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

Abbreviation	LNN Number
MTBU2	L0468

Bead Part #	Bead Batch
500-2023	1000862912
500-2025	1000829676
500-2419	~~1000829695~~
500-2420	1000829717

~~Existing, RHKC, 4/17/23~~

RHKC, 4/20/23

1000885439, New, RHKC, 5/1/23

☑ New Lot
☐ Existing Lot

LSP Testing Required
☑ Yes
☐ No, LSP-_____-____

Materials Planning Approval:
By: _____ Date: 4/17/23

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:** 4/3/2023

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

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

(Requestor and Quality Engineer must verify qualification materials meet acceptance criteria before signing below for lot release)
Note: Manager level of above signature required for QE approval

	Print Name	Signature	Date
Requestor:		*e-sign ☒	
Quality Engineer:		*e-sign ☐	

*Signatures can either be wet or digital using approved Digital Signature Form per D16659

Section Four: Product Release and Closure

Requested Lot Numbers Released ☐ Yes ☐ No

	QA Print Name	QA Signature	Date
QA:			

Comments: ☐ 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. .

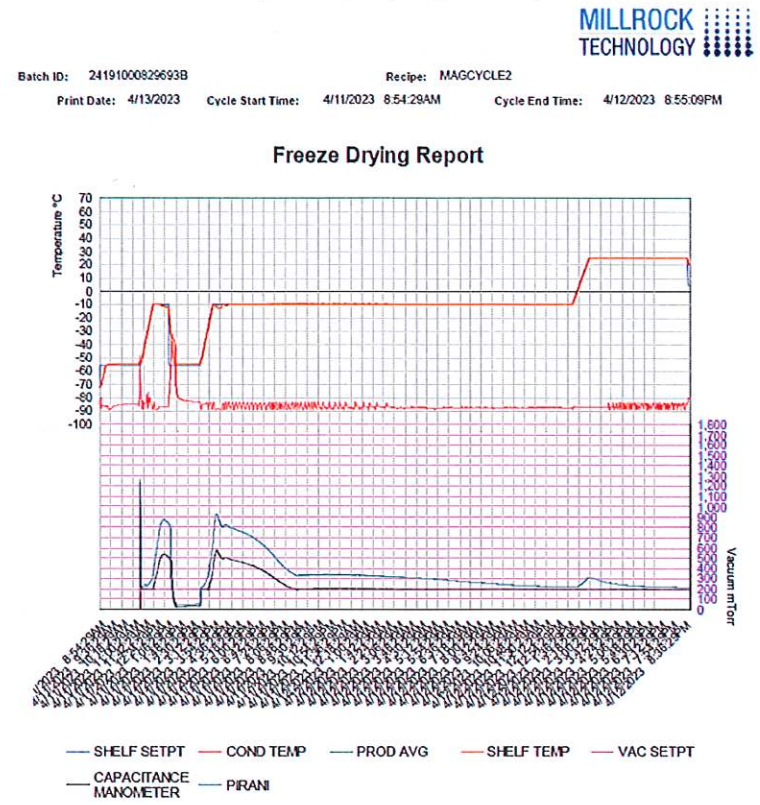
Investigation

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.

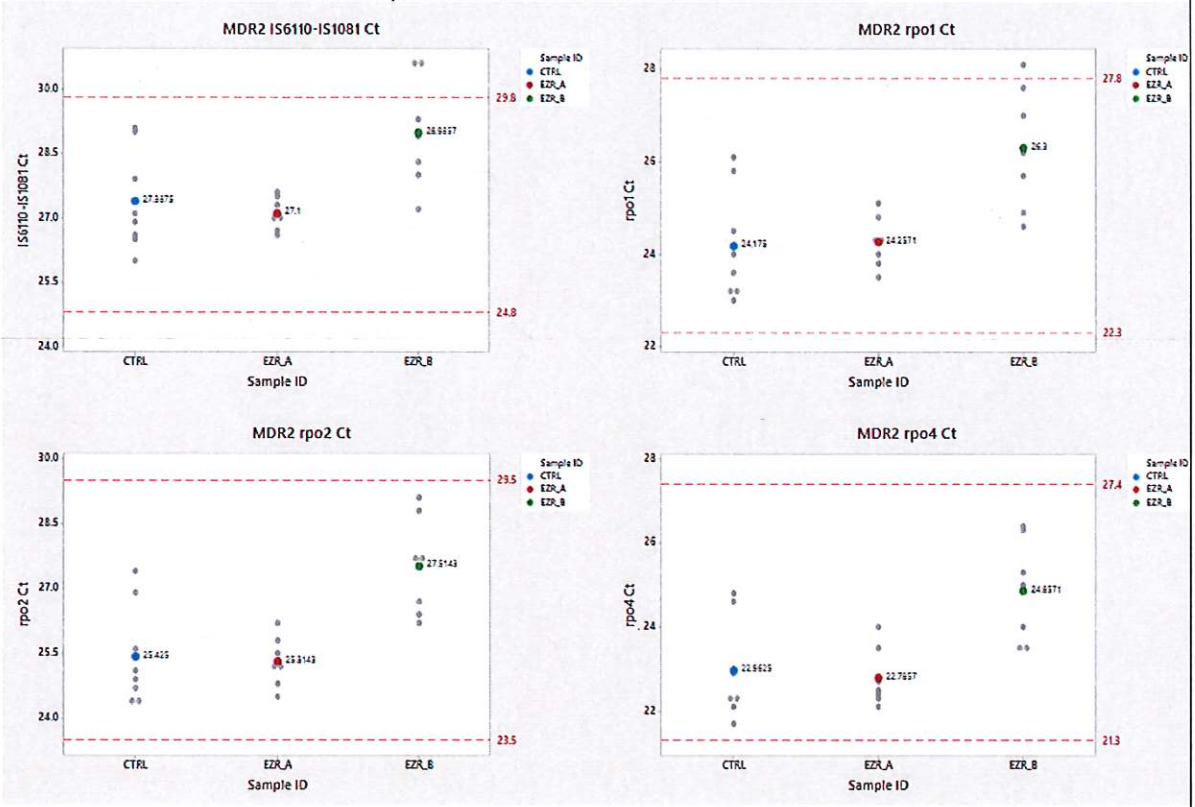
Protocol D64217

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.

