STEM CELL LABORATORY (STCL)

DOCUMENT NUMBER: STCL-QA-007 FRM1

DOCUMENT TITLE:
Non-Conforming Products FRM1

DOCUMENT NOTES:

Document Information

Revision: 04	**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-QA-007 FRM1 Rev 03	**Change Number:** STCL-CCR-564

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NON-CONFORMING PRODUCTS

Discovery	
Tracking#	Date of Discovery
Name of person reporting non-conformance	Unique Product Identifier
Description of the event and immediate action taken	

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Non-Conformance

Final Disposition: (**Check ONE**)

☐ Accept With Rework

☐ Accept Without Rework

☐ Accept With Correction or Re-label

☐ Dispose (*Record of Discard* required)

☐ Other (explain)

Check ALL that apply:

☐ This product has been classified as an "Urgent Medical Need". This means there is no comparable HPC (Hematopoietic Progenitor Cell) product available for this recipient and serious morbidity could result without infusion.

☐ The adult patient (recipient of the HPC) or legal guardian of a pediatric patient (recipient of the HPC) has been informed that the HPC has a **positive culture**: (**Check ONE**)

☐ Product accepted ☐ Product NOT accepted

☐ The allogeneic donor (*if applicable*) has been notified that the HPC product collected has a **positive culture**:

Name of the person who notified the donor of + culture (**PRINT and SIGN**)

Date the donor was notified

Approvals

Stem Cell Laboratory Manager or designee	Date
Medical Director or designee	Date
Quality Manager or designee	Date

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INSTRUCTIONS

Tracking #	Get tracking # from the Clinical Quality Program (CQP)
Date of Discovery	Record the date that the non-conformance was discovered.
Name of person reporting non-conformance	Record the name of the person who reported the non-conformance.
Unique Product Identifier	Reflect unique ISBT 128 label assigned to the non-conforming product.
Description of the event and immediate action taken	Describe, in detail, the situation as it relates to the non-conforming cellular product.
NON-CONFORMANCE	
Final Disposition (**Check ONE**)	☐ **Accept With Rework -** Product will be accepted once it has been reworked (ie filtered, volume reduced, etc). ☐ **Accept Without Rework** – Product will be accepted as it is without rework (ie. if bag found to be leaking at the time of thaw, based on the CD34+ cells/kg available for that patient, the physician may decide that the thawed product must be given to the patient despite the leak). ☐ **Accept With Correction or Re-label** – Product will be accepted once the correction / re-label is completed. ☐ **Dispose** (*Record of Discard* required) – Product will be disposed in biohazard waste or designated for research (once product has been de-identified of all patient-related information). A Record of Discard must be initiated and signed before any cellular products are disposed of. ☐ **Other** (explain) – Describe other situation that is not covered in one of the categories listed.
Check ALL that apply	Urgent Medical Need; notifying recipient or legal guardian of minor recipient that cellular product has a positive culture; notification of allogeneic donor (if applicable) that cellular product collected has a positive culture.
APPROVALS	Obtain approval signatures from the laboratory, medical staff, and quality before issuing the non-conforming cellular product.

Signature Manifest

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Title: Non-Conforming Products FRM1
Effective Date: 08 May 2025

All dates and times are in Eastern Time.

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Document Release

Name/Signature	Title	Date	Meaning/Reason
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