

<h1>Quanterix</h1>	Form	
	Document No: FRM-0081	Revision No: 08
	Name: Homebrew Bead Filling Record	Effective: 02 Apr 2020 Page 1 of 14

1. LOT INFORMATION

Item Number: Item Description	Check One: <input type="checkbox"/> Item 103206: Homebrew Carboxylated Beads, 1.5 mL (779) <input type="checkbox"/> Item 103207: Homebrew Carboxylated Beads, 5 mL (779) <input checked="" type="checkbox"/> Item 103208: Homebrew Helper Bead Vial (1.5 mL) <input type="checkbox"/> Item 103611: Homebrew Carboxylated Beads, 1.5 mL <input type="checkbox"/> Item 103612: Homebrew Carboxylated Beads, 5 mL
Lot Number	019111
Expiration Date (From Source Lot)	09 Jan 2021

1.1. Have all lot information verified prior to labeling.

Performed By	Print Name	Signature	Date
	Razaad Chhoeng	Razaad Chhoeng	17 Jul 2020
Reviewed By	Print Name	Signature	Date
	Courtney SSO	Courtney	17 Jul 2020

2. PURPOSE

2.1. This form is used to record the required information for Bead filling operations.

3. REFERENCES

Document Number	Document Title
SOP-0049	Manual Filling Operation
SOP-0081	Multisizer Procedure for Bead Analysis

4. SAFETY AND ENVIRONMENTAL INFORMATION

4.1. Waste Handling and Disposal

4.1.1 Solutions containing chemical and biological substances must be decontaminated according to the Chemical Hygiene Plan and Biosafety Manual prior to disposal.

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5. EQUIPMENT

	Equipment ID	Calibration Due Date
Pipette(s)	PU02758 16M81971 16K60747 I38793B	31 Oct 2020 30 Sep 2020 31 Jan 2021 30 Sep 2020
Mixer	VTX-1, SMX-1	N/A, N/A
Balance	BAL-29	31 May 2021

6. MATERIALS

6.1. Enter the information for the source item lot number per the table (below) and the component number being filled as part of this form. N/A any unused rows.

Check One	Component Being Filled: Item # and Description	Source Component: Item # and Description	Source Item Lot #
<input type="checkbox"/>	Item 103206, Section 7: Homebrew Carboxylated Beads, 1.5 mL (779)	Item 103205: Bead, Lodestar Aliquoted - 779	
<input type="checkbox"/>	Item 103207, Section 8: Homebrew Carboxylated Beads, 5 mL (779)	Item 103205: Bead, Lodestar Aliquoted - 779	N/A RC17Jul2020
<input checked="" type="checkbox"/>	Item 103208, Section 9: Homebrew Helper Bead Vial (1.5 mL)	Item 103449: Helper Bead Concentrate, - 673/307	019 109
<input type="checkbox"/>	Item 103611, Section : Homebrew Carboxylated Beads, 1.5 mL	Item 103609: Bead, Lodestar Aliquoted, -0322	
<input type="checkbox"/>	Item 103612, Section : Homebrew Carboxylated Beads, 5 mL	Item 103609: Bead, Lodestar Aliquoted, -0322	N/A RC17Jul2020

NOTE: Proceed to complete appropriate Section based on item. N/A all unused Sections.

Description	Item #
Bottle, 4 mL, Amber, PP	100444
Closure, 4mL, White, PP	103086
Bottle and Cap, 8 mL, Clear	101394

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7. PROCEDURE – ITEM 103206 – HOMEBREW CARBOXYLATED BEADS, 1.5 mL (779)

7.1. Obtain source lot for aliquot.

*N/A
RC 17 Jul 2020*

Description	Item #	Lot #	Expiration Date
Bead, Lodestar Aliquoted – 779	103205		

7.2. Mix the source lot on a rotational mixer per SOP-0032. After mix time range has been met, stop the mixer per SOP-0032.

