

DCR INITIATION

DCR Number		Due Date	
Doc ID and Title(s)	LAB302_AlloSeq cfDNA QC Testing and Analysis		
Current version #	3.0	New Version #	
Document Type:	<input type="checkbox"/> SOP <input type="checkbox"/> Workbook/Checklist <input type="checkbox"/> Tech. Doc	<input type="checkbox"/> Training document <input type="checkbox"/> Form <input type="checkbox"/> Other:	Change Type:
<input type="checkbox"/> New <input type="checkbox"/> Change <input type="checkbox"/> Obsolete			

Description of change(s) to document:

C. Banda made the following changes:

Added Section 5.4.9 to ensure the use of LRM when preparing to sequence.

Added section 5.4.10 to prompt the use of LAB139 when loading the sequencer.

Updated section 5.5.1 for operator to email the sample sheet to their email for use while logged onto the server.

Updated section 5.5.4 to ensure verification of sample sheet downloaded from email.


Updated section 5.5.5 with FastQ folder location

Updated section 5.7 to include BaseSpace analysis.

updated AC fair requirements, CS 21 Jun 22
Impact Assessment / Risk Analysis:

Does this change impact any other documents? <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> SOP <input type="checkbox"/> PI <input type="checkbox"/> IFU <input type="checkbox"/> Forms <input type="checkbox"/> Training Material <input type="checkbox"/> Other:
Is this this change related to a Quality process? <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> Change Control <input type="checkbox"/> NCR <input type="checkbox"/> CAPA <input type="checkbox"/> PMS <input type="checkbox"/> Audit <input type="checkbox"/> Other:
Types of training to be utilised:	<input type="checkbox"/> Read and acknowledge <input type="checkbox"/> Presentation <input type="checkbox"/> Notification <input type="checkbox"/> <input type="checkbox"/> Other:
Review Required	<input checked="" type="checkbox"/> Operations <input type="checkbox"/> R&D <input checked="" type="checkbox"/> Quality <input type="checkbox"/> Regulatory <input type="checkbox"/> Tech. Support <input type="checkbox"/> Other:

APPROVALS: AUTHORISATION FOR RELEASE AND DISTRIBUTION (Add rows if required)

Name	Department	Signature	Date
Author/Subject Matter Expert Chele Banda	Ops		15 Jun 22
Document/Process Owner Gabriella Tassone	Ops		22 Jun 22
QA Approval / Delegate			

ISSUANCE (QA/Authorised Issuer to complete)

New SVN #		Effective Date	
FM401-1 updated?	<input type="checkbox"/> Yes	FM605-12 updated?	<input type="checkbox"/> Yes <input type="checkbox"/> N/A
Superseded version replaced & filed?	<input type="checkbox"/> Yes		<input type="checkbox"/> N/A
Obsolete doc(s) removed from circulation?	<input type="checkbox"/> Yes		<input type="checkbox"/> N/A
QP012 Read & Acknowledgment form initiated?	<input type="checkbox"/> Yes		<input type="checkbox"/> N/A
Workbook Verification Attached?	<input type="checkbox"/> Yes		<input type="checkbox"/> N/A
Authorized Issuer	Name	Signature	Date