



STEM CELL LABORATORY (STCL)



DOCUMENT NUMBER: STCL-GEN-002 FRM4

DOCUMENT TITLE:

Package Insert Review Log FRM4

DOCUMENT NOTES:

Changed Form to FRM in numbering

Document Information

Revision: 05

Vault: STCL-General-rel

Status: Release

Document Type: STCL

Date Information

Creation Date: 18 Apr 2025

Release Date: 08 May 2025

Effective Date: 08 May 2025

Expiration Date:

Control Information

Author: MSR68

Owner: WATER002

Previous Number: STCL-GEN-002 FRM4 Rev 04 **Change Number:** STCL-CCR-564

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STCL PACKAGE INSERT REVIEW LOG

Material: _____ Manufacturer: _____

Completed by Supply Coordinator					Completed by Supervisor <i>(only applies when Version Change is “Yes”)</i>					Completed by CQP	
Date Received	Version Date/ Date/ Number	Version Date/Number Change?		Supervisor Notified	Initials/ Date	Procedure Change / Training Required?		Change Control Request Number or N/A <i>(if NO change is required)</i>	Changes Implemented		Initials/ Date
		Yes	No			N/A	Yes		N/A	Yes	

Comments _____

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STCL PACKAGE INSERT REVIEW LOG - Instructions

Note: All package inserts must be reviewed upon receipt and recorded on this log. Prepare one form per supply. Package inserts will be placed in the quarantine cage for CQP review and then filed in the Supply Folder with the receipt log upon CQP release

Field	Requirements
Completed by Supply Coordinator	
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 ✓ Yes if package insert is new, or version date and/or number have changed. Check ✓ No if no change in package insert.
Supervisor Notified N/A or Yes	Check ✓ N/A if no change in package insert. If package insert is new, or it has changed, notify Supervisor, check ✓ Yes and hold supply in quarantine.
Initials/ Date	Record initials and date.
Completed by Supervisor <i>(this section is completed only when there is a change in the version date or number)</i>	
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 or N/A	Record Change Control Request (CCR) Number or 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. Return completed form to Supply Coordinator.
Completed by CQP	
Initials/Date	Responsible CQP personnel verify if the version has changed, and confirms that the required change(s) and/or training has been implemented.

Signature Manifest**Document Number:** STCL-GEN-002 FRM4**Revision:** 05**Title:** Package Insert Review Log FRM4**Effective Date:** 08 May 2025

All dates and times are in Eastern Time.

STCL-GEN-002 FRM4 Package Insert Review Log**Author**

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Document Release

Name/Signature	Title	Date	Meaning/Reason
Amy McKoy (ACM93)	Document Control Specialist	24 Apr 2025, 09:46:01 AM	Approved