


Plant : 1005
Abbreviation MTBU2
LRO # : LSP-MTBU2-455

Abbreviation MTBU2
LNN Number L0468

Bead Part # Bead Batch
500-2023 1000862912
500-2025 1000829676
500-2419 ~~1000829699~~
500-2420 1000829717

} → ~~Existing, RHKE, 4/17/23~~
RHKC, 4/20/23
1000885439, New, RHKC, 5/1/23

<input checked="" type="checkbox"/> New Lot	<input type="checkbox"/> Existing Lot	LSP Testing Required
		<input checked="" type="checkbox"/> Yes
		<input type="checkbox"/> No, LSP-_____
Materials Planning Approval:		
By: <u></u>	Date: <u>4/17/23</u>	



Qualification Lot Release
 Conditional Release Material Request Form

23CRM015

Section One: CRM Scope

(Note: This attachment may be used for placarding when CRM number is populated above)

Initiator/Department: Yujin Shin/ Product Transfer **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	Description: (GX/VBA/Pre-Filter/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 Equipment #	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 Manufacturing PV/TMV Plan - Lodi-B2	
Validation Phase Gate Exit Report	Description	
N/A	N/A	

Section Two: Summary of Lots to be Released/Justification

Summary *(Provide Qualification Lot numbers to be released)*

This PV/TMV is designed for manufacturing transfer of MTB Ultra Reagent beads to Cepheid Lodi B2-IVD. The validation is being performed per D64217 and the validation lots can be released after the PV report is released on Agile.

Validation lot PO and Batch numbers:

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



Qualification Lot Release Conditional Release Material Request Form

23CRM015

Section Three: Review and Approval for Release			
<i>(Requestor and Quality Engineer must verify qualification materials meet acceptance criteria before signing below for lot release)</i>			
<i>Note: Manager level of above signature required for QE approval</i>			
	Print Name	Signature	Date
Requestor:		*e-sign <input checked="" type="checkbox"/>	
Quality Engineer:		*e-sign <input type="checkbox"/>	
*Signatures can either be wet or digital using approved Digital Signature Form per D16659			
Section Four: Product Release and Closure			
Requested Lot Numbers Released <input type="checkbox"/> Yes <input type="checkbox"/> No			
	QA Print Name	QA Signature	Date
QA:			
Comments: <input type="checkbox"/> N/A			



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. .

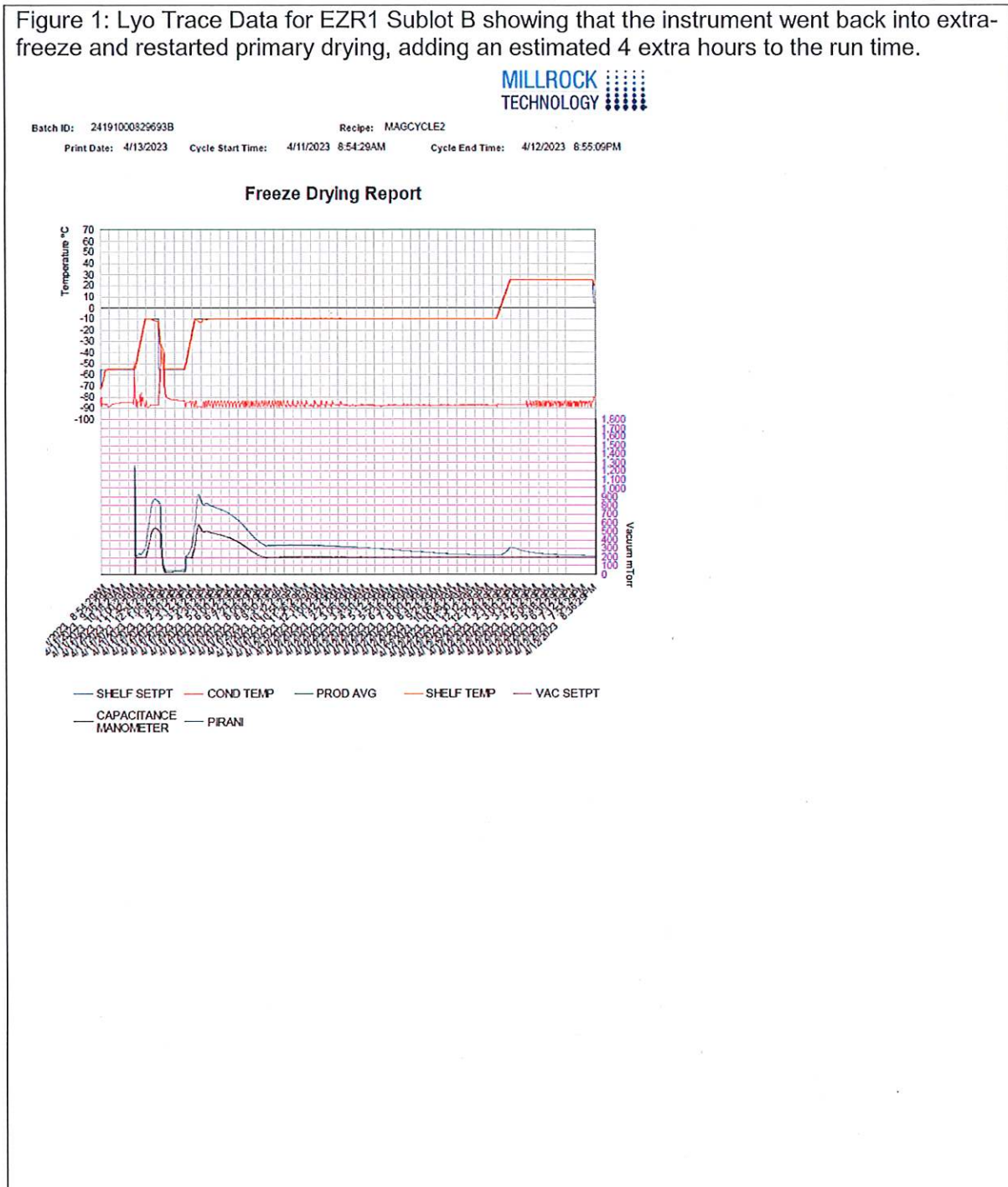
Investigation

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.

