Plant: Abbreviation 1005 MTBU2

LRO#:

LSP-MTBU2-455

Abbreviation

LNN Number

MTBU2

L0468

Bead Part#

Bead Batch

500-2023

1000862912

500-2025

1000829676

500-2419 500-2420 4000829095

1000829717

2-3 Ecisting, RHKC, 4/12/23 RHKC, 4/20/23 1000885439, New, RHKC, 5/1/23

☑ New Lot ☑ Existing Lot	LSP Testing Required ∀es □ No, LSP
Materials Planni By:	ng Approval: Date: 4/17/23



Revision: B Attachment 1

Effective: 07/21/2022 p. 1 of 2

Qualification Lot Release

Conditional Release Material Request Form

			23CRM015
Section One: CRM Scop			
The second secon		en CRM number is populated above)	
Initiator/Department:	Yujin Shin/ Product Transfe	er Request Date:	4/14/2023
Site Impacted:	☐ Sunnyvale	☐ Newark	⊠ Lodi
Molded Part#	Rev]	Part Description (abbreviated)	
N/A	N/A	N/A	
Consumable Part Number	er	Description: (GX/VBA/Pre-Filte	er/OC, etc.)
500-0926		BEAD, SPC, MRSA	
500-2419		BEAD, EZR1, MTB ULTRA V2	
500-2420		BEAD, EZR2, MTB ULTRA V2	
500-2023		BEAD, TSR1, MTB ULTRA, GX	
500-2025		BEAD, TSR2, MTB ULTRA, GX	
Mold Identification #		Cavity Identification #'s	
N/A		N/A	
Manufacturing Equipme	ent #	Description of Automation Line	or Manufacturing Equipment
N/A		N/A	
Assay Material Code		Assay Description	
N/A		N/A	
Qualification Report		Description	
D64217		Xpert MTB Ultra Bead Manufact	turing PV/TMV Plan - Lodi-B2
Validation Phase Gate E	Exit Report	Description	
N/A		N/A	
Section Two: Summary	of Lots to be Released/Justif	ication	
Summary (Provide Qua	lification Lot numbers to be release	ed)	
This PV/TMV is designed	I for manufacturing transfer o	f MTB Ultra Reagent beads to Ceph	eid Lodi B2-IVD. The validation is
being performed per D642	217 and the validation lots car	n be released after the PV report is re	leased on Agile.
Validation lot PO and Ba	tch numbers:		
PO# Batcl	h# P/N	Bead Description	
1078848 100082	9728 500-0926	SPC READ MRSA	

PO#	Batch #	P/N	Bead Description
1078848	1000829728	500-0926	SPC, BEAD, MRSA
1078844	1000829693	500-2419	EZR1, BEAD, MTB ULTRA V2
1078847	1000829717	500-2420	EZR2, BEAD, MTB ULTRA V2
1078837	1000829663	500-2023	TSR1 BEAD, MTB ULTRA, GX
1078843	1000829676	500-2025	TSR2 BEAD, MTB ULTRA, GX
1079169	1000862912	500-2023	TSR1 BEAD, MTB ULTRA, GX
1079378	1000885439	500-2419	EZR1, BEAD, MTB ULTRA V2

Justification for Lot Release

(Provide traceable documents to justify lot release,)

1) Qualification Report Number and Description (report must be released):

D64217 (Xpert MTB Ultra Bead Manufacturing Process and Test method Validation Protocol/Plan-Cepheid Lodi-B2 IVD)

2) Restrictions Document(s) Number and Description (restrictions must be released): N/A

3) Attachment 4 Checklist provided by Initiator and attached to this CRM



Revision: B Attachment 1

Attachment 1 Effective: 07/21/2022 p. 2 of 2

Qualification Lot Release

Conditional Release Material Request Form

23CRM015

(Requestor and Quality Engin	nd Approval for Release eer must verify qualification materials meet e signature required for QE approval	acceptance criteria before s	signing below for lot re	lease)
	Print Name	Signature		Date
Requestor:			*e-sign ⊠	
Quality Engineer:			*e-sign □	¥.
*Signatures can either be	wet or digital using approved Digital	Signature Form per D1	5659	
Section Four: Product R	delease and Closure			
Requested Lot Numbers I	Released 🗆 Yes 🗆 No			
	QA Print Name	QA Signatu	ire .	Date
QA:		0.		
Comments: N/A		•		



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Protocol D64217

DEVIATION REPORT 1

Description

During process validations, TSR1 P/N 500-2023 Batch 1000829663 encountered an equipment (Cepheid Asset ID: L2608) Magnum vacuum overload error that compromised the lyophilization of Sublot B. Further investigations found that EZR1 P/N 500-2419 Batch 1000829693 Sublot B had also utilized the same Magnum (Cepheid Asset ID: L2608) the night prior and the Pirani graph showed that the instrument went back into extra-freeze and restarted primary drying, adding an estimated 4 extra hours to the run time.

Investigation

PO 1078837 was generated for 450,000 beads of TSR1 P/N 500-2023 Batch 1000829663 per the Process and Test Method Validation plan, D64217. Per D64217, all equipment used during process validations had previously undergone IOQ and PQs, in addition to having up to date PM/Calibration records. As part of process validations, bulk formulation of 450,000 beads was split into two Magnum lyophilizers at 225,000 beads each, resulting in the generation of two Sublots – Sublot A and Sublot B. Due to the Magnum equipment "vacuum overload" error, Sublot B was compromised and 23-NC-08401 was initiated to contain the entire TSR1 Batch 1000829663. A BMRAM (EWR-116063) was immediately initiated to investigate the equipment error. In order to rule out that Manufacturing did not accidentally overload the Magnum for TSR1 Batch 1000829663 Sublot B, it was determined to allow the beads to complete the lyophilization cycle and proceed with sieving and moisture testing. Moisture testing passed and sieving confirmed that the Magnum had not been unintentionally overloaded. Further investigations and disposition of the batch will be handled via the nonconformance process.

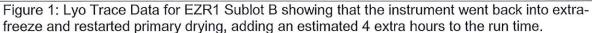
Additionally as part of the investigation, Manufacturing reviewed historical bead batches that had been dried on the same Magnum instrument that had encountered the vacuum overload failure. It was discovered that the same lyophilizer dried 225,000 beads of EZR1 P/N 500-2419 Batch 1000829693 Sublot B for an estimated 4 extra hours the night prior when reviewing the lyo trace data. This EZR1 batch was also being built as part of process validations for MTB Ultra. The lyo trace's Pirani graph showed that the instrument went back into extra-freeze and restarted primary drying, adding an estimated 4 extra hours to the run time. Moisture testing passed. As part of the investigation, FI performed LSP/BR testing on the EZR1 Sublot A and Sublot B beads using reference passing beads for SPC, TSR1, TSR2 and EZR2. The functional testing also passed. However, data analysis showed ~1.5 – 2 Ct delay in Sublot B at Sample Type MDR2, with a few replicates trending outside of the specification limit. Refer to graphs below for further details. As a result, the entirety of EZR1 P/N 500-2419 Batch 1000829693 was also placed on 23-NC-08401. Further investigations and disposition of the batch will be handled via the nonconformance process.

