

# STEM CELL LABORATORY (STCL)



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**DOCUMENT TITLE:** 

Unacceptable Supply/Product Recall Corrective Action Log FRM3

**DOCUMENT NOTES:** 

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## **Control Information**

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## STCL-GEN-002 FRM3 UNACCEPTABLE SUPPLY/PRODUCT RECALL CORRECTIVE ACTION LOG

Initials of person initiating this form:		☐ Product Recall or		or
Date of Discovery:		☐ Unacceptable Supply		
Supply/Product Involved:				
Manufacturer:		Manufacturer's Contact Information:		
Lot Numbers Involved:				
Description of Problem:				
Corrective Action:				Performed by: (Initial/Date)
Material Disposition:				Performed by: (Initial/Date)
Attach any suppo	rting documentation and file co	mpleted packet	appropriately	·
Lab Manager Review:		Da	nte:	
CQP Review:		Da	ate:	

STCL-GEN-002 FRM3 Unacceptable Supply/Product Recall Corrective Action Log Stem Cell Laboratory, DUMC Durham, NC

## UNACCEPTABLE SUPPLY/PRODUCT RECALL CORRECTIVE ACTION LOG - Instructions

To be completed by any staff member upon discovery of an unacceptable supply or notification of a product recall. Provide what information is possible, then forward to the STCL manager and CQP.

Field	Requirements
Product Recall or Unacceptable Supply	Check the appropriate selection.
Initials of the person initiating this form	Record the initials of the person initiating the form.
Date of discovery	Enter the date that supplies are found unacceptable or notice of recall is received. If product is recalled attach documentation to this sheet.
Product Involved	Record the name of the defective supply or recalled product.
Manufacturer	Record the name of the manufacturer of the product.
Manufacturer's Contact Information	If contact is by telephone, record the contact phone number and the name of the person spoken to. If contact is through email, record the email address and person emailed. Attach copies of all communications to this sheet.
Lot Numbers Involved	Enter all lot numbers with expiration dates of defective or recalled item(s).
Description of Problem	Describe the issue(s) with the item(s).
Corrective Action	Describe the corrective action taken.
Material Disposition	Note disposition of material.
Completed by	Sign and date to record the date the document was completed and the issue(s) resolved.
Attach supporting documentation and file	This could be an e-mail notification of recall, etc.
Lab Manager:	Enter the initials of the reviewer, which should be the STCL manager and record the date of review.
CQP review:	CQP reviewer initials and record the date of review.

STCL-GEN-002 FRM3 Unacceptable Supply/Product Recall Corrective Action Log INSTRUCTIONS
Stem Cell Laboratory, DUMC
Durham, NC

## Signature Manifest

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All dates and times are in Eastern Time.

## STCL-GEN-002 FRM3 Unacceptable Supply/Product Recall Corrective Action Log

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## **Document Release**

Name/Signature	Title	Date	Meaning/Reason
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