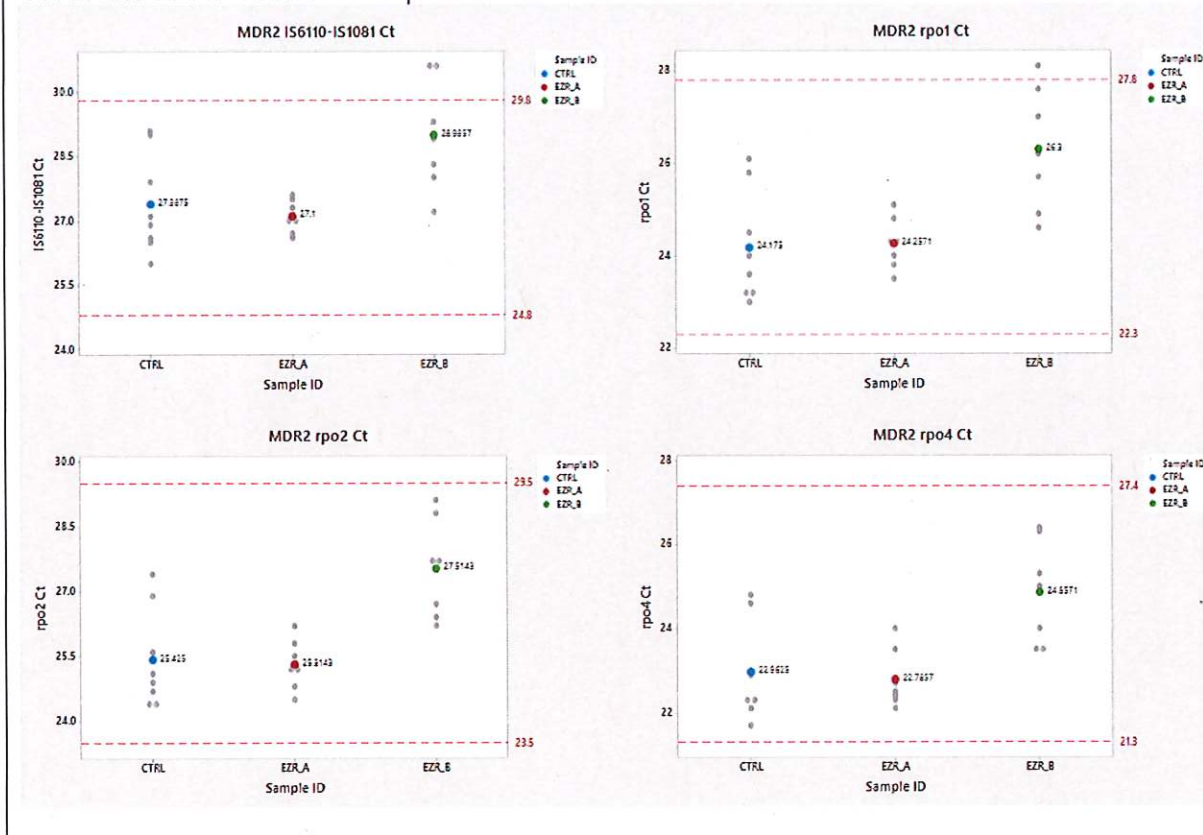
Protocol D64217

Figure 1: Lyo Trace Data for EZR1 Sublot B showing that the instrument went back into extra-freeze and restarted primary drying, adding an estimated 4 extra hours to the run time.