Mix Start Time	Mix Time Range	Mix End Time	Total Mix Time
AM/PM	≥ 30 minutes	AM/PM	min

7.3. Measure the concentration of the source lot per SOP-0081.

Bead Concentration	beads/mL
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7.4. Obtain vial(s)/labels for filling.

Description	Item #	Lot #	Expiration Date
Vial, 2mL, Clear, PP, Sterile	100442	N/A	N/A
Closure, 2mL Clear HDPE, Sterile	100443	N/A	N/A
Label, Blank, 2mL Vial	100371	N/A	N/A

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7.5. Prepare the area for filling per SOP-0049.

N/A RC 17 Jul 2020

Area Clear of Unrelated Material	Material and Paperwork Match	Work Area Clean and Clear of Debris	Equipment Within Calibration
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Performed By	Print Name	Signature	Date

7.6. Have filling preparation verified, per SOP-0049, prior to proceeding.

Area Clear of Unrelated Material	Material and Paperwork Match	Work Area Clean and Clear of Debris	Equipment Within Calibration
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Verified By	Print Name	Signature	Date

7.7. Fill bulk solution into vial(s) per SOP-0049.

Target: 1.9 g	Beginning Vial _____	Middle Vial 1 _____	Middle Vial 2 _____	Middle Vial 3 _____	End Vial _____
Net Weight	_____ g	_____ g	_____ g	_____ g	_____ g
Rounded Net Weight	. _____ g	. _____ g	. _____ g	. _____ g	. _____ g
Acceptable Range	1.8 – 2.0 g	1.8 – 2.0 g	1.8 – 2.0 g	1.8 – 2.0 g	1.8 – 2.0 g
Acceptance	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Performed By	Print Name		Signature		Date

7.8. Proceed to Section 12.

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8. PROCEDURE – ITEM 103207 – HOMEBREW CARBOXYLATED BEADS, 5 mL (779)

8.1. Obtain source lot for aliquot.

N/A
RC 17 Jul 2020

Description	Item #	Lot #	Expiration Date
Bead, Lodestar Aliquoted – 779	103205		

8.2. Mix the source lot on a rotational mixer per SOP-0032. After mix time range has been met, stop the mixer per SOP-0032.

Mix Start Time	Mix Time Range	Mix End Time	Total Mix Time
AM/PM	≥ 30 minutes	AM/PM	min

8.3. Measure the concentration of the source lot per SOP-0081.

Bead Concentration	beads/mL
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8.4. Obtain bottle(s)/labels for filling.

Description	Item #	Lot #	Expiration Date
Bottle and Cap, 8 mL, Clear	101394	N/A	N/A
Label, 4mL Vial Matte finish	103092	N/A	N/A

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8.5. Prepare the area for filling per SOP-0049.

Area Clear of Unrelated Material	Material and Paperwork Match	Work Area Clean and Clear of Debris	Equipment Within Calibration
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Performed By	Print Name	Signature	Date

N/A
RC 17 Jul 2020

8.6. Have filling preparation verified, per SOP-0049, prior to proceeding.

Area Clear of Unrelated Material	Material and Paperwork Match	Work Area Clean and Clear of Debris	Equipment Within Calibration
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Verified By	Print Name	Signature	Date

8.7. Fill bulk solution into bottle(s) per SOP-0049.

Target: 5.1 g	Beginning Bottle	Middle Bottle 1	Middle Bottle 2	Middle Bottle 3	End Bottle
	_____	_____	_____	_____	_____
Net Weight	_____ g	_____ g	_____ g	_____ g	_____ g
Rounded Net Weight	. _____ g	. _____ g	. _____ g	. _____ g	. _____ g
Acceptable Range	5.0 – 5.2 g	5.0 – 5.2 g	5.0 – 5.2 g	5.0 – 5.2 g	5.0 – 5.2 g
Acceptance	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Performed By	Print Name	Signature		Date	

8.8. Proceed to Section 12.

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9. PROCEDURE – ITEM 103208 – HOMEBREW HELPER BEAD VIAL (1.5 mL)

9.1. Obtain source lot for aliquot.

Description	Item #	Lot #	Expiration Date
Helper Bead Concentrate, - 673/307	103449	019109	09 Jan 2021

9.2. Mix the source lot on a rotational mixer per SOP-0032. After mix time range has been met, stop the mixer per SOP-0032.

