

Form ID: 01-21-008A	Rev: 01	Page 2 of 2
Form Title: Non-Conforming Material and Product Concession Form		

<b>Part B: Product Concession</b> ( <i>customer facing</i> )		<b>NCM Number</b>	NCM2020-0023
<b>Initiate Request</b> (Requestor)			
Requestor (Horizon Discovery Employee): Eleanor Williams		Date: 02-Mar-2020	
Part Number/Catalogue Number: HD729		Description of Material: Tru-Q NGS DNA 2 Multiplex	
Lot or Batch Number: 40755	Production Date: 12-Nov-2019	Quantity: 250	PO or SO Number: N/A
Description of Defect: ddPCR does not meet current acceptance criteria for the K-Ras G12V assay (expected allelic frequency: 3.8%, acceptance criteria: 2.66% - 4.94%, observed: 5.30%).			
Risk Evaluation: Specifications for this product are in the process of being updated (K-Ras G12V expected: 5%, acceptance criteria: 4% - 6% VAL-0150/Change Control: CC0001-19). All other assays passed ddPCR testing. This impacted batch (released under concession) will be available to customers and will be notified of the concession prior to purchase via the website (attachment 1). Risk is therefore considered to be low.			Risk Outcome: <input type="checkbox"/> High <input type="checkbox"/> Medium <input checked="" type="checkbox"/> Low
Justification for Product Concession: Release under new specification cannot be done until customers have been notified (as per quality agreements). Release under concession means the product release does not have to be delayed, allowing customers to receive orders sooner.			
<b>Horizon Discovery Product Manager Approval</b>			
Authorization of Customer required for Approval? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
Name: Sian Constantine	Signature: Sian Constantine <small>Digitally signed by Sian Constantine Date: 2020.03.05 10:51:06 Z</small>		Date: 05-Mar-2020
<b>Customer Approval</b>			
Customer (Company Name): N/A			
Customer Approver's Name: N/A		Customer Approver's Signature:	
Customer Approver's Title/Role: N/A		Date:	

Return Product Concession to [quality@horizondiscovery.com](mailto:quality@horizondiscovery.com)