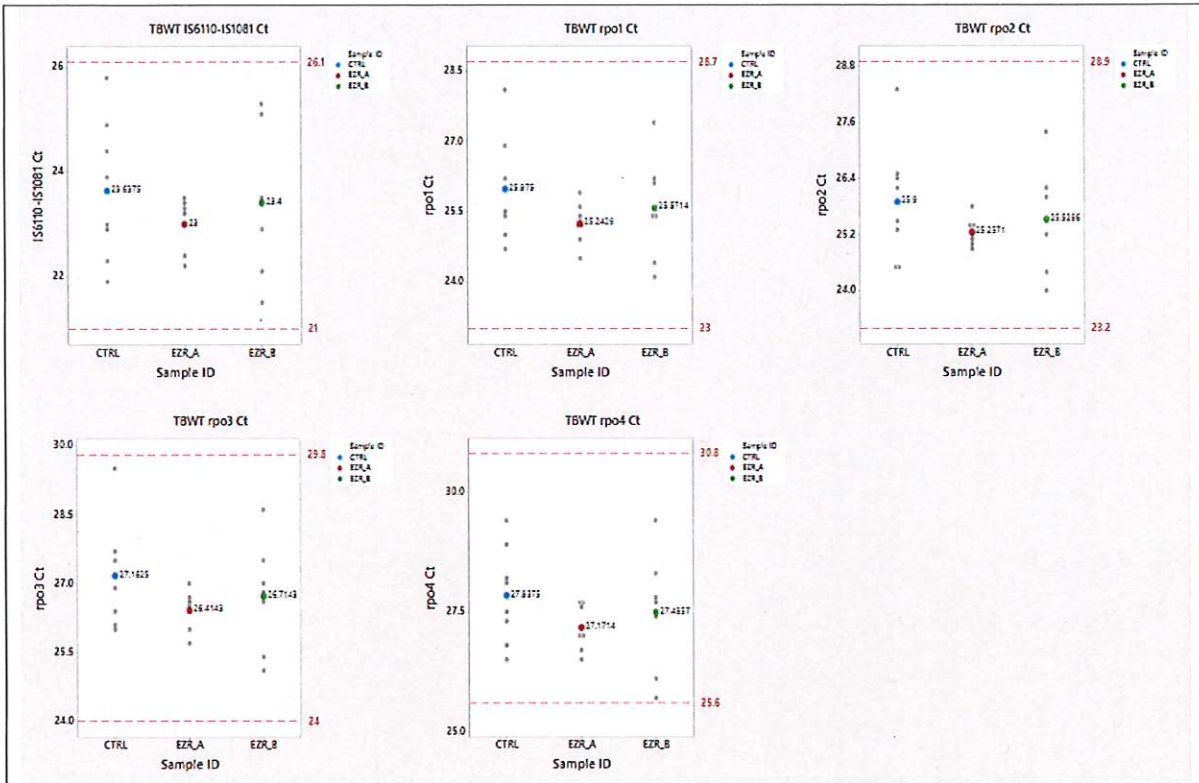


Protocol D64217

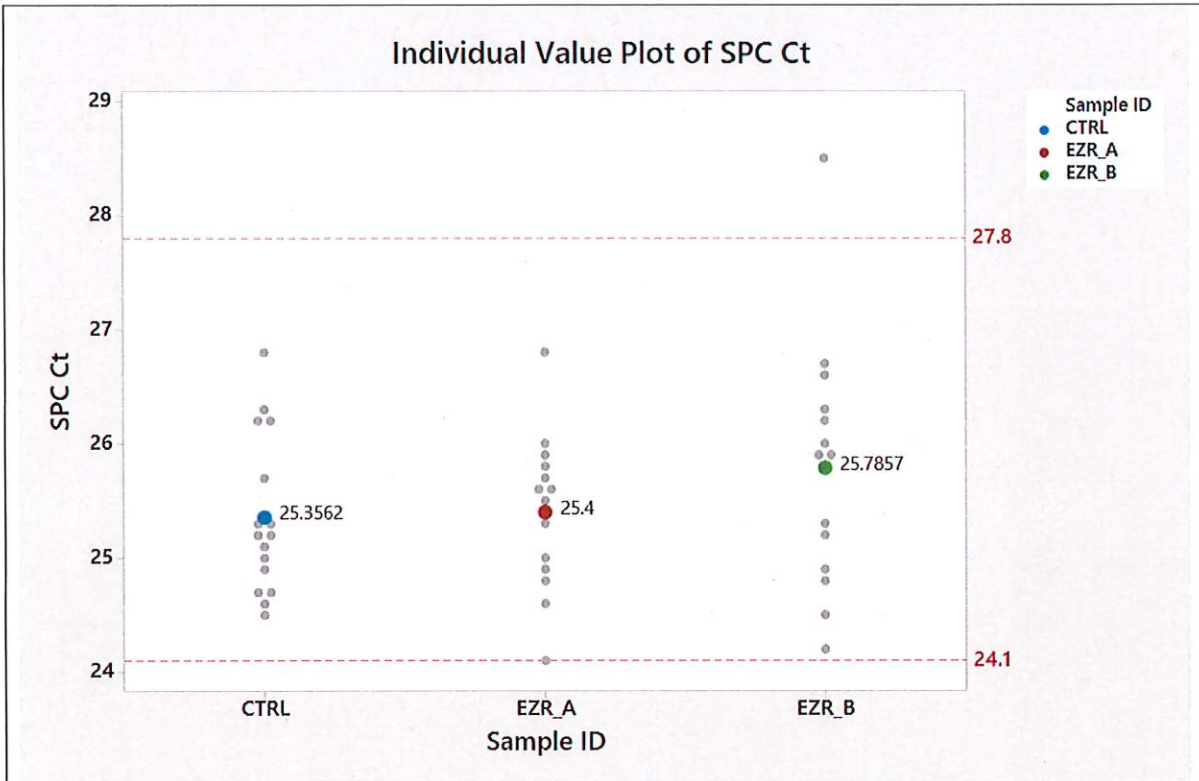
Figure 2: FI LSP BR Data for EZR1 Sublot A & B at Sample Type MDR2 (POS), TBWT (POS) and SPC (NEG) analysis. EZRA (EZR1 Sublot A) and EZRB (EZR1 Sublot B) were tested using reference passing beads for EZR2, TSR1, TSR2 and SPC. The CTRL sample was a reference set that used all pre-existing passing beads.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



Protocol D64217



Protocol D64217



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.

Protocol D64217

- Although the team will not have 2 sublots for TSR1 and EZR1, subplot 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 subplot 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.