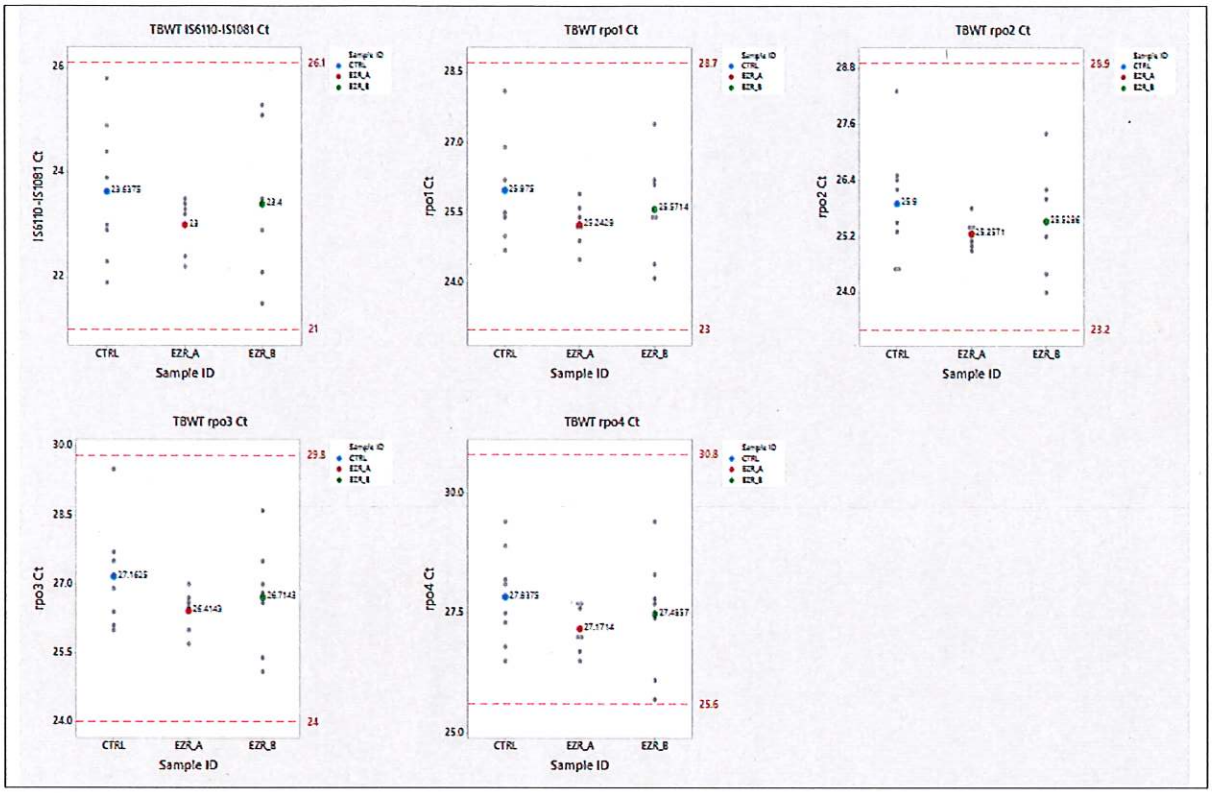


Protocol D64217

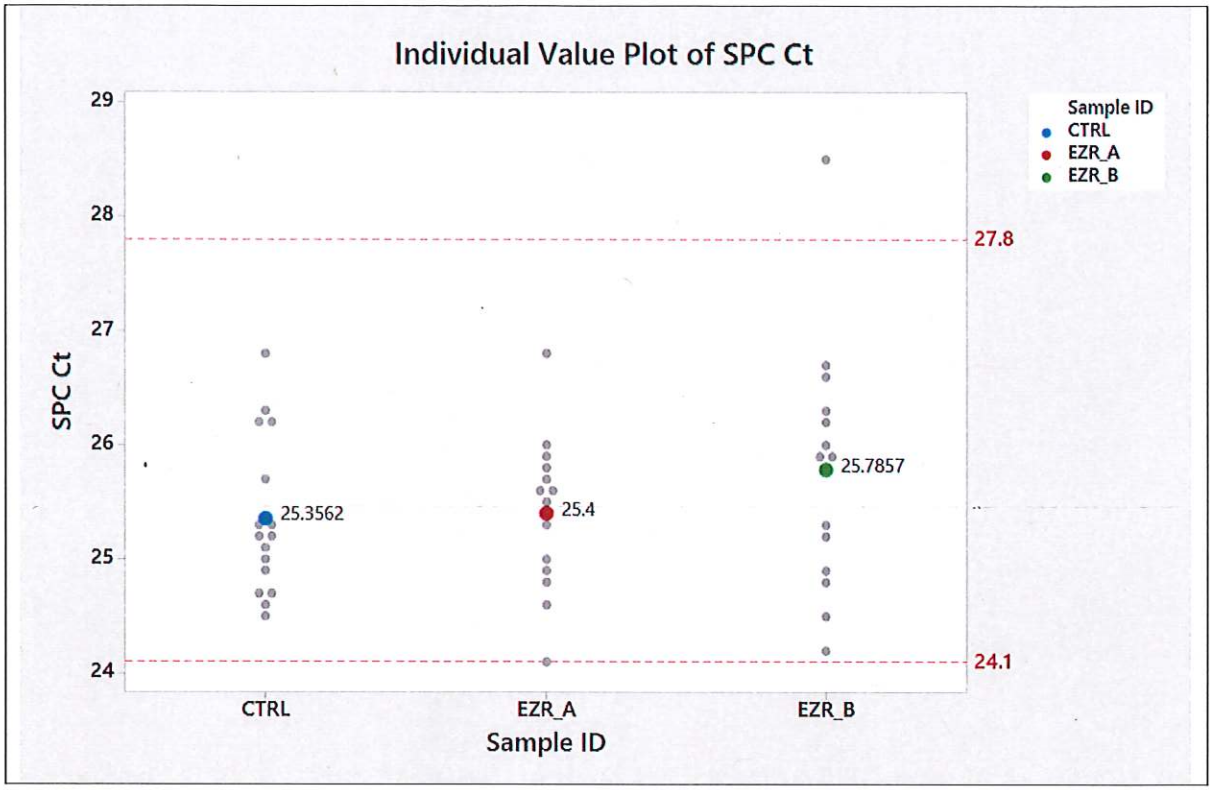
Figure 2: FI LSP BR Data for EZR1 Sublot A & B at Sample Type MDR2 (POS), TBWT (POS) and SPC (NEG) analysis. EZRA (EZR1 Sublot A) and EZRB (EZR1 Sublot B) were tested using reference passing beads for EZR2, TSR1, TSR2 and SPC. The CTRL sample was a reference set that used all pre-existing passing beads.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

Protocol D64217

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

Digital Signature Form

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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:

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

CC only:

N/A

(•) Approved as-is ( ) Approved with changes (below)	Kimberly Dang	Kimberly Dang Digitally signed by Kimberly Dang Date: 2023.04.27 17:22:39 -07'00'	Department: Product Transfer
(•) Approved as-is ( ) Approved with changes (below)	Olin P Boling	Olin P Boling Digitally signed by Olin P Boling Date: 2023.04.28 10:32:14 -07'00'	Department: Quality Systems
(•) Approved as-is ( ) Approved with changes (below)	Marilyn Nourse	Marilyn Nourse Digitally signed by Marilyn Nourse Date: 2023.04.28 11:18:37 -07'00'	Department: Product Transfer
(•) Approved as-is ( ) Approved with changes (below)	Oriole Moeras	Oriole Moeras Digitally signed by Oriole Moeras Date: 2023.04.28 11:24:39 -07'00'	Department: Manufacturing
(•) Approved as-is ( ) Approved with changes (below)	Mary McKay	Mary McKay Digitally signed by Mary McKay Date: 2023.04.28 13:18:57 -07'00'	Department: Quality Systems
( ) Approved as-is ( ) Approved with changes (below)	N/A		Department: N/A

Comments:

You must use Adobe Reader v8.0 or higher to use this form. Adobe Reader is available for free at www.adobe.com.
Click in the signature field to sign the document. A wizard will teach you how to create a digital signature. For details, see D16656 Procedure, Digital Signature Creation and Use.

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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:

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

CC only:

N/A

(●) Approved as-is ( ) Approved with changes (below) Kimberly Dang / Kimberly Dang Digitally signed by Kimberly Dang Date: 2023.04.27 17:22:39 -07'00' Department: Product Transfer	(●) Approved as-is ( ) Approved with changes (below) N/A / Jessica Cortopasi Digitally signed by Jessica Cortopasi Date: 2023.04.28 19:48:55 -07'00' Department: Failure Investigation	( ) 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	( ) Approved as-is ( ) Approved with changes (below) N/A Department: N/A

Comments:

You must use Adobe Reader v8.0 or higher to use this form. Adobe Reader is available for free at www.adobe.com.
Click in the signature field to sign the document. A wizard will teach you how to create a digital signature. For details, see D16656 Procedure, Digital Signature Creation and Use.

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Planned Deviation / Temporary Change

22-PDR-131

SECTION A: Implementation (Completed by Quality)		
Quality Reviewer: Steven Ainley	Signature:	Effective Date: 8/24/22
SECTION B: Initiation (Completed by Initiator)		
Initiator: Jessica Cortopassi	Department Name: Failure Investigation	End Date: ~~05/01/2023~~ ① 9/30/2023 AK 3/23

Document #	Rev #	Step #	Document Title ☐ 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** ☐ Additional Attachments
001-1683	J	C24SEP21A	INTROL TBWT-04

Description of Change ☐ Additional Attachments
(describe current process and in general terms what will be done differently in this change)

This PDR will change the current production TBWT sample dilution for MTB G4, MTB Ultra V2 assays, and corresponding bead release / LSP testing.

Note: The PDR is only applicable to TBWT Control Material P/N 001-1683 lot **C24SEP21A**.

Examples of dilution changes are below:

- 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.

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

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

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.