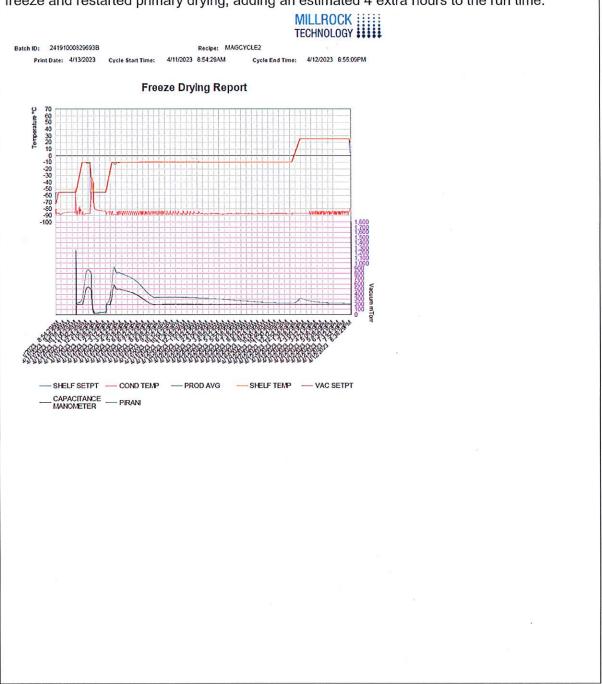


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Protocol D64217





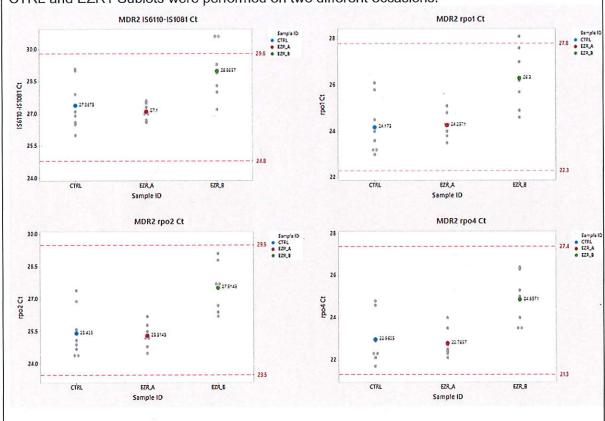


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Figure 2: FI LSP BR Data for EZR1 Sublot A & B at Sample Type MDR2 (POS), TBWT (POS) and SPC (NEG) analysis. EZRA (EZR1 Sublot A) and EZRB (EZR1 Sublot B) were tested using reference passing beads for EZR2, TSR1, TSR2 and SPC. The CTRL sample was a reference set that used all pre-existing passing beads. Sample preparation and testing of the CTRL and EZR1 Sublots were performed on two different occasions.

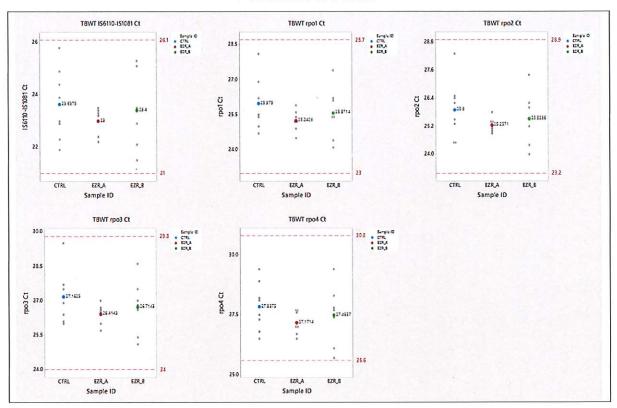




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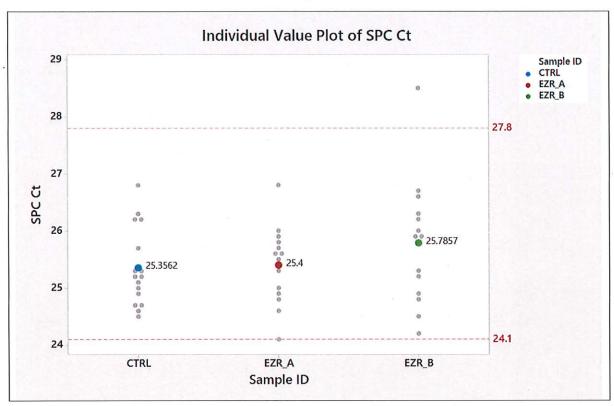




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Risk Assessment

The bead lots produced that had Sublots drying in the impacted Magnum instrument were both contained and immediately placed on 23-NC-08401. They will be dispositioned per the nonconformance process.

The Magnum instrument has been pulled from production and an Out of Service sign has been placed on the instrument. The equipment vendor has been contacted and is scheduled to assess the equipment on 04/25/23.

As part of the corrective action, Manufacturing will be building an additional 225,000 beads for both TSR1 P/N 500-2023 and EZR1 P/N 500-2419. This quantity was determined in order to bring the overall combined build quantities across the two TSR1 batches (Batch 1000829663 Sublot A and new TSR1 build) and EZR1 batches (Batch 1000829693 Sublot A and new EZR1 build) to 450,000 beads. The overall risk with proceeding with the process and test method validations are low due to the below justifications:

 The bead bulk formulation event had originally occurred for 450,000 beads and was split into two lyophilizers. TSR1 Sublot A and EZR1 Sublot A will still proceed forward with testing and passing results will demonstrate that the bulk formulation event was successful.



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- Although the team will not have 2 sublots for TSR1 and EZR1, sublot testing is still being performed for the remaining MTB Ultra beads within LSP 454. Additionally, there will be a new LSP number generated for the new TSR1 and EZR1 bead build, where sublot testing will again be performed utilizing the remaining MTB Ultra bead batches from LSP 454.

Corrective Action / Resolution

Corrective Action: Manufacturing will initiate a new build of another 225,000 beads of TSR1 P/N 500-2023 and EZR1 P/N 500-2419 during concurrent approvals of the Deviation Report. Another LSP number (LSP 455) will be generated in order to test this new TSR1 bead and EZR1 bead manufacturing event. LSP Bead Release will occur two times for this new LSP number. Refer to below for testing information for each LSP.

LSP 454: 2 LSP BR and 2 operators

- EZR1 Batch 1000829693: Sublot A
- EZR2 Batch 1000829717: Sublot A and B
- TSR1 Batch 1000829663: Sublot A
- TSR2 Batch 1000829676: Sublot A and B

LSP 455: 2 LSP BR and 2 operators

- EZR1: New Build, Sublot A
- EZR2 Batch 1000829717; Sublot A and B
- TSR1: New Build, Sublot A
- TSR 2 Batch 1000829676: Sublot A and B

The Magnum instrument has been pulled from production and an Out of Service sign has been placed on the instrument. The equipment vendor has been contacted and is scheduled to assess the equipment on 04/25/23.

Resolution: The process validation and test method validations will be considered successful if LSP BR testing for both LSP 454 and LSP 455 passes the acceptance criteria within the bead release worksheet for MTB Ultra.



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Approval

	Name (print)	Signature	Date
Originator	Kimberly Dang	Refer to DSF	Refer to DSF

Department	Name (print)	Signature	Date
Failure Investigation	Jessica Cortopassi	Refer to DSF	Refer to DSF
Product Transfer	Marilyn Nourse	Refer to DSF	Refer to DSF
Manufacturing	Oriole Moeras	Refer to DSF	Refer to DSF
Quality Systems	Olin Boling	Refer to DSF	Refer to DSF
Quality Systems	Mary McKay	Refer to DSF	Refer to DSF



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Digital Signature Form

Before using this form, you must complete training per D16659

Originator Instructions:

Name the document to be reviewed something unique and easy to identify Verify the document name matches the one in the **Document Name** box. Verify the list of approvers and anyone listed in the **CC only** box are all on the outgoing e-mail. Use the **Comments** box to provide any pertinent information. Save, then distribute the form and document by e-mail.

Document Name:	Protocol D64217 - Deviation Report #1	
Date Delive	red: Apr 27, 2023	
Date Due:	Apr 27, 2023	

information. Save, then distribute the form and document by e-mail. Approver Instructions: CC only: Please review the attached document as soon as possible but no later than the due date. Click on the N/A signature box by your name to sign the document. Return the signed form to the originator. If you have questions or concerns, contact the originator: Originator Kimberly Dang E-mail kimberly.dang@cepheid.com Phone N/A Approved as-is Approved as-is Approved as-is Approved with changes (below) Approved with changes (below) C Approved with changes (below) Kimberl Digitally signed by Digitally signed by Jessica Kimberly Dang y Dang Date: 2023.04.27 N/A N/A Cortopasi Date: 2023.04.28 Department Product Transfer Department | Failure Investigation Department N/A Approved as-is Approved as-is Approved as-is Approved with changes (below) Approved with changes (below) Approved with changes (below) N/A N/A N/A Department N/A Department N/A Department N/A Comments:



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Name the document to be reviewed something unique and easy to identify Verify the document name matches the one in the **Document Name** box. Verify the list of approvers and anyone listed in the **CC only** box are all on the outgoing e-mail. Use the **Comments** box to provide any pertinent information. Save, then distribute the form and document by e-mail.