Protocol D64217

Approval

Originator	Name (print)	Signature	Date
	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



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 Delivered:	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:

CC only:

N/A

Originator E-mail Phone

Approved as-is
 Approved with changes (below)

<input type="text" value="Kimberly Dang"/>	Digitally signed by Kimberly Dang Date: 2023.04.27 17:22:39 -0700
--	--

Department

Approved as-is
 Approved with changes (below)

<input type="text" value="N/A"/>	Digitally signed by Jessica Cortopasi Date: 2023.04.28 19:48:55 -0700
----------------------------------	--

Department

Approved as-is
 Approved with changes (below)

<input type="text" value="N/A"/>	<input type="text"/>
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Department

Approved as-is
 Approved with changes (below)

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Department

Approved as-is
 Approved with changes (below)

<input type="text" value="N/A"/>	<input type="text"/>
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Department

Comments:



Digital Signature Form

Before using this form, you must complete training per D16659

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CC only:

N/A

Originator E-mail Phone

Approved as-is
 Approved with changes (below)

<input type="text" value="Kimberly Dang"/>	<input type="text" value="Kimberly Dang"/>	Digitally signed by Kimberly Dang Date: 2023.04.27 17:22:39 -07'00'
--	--	--

Department

Approved as-is
 Approved with changes (below)

<input type="text" value="Olin P Boling"/>	<input type="text" value="Olin P Boling"/>	Digitally signed by Olin P Boling Date: 2023.04.28 10:32:14 -07'00'
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Department

Approved as-is
 Approved with changes (below)

<input type="text" value="Marilyn Nourse"/>	<input type="text" value="Marilyn Nourse"/>	Digitally signed by Marilyn Nourse Date: 2023.04.28 11:18:37 -07'00'
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Department

Approved as-is
 Approved with changes (below)

<input type="text" value="Oriole Moeras"/>	<input type="text" value="Oriole Moeras"/>	Digitally signed by Oriole Moeras Date: 2023.04.28 11:24:39 -07'00'
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Department

Approved as-is
 Approved with changes (below)

<input type="text" value="Mary McKay"/>	<input type="text" value="Mary McKay"/>	Digitally signed by Mary McKay Date: 2023.04.28 13:18:57 -07'00'
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Department

Approved as-is
 Approved with changes (below)

<input type="text" value="N/A"/>	<input type="text" value=""/>	
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Department

Comments:



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Planned Deviation / Temporary Change

22-PDR-131

SECTION A: Implementation (Completed by Quality)			
Quality Reviewer: <i>Steven Aulis</i>		Signature: <i>[Signature]</i>	Effective Date: <i>9/24/22</i>
SECTION B: Initiation (Completed by Initiator)			
Initiator: Jessica Cortopassi		Department Name: Failure Investigation	End Date: 05/01/2023 <i>9/30/2023</i> <i>AK/3/23</i>
Document #	Rev #	Step #	Document Title <input type="checkbox"/> Additional Attachments
D31503	R & up	Section 5 (4)	MTB G4 Product QC Testing Procedure and Worksheet
D25862	AC & Up	Section 5 TBWT POSITIVE (Sample Type 2)	Xpert MTB/RIF Ultra V2 Product QC Testing Procedure and Worksheet
D13598	AE & Up	Table 4.2	Xpert MTB G4 Bead Release and LSP Testing Worksheet
D22564	H & Up	3b	Xpert MTB Ultra V2 Bead Release and LSP Testing Worksheet
D26001	D & Up	Table 2	MTB G4 PCR1 Reagent Pilot Testing Worksheet
D26002	D & Up	Table 2	MTB G4 PCR2 Reagent Pilot Testing Worksheet
D29996	D & Up	3b	Xpert MTB/RIF Ultra V2 Bead Release and LSP Testing Worksheet
Affected Part#	Rev #	Lot# / Serial#	Part Description <input type="checkbox"/> Additional Attachments
001-1683	J	C24SEP21A	INTROL TBWT-04
Description of Change <input type="checkbox"/> Additional Attachments			
<p><i>(describe current process and in general terms what will be done differently in this change)</i></p> <p>This PDR will change the current production TBWT sample dilution for MTB G4, MTB Ultra V2 assays, and corresponding bead release / LSP testing.</p> <p>Note: The PDR is only applicable to TBWT Control Material P/N 001-1683 lot C24SEP21A.</p> <p>Examples of dilution changes are below:</p> <ul style="list-style-type: none"> For MTB G4 Positive Sample (TBWT) testing per D31503, the sample dilution will change as proposed in Table 1 below. For MTB Ultra V1 and V2 Positive Sample Type 2 (TBWT) testing per D25862, the sample dilution will change as proposed in Table 2 below. 			

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① New end date is 9/30/2023 as noted in the extension request D6256 attachment 4. AK/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

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Table 2. Current and Proposed Change for MTB Ultra V2 Positive Sample Type 2 (TBWT) Dilution:

For 10 Cartridges		
	Current Dilution (based on D25862)	Proposed Dilution
Materials*	Measure (ml)	Measure (ml)
500-1315	7.75	7.96
001-1683	0.24	0.032
Sample Reagent	16	16.00
Total	24.0	24.0
	100-fold dilution	750-fold dilution

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 higher than the normal concentration used for testing. During Control Qual testing, results were observed at Ct = 24.5. Even though this passed according to D38785 (Ct range: 24.5 - 28) it has potential to fail the lower spec limit. A titration study was performed to dilute from 1.5e5 to 2.0e4 cell/ml and tested with MTB-G4 and MTB-Ultra cartridges (reference 21-NC-03826). The result was more centered within the spec range.

