


DCR INITIATION			
DCR Number		Due Date	22-Jul-22
Doc ID and Title(s)	FM001-1 CareDx Pty Ltd Product List		
Current version #		New Version #	
Document Type:	<input checked="" type="checkbox"/> SOP <input type="checkbox"/> Workbook/Checklist <input type="checkbox"/> Tech. Doc	<input type="checkbox"/> Training document <input checked="" type="checkbox"/> Form <input type="checkbox"/> Other:	Change Type: <input type="checkbox"/> New <input checked="" type="checkbox"/> Change <input type="checkbox"/> Obsolete
Description of change(s) to document:			
Add "intent to sell" to Brazil. Change SBT in Canada to RUO (as MDL licenses are cancelled).			
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 type="checkbox"/> N/A		<input checked="" type="checkbox"/> Change Control <input type="checkbox"/> NCR <input type="checkbox"/> CAPA <input type="checkbox"/> PMS <input type="checkbox"/> Audit <input type="checkbox"/> Other: CR-2021-080 and CR-2021-071	
Types of training to be utilised:		<input type="checkbox"/> Read and acknowledge <input type="checkbox"/> Presentation <input type="checkbox"/> Notification <input type="checkbox"/> Other: N/A	
Review Required		<input type="checkbox"/> Operations <input type="checkbox"/> R&D <input checked="" type="checkbox"/> Quality <input checked="" 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 Beta Kmiec	Product Manager	Email approval	21-07-22
Document/Process Owner Kelly Hunter John Morri	QA/RA		21-07-22
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Superseded version replaced & filed?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