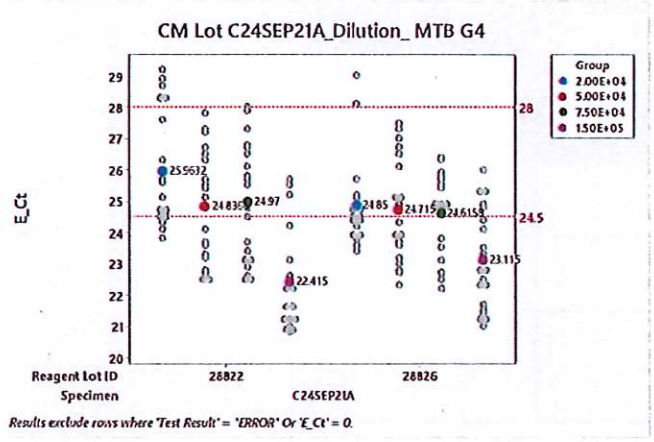
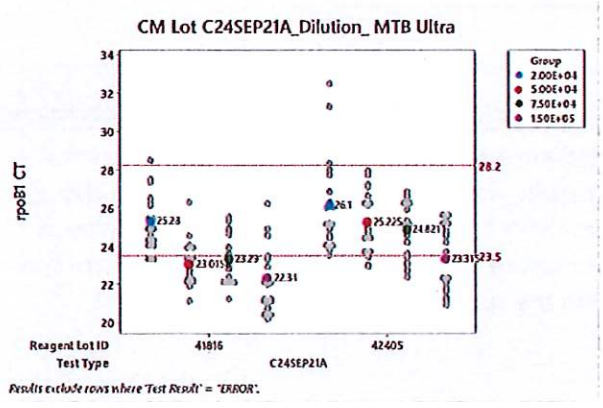
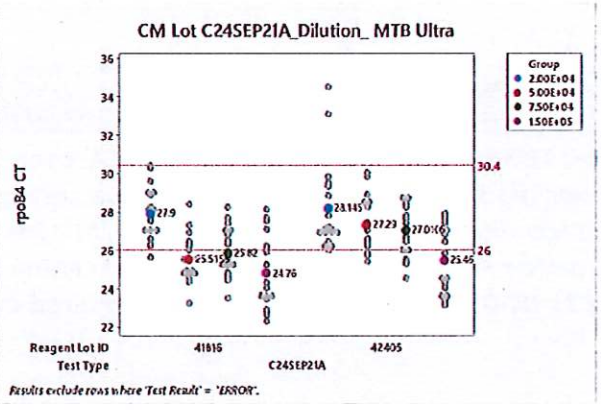


Figure 2: MTB-Ultra ct average data shows 2.0e4 cell/ml dilution is within the spec range.





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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.
  - 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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8/24/22

Planned Deviation / Temporary Change

22-PDR-131

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
	[signature] *e-sign ☐	08/24/2022 *e-sign ☐	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 ☒	*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 SC082422 *e-sign ☐	*e-sign ☐
Stakeholder Dept.: Quality Control	Ia Xiong	*e-sign ☐	*e-sign ☐
Stakeholder Dept.: Quality Control	Sean McIntyre	*e-sign ☐	*e-sign ☐
Stakeholder Dept.: Quality Control	Marites Abriam	*e-sign ☐	*e-sign ☐
Stakeholder Dept.: Quality Systems	Steven Aviles	[signature] *e-sign ☐	8/24/22 *e-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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8/24/22

Cepheid

Planned Deviation /Temporary Change– Commitment Form

SECTION A: Commitment Form (Completed by Initiator)

Planned Deviation 22-PDR-131

	Commitments				Quality				
Commitment # (01, 02 etc.)	Description of Commitment	Owner Name	Owner Initial/ Date	Due Date	Date of Commitment Completion	Date of Closure Verification	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	8/24/2022 DD *e-sign☐	08/10/2022	8/9/22	22SEP09	N/A	N/A	RDC 22SEP09
02	Training for affected group(s): -Lodi IPT/QC/PQC team Lodi Bead Release/LSP Team	Jessica Cortopassi	8/8/22 *e-sign☐	8/12/2022	8/10/2022	8/24/22	N/A	N/A	S.A
03	Notify the PDR initiator once the affected control material lot is consumed.	Demseen Danielson	8/24/2022 DD *e-sign☐	09/15/23 ① ~~05/01/2025~~ DD 04/21/23					
04	Removal of physical copies of this PDR from all manufacturing and testing areas.	Jessica Cortopassi	08/08/22 *e-sign☐	09/25/23 ② ~~05/02/2025~~	04/26/23				

① Based on extended end date of 09/30/2023. DD 04/21/23.
② Based on extention and further end date of 9/30/2023, copies will be need until 9/25/23. JC 04/24/23.

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8/24/22

Planned Deviation /Temporary Change– Commitment Form

SECTION A: Commitment Form (Completed by Initiator)									
Planned Deviation 22-PDR-131									
	Commitments				Quality				
Commitment # (01, 02 etc.)	Description of Commitment	Owner Name	Owner Initial/ Date	Due Date	Date of Commitment Completion	Date of Closure Verification	Date Transferred to NC	NC Number	Quality initial
05	Notification to all teams affected once the PDR in inactive.	Jessica Cortopassi	JC *e-sign ☐ 8/24/22	09/25/23 ~~05/02/2023~~ (2)	04/26/23				
*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									
COMMITMENTS COMPLETED: VERIFIED BY (Quality):	Name:		Signature:			Date:			

Cepheid.