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Planned Deviation / Temporary Change

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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.

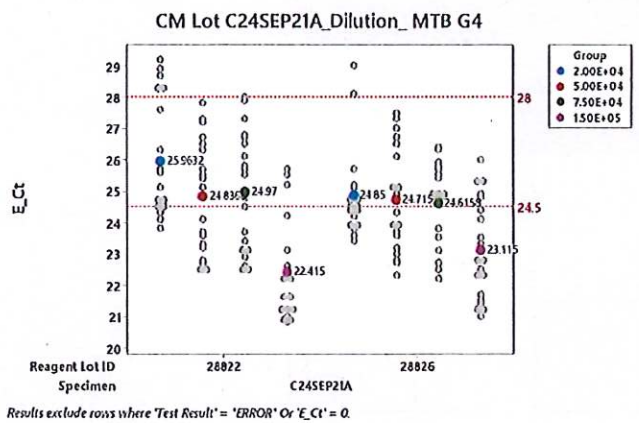
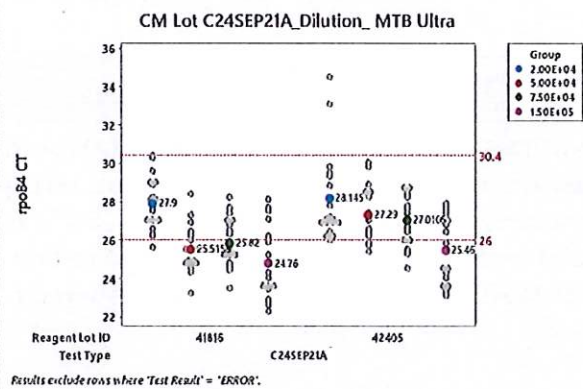
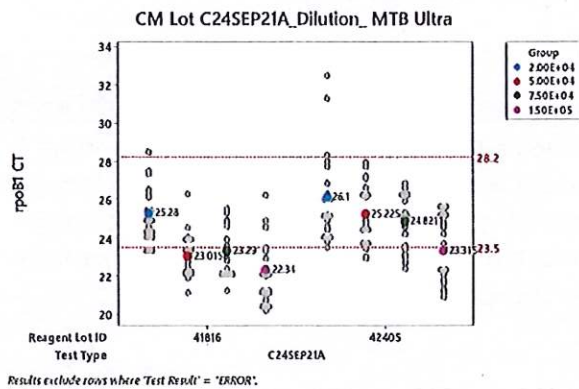


Figure 2: MTB-Ultra ct average data shows 2.0e4 cell/ml dilution is within the spec range.



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Planned Deviation / Temporary Change

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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.
 - 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:
 - PRD Number
 - Cepheid Part Number
 - Description
 - Vendor Lot
 - Quantity
 - Concentration
 - 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? YES NO (If Yes, complete Attachment 2 Commitment Form)

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Planned Deviation / Temporary Change

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Is training required to be conducted before executing this PDR?
 YES If Yes, attach training documentation once all required approvals are received in section C.
 NO If No, justify why training is not required below

Initiator	Signature	Date	Department Manager Name
	<i>Amir Cepheid</i> *e-sign <input type="checkbox"/>	<i>08/24/2022</i> *e-sign <input type="checkbox"/>	Jason Dallwig
SECTION C: REVIEW AND APPROVAL (Completed by Stakeholder departments)			
NOTE: Manager or above level signatures required			
Department	Name	Signature	Date
Manufacturing:	Stephan Povio	*e-sign <input checked="" type="checkbox"/>	*e-sign <input checked="" type="checkbox"/>
Materials:	Grace Martin	*e-sign <input checked="" type="checkbox"/>	*e-sign <input checked="" type="checkbox"/>
Quality:	Richard Moore	*e-sign <input checked="" type="checkbox"/>	*e-sign <input checked="" type="checkbox"/>
Stakeholder Dept.: Quality Control	Jamie Tobin	*e-sign <input checked="" type="checkbox"/>	*e-sign <input checked="" type="checkbox"/>
Stakeholder Dept.: Quality Control/Control Material	Demseen Danielson	<i>NA JC082422</i> *e-sign <input type="checkbox"/>	*e-sign <input type="checkbox"/>
Stakeholder Dept.: Quality Control	la Xiong	*e-sign <input type="checkbox"/>	*e-sign <input type="checkbox"/>
Stakeholder Dept.: Quality Control	Sean McIntyre	*e-sign <input type="checkbox"/>	*e-sign <input type="checkbox"/>
Stakeholder Dept.: Quality Control	Marites Abriam	*e-sign <input type="checkbox"/>	*e-sign <input type="checkbox"/>
Stakeholder Dept.: Quality Systems	Steven Aviles	<i>Aviles</i> *e-sign <input type="checkbox"/>	<i>8/24/22</i> *e-sign <input type="checkbox"/>
Additional Controls (Quality): <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If Yes, explain:			
*Signatures can either be wet or digital using approved Digital Signature Form per D16659.			