Mix Start Time	Mix Time Range	Mix End Time	Total Mix Time
7:48 AM/PM	≥ 30 minutes	8:34 AM/PM	46 min

9.3. Measure the concentration of the source lot per SOP-0081.

Bead Concentration	1.252 x 10 ⁹ beads/mL
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9.4. Obtain bottle(s)/labels for filling.

Description	Item #	Lot #	Expiration Date
Bottle, 4 mL, Amber, PP	100444	N/A	N/A
Closure, 4mL, White, PP	103086	N/A	N/A
Label, 4mL Vial Matte finish	103092	N/A	N/A

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9.5. Prepare the area for filling per SOP-0049.

Area Clear of Unrelated Material	Material and Paperwork Match	Work Area Clean and Clear of Debris	Equipment Within Calibration
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Performed By	Print Name	Signature	Date
	Razaad Chhoeng	Razaad Chhoeng	17 Jul 2020

9.6. Have filling preparation verified, per SOP-0049, prior to proceeding.

Area Clear of Unrelated Material	Material and Paperwork Match	Work Area Clean and Clear of Debris	Equipment Within Calibration
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Verified By	Print Name	Signature	Date
	Courtney Russo	Courtney Russo	17 Jul 2020

9.7. Fill bulk solution into bottle(s) per SOP-0049.

Target: 1.9 g	Beginning Bottle	Middle Bottle 1	Middle Bottle 2	Middle Bottle 3	End Bottle
	1	10			17
Net Weight	1.909 g	1.877 g		N/A RC 17 Jul 2020	1.857 g
Rounded Net Weight	1.91 g	1.88 g			1.86 g
Acceptable Range	1.8 – 2.0 g	1.8 – 2.0 g	1.8 – 2.0 g	1.8 – 2.0 g	1.8 – 2.0 g
Acceptance	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Performed By	Print Name	Signature	Date		
	Razaad Chhoeng	Razaad Chhoeng	17 Jul 2020		

9.8. Proceed to Section 12.

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10. PROCEDURE – ITEM 103611 – HOMEBREW CARBOXYLATED BEADS, 1.5 mL

10.1. Obtain source lot for aliquot.

Description	Item #	Lot #	Expiration Date
Bead, Lodestar Aliquoted, -0322	103609		

N/A
RC 17 Jul 2020

10.2. Mix the source lot on a rotational mixer per SOP-0032. After mix time range has been met, stop the mixer per SOP-0032.

Mix Start Time	Mix Time Range	Mix End Time	Total Mix Time
AM/PM	≥ 30 minutes	AM/PM	min

10.3. Measure the concentration of the source lot per SOP-0081.

Bead Concentration	beads/mL
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10.4. Obtain vial(s)/labels for filling.

Description	Item #	Lot #	Expiration Date
Vial, 2mL, Clear, PP, Sterile	100442	N/A	N/A
Closure, 2mL Clear HDPE, Sterile	100443	N/A	N/A
Label, Blank, 2mL Vial	100371	N/A	N/A

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10.5. Prepare the area for filling per SOP-0049.

Area Clear of Unrelated Material	Material and Paperwork Match	Work Area Clean and Clear of Debris	Equipment Within Calibration
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Performed By	Print Name	Signature	Date

N/A RC17Jul2020

10.6. Have filling preparation verified, per SOP-0049, prior to proceeding.

Area Clear of Unrelated Material	Material and Paperwork Match	Work Area Clean and Clear of Debris	Equipment Within Calibration
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Verified By	Print Name	Signature	Date