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Date Delivered:	08/08/2022
Date Due:	08/10/2022

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Originator: Jessica Cortopassi | E-mail: jessica.cortopassi@cepheid.com | Phone: 925-848-0001

CC only:

(•) Approved as-is ( ) Approved with changes (below) Jamie Tobin — Digitally signed by Jamie Tobin Date: 2022.08.12 09:42:20 -07'00' Department: Quality Systems	( ) 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	( ) Approved as-is ( ) Approved with changes (below) N/A Department: N/A	( ) Approved as-is ( ) Approved with changes (below) N/A Department: N/A

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Originator: Jessica Cortopassi | E-mail: jessica.cortopassi@cepheid.com | Phone: 925-848-0001

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(●) Approved as-is ( ) Approved with changes (below) Stephan Povio Stephan Povio Digitally signed by Stephan Povio Date: 2022.08.08 12:13:48 -07'00' Department: Manufacturing	( ) 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	( ) Approved as-is ( ) Approved with changes (below) N/A Department: N/A	( ) Approved as-is ( ) Approved with changes (below) N/A Department: N/A

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Originator: Jessica Cortopassi | E-mail: jessica.cortopassi@cepheid.com | Phone: 925-848-0001

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(●) Approved as-is ( ) Approved with changes (below) Grace Martin — Digitally signed by Grace Martin Date: 2022.08.16 14:59:35 -07'00' Department: Materials	( ) 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	( ) Approved as-is ( ) Approved with changes (below) N/A Department: N/A	( ) Approved as-is ( ) Approved with changes (below) N/A Department: N/A

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8/24/22

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Originator: Jessica Cortopassi E-mail: jessica.cortopassi@cepheid.com Phone: 925-848-0001

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(•) Approved as-is ( ) Approved with changes (below) Ia Xiong Digitally signed by Ia Xiong Date: 2022.08.08 11:01:21 -07'00' Department: Quality Control	( ) Approved as-is ( ) Approved with changes (below) N/A Richard Moore, Sr. Director Quality Systems Department: Quality Systems	( ) 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	( ) Approved as-is ( ) Approved with changes (below) N/A Department: N/A

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LSP Testing Line Clearance and Setup Form

LRO #	LSP #/Cartridge Lot #
LSP-MTBU2-455	455/1000747628

Process Description:	**Worksheet #:**
LSP Fill	**D29996**

1. Line Clearance	**Entry**
Ensure area/work station is clear of material from previous Production Order/Work Request.	☑ Yes ☐ N/A
Remove any expired material from the area/work station and discard as appropriate.	☐ Yes ☑ N/A (1)
Ensure there is adequate separation between any other processes/lots, if applicable.	☑ Yes ☐ N/A
Ensure area/work station is clean and orderly.	☑ Yes ☐ N/A
2. Line Setup	**Entry**
Ensure the material to be used matches the LSP Lot Number Assignment Form specified in the specific LSP/SOP Worksheet • Part # • Batch #	☑ Yes ☐ N/A
Ensure the material to be used has no restrictions, if applicable	☑ Yes ☐ N/A
For **BCR-ABL V2/Ultra:** Ensure open cartridge part and lot number match the LSP Lot Number Assignment Form	☐ Yes ☑ N/A
3. CRM, PDR, and/or NCR applicable	**Entry**
Copy of CRM, NCR and/or PDR, present, if applicable — #23CRM015	☑ Yes ☐ N/A
Copy of CRM, NCR and/or PDR, forwarded to QA, if applicable	☑ Yes ☐ N/A

Comments: ☑ **N/A**

Performed By:	JT MM	**Date:**	05/01/2023
Verified By:	JT	**Date:**	5/1/23

(1) Box was not selected.
JT 5/2/23

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
Phuong-Thao Huynh		PTH
N/A PTH 05/01/2023		

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

Item	Part #	Lot #
Bead #1	500-2023	1000862912
Bead #2	500-2025	1000829676 A, B
Bead #3	500-2419	~~1000829693 A, B~~ 1000885439 A, B 5/2/23
Bead #4	500-2420	1000829717 A, B JT
Bead #5	~~N/A~~ 506-0926 JT 5/2/23	~~N/A~~ 1000673125 JT 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. PTH 05/01/2023

6. Approved By

Name	Signature	Date
JT	Jennifer Tang	5/2/23

A. Bead Release/LSP Testing

1. Bead/Reagent Information

LSP Lot #	455	Enter "N/A", if not applicable.
Test Date (YYYYMMDD)	20230501	
# 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	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
Small Retaining Ball	300-6099	2096678
Large Retaining Ball	500-0037	1881621
Frit	300-5115 or 301-9582 Underscore one	301251
Pre-filter	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-filter insertion tool	700-0916	N/A

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

No. of Sublots	2			
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.

a. Obtain cartridges in accordance with the table above..
b. 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)

a. Attach a pre-filter at the end of the pre-filter insertion tool **700-0916**.
b. Place the cartridge upright on a flat, solid surface.
c. Align the pre-filter on top of the groove at the bottom of Chamber 3. Push down to secure.
d. Remove the pre-filter 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

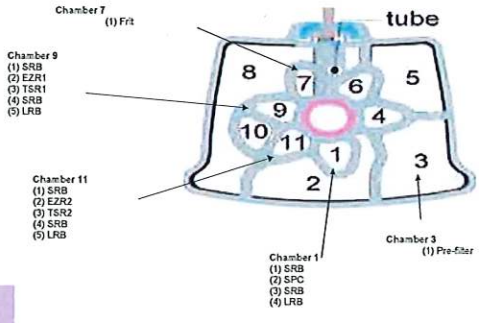
a. Insert 1 small retain ball (300-6099) into Chamber 9.
b. Insert 1 EZR1 Bead (500-2419) into Chamber 9.
c. Insert 1 TSR1 Bead (500-2023) into Chamber 9.
d. Insert 1 small retain ball (300-6099) into Chamber 9.
e. Insert 1 large retain ball (500-0037) into Chamber 9.
f. Push large retain ball down with 300-4434 Retain Ball Insertion Tool.

g. 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 (500-2025) into Chamber 11.
j. Insert 1 small retain ball (300-6099) into Chamber 11.
k. Insert 1 large retain ball (500-0037) into Chamber 11.
l. 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.
o. Insert 1 small retain ball (300-6099) into Chamber 1.
p. Insert 1 large retain ball (500-0037) into Chamber 1.
q. Push large retain ball down with 300-5643 Retain Ball Insertion Tool.
r. 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.