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Planned Deviation / Temporary Change - Commitment Form

SECTION A: Commitment Form (Completed by Initiator)

Planned Deviation 22-PDR-131

Commitment # (01, 02 etc.)	Description of Commitment	Owner Name	Owner Initial/Date	Due Date	Date of Commitment Completion	Date of Closure Verification	Quality		
							Date Transferred to NC	NC Number	Quality initial
01	Control Material group will relabel the current PN 001-1683 lot (C24SEP21A) as outlined in attachment 1.	Demseen Danielson	<i>DD</i> 8/24/2022 *c- sign □	08/10/2022	8/9/22	22SEP22	N/A	N/A	<i>DD</i> <i>22SEP22</i>
02	Training for affected group(s): -Lodi IPT/QC/PQC team -Lodi Bead Release/LSP Team	Jessica Cortopassi	<i>JC</i> 8/10/2022 *c- sign □	8/10/2022	8/10/2022	8/24/22	N/A	N/A	<i>S.A</i>
03	Notify the PDR initiator once the affected control material lot is consumed.	Demseen Danielson	<i>DD</i> 8/24/2022 *c- sign □	09/15/23 05/01/2023 05/21/2023					
04	Removal of physical copies of this PDR from all manufacturing and testing areas.	Jessica Cortopassi	<i>JC</i> 09/25/23 *c- sign □	09/25/23 05/02/2025	04/20/23				

① Based on extended end date of 09/30/2023. DD 04/21/23.

② Based on extension and future end date of 9/30/2023, copies will be read until 9/25/23. JC 04/24/23.

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Page 5-A
8/24/22

Planned Deviation /Temporary Change- Commitment Form

SECTION A: Commitment Form (Completed by Initiator)

Planned Deviation 22-PDR-131

Commitment # (01, 02 etc.)	Description of Commitment	Owner Name	Owner Initial/ Date	Due Date	Date of Commitment Completion	Date of Closure Verification	Quality		
							Date Transferred to NC	NC Number	
05	Notification to all teams affected once the PDR is inactive.	Jessica Cortopassi	<i>JC</i> *sign <input type="checkbox"/>	09/25/23 05/02/2023 ²	09/24/23				
*Signatures can either be wet or digital using approved Digital Signature Form per DI6659 All commitment due dates should be two weeks before the PDR End Date COMMITMENTS COMPLETED: VERIFIED BY (Quality):									
						Signature:	Date:		

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*Page 9 of 12
J.A
8/24/22*

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Document Name:	22-PDR-131
Date Delivered:	08/08/2022
Date Due:	08/10/2022

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Originator E-mail Phone

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 Approved with changes (below)

Digitally signed by Jamie Tobin
 Date: 2022.08.12 09:42:20 -07'00'

Department

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Department

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S.A
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 Approved with changes (below)

<input type="text" value="Stephan Povio"/>	Digitally signed by Stephan Povio Date: 2022.08.08 12:13:48 -07'00'
Department <input type="text" value="Manufacturing"/>	

Approved as-is
 Approved with changes (below)

<input type="text" value="N/A"/>	<input type="text"/>
Department <input type="text" value="N/A"/>	

Approved as-is
 Approved with changes (below)

<input type="text" value="N/A"/>	<input type="text"/>
Department <input type="text" value="N/A"/>	

Approved as-is
 Approved with changes (below)

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Department <input type="text" value="N/A"/>	

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<input type="text" value="N/A"/>	<input type="text"/>
Department <input type="text" value="N/A"/>	

Approved as-is
 Approved with changes (below)

<input type="text" value="N/A"/>	<input type="text"/>
Department <input type="text" value="N/A"/>	

Comments:



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*Page 11 of 12
3 A
8/24/22*

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	Digitally signed by Grace Martin Date: 2022.08.16 14:59:35 -0700'
Department	<input type="text" value="Materials"/>

Approved as-is
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<input type="text" value="N/A"/>	<input type="text"/>
Department	<input type="text" value="N/A"/>

Approved as-is
 Approved with changes (below)

<input type="text" value="N/A"/>	<input type="text"/>
Department	<input type="text" value="N/A"/>

Approved as-is
 Approved with changes (below)

<input type="text" value="N/A"/>	<input type="text"/>
Department	<input type="text" value="N/A"/>

Approved as-is
 Approved with changes (below)

<input type="text" value="N/A"/>	<input type="text"/>
Department	<input type="text" value="N/A"/>

Approved as-is
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<input type="text" value="N/A"/>	<input type="text"/>
Department	<input type="text" value="N/A"/>

Comments:



*Page 12 of 12
 J-A
 8/24/22*

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Document Name:	22-PDR-131
Date Delivered:	08/08/2022
Date Due:	08/10/2022

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Originator E-mail Phone

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la Xiong
Digitally signed by la Xiong
 Date: 2022.08.08 11:01:21 -07'00'

Department

Approved as-is
 Approved with changes (below)

Richard Moore, Sr. Director
Digitally signed by Richard Moore, Sr. Director
 Date: 2022.08.08 11:28:17 -07'00'

Department

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Department

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Department

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Department

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Department

Comments:



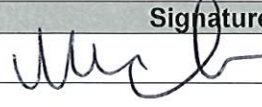
GX Cartridge Manual Fill Worksheet

Product Reference #: LSP-MTBU2-455 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		ML
N/A ML	5/2/23	

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 <u>301-9582</u>	301251
Pre-filter	(circle one) 700-0894 <u>700-5124</u> 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

Item	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 5/2/23
Bead #6	N/A	N/A

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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	≤ 10%	N/A
Humidity – Middle	N/A	N/A		N/A
Humidity – End	N/A	N/A		N/A

COMMENTS: N/A

Initial and date after each comment.