Document Name:	Protocol D64217 - Deviation Report #1
Date Delive	red: Apr 27, 2023
Date Due:	Apr 27, 2023

Approver Instructions:

Please review the attached document as soon as possible but no later than the due date. Click on the signature box by your name to sign the document. Return the signed form to the originator. If you have questions or concerns, contact the originator:

If you have questions or concerns, contact the originator:

Originator Kimberly Dang E-mail kimberly.dang@cepheid.com Phone N/A

Approved wit	th changes (below)
Kimberly Dang	Kimberl Digitally signed by Mimberly Dang Date: 2023.04.27 17:22:39-07'00'





CC only:

N/A

Approved with	th changes	(below)
Oriole Moeras	Oriole Moeras	Digitally signed by Oriole Moeras Date: 2023.04.28 11:24:39 -07'00'

Mary McKay	Mary McKay	Digitally signed by Mary McKay Date: 2023.04.28 13:18:57 -07'00'
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Approved as	
Approved wi	ith changes (below)
I/A	

Comments:

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Document Number: D6256
Rev: T
Atlachment 1
Effective: 04/26/2022
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Planned Deviation / Temporary Change

22-PDR-131

		,				
		SECT	ION A: Imple	ementation (Completed by Q	uality)	
Quality Reviewer:	Steven,	Airles	Signature:	the state	Effective Date: 9/24/22	
		SE	CTION B: In	itiation (Completed by Initiat	tor)	
Initiator: Jessica (Cortopassi		Department	Name: Failure Investigation	End Date: 05/01/2023 9/30/2023	
Document #	Rev#	Step#		Document Title	Additional Attachments	
D31503	R & up	Section	5 (4)	MTB G4 Product QC Testin	ng Procedure and Worksheet	
D25862	AC & Up	Section POSITIV Type 2)	5 TBWT E (Sample	Xpert MTB/RIF Ultra V2 Pi Worksheet	roduct QC Testing Procedure and	
D13598	AE & Up	Table 4.2 Xpert MTB G4 Bead Release and LSP Testing Worksheet				
D22564	Н & Up	3b Xpert MTB Ultra V2 Bead Release and LSP Testing Worksheet				
D26001	D & Up	Table 2	The state of the s			
D26002	D & Up	Table 2				
D29996	D & Up	3b	3b Xpert MTB/RIF Ultra V2 Bead Release and LSP Testing Workshee			
Affected Part#	Rev#	Lot#/Se	ot# / Serial# Part Description Additional Attachmen			
001-1683	J	C24SEP2	21A	INTROL TBWT-04		
Description of Change (describe current process and in general terms what will be done differently in this change) Additional Attachments					Additional Attachments	
This PDR will char bead release / LS		ent produ	ction TBWT sa	ample dilution for MTB G4,	MTB Ultra V2 assays, and corresponding	
				aterial P/N 001-1683 lot C2 4	ISEP21A.	
Examples of dilut	_					
 For MTB below. 	G4 Positive	Sample (T	BWT) testing	per D31503, the sample dilu	ution will change as proposed in Table 1	
*	Ultra V1 and I in Table 2 k		ve Sample Ty	pe 2 (TBWT) testing per D25	5862, the sample dilution will change as	
1						

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O New end date is 9/30/2023 as noted in the extension request D6256 attachment 4. 7+4/3/23

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Planned Deviation / Temporary Change

22-PDR-131

Table 1. Current and Proposed Change for MTB G4 Positive Sample (TBWT) Dilution:

For 20 Cartridges					
	Current Dilution (based on D31503)	Proposed Dilution			
Materials*	Measure (ml)	Measure (ml)			
500-1315	14.4	15.8			
001-1683	1.6	0.21			
Sample Reagent	32	32			
Total	48	48			
	30-fold dilution	225-fold dilution			

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Planned Deviation / Temporary Change

22-PDR-131

For 10 Cartridges					
Current Dilution (based on D25862)	Proposed Dilution				
Measure (ml)	Measure (ml)				
7.75	<mark>7.96</mark>				
0.24	0.032				
16	16,00				
24.0	24.0				
100-fold dilution	750-fold dilution				
	Current Dilution (based on D25862) Measure (ml) 7.75 0.24 16 24.0				

Justification of Change (describe permissibility to perform change; describe risk and impact to validated state and end-user)	Additional Attachments
The affected TBWT control material lot (C24SEP21A) concentration 1.5e5 cell/ml is concentration used for testing. During Control Qual testing, results were observed this passed according to D38785 (Ct range: 24.5 - 28) it has potential to fail the low study was performed to dilute from 1.5e5 to 2.0e4 cell/ml and tested with MTB-G4 (reference 21-NC-03826). The result was more centered within the spec range.	at Ct = 24.5. Even though er spec limit. A titration

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Planned Deviation / Temporary Change

22-PDR-131

Data from Titration Study:

Figure 1: MTB-G4 ct average data shows 2.0e4 cell/ml dilution has the best performance. Cartridge lot 28826 shows earlier Ct may be due to sampling.

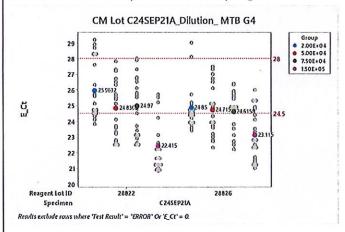
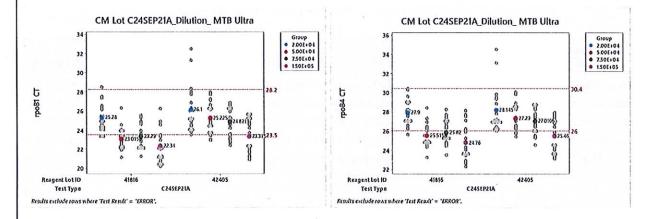


Figure 2: MTB-Ultra ct average data shows 2.0e4 cell/ml dilution is within the spec range.



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Planned Deviation / Temporary Change

22-PDR-131
Risk/Impact Assessment:
Risk/Impact to Manufacturing:
 Low risk The PDR will only affect internal product testing for MTB product: IPT/PQC testing, bead
release and LSP testing
 The dilution change will minimize the number of aborts that are caused due to false call/indeterminate failures rather than the product being non-conforming.
o The dilution change will decrease the amount of LFI retest and Resampling during IPT testing.
Risk/Impact to Customer:
 No impact and no risk as the TBWT control material dilution scheme change is only for internal production testing.
Risk/Impact to MTB final product
 Low impact as the PDR does not change the MTB final product release acceptance criteria and release specification.
Low risk as the proposed change is for the control material only. There is no change to the MTB product. MTB product will have to meet current procedure specification before released.
Action Plan (describe all actions to occur for this change, including: Work Order #; detailed responsibilities & actions of all stakeholder departments; closure criteria; Commitments and responsible person) Additional Attachments
 Control Material group will relabel the current PN 001-1683 lot (C24SEP21A) vials with:
o PRD Number
o Cepheid Part Number
o Description
o Vendor Lot
o Quantity
o Concentration
o Expiration date
Failure Investigation will train QC/IPT and Bead Release/LSP team on the PDR, the new dilution and
requirement to add the PDR to the DHR.
Bead Release/LSP team and IPT team will follow the new TBWT dilution scheme specified per the provided
applicable documents or worksheets when using the affected TBWT (001-1683) control material lot C24Sep21A.
All testing still follows normal production SOP for the IPT/PQC and bead release/LSP testing.
Disposition Action
(describe the requirement for disposition of product or materials manufactured from this change) Additional Attachments
 The TBWT (001-1683) control material lot (C24SEP21A) will be relabeled with PDR number and released for production use under PDR.
Closure Criteria: This PDR will be closed once the affected control material lot is consumed and all commitments have been closed.
Commitments Exist? XES NO (If Yes, complete Attachment 2 Commitment Form)

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ument Number: D6266 Rev: T Attachment 1 Effective: 04/26/2022 p. 6 of 6

Planned Deviation / Temporary Change

22-PDR-131

		? red approvals are received in sec	tion C.			
	and in not reduited solo!!	·				
	Signature	Date	Department Manager Name			
Initiator	Ann Cetur *e-sign [08/24/2022 *c-sign []	Jason Dallwig			
SECTION C: REVIEW AND APPROVAL (Completed by Stakeholder departments)						
	NOTE: Manager or above	e level signatures required				
Department	Name	Signature	Date			
Manufacturing:	Stephan Povio	*e-sign ⊠	*e-sign ₩			
Materials:	Grace Martin	*e-sign \⊅	*e-sign ⊠			
Quality:	Richard Moore	*e-sign ⊠	*e-sign ⊠			
Stakeholder Dept.: Quality Control	Jamie Tobin	*e-sign □	*e-sign			
Stakeholder Dept.: Quality Control/Control Material	Demseen Danielson	NA 3C082422 *c-sign [*e-sign □			
Stakeholder Dept.: Quality Control	la Xiong	*e-sign □	*e-sign □			
Stakeholder Dept.: Quality Control	Sean McIntyre	*e-sign □	*e-sign □			
Stakeholder Dept.: Quality Control	Marites Abriam	*e-sign □	*c-sign □			
Stakeholder Dept.: Quality Systems	Steven Aviles	Alle > *c-sign [8/24/22 *c-sign [
Additional Controls (Quality): YES NO If Yes, explain:	-					
*Signatures can either be wet or	digital using approved Digital	Signature Form per D16659.				