10.7. Fill bulk solution into vial(s) per SOP-0049.

Target: 1.9 g	Beginning Vial _____	Middle Vial 1 _____	Middle Vial 2 _____	Middle Vial 3 _____	End Vial _____
Net Weight	_____ g	_____ g	_____ g	_____ g	_____ g
Rounded Net Weight	. _____ g	. _____ g	. _____ g	. _____ g	. _____ g
Acceptable Range	1.8 – 2.0 g	1.8 – 2.0 g	1.8 – 2.0 g	1.8 – 2.0 g	1.8 – 2.0 g
Acceptance	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Performed By	Print Name		Signature		Date

10.8. Proceed to Section 12.

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11. PROCEDURE – ITEM 103612 – HOMEBREW CARBOXYLATED BEADS, 5 mL

11.1. Obtain source lot for aliquot.

N/A
RC 17 Jul 2020

Description	Item #	Lot #	Expiration Date
Bead, Lodestar Aliquoted, -0322	103609		

11.2. Mix the source lot on a rotational mixer per SOP-0032. After mix time range has been met, stop the mixer per SOP-0032.

Mix Start Time	Mix Time Range	Mix End Time	Total Mix Time
AM/PM	≥ 30 minutes	AM/PM	min

11.3. Measure the concentration of the source lot per SOP-0081.

Bead Concentration	beads/mL
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11.4. Obtain bottle(s)/labels for filling.

Description	Item #	Lot #	Expiration Date
Bottle and Cap, 8 mL, Clear	101394	N/A	N/A
Label, 4mL Vial Matte finish	103092	N/A	N/A

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11.5. Prepare the area for filling per SOP-0049.

Area Clear of Unrelated Material	Material and Paperwork Match	Work Area Clean and Clear of Debris	Equipment Within Calibration
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Performed By	Print Name	Signature	Date

N/A
RC17 Jul 2020

11.6. Have filling preparation verified, per SOP-0049, prior to proceeding.

Area Clear of Unrelated Material	Material and Paperwork Match	Work Area Clean and Clear of Debris	Equipment Within Calibration
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Verified By	Print Name	Signature	Date

11.7. Fill bulk solution into bottle(s) per SOP-0049.

Target: 5.1 g	Beginning Bottle	Middle Bottle 1	Middle Bottle 2	Middle Bottle 3	End Bottle
	_____	_____	_____	_____	_____
Net Weight	_____ g	_____ g	_____ g	_____ g	_____ g
Rounded Net Weight	. _____ g	. _____ g	. _____ g	. _____ g	. _____ g
Acceptable Range	5.0 – 5.2 g	5.0 – 5.2 g	5.0 – 5.2 g	5.0 – 5.2 g	5.0 – 5.2 g
Acceptance	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Performed By	Print Name	Signature	Date		

11.8. Proceed to Section 12.

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12. PROCEDURE – STORAGE

12.1. Document number of bottle(s) filled.

Bottle(s) Filled
17 ea

12.2. Store filled bottle(s) at 2–8°C. Record storage location and calibration due date.

Storage Location	Storage Location Calibration Due Date
CRM-03	31 May 2021

Performed By	Print Name	Signature	Date
	Razaad Chhoeng	<i>Razaad Chhoeng</i>	17 Jul 2020

13. DOCUMENT APPROVAL

Approved By	Print Name	Signature	Date
Manufacturing	Rajina Monandhar	<i>Rajina Monandhar</i>	20 Jul 2020
Quality Assurance	Linda Carr	<i>Linda Carr</i>	20 Jul 2020