Figure 1: Bead fill procedure



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.

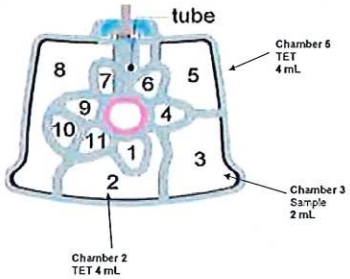
3. Sample Preparation

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.

b. 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 failed replicates. Discard positive control mixes and prepare a new mix if needing to retest beyond > 4h.

Figure 2: Liquid Reagents fill procedure



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

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".

3b. POSITIVES-TBWT

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.

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, P0808 (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
L2682	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. PTH 05/01/2023

Performed by: PTH Date: 05/01/2023

Reviewed by: JT Date: 5/2/23

I. Result Summary

LSP Lot #	455
Test Date (YYYYMMDD)	20230501
# of Sublots in this LSP lot	2

Table 1: Beads used in testing

Beads	Part #	Lot #	Previously released Bead? (Y/N)	Sublots tested for this lot
BEAD,TSR1 MTB ULTRA GX	500-2023	1000862912	N	N/A
BEAD,TSR2 MTB ULTRA GX	500-2025	1000829976	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	500-0906	1000673125		

Table 2: Validity and Outlier test results

Sample type	Sample ID	Test start time	Result	Validity test PASS/FAIL	Type of failure
MTBU2 NEG	455A_NEG_01	2023-05-01 13:21	MTB NOT DETECTED	Test Result PASSES	none
	455A_NEG_02	2023-05-01 13:21	MTB NOT DETECTED	Test Result PASSES	none
	455A_NEG_03	2023-05-01 13:21	MTB NOT DETECTED	Test Result PASSES	none
	455A_NEG_04	2023-05-01 13:23	MTB NOT DETECTED	Test Result PASSES	none
	455A_NEG_05	2023-05-01 13:24	MTB NOT DETECTED	Test Result PASSES	none
	455A_NEG_06	2023-05-01 13:24	MTB NOT DETECTED	Test Result PASSES	none
	455A_NEG_07	2023-05-01 13:24	MTB NOT DETECTED	Test Result PASSES	none
	455A_NEG_08	2023-05-01 13:24	MTB NOT DETECTED	Test Result PASSES	none
	455A_NEG_09	2023-05-01 13:25	MTB NOT DETECTED	Test Result PASSES	none
	455A_NEG_10	2023-05-01 13:25	MTB NOT DETECTED	Test Result PASSES	none
	455A_NEG_11	2023-05-01 13:25	MTB NOT DETECTED	Test Result PASSES	none
	455A_NEG_12	2023-05-01 13:25	MTB NOT DETECTED	Test Result PASSES	none
	455A_NEG_13	2023-05-01 13:26	MTB NOT DETECTED	Test Result PASSES	none
	455A_NEG_14	2023-05-01 13:26	MTB NOT DETECTED	Test Result PASSES	none
	455B_NEG_01	2023-05-01 13:27	MTB NOT DETECTED	Test Result PASSES	none
	455B_NEG_02	2023-05-01 13:27	MTB NOT DETECTED	Test Result PASSES	none
	455B_NEG_03	2023-05-01 13:27	MTB NOT DETECTED	Test Result PASSES	none
	455B_NEG_04	2023-05-01 13:28	MTB NOT DETECTED	Test Result PASSES	none
	455B_NEG_05	2023-05-01 13:28	MTB NOT DETECTED	Test Result PASSES	none
	455B_NEG_06	2023-05-01 13:28	MTB NOT DETECTED	Test Result PASSES	none
	455B_NEG_07	2023-05-01 13:28	MTB NOT DETECTED	Test Result PASSES	none
	455B_NEG_08	2023-05-01 13:29	MTB NOT DETECTED	Test Result PASSES	none
	455B_NEG_09	2023-05-01 13:29	MTB NOT DETECTED	Test Result PASSES	none
	455B_NEG_10	2023-05-01 13:29	MTB NOT DETECTED	Test Result PASSES	none
	455B_NEG_11	2023-05-01 13:29	MTB NOT DETECTED	Test Result PASSES	none
	455B_NEG_12	2023-05-01 13:30	MTB NOT DETECTED	Test Result PASSES	none
	455B_NEG_13	2023-05-01 13:30	MTB NOT DETECTED	Test Result PASSES	none
	455B_NEG_14	2023-05-01 13:30	MTB NOT DETECTED	Test Result PASSES	none
			ND	N/A	N/A
			ND	N/A	N/A
			ND	N/A	N/A
			ND	N/A	N/A
			ND	N/A	N/A
	N/A PTH 05/01/2023		ND	N/A	N/A
			ND	N/A	N/A
			ND	N/A	N/A
			ND	N/A	N/A
			ND	N/A	N/A
			ND	N/A	N/A
			ND	N/A	N/A
			ND	N/A	N/A
			ND	N/A	N/A
			ND	N/A	N/A
			ND	N/A	N/A
			ND	N/A	N/A
			ND	N/A	N/A
			ND	N/A	N/A
			ND	N/A	N/A
			ND	N/A	N/A
			ND	N/A	N/A
			ND	N/A	N/A
			ND	N/A	N/A