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Attachment 2
Effective: 04/26/2022

Planned Deviation /Temporary Change-Commitment Form

			Quality initial	CX . We did to	v. 4.		
					.v.)		
			NC Number	Ĭ.	4/2		,
	¹⁰ 8	Quality	Date Transferred to NC	Š Z	2/0		
tor)			Date of Closure Verification	20552	3/24/22		
SECTION A: Commitment Form (Completed by Initiator)	DR-131		Date of Commitment Completion	8/9/22	8/10/2022 3/20/23		इट)वर्र
ment Form (Cor	Planned Deviation 22-PDR-131		Due Date	08/10/2022	8/12/2022	3/24/2-22 DD Q9/15/23 sign□ Q5/01/2025 sign□ Q5/01/2025	04/25/23_04/20123 05:02/2025
On / Temp	Planned		Owner Initial/ Date	2/2/{202/ -3* sign	SCINIO.	\$/24/2-72 \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Stan Sign
SECTION A: Commitment Form (Completed by Initiator)	,	Commitments	Owner Name	Demseen Danielson	Jessica Cortopassi	Demseen Danielson	Jessica Cortopassi
Y Z			Description of Commitment	Control Material group will relabel the current PN 001-1683.lot (C24SEP21A) as outlined in attachment 1.	Training for affected group(s): -Lodi IPT/QC/PQC team Lodi Bead Release/LSP Team	Notify the PDR initiator once the affected control material lot is consumed.	Removal of physical copies of this PDR from all manufacturing and testing areas.
			Commitment # (01, 02 etc.)	01	02	. 03	64

() Based on extention and further of 09/30/2023. DOO4/21/23.

(2) Based on extention and forther one date of 9/30/2023, copies wilks need will 9/25/23. SO 04/20/23.

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Planned Deviation / Temporary Change - Commitment Form

			SECTION	A: Commitment For	ment Form (Con	SECTION A: Commitment Form (Completed by Initiator)	tor)			
2				Planned]	Planned Deviation 22-PDR-131)R-131				
			Commitments					Quality		
Commitment # (01, 02 etc.)	Description of Commitment	mitment	Owner Name	Owner Initial/ Date	Due Date	Date of Commitment Completion	Date of Closure Verification	Date Transferred to NC	NC Number	Quality initial
92	Notification to all teams affected once the PDR in inactive.	ams OR in	Jessica Cortopassi	*c-	55/202120 55/202120150	इटाकंटीस				
*Signatures ca All commitmen	*Signatures can either be wet or digital using approved Digital Signature Form per D16659 All commitment due dates should be two weeks before the PDR End Date	ital using at two weeks	oproved Digital Signerates before the PDR E	ital Signature Forn PDR End Date	n per D16659					
COMMITMENTS COMPLETED: VERIFIED BY (Quality):		Name:			Signature:			Date:	-	

User of a printed copy of this document is responsible for using the current revision and discarding expired or obsolete revisions. Current released version of this document resides in Agile Workplace.

Cepheid Confidential Date Printed: 8/8/2022 9:37:38 AM



Effective: 06/27/2013

Digital Signature Form

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Originator Instructions:

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Date Due:	08/10/2022	

Approver Instructions:		CC only:
	on as possible but no later than the due date. cument. Return the signed form to the origina	
f you have questions or concerns, contact	-	ator.
Originator Jessica Cortopassi E-mail	jessica.cortopassi@cepheid.com Phone	925-848-0001
Approved as-is	○ Approved as-is	
Approved with changes (below)	Approved with changes (below)	Approved with changes (below)
Jamie Digitally signed by Jamle Tobin Date: 2022.03.12	N/A	N/A
Tobin Date:2022.08.12	N/A	IN/A
Department Quality Systems	Department N/A	Danasta and MA
Department Quality Systems	Department N/A	Department N/A
Approved as-is	○ Approved as-is	○ Approved as-is
Approved with changes (below)	Approved with changes (below)	Approved with changes (below)
N/A	N/A	N/A
Department N/A	Department N/A	Department N/A
somments:		
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		280



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Page 1 of 1 18/

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Tryou have questions or concerns, contact to	ne originator.	
Originator Jessica Cortopassi E-mail Je	essica.cortopassi@cepheid.com Phone 92	25-848-0001
Approved as-is	C Approved as-is	
C Approved with changes (below)	C Approved with changes (below)	C Approved with changes (below)
Stephan Povio Stephan Povio Povio Date: 2022.03.08		
Stephan Povio Povio Povio Date: 2022.03.08 12:13:48-0700	N/A	N/A
Department Manufacturing	Department N/A	Department N/A
		,
↑ Approved as-is		○ Approved as-is
Approved with changes (below)	Approved with changes (below)	Approved with changes (below)
N/A	N/A	N/A
Department N/A	Department N/A	Department N/A
•		Department 1771
	*	
Comments:		
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,	396	
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Originator Jessica Cortopassi E-mail j	essica.cortopassi@cepheid.com P	hone 925-848-0001
Approved as-is Approved with changes (below) Grace Digitally signed by Grace Martin Date: 2022.08.16 14:59.35-07.00 Department Materials	C Approved as-is C Approved with changes (below N/A Department N/A	(C) Approved as-is (C) Approved with changes (below) (N/A) (Department N/A)
Approved as-is Approved with changes (below) N/A Department N/A	Approved as-is Approved with changes (below N/A Department N/A	Approved as-is Approved with changes (below) N/A Department N/A
Comments:		



Effective: 06/27/2013 Page 1 of 1 11.0

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Originator Jessica Cortopassi E-mail je	essica.cortopassi@cepheid.com Pho	one 925-848-0001
Approved as-is Approved with changes (below) Ia Xiong byla Xiong byla Xiong byla Xiong byla Xiong 11.01:21-0700 Department Quality Control Approved as-is Approved with changes (below) N/A Department N/A	Approved as-is Approved with changes (below) N/A Richard Moore, Septiments St. Director Quality Systems Page 100 Approved as-is Approved as-is Approved with changes (below) N/A Department N/A	N/A Department N/A Approved as-is
Comments:		
9		
	*	



Attachment 8 Rev: BE.1

Effective: 02/09/2023 p. 1 of 1

LSP Testing Line Clearance and Setup Form

LRO # LSP-MTBU2-455	LSP #/Cartridge Lot # 455/1000747628		
Process Description: LSP Fill	Worksheet #: D29996		
1. Line Clearance		Er	ntry
Ensure area/work station is clear of material fro Request.	m previous Production Order/Work	M√Yes	□ N/A
Remove any expired material from the area/wor appropriate.	rk station and discard as	√Yes	□ N/A
Ensure there is adequate separation between a applicable.	ny other processes/lots, if	⊠Yes	□ N/A
Ensure area/work station is clean and orderly.		⊠Yes	□ N/A
2. Line Setup		Er	ntry
Ensure the material to be used matches the LS specified in the specific LSP/SOP Worksheet Part # Batch #	P Lot Number Assignment Form	Yes	□ N/A
Ensure the material to be used has no restriction	ns, if applicable	☑ Yes	□ N/A
For BCR-ABL V2/Ultra: Ensure open cartridge Lot Number Assignment Form	e part and lot number match the LSP	□ Yes	⊠ N/A
3. CRM, PDR, and/or NCR applicable		Er	ntry
Copy of CRM, NCR and/or PDR, present, if applicable	#23CRM015	⊻Yes	□ N/A
Copy of CRM, NCR and/or PDR, forwarded to C		M✓Yes	□ N/A
Comments:	™ N/A		
Performed By: ML	Date: 5/	2/23	
Verified By:	Date: 5	2/23	



Document Number: D10149 Rev: K

Effective: 03/19/2020 p. 1 of 2

GX Cartridge Manual Fill Worksheet

Product Reference #.:	LSP-MTBU2-455_	18	Lot #.:455

(Enter "N/A" for fields that do not apply.)

Signature List

All individuals performing steps must sign in below.

