

# STEM CELL LABORATORY (STCL)



DOCUMENT NUMBER: F	FLOW-FORM-011
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**DOCUMENT TITLE:** 

BD FACS CANTO II Maintenance Log

**DOCUMENT NOTES:** 

Document required for the BLA.

**Document Information** 

Revision: 02 Vault: FLOW-Form-rel

Status: Release Document Type: FORM

**Date Information** 

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Effective Date: 01 Jul 2014 Expiration Date:

**Control Information** 

Author: MGREESE Owner: MGREESE

Previous Number: FLOW-FORM-011 Rev 01 Change Number: STCL-CCR-199

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## Instructions for FLOW-FORM-011, BD FACS CANTO II MAINTENANCE LOG for Daily Use

- 1. Record the Month and Year in the first column.
- 2. If equipment is Not In Use, record NIU in START-UP OPERATOR INITIAL block
- 3. If equipment is in use and step is missed or not recorded, record NP (*Not Performed*) in block and write deviation report
- 4. Daily Use
  - a. Initial START-UP OPERATOR INITIAL block
  - b. (✓CHECK) equals task completed or system ok, N/A any field that is *Not Applicable* on the day instrument is used.
  - c. P in field means instrument bead setup <u>Passed</u> specification and is cleared for use. F in field means setup <u>Failed</u> and further troubleshooting is required. Printed result report is placed in the instrument record book.
  - d. Record any problems on separate trouble shooting log page designated for this instrument in the instrument troubleshooting log book.
  - e. Initial shut-down operator initial block.
- 5. System clean is performed, as needed, only when instrument performance indicates a Long Clean is needed. This requires a 75 minute time period in order to complete.
- 6. Place check SERVICE REQURIED AND REPORT FILED block, if technical service call was required and file the report left by the service engineer.
- 7. End of month review must be signed by the flow supervisor or designee.
- 8. Record the date the monthly review was completed.

#### Signature Manifest

**Document Number: FLOW-FORM-011** 

Revision: 02

Title: BD FACS CANTO II Maintenance Log

All dates and times are in Eastern Time.

### FLOW-FORM-011 BD FACS CANTO II Maintenance Log

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Name/Signature	Title	Date	Meaning/Reason	
Melissa Reese (MGREESE)		22 May 2014, 12:31:16 PM	Approved	

#### Manager

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		22 May 2014, 01:44:50 PM	Approved

#### **Medical Director**

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		24 May 2014, 06:32:37 AM	Approved

#### Quality

	Title	Date	Meaning/Reason	
John Carpenter (JPC27)		Title	Title Date 27 May 2014, 12:40:27 PM	

#### **Document Release**

Name/Signature	Title	Date	Meaning/Reason	
Sandy Mulligan (MULLI	026)	11 Jun 2014, 05:00:05 PM	Approved	