Sample type	Sample ID	Test start time	Result	Validity test PASS/FAIL	Type of failure	IS6110-IS1081 Ct Outlier	rpo1 Ct Outlier	rpo2 Ct Outlier	rpo3 Ct Outlier	rpo4 Ct Outlier	SPC Ct
TBWT	455A_TBWT_01	2023-05-01 13:32	MTB DETECTED VERY LOW;RIF Resistance NOT DETECTED	Test Result PASSES	none	No	No	No	No	No	25.3
	455A_TBWT_02	2023-05-01 13:33	MTB DETECTED LOW;RIF Resistance NOT DETECTED	Test Result PASSES	none	No	No	No	No	No	27.6
	455A_TBWT_03	2023-05-01 13:33	MTB DETECTED LOW;RIF Resistance NOT DETECTED	Test Result PASSES	none	No	No	No	No	No	26.4
	455A_TBWT_04	2023-05-01 13:33	MTB DETECTED LOW;RIF Resistance NOT DETECTED	Test Result PASSES	none	No	No	No	No	No	27.1
	455A_TBWT_05	2023-05-01 13:33	MTB DETECTED LOW;RIF Resistance NOT DETECTED	Test Result PASSES	none	No	No	No	No	No	25.4
	455A_TBWT_06	2023-05-01 13:34	MTB DETECTED LOW;RIF Resistance NOT DETECTED	Test Result PASSES	none	No	No	No	No	No	26.3
	455A_TBWT_07	2023-05-01 13:34	MTB DETECTED LOW;RIF Resistance NOT DETECTED	Test Result PASSES	none	No	No	No	No	No	25.2
	455B_TBWT_01	2023-05-01 13:34	MTB DETECTED VERY LOW;RIF Resistance NOT DETECTED	Test Result PASSES	none	No	No	No	No	No	26.6
	455B_TBWT_02	2023-05-01 13:35	MTB DETECTED LOW;RIF Resistance NOT DETECTED	Test Result PASSES	none	No	No	No	No	No	26.1
	455B_TBWT_03	2023-05-01 13:35	MTB DETECTED LOW;RIF Resistance NOT DETECTED	Test Result PASSES	none	No	No	No	No	No	25.8
	455B_TBWT_04	2023-05-01 13:35	MTB DETECTED LOW;RIF Resistance NOT DETECTED	Test Result PASSES	none	No	No	No	No	No	25.8
	455B_TBWT_05	2023-05-01 13:36	MTB DETECTED VERY LOW;RIF Resistance NOT DETECTED	Test Result PASSES	none	No	No	No	No	No	26.4
	455B_TBWT_06	2023-05-01 13:36	MTB DETECTED VERY LOW;RIF Resistance NOT DETECTED	Test Result PASSES	none	No	No	No	No	No	28.6
	455B_TBWT_07	2023-05-01 13:36	MTB DETECTED LOW;RIF Resistance NOT DETECTED	Test Result PASSES	none	No	No	No	No	No	25.3
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	N/A PTH 05/01/23		ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

	455B_MDR2_01	2023-05-01 13:39	MTB DETECTED LOW;RIF Resistance DETECTED	Test Result PASSES	none	No	No	No		No	26.1
	455B_MDR2_02	2023-05-01 13:39	MTB DETECTED LOW;RIF Resistance DETECTED	Test Result PASSES	none	No	No	No		No	28.1
	455B_MDR2_03	2023-05-01 13:39	MTB DETECTED LOW;RIF Resistance DETECTED	Test Result PASSES	none	No	No	No		No	25.4
	455B_MDR2_04	2023-05-01 13:39	MTB DETECTED LOW;RIF Resistance DETECTED	Test Result PASSES	none	No	No	No		No	26.3
	455B_MDR2_05	2023-05-01 13:40	MTB DETECTED LOW;RIF Resistance DETECTED	Test Result PASSES	none	No	No	No		No	26.6
	455B_MDR2_06	2023-05-01 13:40	MTB DETECTED LOW;RIF Resistance DETECTED	Test Result PASSES	none	No	No	No		No	26.1
	455B_MDR2_07	2023-05-01 13:40	MTB DETECTED LOW;RIF Resistance DETECTED	Test Result PASSES	none	No	No	No		No	26.5
	455A_MDR2_01	2023-05-01 13:37	MTB DETECTED LOW;RIF Resistance DETECTED	Test Result PASSES	none	No	No	No		No	25.2
	455A_MDR2_02	2023-05-01 13:37	MTB DETECTED LOW;RIF Resistance DETECTED	Test Result PASSES	none	No	No	No		No	25.5
	455A_MDR2_03	2023-05-01 13:37	MTB DETECTED LOW;RIF Resistance DETECTED	Test Result PASSES	none	No	No	No		No	26.4
	455A_MDR2_04	2023-05-01 13:37	MTB DETECTED LOW;RIF Resistance DETECTED	Test Result PASSES	none	No	No	No		No	25.7
	455A_MDR2_05	2023-05-01 13:38	MTB DETECTED LOW;RIF Resistance DETECTED	Test Result PASSES	none	No	No	No		No	25.2
	455A_MDR2_06	2023-05-01 13:38	MTB DETECTED LOW;RIF Resistance DETECTED	Test Result PASSES	none	No	No	No		No	26.1
	455A_MDR2_07	2023-05-01 13:38	MTB DETECTED LOW;RIF Resistance DETECTED	Test Result PASSES	none	No	No	No		No	27.0
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
	N/A PH 05/01/2023		ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
MDR 2			ND	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A
			ND	N/A	N/A	N/A	N/A	N/A		N/A	N/A