Name	Signature	Initials
Mai Lo	Murk	ML
N/A ML	5/2/22	
	0/2/13	y

1. Reference Documents

Item	Document #	Revision
Product-Specific Fill Procedure	D29998	E

2. Consumable Parts

Item	Part No.	Lot#
Open Cartridge	700-5791	1000747628
Funnel	300-8371	N/A
Frit	(circle one) 300-5115 301-9582	301251
Pre-filter	(circle one) 700-0894 700-5124 700-4100	1000764506
Very Large Retaining Ball	300-4651	N/A
Large Retaining Ball	500-0037	1881621
Small Retaining Ball	300-4344	N/A
Very Small Retaining Ball	300-6099	2098678

3. Reagent Parts

ltem	Part #	Lot#
Bead #1	500-2023	1000862912
Bead #2	500-2025	1000829676 A, B
Bead #3	500-2419	1000885439
Bead #4	500-2420	1000829717 A, B
Bead #5	N/A 500-0926 ML 5/2/23	N/A 1000673125 ML 5/2
Bead #6	N/A	N/A



Effective: 03/19/2020 p. 2 of 2

GX Cartridge Manual Fill Worksheet

Product Reference #.:	LSP-MTBU2-455	Lot #.:	455	
	(Enter "N/A" for fields that do not apply.)			

4. Equipment Retaining Ball, Pre-filter & Frit Insertion Tools

Part No.	ID	GX chamber(s) in which tool was used
300-3424	N/A	N/A
300-3578	N/A	N/A
300-3579	N/A	N/A
300-3580	N/A	N/A
300-3581	N/A	N/A
300-4345	N/A	N/A
300-4432	N/A	N/A
300-4433	N/A	N/A
300-4434	N/A	9, 11
300-6799	N/A	7
300-5643	N/A	1
700-0916	N/A	3
Funnel Insertion Block: 300-3614	N/A	N/A

5. Environment

Item	Time	Humidity	Specification	Pass/Fail
Humidity – Beginning	N/A	N/A		N/A
Humidity – Middle	N/A	N/A	≤ 10%	N/A
Humidity – End	N/A	N/A		N/A

Initial and date after each comr	nent.	N/AL_
In 5 Environment, per D7849, r	nanual fill	does not need to be performed in a dry room. Humidity check and
Spec apply to dry room only.	ML	5/2/23

6. Approved By

Name	Signature	Date
JT	Juden Terry	5/2/23



LSP-MTBU2-455

A. Bead Release/LSP Testing 1. Bead/Reagent Information

LSP Lot #	455	Enter "N/A", if not applicable
Test Date (YYYYMMDD)	20230502	
# of Sublots in this LSP lot	2	1

Replicates per Sublot

1. Enter the number of bead sublots in the box above. If testing a single lot, enter "1".

2. If number of sublots to be tested do not match between beads, enter the largest number of sublots.

3. Match sublots to the extent possible, e.g. test all sublots A together, all sublots B together etc.

4. If there are unmatched sublots, The unmatched sublots can be tested together with any sublot of the other beads.

Example: 500-2023 has sublots A-D whist other beads have sublots A-C. 500-2023 Sublot D can then be tested with any combination of beads A-C for the other bead types.

Beads	Part#	Lot#	Previously released Bead? (Y/N)	Write which sublots are tested e.g. A, B, C (N/A is none)
BEAD,TSR1,MTB,ULTRA,GX	500-2023	1000662912	N	N/A
BEAD,TSR2,MTB,ULTRA,GX	500-2025	1000829676	N	A, B
BEAD,EZR1,MTB ULTRA V2	500-2419	1000885439	N	N/A
BEAD,EZR2,MTB ULTRA V2	500-2420	1000829717	N	A, B
MRSA SPC Bead	500-0926	1000673125	N/A	

Cartridge-related material	Part#	Lot#
Open Cartridge RPST, no vent cut (50µL)	700-5114 or 700-5791 or 700-5754 Underscore one	1000747628
Sma'l Retaining Ba'l	300-6099	2098678
Large Retaining Ball	500-0037	1881621
Frit	300-5115 or 301-9582 Underscore one	301251
Pre-fiter	700-5124	1000764506
Retain Ball Insertion Tool (chamber 1)	300-5643	N/A
Retain Ball Insertion Tool (chamber 11)	300-4434	N/A
Frit insertion tool	300-6799	N/A
Pre-fiter insertion tool	700-0916	N/A

Liquid reagents and control material	Part#	Lot#	
TET	500-1315 or 500-0995 Underscore one	1000728681-E	5
Sample Reagent	700-5208 700-6052 <u>Underscore one</u>	1000509051	
			Expiration Date
MMQCITBWT	001-1683	C24SEP21A	9/30/2023
MMQCITB1081MDR2	001-1923	M03MAY22A	5/31/2024

No. of Sublots	2			
Sublot		Replicates		T. 1. 11 1. 1. 1
Subjet	Neg	TBWT	MDR 2	TotaVsublot
Α	14	7	7	28
В	14	7	7	28
С	N/A	N/A	N/A	N/A
D	N/A	N/A	N/A	N/A
E	N/A	N/A	N/A	N/A
F	N/A	N/A	N/A	N/A
G	N/A	N/A	N/A	N/A
Н	N/A	N/A	N/A	N/A
1	N/A	N/A	N/A	N/A
J	N/A	N/A	N/A	N/A
Total	28	14	14	56

Recommended dry carts to prepare per Sublot.

Sublot	Total/sublot
Α	30
В	30
С	N/A
D	N/A
E	N/A
F	N/A
G	N/A
Н	N/A
1	N/A
J	N/A
Total	60



2. Cartridge and Sample Preparation

2.1 Cartridge preparation
NOTE: For each step of cartridge preparation, verify that all components are inserted correctly.
a. Obtain cartridges in accordance with the table above.
b. If manual insertion of pre-fitters or first is required, follow instructions in 2.2 and/or 2.3. Otherwise, proceed to subsection 2.4.

2.2 Pre-filter insertion (Chamber 3)

- Attach a pre-fiter at the end of the pre-fiter insertion tool 700-0916.

 Place the cartridge upright on a flat, solid surface.
- c. Align the pre-fiter on top of the groove at the bottom of Chamber 3. Push down to secure.
- d. Remove the pre-fiter insertion tool from the cartridge.

2.3 Frit insertion (Chamber 7)

- a. Grasp a frit along its long sides with the forceps.
 b. Align the frit over the opening to Chamber 7. The base of the frit should be near the plunger opening and the apex of the frit should be pointed away from the plunger opening.

- c. Lower the frit approximately halfway into Chamber 7. Release the forceps' grasp on the frit.
 d. Close the forceps and use the closed ends to gently push the frit into Chamber 7 until you feel resistance.
 e. Use the Insertion tool (15mm) 300-6799 to push the frit down into chamber 7 until the proper depth has been achieved.

f. Remove the Insertion tool from the cartridge.

- 2.4 Bead preparation
 a. Insert 1 small retain ball (300-6099) into Chamber 9.
 b. Insert 1 EZRT Bead (500-2419) into Chamber 9.
 c. Insert 1 TSRT Bead (500-2023) into Chamber 9.
 d. Insert 1 small retain ball (300-6099) into Chamber 9.

 - e. Insert 1 large retain ball (500-0037) into Chamber 9. f. Push large retain ball down with 300-4434 Retain Ball Insertion Tool.

 - q. Insert 1 small retain ball (300-6099) into Chamber 11.
 h. Insert 1 EZR2 Bead (500-2420) into Chamber 11.
 i. Insert 1 TSR2 Bead (600-2025) into Chamber 11.
 i. Insert 1 small retain ball (300-6099) into Chamber 11.
 k. Insert 1 small retain ball (300-6099) into Chamber 11.
 i. Push large retain ball (300-0097) into Chamber 11.
 i. Push large retain ball down with 300-4434 Retain Ball Insertion Tool.
 - m. Insert 1 small retain ball (300-6099) into Chamber 1.
 - n. Insert 1 SPC Bead (500-0926) into Chamber 1.

 - in insert 1 SPC Design (2009-22) in Chamber 1.

 D. Insert 1 Small retain bail (300-809) into Chamber 1.

 D. Insert 1 Singer retain bail (500-0037) into Chamber 1.

 P Ush large retain bail down with 300-5648 Retain Bail Insertion Tool.

 T Verify that all remaining beads are sealed in bead containers.

s. Label 28 cartridges with sample type "NEG" and replicate number.

t Label 14 cartridges with sample type "TBWT" and replicate number, u. Label 14 cartridges with sample type "MDR2" and replicate number

2.5 Liquid reagents fill
a. Add 4mL of TET Buffer to chamber 2 of each cartridge.

b Add 4mL of TET Buffer to chamber 5 of each cartridge

3. Sample Preparation

a. It is recommended to prepare the negative sample mix and load the negative control cartridges prior to handling any positive control material in order to minimize the risk of false positives.