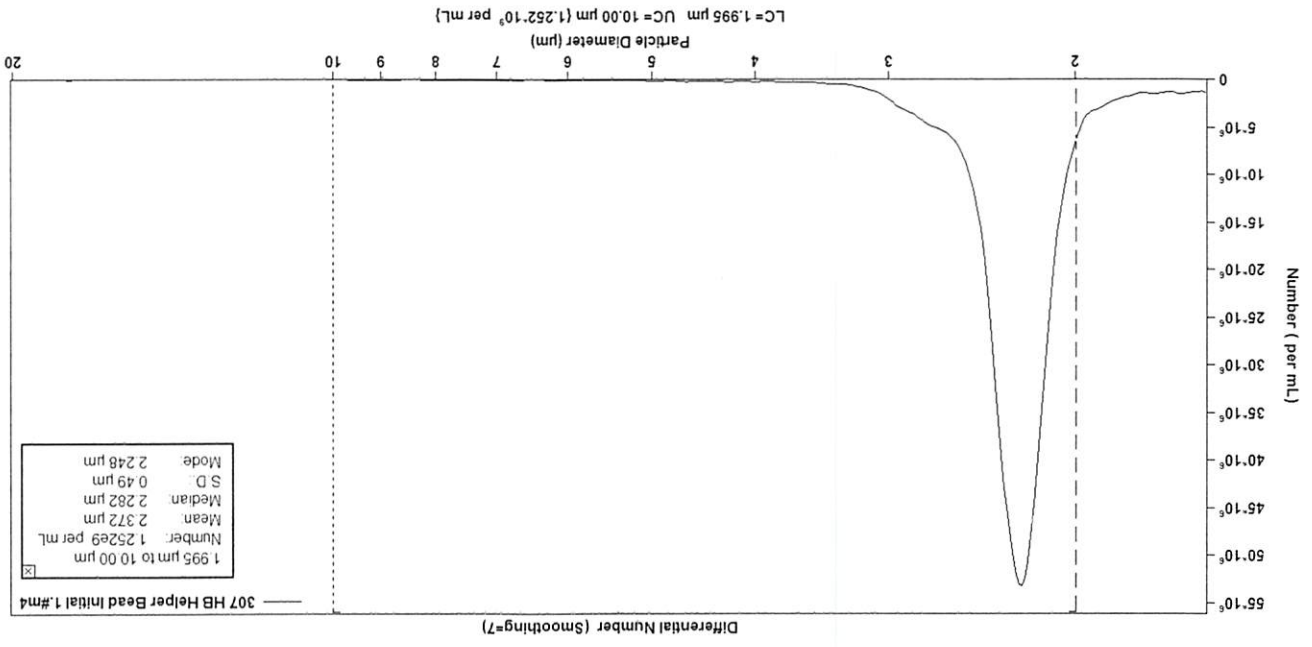
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14. REVISION HISTORY

Revision	Detailed Description	Date	Originator
01	Initial Release	07Jan2016	B. Flaherty
02	DCR-16-1150: The fill range for part # 100451 was changed from "1.8 – 2.0 g" to "1.5-1.7g" to accurately reflect the fill range of this product.	18Jan2017	R. Fregeolle
03	DCR-18-0474: Update to new HB part numbers.	07May2018	B. Pink
04	DCR-19-2110: Hard code all item numbers with their description. Add new item number 103449 (Helper bead concentrate) as a source item. Add field to input source item and lot numbers.	31Jul2019	D. Ahuja
05	DCR-19-2176: Updated Section 1 flow for operator clarity Added calibration due date to Section 5 Updated Section 6 to list sequentially based on item # being filled Separated each fill operation into separate section for ease of use Added space for approval signatures	07Jan2020	D. Sorel
06	DCR-20-0482: Section 1, updated to align with template Section 3, added reference to SOP-0081 Section 6, removed Multiplex Homebrew Beads from scope Section 7, 8 & 9, added requirement to record concentration; added requirement to perform filling line clearance	20Feb2020	E. Ferrell D. Sorel
07	DCR-20-0512 (admin): Updated item # and description for bottle/caps used for item # 103208 Added label item # and description	25Feb2020	D. Sorel
08	DCR-20-0571: Added item # (103611, 103612, 103609) and description of homebrew carboxylated beads per CC-20-0001	09Mar2020	D. Sorel

End of Document



Homebrew Helper Bead 1.5mL vial
 Item #: 103808
 Lot #: 019111
 Exp: 09 Jan 2021
 RC 17 Jul 2020

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Use of Form: Only the Manufacturing and Quality Control groups are required to complete all documentation on form, following instructions in steps 4-6 for operation type. Other groups (i.e., Accelerator, AD, ATS) can strike through with N/A and initial date for the 'Verified By' fields and/or any sections of this form that do not apply in your functional area.