In 5 Environment, per D7849, manual 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
JI	<i>Jordan J...</i>	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	

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 whilst 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	1000555439	N	N/A
BEAD.EZR2.MTB.ULTRA.V2	500-2420	1000929717	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 <i>Underscore one</i>	1000747628
Small Retaining Ball	300-6099	2098678
Large Retaining Ball	500-0037	1881621
Frit	300-5115 or 301-5582 <i>Underscore one</i>	301251
Pre-filter	700-5124	1000784506
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-filter insertion tool	700-0916	N/A

Liquid reagents and control material	Part #	Lot #	Expiration Date
TET	500-1315 or 500-0995 <i>Underscore one</i>	1000728681-E	
Sample Reagent	700-5208 700-6052 <i>Underscore one</i>	1000509051	
MMQCI TBWT	001-1683	C24SEP21A	9/30/2023
MMQCI TB1081MDR2	001-1923	M03MAY22A	5/31/2024

Sublot	Replicates			Total/sublot
	Neg	TBWT	MDR 2	
A	14	7	7	28
B	14	7	7	28
C	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
H	N/A	N/A	N/A	N/A
I	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
A	30
B	30
C	N/A
D	N/A
E	N/A
F	N/A
G	N/A
H	N/A
I	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.

- Obtain cartridges in accordance with the table above.
- If manual insertion of pre-filters or frits 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-filter at the end of the pre-filter insertion tool 769-0316.
- Place the cartridge upright on a flat, solid surface.
- Align the pre-filter on top of the groove at the bottom of Chamber 3. Push down to secure.
- Remove the pre-filter insertion tool from the cartridge.

2.3 Frit insertion (Chamber 7)

- Grasp a frit along its long sides with the forceps.
- 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.
- Lower the frit approximately halfway into Chamber 7. Release the forceps' grasp on the frit.
- Close the forceps and use the closed ends to gently push the frit into Chamber 7 until you feel resistance.
- Use the Insertion tool (15mm) 300-6799 to push the frit down into chamber 7 until the proper depth has been achieved.
- Remove the Insertion tool from the cartridge.

2.4 Bead preparation

- Insert 1 small retain ball (300-6099) into Chamber 9.
- Insert 1 EZR1 Bead (500-2419) into Chamber 9.
- Insert 1 TSR1 Bead (500-2023) into Chamber 9.
- Insert 1 small retain ball (300-6099) into Chamber 9.
- Insert 1 large retain ball (500-0037) into Chamber 9.
- Push large retain ball down with 300-4434 Retain Ball Insertion Tool.
- Insert 1 small retain ball (300-6099) into Chamber 11.
- Insert 1 EZR2 Bead (500-2420) into Chamber 11.
- Insert 1 TSR2 Bead (600-2025) into Chamber 11.
- Insert 1 small retain ball (300-6099) into Chamber 11.
- Insert 1 large retain ball (500-0037) into Chamber 11.
- Push large retain ball down with 300-4434 Retain Ball Insertion Tool.
- Insert 1 small retain ball (300-6099) into Chamber 1.
- Insert 1 SPC Bead (500-0926) into Chamber 1.
- Insert 1 small retain ball (300-6099) into Chamber 1.
- Insert 1 large retain ball (500-0037) into Chamber 1.
- Push large retain ball down with 300-5643 Retain Ball Insertion Tool.
- Verify that all remaining beads are sealed in bead containers.

- Label 28 cartridges with sample type "NEG" and replicate number.
- Label 14 cartridges with sample type "TBWT" and replicate number.
- Label 14 cartridges with sample type "MDR2" and replicate number.

2.5 Liquid reagents fill

- Add 4mL of TET Buffer to chamber 2 of each cartridge.
- Add 4mL of TET Buffer to chamber 5 of each cartridge.

3. Sample Preparation

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

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

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.

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

3b. POSITIVES-TBWT

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

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

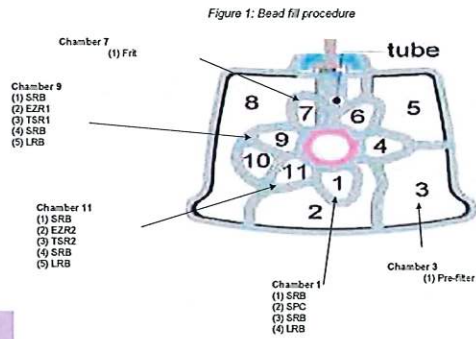
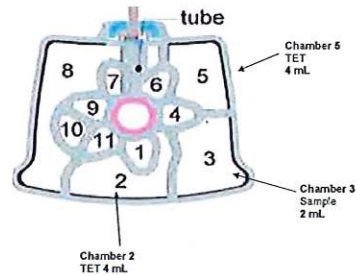


Figure 2: Liquid Reagents fill procedure





LSP-MTB2-455

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 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 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
MMQCI TB1081MDR2	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".

4. GeneXpert Testing

Run cartridges on the GX systems per instructions in D29997 Xpert MTB Ultra LSP and Bead Release Testing Procedure. Select the most currently released assay protocol, P0609 (MTB-RIF-Ultra V2 BeadLSP). Obtain from Agile if necessary.