Any surplus from the prepared negative control material mixes can be stored at +4°C up to 24h and can be used for retesting of failed replicates.

c. Any surplus from the prepared positive control mixes can be stored at +4°C up to 4h and can be used for retesting of falled replicates. Discard positive control mixes and prepare a new mix if needing to retest beyond > 4h.

3a. NEGATIVES

CAUTION - Sample Reagent contains Sodium Hydroxide & Isopropanol. Be sure to wear personal protective equipment.

a. If needed, pool multiple bottles of sample reagent into a single container.

b. prepare negative sample mix in a suitable container according to the table below

Material	Part#	Volume (mL)
TET	500-1315 or 500-0995	22.4
Sample Reagent	700-5208 700-6052	44.8
Total Volume	N/A	67.2

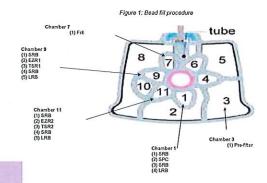
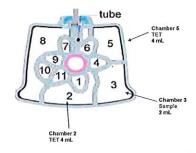


Figure 2: Liquid Reagents fill procedure



Note: An additional 20% have been added to the required volumes in order to allow for retesting of failed replicates without preparing a new mixture.

- c. Vortex for 5 seconds
- d. Store the mixture at room temperature until ready for use.
- e. Add 2mL of TET/SR mixture prepared in section 3a to chamber 3 of the replicates marked "NEG".

CAUTION - Sample Reagent contains Sodium Hydroxide & Isopropanol. Be sure to wear personal protective equipment.

- a. If needed, pool multiple bottles of sample reagent into a single container.
 b. prepare TBWT sample mix according to the table below. Vortex stock tube of INTROL TBWT cells for 5 seconds prior to adding to the mix.

GeneXpert Information



Material	Part#	Volume (mL)
TET	500-1315 or 500-0995	10.99
Sample Reagent	700-5208 700-6052	22.7
MMQCI TBWT	001-1683	0.340
Total Volume	N/A	34.0

Note: A surplus has been added to the required volumes in order to allow for relesting of failed replicates without preparing a new mixture.

- c. Vortex the prepared sample mix for 5 seconds.
- d. Store the mixture at room temperature and load the cartridges within the hour,
 e. Add 2mL of TET/Sample/SR mixture prepared in section 3b to chamber 3 of the replicates marked "TBWT".

3c. POSITIVES-TB1081MDR2

CAUTION - Sample Reagent contains Sodium Hydroxide & Isopropanol. Be sure to wear personal protective equipment.

a. If needed, pool multiple bottles of sample reagent into a single container.

b. prepare MDR2 sample mix according to the table below. Vortex stock tube of INTROL TB1081MDR2 cells for 5 seconds prior to adding to the mix.

Material	Part#	Volume (mL)
TET	500-1315 or 500-0995	10.65
Sample Reagent	700-5208 700-6052	22.7
MMQCITB1081MDR2	001-1923	0.680
Total Volume	N/A	34.0

Note: A surplus has been added to the required volumes in order to allow for retesting of failed replicates without preparing a new mixture.

- c. Vortex the prepared sample mix for 5 seconds.
- d. Store the mixture at room temperature and load the cartridges within the hour.

 e. Add 2mL of TET/Sample/SR mixture prepared above in Section 3c to chamber 3 of the replicates marked "MDR2".

GeneXpert Testing
Run catridges on the GX systems per instructions in D2999T Xpert MTB Utra LSP and Bead Release Testing Procedure.
Select the most currently released assay protocol, P0808 (MTB-RIF Utra V2 BeadLSP). Obtain from Agile if necessary.

5. Equipment

Cepheld ID	Cal. Due Date
L3443	06/30/2023
L2690	06/30/2023
L2682	06/30/2023

GeneXpert Software Version 6.4

L3323 04/30/2024 02/29/2024 L3321

Comments (optional):

Refer to D64217 and Deviation Report 1. Refer to 22PDR131 for Positives-TBWT's dilution recipe.

ML 5/2/23



L Result Summary

LSP Lot#	455
Test Date	
(YYYYMMDD)	20230502
# of Sublots in this LSP lot	2

Table 1: Beads used in testing				
Bearls	Part#	Part# Lot# Pr		Sublots tested for this lot
BEAD TSRIMTBULTRAGE	500-2023	1000862912	N	N/A
BEAD TSR2 MTB ULTRAGX	500-2025	1000829576	N	A.B
BEAD EZRI MTB ULTRA V2	500-2419	1000885439	l N	N/A
EEAD EZR2 MTB ULTRA V2	500-2420	1000829717	N	AB

	MRSA SPC Bead	500-0926 1000673125			
able 2: Validity	and Outiler test results				
Sample type	Sample ID	Test start time	Result	Validity test PASSTAIL	Type of failure
	455A_NEG_01	2023-05-02 10:52	NVALIO	Test Result FAUS	Mon Falure
	455A_NEG_02	2023-05-02 10 52	MTB NOT DETECTED	Test Result PASSES	none
	455A_NEG_03	2023-05-02 10 52	MTB NOT DETECTED	Test Result FASSES	rone
	455A_NEG_04	2023-05-02 10.53	MTB NOT DETECTED	Test Result PASSES	none
	456A_NEG_05	2023-05-02 10 53	MTB NOT DETECTED	Test Result PASSES	none
	455A_NEG_06	2023-05-02 10 53	MTB NOT DETECTED	Test Result PASSES	none
	455A_NEG_07	2023-05-02 10:53	MTB NOT DETECTED	Test Result PASSES	NO.
	455A_NEG_08	2023-05-02 10 54	MTB NOT DETECTED	Test Result PASSES	none
	USA_NEG_09	2023-05-02 10:54	MTB NOT DETECTED	Test Result PASSES	tone
	455A_NEG_10	2023-05-02 10 54	MTB NOT DETECTED	TedResotFASSES	none
	456A_NEG_11	2023-05-02 10:55	MTB NOT DETECTED	Test Peruit PASSES	1016
	456A_NEG_12	2023-05-02 10 55	MTB NOT DETECTED	Test Result FASSES	none
	456A_NEG_13	2023-05-02 10:55	MTB NOT DETECTED	Test Resett PASSES	nere!
	455A_NEG_14	2023-05-02 10 56	MTB NOT DETECTED	Test Result PASSES	norma.
	4558_NEG_01	2023-05-02 10 56	MTB NOT DETECTED	Test Result FASSES	TOTAL .
	4558_NEG_02	2023-05-02 10 56	MTB NOT DETECTED	Test Result PASSES	none
	4568_NEG_03	2023-05-02 10 57	MTB NOT DETECTED	Test Recut PASSES	none
	4558_NEG_04	2023-05-02 10.57	MTB NOT DETECTED	Test Reset PASSES	none
	4558_NEG_66	2023-05-02 10 57	MTB NOT DETECTED	Test Result PASSES	7016
	4558_NEG_06	2023-05-02 10:58	MTB NOT DETECTED	Test Result PASSES	nore
	45/A_NEG_07	2023-05-02 10:58	MTB NOT DETECTED	Test Result PASSES	none
	4568_NEG_08	2023-05-02 10.58	MTB NOT DETECTED	Test Result FASSES	nore
	4558_NEG_09	2023-05-02 10 58	MTB NOT DETECTED	Yest Result PASSES	tote
	4558_NEG_10	2023-05-02 10 59	MTB NOT DETECTED	Test Result PASSES	hore
	4568_NEG_11	2023-05-02 10:59	MTB NOT DETECTED	Test Result PASSES	hone
MTBU2 NEG	4558_NEQ_12	2023-05-02 10 59	MTB NOT DETECTED	Test Result PASSES	none
	4558_NEO_13	2023-05-02 11:00	MTB NOT DETECTED	Test Result PASSES	none
	4558_NEG_14	2023-05-02 11:00	MTB NOT DETECTED	Test Poset PASSES	none
	1		NO ON	NA	NA
			NO	N/A	NA
			ND	N/A	NA
			NO	NA.	NA.
	1.	Market Areas	NO	NA NA	NA
	10	NAME OF BRIDE	NO	N/A	NA
	19		ND	N/A	NA
	1.		ND	NA NA	NA.
	12		NO NO	NA	NA
	10		NO	N/A	N/A
		10	ND	NA NA	NA
	1	13	NO	NA NA	NA.
		1	NO	N/A	NA
		1 %	10	N/A	NA.
		10	10	NA	NA NA
		1	ND ND	NA NA	NA NA
		1	NO NO	NA NA	NA NA
		1	10	NA NA	NA NA
		1	ND ND	NA NA	NA NA
		1	NO NO	NA NA	NA NA
		1	NO NO	NA NA	NA.
		1			
			NO	N/A	NA