1. Component or Kit Information

		Performed By: (Mfg) Initial/Date	Verified By: (Mfg) Initial/Date
Component Name:	Homebrew Helper Bead, 1.5mL vial	RC 17 Jul 2020	BB 17 Jul 2020
Part Number:	103208		
Lot Number:	019111		
Expiration Date:	09 Jan 2021		
Storage Temperature:	2-8°C		
Number of labels requested:	20		

		Performed By: (Mfg) Initial/Date	Verified By: (Mfg) Initial/Date
Number of Labels Printed:	20	RC 17 Jul 2020	BB 17 Jul 2020

2. Label Inspection, completed by Verifier (Mfg)

2.1. Verifier attach label below, initial and date label

N/A RC 17 Jul 2020

Homebrew Helper Bead Vial 1.5 mL

REF	103208	2-8°C	Conc: 1.25 x10 ⁹ beads/mL
LOT	103208		Quanterix Corp.
	09-Jan-2021		

N/A RC 17 Jul 2020

Homebrew Helper Bead Vial 1.5 mL

REF	103208	2-8°C	Conc: 1.25 x10 ⁹ beads/mL
LOT	019111		Quanterix Corp.
	09-Jan-2021		

BB 17 Jul 2020
BB 17 Jul 2020
BB 17 Jul 2020

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2.2. Label accuracy verification (Mfg):

		Performed By: (Mfg) Initial/Date	Verified By: (Mfg) Initial/Date
Print Quality	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	RC 17 Jul 2020	BB 17 Jul 2020
Item #	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A		
Lot #	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A		
Expiration Date	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A		
Storage Temp.	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A		
Barcode Check & Scan	<input type="checkbox"/> Pass <input type="checkbox"/> Fail <input checked="" type="checkbox"/> N/A		

	Print Name	Signature	Date
Label Amount and Quality Verified by (Quality Control):	N/A	RC	17 Jul 2020

3. Labeling Line Clearance (✓ appropriate box)

		Performed By: (Mfg) Initial/Date	Verified By: (Mfg) Initial/Date
Area clear of unrelated material	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	RC 17 Jul 2020	BB 17 Jul 2020
Material lot #, paperwork & labels match	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		
Work area clean and clear of debris	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

4. Filling Line Clearance (✓ appropriate box)

4.1. Manufacturing Operators; N/A the tables in this section if the data is captured in the appropriate WI. If performing a Kitting operation, N/A this section and proceed to step 6.

		Performed By: (Mfg) Initial/Date	Verified By: (Mfg) Initial/Date
Area clear of unrelated material	<input type="checkbox"/> Yes <input type="checkbox"/> No	N/A RC 17 Jul 2020	
Material & Paperwork match	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Work area clean and clear of debris	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Equipment within calibration	<input type="checkbox"/> Yes <input type="checkbox"/> No		

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5. Filling Bulk Solution into Reagent Bottles

5.1. Manufacturing Operators; N/A the tables in this section if the data is captured in the appropriate WI. If performing a kitting operation N/A this section and proceed to step 6.

5.2. Calculate the top and bottom of the fill range in the Fill Volume Range Calculation table below.

5.3. For the following steps, record data in the Weight Check Calculation table below:

5.3.1. Record serial number of the bottle used for weight check if applicable, if not then identify the bottle with a number.

NOTE: If the total number of bottles is less than 300, identify 3 bottles for weight verification check. If the total number of bottles is greater than 300, use 5 bottles for weight verification. The bottles should be from the beginning, middle, and end of the filling episode. If 3 bottles are used for verification, then record N/A for Middle Bottle 2 and 3.

5.3.2. Record the tare weight of each weight verification bottle with a cap.

5.3.3. Fill the bulk into the labeled reagent bottles then cap. Verify the fill weight of each weight verification bottle throughout the filling event.

5.3.4. Once a weight verification bottle is filled, pause the filling event to weigh the sample to ensure it is in the specific range.