5. Equipment

Pipette Information	
Cepheid ID	Cal. Due Date
L3443	06/30/2023
L2690	06/30/2023
L2692	06/30/2023

GeneXpert Information	
Cepheid ID	Cal. Due Date
L3251	11/30/2023
L3323	04/30/2024
L3321	02/29/2024
L3322	04/30/2024

GeneXpert Software Version
6.4

Comments (optional)

Refer to D64217 and Deviation Report 1.
Refer to 22PDR131 for Positives-TBWT's dilution recipe.
ML 5/2/23

Performed by: ML
Reviewed by: JT

Date: 5/2/23
Date: 5/2/23

LSP-MTBU2-455

Table 3: Probe Check results for LSP Output

Analyte Name	Pb Ckx 1.3 Min	Pb Ckx 1.3 Max	Pb Ckx 2 Min	Pb Ckx 2 Max	Norm. Factor
SPC	0	479	151	0	376
IS1511-155110	0	334	182	0	456
rp01	0	343	225	0	563
rp02	0	143	111	0	278
rp03	0	229	139	0	347
rp04	0	189	127	0	317
OC1	0	170	99	0	NA
OC2	0	164	37	0	NA
rp01 met	0	0	0	0	0
rp02 met	0	0	0	0	0
rp03 met	0	0	0	0	0
rp04 met	0	0	0	0	0
rp01 M.t.met	0	0	0	0	0
rp02 M.t.met	0	0	0	0	0
rp03 M.t.met	0	0	0	0	0
rp04 M.t.met A	0	0	0	0	0
rp04 M.t.met B	0	0	0	0	0

When exporting gub file, only select the analytes that are selected below:

Select Analytes

Select analytes to include in the exported gub file.

- SPC
- IS1511-155110
- rp01
- rp02
- rp03
- rp04
- OC1
- OC2
- rp01 met
- rp02 met
- rp03 met
- rp04 met
- rp01 M.t.met
- rp02 M.t.met
- rp03 M.t.met
- rp04 M.t.met A
- rp04 M.t.met B

OK Cancel

Table 4a: Ct and EndPt test results - Negative Control

Target	SPC Ct		SPC EPF	
Negative Results Average	28.4		131	
Specification	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	
	24.1	27.8	84.0	
PASS/FAIL	PASS		PASS	
Overall Result	PASS			

Table 4b: Ct and EndPt test results - TBWT Positive control

Target	IS6110-151081 Ct		IS6110-151081 EPF		rp01 Ct		rp01 EPF		rp01 Tm		rp01 M.t. Peak Height		rp02 Ct		rp02 EPF		rp02 Tm		rp02 M.t. Peak Height	
Average	24.9		438		27.4		378		68.5		73		27.0		245		73.2		98	
Specification	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)
	21.0	26.1	378.0	23.0	28.7	300.0	68.6	70.6	47.0	23.2	28.9	196.0	72.3	74.3	50.0					
PASS/FAIL	PASS		PASS		PASS		PASS		PASS		PASS		PASS		PASS		PASS		PASS	
Target	rp03 Ct		rp03 EPF		rp03 Tm		rp03 M.t. Peak Height		rp04 Ct		rp04 EPF		rp04 Tm		rp04 M.t. Peak Height					
Average	28.2		166		75.9		87		29.1		124		67.2		99					
Specification	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)				
	24.0	29.8	118.0	75.0	77.0	57.0	25.6	30.8	80.0	66.2	68.2	55.0								
PASS/FAIL	PASS		PASS		PASS		PASS		PASS		PASS		PASS		PASS					
Overall Result	PASS																			

Table 4c: Ct and EndPt test results - MDR2 Positive control

Target	IS6110-151081 Ct		IS6110-151081 EPF		rp01 Ct		rp01 EPF		rp01 Tm		rp01 M.t. Peak Height		rp02 Ct		rp02 EPF		rp02 Tm		rp02 M.t. Peak Height	
Average	28.3		107		26.8		384		69.6		48		24.8		168		79.3		42	
Specification	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)	Lower Limit (mean)	Upper Limit (mean)
	24.8	29.8	72.0	22.3	27.8	259.0	68.7	70.7	15.0	23.5	29.5	106.0	83.4	74.4	50.0					
PASS/FAIL	PASS		PASS		PASS		PASS		PASS		PASS		PASS		PASS		PASS		PASS	
Target	rp03 Ct		rp03 EPF		rp03 Tm		rp03 M.t. Peak Height		rp04 Ct		rp04 EPF		rp04 Tm		rp04 M.t. Peak Height					
Average									24.4		308		73.8		117					
Specification			NA						Lower Limit (mean)		Upper Limit (mean)		Lower Limit (mean)		Upper Limit (mean)					
									21.3		27.4		241.0		72.8		74.8		62.0	
PASS/FAIL									PASS		PASS		PASS		PASS					
Overall Result	PASS																			

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Table 5 - Probe Check 2 Results

Analyte	PC2 Average	Lower Limit	Upper Limit	PASS/FAIL
SFC	378	200	800	PASS
IS1001-05110	456	224	896	PASS
rpo1	563	313	1276	PASS
rpo2	278	158	632	PASS
rpo3	347	200	800	PASS
rpo4	317	192	648	PASS
QC1	87	53	236	PASS
QC2	93	51	206	PASS
Overall Result	PASS			

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

Final Results (PASS/FAIL):	PASS
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Comments (optional): N/A ML 5/2/23

Performed By: ML Date: 5/2/23
 Reviewed By: JT Date: 5/2/23

Any retest performed? (Yes/No) No (tap-down)

Table 5: Data replaced by retest

Note: Remember to adjust row height in order to display the full error code

Sample ID	Test start time	Test result	Instrument	Module	Error
N/A ML 5/2/23					