LSP-MTBU2-455

Sample type	Sample ID	Test start time	Result	Validay test PASS FAIL	Type of failure	IS4110- IS1081 Ct Outlier	rpo1 Ct Outlier	rpo2 Ct Outlier	rpe3 Ct Outlier	rpol Ct Outlier	SPCCI
	455A_TBWT_01	2023-05-02 11:06	MTB DETECTED LOW/RIF Resistance NOT DETECTED	Text Parent PARSES	574	No	No	No	No	No	250
	456A_TBWT_02	2023-05-02 11 06	MTB DETECTED VERY LOW RF	Tind Result PASSES	tora	No	No	No	No	No	27.0
	455A_TBWT_03	2023-05-02 11:07	MTB DETECTED LOW/RIF Resistance NOT DETECTED	Test Rissot PASSES	204	No	No	No	No	No	26.7
	455A_TBWT_04	2023-05-02 11 07	MTB DETECTED LOW RF Resistance NOT DETECTED	Test Result PASSES	A354	No	1io	No	No	No	25 3
	455A_TBWT_05	2023-05-02 11 07	MTB DETECTED VERY LOW RF Resistance NOT DETECTED	Text Result PASSES	note	No	No	No	No	No	27.9
	455A_TBWT_06	2023-05-02 11 08	MTB DETECTED LOW RF Resistance NOT DETECTED	Test Result PASSES	2004	No	No	No	No	No	25.5
	455A_TBWT_07	2023-05-02 11 08	MTB DETECTED LOW/RIF Resistance NOT DETECTED	Technicipasses	ACCE	No	No	No	No	No	25.7
	4558_TBWT_01	2023-05-02 11.08	MTB DETECTED VERY LOW RIF Resistance NOT DETECTED	Test Resut PASSES	total	No	No	No	No	No	27.4
	4558_TBWT_02	2023-05-02 11 09	MTB DETECTED LOW/RIF Resistance NOT DETECTED	TextResul PANSES	none	No	No	No	No	No	257
	4568_TBWT_03	2023-05-02 11 09	MTB DETECTED LOW RF Resistance	Test Result PASSES	nene	No	No	No	No	No	25.1
	4558_TBWT_04	2023-05-02 11 09	MTB DETECTED LOW RIF Resistance	TestResul FASSES	none	No	No	No	No	No	26.8
	4558_TBWT_05	2023-05-02 11:10	MTB DETECTED LOW RF Resistance NOT DETECTED	Test Resort PASSES	104	No	No	No	No	No	26.8
	4558_TBWT_06	2023-05-02 11 10	MTB DETECTED LOW/RF Resistance	Test Result PARSES	nora	No	No	No	No	No	257
	4558_TBNT_07	2023-05-02 11 10	MTB DETECTED LOW RF Resistance	Test Result PASSES	2016	No	No	No	No	No	25.6
		A COMPANY	NOT DETECTED NO	NA	NA	NA	NA	NA	N/A	NA.	NA
			NO	NA NA	NA	NA	NA	NA	NIA	NA	NA
			ND	NA NA	NA	NA	NA.	NA	NA	NA	NA
			ND	NA NA	NA NA	NA	NA	NA	NA.	NA	NA.
			NO	NA NA	NA	N/A	NA	N/A	NA	N/A	NA
	10		10	NA	NA	NA.	NA	NA	NA.	NA.	N/A
	10	de la posiciona Ac	10	NA NA	NA	NA	NA	NA	NA.	N/A	N/A
	17		NO	NA NA	NA.	NA	NA	NA	NA	NA	N/A
			10	NA	NA	N/A	NA	NA	NA.	NA.	NA NA
	1.5		NO	NA NA	NA	NA	NA	NA	NA	NA	NA.
	17		NO	NA.	NA	NA.	NA	NA	N/A	NA	NA
TEWT			NO.	NA NA	NA	NA	NA	NA	NA	NA.	NA
	15		NO ON	N/A	NA	NA.	NA	NA	NA	NA	NA
	17		NO	NA NA	N/A	NA	NA	NA	NA	NA.	NA
	1-		10	NA NA	NA.	NA	NA.	NA	NA	NA	NA
	15		NO	NA NA	NA	NA.	NA	NA.	N/A	N/A	NA
	10		NO NO	NA NA	NA	NA	NA.	NA.	NA.	NA.	N/A
			100	NA NA	NA	NA	NA.	NA.	NA	NA.	N/A
			NO NO	NA NA	NA.	NA NA	NA.	NA	N/A	NA.	NA NA
			10	NA	NA NA	NA.	NA.	NA	NA.	NA.	
			10	N/A	NA NA	NA NA	NA NA	NA NA	NA NA	NA NA	NA NA
			100	NA NA	NA NA	-					
			100	NA NA	NA.	NA	N/A	N/A	N/A	NA	NA
			NO NO	NA NA	NA NA	NA NA	NA	NA.	NA	NA	NA
		_		NA NA	N/A	1200	NA	NA	NA	NA	NA
			NO NO	NA NA	NA NA	N/A	NA	NA	NA	NA .	NA
			NO NO		10.000	NA	NA	N/A	NA	NA	NA
		7.5	10	N/A	NA	NA	NA	NA.	NA	NA	NA
			10	NA NA	NA NA	NA	NA	N/A	NA	NA .	NA
			10	NA	NA NA	NA	NA	NA	NA	NA	NA
			10	NA NA	N/A	NA	NA	NA.	NA	NA	NA
			ND	NA	NA.	N/A	NA	NA	NA	NA	N/A
			NO	NA NA	NA NA	NA	NA	NA	NA	NA	NA
			10	NA .	NA	NA.	NA	NA	N/A	NA	N/A
			NO	NA	NA	NA	N/A	NA	NA	NA	NA
	Market Street Street	Market Market 1996	ND	NA	NA	NA	NA	NA	NA	NA	NA
			ND ND	NA	NA	NA	NA	NA	NA	NA	NA



