		21 Mar 2019, 04:17:19 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Betsy Jordan (BJ42)		22 Mar 2019, 10:41:23 AM	Approved