NOTE: If bottle passes specified range continue the filling process. If bottle fails the specified range, stop the filling process and contact immediate supervisor.

5.3.5. To convert target fill and target range into grams, calculate conversion as 1:1 ratio.

Table: Fill Volume Range Calculation

Vial/Bottle Size	Target Fill	Filling Equipment	
Top of range 2%			
Target Fill	X	Factor 0.02	= 2% of Top range
Target Fill	+	2% of Top range	= Top of range

Bottom of range 2%			
Target Fill	X	Factor 0.02	= 2% of Bottom range
Target Fill	-	2% of Bottom range	= Bottom of Range
Performed By: (Mfg) Initial/Date		Verified By: (Mfg) Initial/Date	

N/A
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Table: Weight Check Calculation

	Bottle Number	Gross weight	Tare Weight	Net weight	Target Range	Net Weight Meets Target Range
Beginning Bottle						<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Middle Bottle 1						<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Middle Bottle 2						<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Middle Bottle 3						<input type="checkbox"/> Pass <input type="checkbox"/> Fail
End Bottle						<input type="checkbox"/> Pass <input type="checkbox"/> Fail

N/A
RC 17 Jul 2020

Performed By (Mfg) Initial/Date:		Verified By (Mfg) Initial/Date:	
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6. Kitting: Line Clearance (Quality Control)

6.1. If performing a reagent filling operation N/A this section and proceed to step 7.

	Performed by (QC): Initial/Date
Item # verified	<input type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A
Lot # verified:	<input type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A
Verified #. of Reagents equal to # of Kits to be built:	<input type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A
Verified correct kitting document:	<input type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A
Verified correct # of accessories (ie: insert cards, bottles, labels):	<input type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A


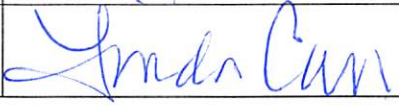
Quanterix	Form	
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7. Label Accountability

		Quantity:	Performed By: (Mfg) Initial/Date	Verified By: (Mfg) Initial/Date
A	Total number of Bottles/Kits Labeled:	17	RC 17 Jul 2020	BB 17 Jul 2020
B	Total number of Labels on Form:	1		
C	Total number of Labels (A+B):	① 20 18		
D	Number of Labels Requested:	20		
E	Calculate difference (D-C):	2		
F	Number of Labels Destroyed:	2		
G	Calculate Label Reconciliation (F-E):	0		

Label Accountability Verified by (Quality Control):	Print name	Signature	Date
		NIA RC 17 Jul 2020	

8. Final Document Review Signatures

	Print name	Signature	Date
Reviewed by	Rajina Mansandhor		20 Jul 2020
QA Reviewed By	Linda Cam		20 Jul 2020

① Transcribe error. RC 17 Jul 2020

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9. REVISION HISTORY

Revision	Detailed Description	Date	Originator
1.0	Initial Release. Created new doc number FRM-100-0035 that replaces FRM.009. (Doc number follows convention FRM-NNN-NNNN.)	30Oct2015	K. Lerma
1.1	Add specific gravity calculation to convert from mL to grams. Formatting.	18Dec2015	K. Lerma
1.2	DCR-16-0598: Transfer documents from QMS 2.0 to R&D vault. Archive the document in QMS 2.0 once released in R&D.	28Sep2016	S. Chin
03	DCR-16-1219: Update header and footer format from M-Files to MasterControl	16Nov2016	S. Moriarty
04	DCR-18-0218: Add Line Clearance to improve the accuracy of the kitting process.	08Feb2018	D. Ahuja
05	DCR-18-0363: Delete step header, unnecessary header causing issues with use of n/a box.	16Mar2018	B. Flaherty
06	DCR-19-0903: Created new signature section (8)	21Feb2019	K. Lerma
07	DCR-19-1111: Change vault so that a PDF will generate after release.	04Apr2019	S. Moriarty
08	DCR-19-1233: Formatting changes for improved GDP. Specified Mfg and QC responsibilities.	25Apr2019	M. Green

End of Document