	455A_MGR2_01	2023-05-02 11 11	MTB DETECTED LOW RF Resistance	Test Frank PASSES	mane	No	No	No	STREET, STREET,	No	26.0
	455A_MCR2_02	2023-05-02 11 11	MTB DETECTED LOW/RIF Resistance	Test Result PASSES	2004	No	No	No		tio	27.7
	455A_MDR2_03	2023-05-02 11 12	MTB DETECTED LOW/R F Resistance	Test Result FASCES	rane	No	No	No	19.5	No	25.9
	455A_MDR2_04	2023-05-02 11 12	MTB DETECTED LOW/RF Resistance	Test Rosat PASSES	none	No	No	No	TE!	No	26
	456A_MOR2_05	2023-05-02 11-12	MTB DETECTED LOW/RF Resistance	Test Rose PASSES	total	No	No	No	100	No	24
	455A_MOR2_06	2023-05-02 11 13	MTB DETECTED LOW/R/F Resistance	Test Rimit PASSES	2004	No	No	No		No	27.
	455A_MDR2_67	2023-05-02 11 13	MTB DETECTED LOW/RIF Resistance	Test Rocat PASSES	none:	No	No	No	23	No	29
	455B_MDR2_01	2023-05-02 11.14	MTB DETECTED LOW RIF Resistance	Test Result PASSES	none	No	No	No		No	25
	4568_MDR2_02	2023-05-02 11 14	MTB DETECTED LOW/RIF Resistance	Tart Recir FASSES	2014	No	No	No		No	26
	4558_MDR2_03	2023-05-02 11 14	MTB DETECTED LOW/RIF Resistance	Test Resist PASSES	rone	No	No	No	15.50	No	27
	4558_MDR2_04	2023-05-02 11 14	MTB DETECTED LOW R F Resistance	Test Remit PASSES	Pone	No	No	No	1300	No	25
	4558_MDR2_05	2023-05-02 (1.15	MTB DETECTED LOW,RF Resistance	Test Result PASSES	nane	No	No	No		No	25
	4568_MDR2_06	2023-05-02 11 15	DETECTED MTB DETECTED LOW/RF Resistance	Ter Real PASSES	rose	No	No	No		No	25
	4558_MCR2_07	2023-05-02 11 16	MTB DETECTED LOW, RF Residance	Test Result FASSES	rora.	No	No	No		No	25
	4000_MORZ_07	2007001110	DETECTED NO	NA	NA NA	NA NA	NA	NA		NA NA	N
			ND ND	NA NA	NA.	N/A		NA.		NA NA	N
				NA NA	NA NA		NA				_
			NO NO	NA NA	NA NA	NA.	N/A	NA		NA	10
			ND	NA NA		NA	N/A	NA		NA	10
			0.0	NA NA	NA NA	NA	NA	NA	934	NA .	N
			18			NA	NA.	NA	155	NA	N
			NO	NA	NA .	NA	NA	NA.		N/A	No
	12		100	N/A	NA	NA	N/A	NA	1	NA	N
	10		NO	NA NA	NA	NA	NA.	NA		NA	N
	\'		ND	NA.	NA	NA	NA	NIA	330	NA	N
MOR 2			ND	NA	NA	NA	NA.	NA	N'A	NA	N
	13		ND	N/A	NA .	NA	NA	NA	357	NA	N
	1.0		NO	N/A	NA	NA	N/A	NA		NA	N
			NO NO	NA.	NA	NA	NA	NA	1830	NA	N
	101		ND	N/A	NA	NA	NA	NA		NA	14
	\		ND	NA NA	NA NA	NA	NA	NA		NA	N
			NO	NA NA	NA NA	NA	NA	N/A		NA	N
		٥	ND	NA.	NA	NA	NA	NA.		NA	N
		<i>(</i> 2)	ND	N/A	NA	NA	NA	NA		N/A	N
			ND	NA NA	NA	NA	NA	NA		NA	N
			ND	NA NA	NA	NA	NA	NA		NA	N
			ND	NA NA	NA	NA	NA	NA	1	NA	N
			NO	NA.	NA	NA	NA	N/A	200	NA	10
			ND	NA	N/A	NA	NA	NA	33	NA	N
			NO	NA	NA.	NA	NA	NA	1 1 1 1	N/A	N:
	WEST HOLDS		ND	NA	N/A.	NA	NA	NA	329	NA.	N
			ND CAN	NA	NA NA	NA	NA	NA	1	NA	10
			ND	NA.	NA	NA	NA	NA	15 85	NA	N
	Market School School		NO NO	NA .	NA.	NA	NA	NA	2 3 1	NA	N
	To all the second		ND	NA	NA.	NA	NA	NA	1	NA	14
			ND OA	NA NA	NA.	NA	NA	NA	3.73	NA	1e
		\	ND CA	N/A	N/A	NA	NA	NA	1000	NA.	N
	STATE OF THE SAME		COL	NA	NA	NA	N/A	NA	936	NA	N
			NO	N/A	NA	NA	NA	NA	1	NA	N



LSP-MTBU2-455

Analyte Name	Pri Cak 1,3	Pris Chk 1,3 Max	Pri Chk 2 Min	Prò Chk 2 Max	Norm. Factor
SPC	0	473	151	0	376
IS1081-IS6110	0	334	182	0	456
rpo1	0	343	225	0	563
rpo2	0	143	111	0	278
rpo3	0	229	139	0	347
rpo4	0	189	127	0	317
OC1	0	170	39	0	NA.
OC2	0	164	37	0	NA NA
rpo1 melt	0	0	0	0	0
rpo2 melt	0	0	0	0	0
rpo3 meit	0	0	0	0	0
rpc4 melt	0	0	0	0	0
rpa1 Mut melt	0	0	0	0	0
rpo2 Mut melt	0	0	0	0	0
rpo3 Mut melt	0	0	0	0	0
rpo4 Mut meit A	0	0	0	0	0
rpo4 Mut meit B	0	0	0	0	0

Select analytes to include in the exported public.	
97 SPC	
₩ 151001256119	
2 rpot	
₹ rpe2	
Com St	
P pot	
2 oct	
S 003	
☐ mot met	
☐ rpo2 melt	
fron Corp.	
☐ rpo4 melt	
☐ spof Mut melt	
☐ spo2 that melt	
☐ rpo3 Mut meh	
☐ spoil Mat met A	
☐ spod Mut melt B	

Target	SPC Ct		SPC EPF	
Negative Results Average	3	131		
Specification	Lower limit	Upper limit (maan)	Lower Emit	
	24.1	27.8	54.0	
PASSFAIL	PASS	PASS	PASS	
Overall Result		PASS		

Target	156110-151081 Ct	156110-151001 Ct		rpo1Ct		ISINE POICE		rpo1 EPF	rpo11	re .	rpo1 Melt Peak Height	rpo	201	rpo2 EPF	rpe:	2Tm	rpo2 Mait I Height
Arerage	243		438	2	7.1	379	69.5		73	21	1.0	245	7	1.2	98		
Specification	Lower limit (mean)	Upper limit (mean)	Lower limit (mean)	Lower limit (mean)	Upper limit (mean)	Lower limit (mean)	Lowerlimit (mem)	Upper limit (mean)	Lower limit (mean)	Lower Emit (mean)	Upper Emit (mean)	Lower limit (mean)	Lower limit (mean)	Upper limit (mean)	Lower lin		
	21.0	26.1	376.0	23.0	28.7	300.0	68.5	70.6	47.0	23.2	28.9	196.0	723	74.3	50.0		
PASSTAL	PASS		PASS	PASS		PASS	PASS		FASS	PASS		PASS	PI	35	PASS		
Target	розся		rpo3 EPF	rpo!	Tm	rpo3 Melt Peak Height	rpo4 (CH	rpol EPF	rpol	Im	rpod Melk Peak Height					
Average	28.2		166	71	.9	87	29.1		124	61	2	90					
Specification	Lower limit (mem)	Upper limit (mean)	Lower limit (mean)	Lower fimit (mean)	Upper limit (mean)	Lower limit (mean)	Lower limit (mean)	Upper limit (mean)	Lower limit (mean)	Lower Smit (mean)	Upper limit (mean)	Lower Emit (mem)					
	24.0	29.8	119.0	75.0	77.0	57.0	25.5	30.8	86.0	66.2	68.2	55.0					
PASSFAIL	PASS		PASS	PA	22	PASS	PAS	5	PASS	PA	55	PASS					
Overall Result	PASS																

Target	156119-451081 C	P. Land	IS4110-LS1081 EPF	rpo	101	rpo1 EPF	rpo1	in .	rpo1 Melt Feak Helohi	rpo	2 Ct	rpo2 EPF	rpe	2 Tm	rpo2 Melt Peak Helohi
Average	28.3		107	2	5.8	384	63.	5	43	2	6.8	169	7	2.3	42
Specification	Lower limit (mean)	Upper limit (mean)	Lower limit (mean)	Lower limit (mean)	Upper limit (mean)	Lower limit (mean)	Lower limit (mean)	Upper limit (maan)	Lower limit (mean)	Lowse limit (mean)	Upper limit (mean)	Lower Emit (mass)	Lower Ent (mem)	Upper Emit	Lower Hmit (mean)
	24.8	29.8	72.0	22.3	27.8	250.0	68.7	70.7	15.0	23.5	29.5	106.0	63.4	71.4	10.0
PASSFAIL	PASS		PASS	P)	uss	PASS	PAS	5	PASS	PA	55	PASS	P.	uss	PASS
Target	rpo3 Ct		rpo1 EPF	rpo:	3 Tm	rpo3 Melt Peak Helght	rpol	Ct	rpo4 EPF	rpod	Tm	rpod Mala Peak Height			
Average						AL THE	24.		398	71	1.8	167			
Specification			NA				Lower limit (mean)	Upper limit fmeanl	Lower limit (mean)	Lower Emit (mass)	Upper limit (mean)	Lower Emit Imeans			
							213	27.A	241.0	72.8	74.8	62.0			
PASSFAIL							FAS	2	FASS	PA.	55	PASS			
Overall Result	PASS	C. S. Contraction										2000			



I SPATELOUS

Analyte	PC2 Average	Lower Limit	Upper Limit	PASSFAIL	
SPC	376	200	800	PASS PASS	
IS1061-IS6110	456	224	896		
rpot	563	319	1276		
rpo2	278	158	632	PASS	
rpo3	347	200	800	PASS	
rpo4	317	152	648	PASS	
QC1	97	59	236	PASS	
OC2	93	51	206	PASS	
Overall Result		ASS			

Failure Analysis	PASS .		
Sublot PC and Ct comparison	PASS		
Probe check (LSP Values)	PASS:		
Bead Release Results	PASS		

