



## STEM CELL LABORATORY (STCL)



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Disposition of Labels, Barcodes and Ribbons JA3

**DOCUMENT NOTES:**

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**Author:** WATER002

**Owner:** WATER002

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## STCL-GEN-015 JA3

### DISPOSITION OF LABELS, BARCODES, AND RIBBON

#### 1 PURPOSE

- 1.1 To describe the process for the destruction of unused Avery patient/donor demographic labels and ISBT barcode labels used for CART-T commercial/clinical products and standard cellular products used for transplant.
- 1.2 To describe the process for disposal of used printer ribbons when having to replace them on the Hema-Trax CT label printer (*or equivalent*).

#### 2 INTRODUCTION

- 2.1 Any ISBT barcode and patient/donor demographic label not used during collection, processing, and infusion for any patient enrolled in a commercial (*FDA-approved*) program, must be destroyed in such a way that those barcodes and labels can not be used inadvertently.
- 2.2 When replacing the Hema-Trax CT printer ribbon, since protected health information (PHI) is visible on the ribbon, it must be disposed of appropriately.

#### 3 SCOPE AND RESPONSIBILITIES

- 3.1 The medical director, laboratory manager, and laboratory staff are responsible for making sure that the requirements of this procedure are successfully met.

#### 4 DEFINITIONS/ACRONYMS

- 4.1 N/A

#### 5 MATERIALS

- 5.1 N/A

#### 6 EQUIPMENT

- 6.1 N/A

#### 7 SAFETY

- 7.1 N/A

#### 8 PROCEDURE

- 8.1 Barcodes and Labels: After the last stored CART-T commercial/clinical product (*i.e. Novartis, Kite, etc.*) and/or standard cellular transplant products have been infused to a designated patient (*recipient*)
  - 8.1.1 Review the patient's laboratory file using the appropriate checklist (*STCL-QA-005 FRMS 1-4*) to document the file review process.
  - 8.1.2 Remove all unused Avery Patient/Donor demographic labels and ISBT barcodes from the designated patient lab file, **after** associated CAR T or standard cellular product has been infused (*administered*). See *STCL-GEN-015 FRM2 Infusion Record Checklist* to document disposition of labels.
  - 8.1.3 Place all unused Avery patient Labels into the SHRED-IT bin (*located in the Receiving Area of the STCL*) so those labels are destroyed and can not be used mistakenly.

- 8.1.4 Reconcile the remaining labels at the bottom of *STCL-SOP-030 FRM2 ISBT Barcode Label Reconciliation Log* and place the remaining ISBT barcodes into the SHRED-IT bin (*located in the Receiving Area of the STCL*) so those barcodes will be destroyed and not be used mistakenly.
- 8.2 Ribbons: When the ribbon on the Hema-Trax CT printer needs to be replaced, since the ribbon may contain visible protected health information (PHI), the used ribbon **MUST** be disposed of in the SHRED-IT bin (*located in the Receiving Area of the STCL*) to ensure that no PHI is accessible to unauthorized individuals.

## 9 RELATED DOCUMENTS/FORMS

- 9.1 STCL-GEN-015 Records Management
- 9.2 STCL-GEN-015 JA1 EMMES System Advantage EDC<sup>SM</sup>
- 9.3 STCL-GEN-015 JA2 Duke Stem Cell Laboratory System Internet Data Entry System User's Guide
- 9.4 STCL-SOP-030 FRM2 ISBT Barcode Label Reconciliation Log
- 9.5 STCL-QA-005 Review of Processing Records
- 9.6 STCL-QA-005 FRM1 Apheresis Record Checklist
- 9.7 STCL-QA-005 FRM2 Infusion Record Checklist
- 9.8 STCL-QA-005 FRM3 Selection Record Checklist
- 9.9 STCL-QA-005 FRM4 Bone Marrow Harvest Record Checklist

## 10 REFERENCES

- 10.1 N/A

## 11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
03	B. Waters-Pick	<ul style="list-style-type: none"> <li>Section 1.1 included "<i>and standard cellular products used for transplant</i>" to this section in addition to CAR T products</li> <li>Section 8.1 included <i>standard cellular transplant products in addition to just CAR T products</i></li> <li>Section 8.1.1 added use of <i>checklists STCL-QA-005 FRM 1-4 to document the file review process</i></li> <li>Section 8.1.2 – added "<i>after associated CAR T or standard cellular product has been infused (administered). See STCL-GEN-015 FRM2 Infusion Record Checklist to document disposition of labels</i>"</li> <li>Section 8.1.3 added reference to Avery Labels</li> <li>Section 8.1.4 Added section addressing disposition and reconciliation of ISBT barcodes</li> <li>Section 9 – added references to 9.4 thru 9.9</li> </ul>

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**STCL-GEN-015 JA3 Disposition of Labels, Barcodes and Ribbons JA3****Author**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATER002)		17 Jan 2024, 02:47:41 PM	Approved

**Management**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATER002)		17 Jan 2024, 02:47:56 PM	Approved

**Medical Director**

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		17 Jan 2024, 03:06:28 PM	Approved

**Quality**

Name/Signature	Title	Date	Meaning/Reason
Melissa Ritt (MSR68)	GMP, Quality Assurance Associate I	18 Jan 2024, 10:28:32 AM	Approved

**Document Release**

Name/Signature	Title	Date	Meaning/Reason
Amy McKoy (ACM93)	Document Control Specialist	18 Jan 2024, 03:51:39 PM	Approved