Table 3: Probe Check results for LSP Output

Analyte Name	Prb Chk 1,3 Min	Prb Chk 1,3 Max	Prb Chk 2 Min	Prb Chk 2 Max	Norm. Factor
SPC	0	474	153	0	361
IS1081-IS6110	0	338	185	0	461
rpo1	0	347	228	0	571
rpo2	0	145	112	0	281
rpo3	0	229	139	0	349
rpo4	0	187	126	0	314
QC1	0	171	39	0	NA
QC2	0	163	37	0	NA
rpo1 melt	0	0	0	0	0
rpo2 melt	0	0	0	0	0
rpo3 melt	0	0	0	0	0
rpo4 melt	0	0	0	0	0
rpo1 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 melt A	0	0	0	0	0
rpo4 Mut melt B	0	0	0	0	0

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

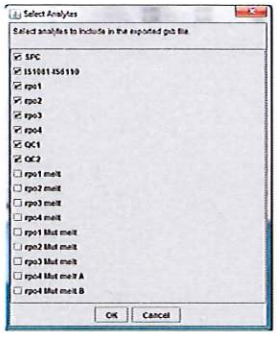


Table 4a: Ct and EndPt test results - Negative Control

Target	SPC Ct		SPC EPF
Negative Results Average	28.3		136
Specification	Lower limit (mean)	Upper limit (mean)	Lower limit (mean)
	24.1	27.8	54.0
PASS/FAIL	PASS	PASS	PASS
Overall Result	PASS		

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

Target	IS6110-IS1081 Ct		IS6110-IS1081 EPF	rpo1 Ct		rpo1 EPF	rpo1 Tm		rpo1 Melt Peak Height	rpo2 Ct		rpo2 EPF	rpo2 Tm		rpo2 Melt Peak Height
Average	24.9		441	27.2		383	69.4		70	27.2		248	73.2		95
Specification	Lower limit (mean)	Upper limit (mean)	Lower limit (mean)	Lower limit (mean)	Upper limit (mean)	Lower limit (mean)	Lower limit (mean)	Upper limit (mean)	Lower limit (mean)	Lower limit (mean)	Upper limit (mean)	Lower limit (mean)	Lower limit (mean)	Upper limit (mean)	Lower limit (mean)
	21.0	29.1	376.0	23.0	28.7	300.0	68.6	70.6	47.0	23.2	28.9	186.0	72.3	74.3	50.0
PASS/FAIL	PASS		PASS	PASS		PASS	PASS		PASS	PASS		PASS	PASS		PASS
Target	rpo3 Ct		rpo3 EPF	rpo3 Tm		rpo3 Melt Peak Height	rpo4 Ct		rpo4 EPF	rpo4 Tm		rpo4 Melt Peak Height			
Average	28.4		166	75.9		84	29.3		129	67.1		94			
Specification	Lower limit (mean)	Upper limit (mean)	Lower limit (mean)	Lower limit (mean)	Upper limit (mean)	Lower limit (mean)	Lower limit (mean)	Upper limit (mean)	Lower limit (mean)	Lower limit (mean)	Upper limit (mean)	Lower limit (mean)			
	24.0	29.8	119.0	75.0	77.0	57.0	25.6	30.8	86.0	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-IS1081 Ct		IS6110-IS1081 EPF	rpo1 Ct		rpo1 EPF	rpo1 Tm		rpo1 Melt Peak Height	rpo2 Ct		rpo2 EPF	rpo2 Tm		rpo2 Melt Peak Height
Average	28.2		110	25.9		386	69.6		49	26.9		169	70.3		43
Specification	Lower limit (mean)	Upper limit (mean)	Lower limit (mean)	Lower limit (mean)	Upper limit (mean)	Lower limit (mean)	Lower limit (mean)	Upper limit (mean)	Lower limit (mean)	Lower limit (mean)	Upper limit (mean)	Lower limit (mean)	Lower limit (mean)	Upper limit (mean)	Lower limit (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	69.4	71.4	10.0
PASS/FAIL	PASS		PASS	PASS		PASS	PASS		PASS	PASS		PASS	PASS		PASS
Target	rpo3 Ct		rpo3 EPF	rpo3 Tm		rpo3 Melt Peak Height	rpo4 Ct		rpo4 EPF	rpo4 Tm		rpo4 Melt Peak Height			
Average	N/A						24.5		385	73.8		164			
Specification							Lower limit (mean)	Upper limit (mean)	Lower limit (mean)	Lower limit (mean)	Upper limit (mean)	Lower limit (mean)			
							21.3	27.4	241.0	72.8	74.8	62.0			
PASS/FAIL							PASS		PASS	PASS		PASS			
Overall Result	PASS														

Table 5 - Probe Check 2 Results

Analyte	PC2 Average	Lower Limit	Upper Limit	PASS/FAIL
SPC	381	200	800	PASS
IS1081-IS6110	451	224	896	PASS
rpo1	571	319	1276	PASS
rpo2	281	158	632	PASS
rpo3	349	200	800	PASS
rpo4	314	162	648	PASS
QC1	98	59	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

Comments (optional): N/A

Performed By: PM Date: 05/01/2023

Reviewed by: JT Date: 5/2/23

Any retest performed? (Yes/No)	No (drop-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 JT 5/2/23 JT 5/2/23