

STEM CELL LABORATORY (STCL)



DOCUMENT NUMBER: STCL-SOP-030 FRM3
DOCUMENT TITLE: ISBT Barcode Label Receipt Log FRM3
DOCUMENT NOTES:

Document Information

Revision: 02 Vault: STCL-Processing-rel

Status: Release Document Type: STCL

Date Information

Creation Date: 07 Sep 2022 Release Date: 17 Oct 2022

Effective Date: 17 Oct 2022 Expiration Date:

Control Information

Author: WATER002 Owner: WATER002

Previous Number: STCL-SOP-030 FRM3 Rev 01 Change Number: STCL-CCR-535

STCL-SOP-030 FRM3 ISBT Barcode Label Receipt Log

LABEL SETS

(year	
Comments (Describe what is being released): _	

RELEASE OF

Action Steps:

- 1. The beginning and ending number are printed on the first page and verified manually by checking a sampling of barcodes of each packet or by reviewing the Certificate of Conformance (COC) accompanying the label sets.
- 2. Labels are reviewed to ensure conformance to the proof and any label specifications as well as that the number of labels ordered matches the number received. Additionally, labels should be checked to ensure all are attached and that labels are not faded, truncated, and/or missing.
- 3. After verifying the label sets are acceptable, a released date is placed on the outer wrappings of the label packets.
- 4. The STCL manager or QSU representative will initial and date this form to reflect that the entire annual label set order has been inspected and released.
- 5. Signed form will remain with the label set supply for the year and then filed along with the *STCL-SOP-030 FRM4 ISBT Barcode Label Destruction Log*.

Beginning Barcode of Packet	Ending Barcode of Packet	# of Small White Labels (60) Check if # matches	# of Large White Labels (21) Check if # matches	Review of COC (if applicable)	Inspected and Approved by STCL Manager or QSU (initial and date)

STCL Manager or QSU Signature/Date:	
-------------------------------------	--

STCL-SOP-030 FRM3 Instructions for Use ISBT128 Barcode Label Receipt Log

- 1. Insert year in header
- 2. Comments Describe what is being released.
- 3. Beginning Barcode of Packet Record the beginning number of the packet.
- 4. Ending Barcode of Packet Record the ending number of the packet.
- 5. # of Small White Labels Confirm each label set has 44 small white labels. Check if there are 60 labels for each label set.
- 6. # of Large White Labels Confirm each label set has 21 large white labels. Check if there are 21 labels for each label set.
- 7. Review of Certificate of Conformance (COC) (*if applicable*) starting in 2021, the STCL plans to order annual label sets to include a certification to that will generate a COC; if for someone reason, the COC is not purchased, labels will be visually inspected upon receipt.
- 8. Inspected and Approved by STCL manager or QSU (*initial and date*) Initial and date when the batch of barcodes has been approved for use.
- 9. STCL Manager or QSU Signature/Date STCL Manager or QSU representative reviews the form for completeness and compliance with GMP requirements. If all of the information is correct, sign and date. If the information is not correct, make corrections in order to comply with the standards.

Signature Manifest

Document Number: STCL-SOP-030 FRM3 **Revision:** 02

Title: ISBT Barcode Label Receipt Log FRM3

Effective Date: 17 Oct 2022

All dates and times are in Eastern Time.

STCL-SOP-030 FRM3 ISBT Barcode Label Receipt Log FRM3

Author

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATER002)		08 Sep 2022, 07:04:02 PM	Approved

Management

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATER002)		08 Sep 2022, 07:04:22 PM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		08 Sep 2022, 09:34:23 PM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Isabel Storch De Gracia (IMS19)		05 Oct 2022, 04:39:38 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandra Mulligan (MULLI026)		11 Oct 2022, 06:18:49 PM	Approved