Quanterix	**Form**	
	Document No: FRM-0081	Revision No: 03 Effective: 07 May 2018 Page 1 of 5
	Name: Homebrew Bead Filling Record	

1. BATCH INFORMATION

Component name	Homebrew Helper Bead (779) 1.5mL
Item number	103208
Lot Number (Vialed Reagent)	825608
Lot Number (Source Material/ Concentrate lot)	825605
Expiration date (DDMMMYYYY)	13 Mar 2019
Bead Concentration (beads/ml)	1.219×10^9
Quantity (# of units to be filled)	16
Vial / bottle size	4mL
Fill Volume Target	1.8g
Filling date (DDMMMYYYY)	24 Sep 2018
Filling operator	BR
Checked by	Rajina Manandhar

2. PURPOSE

The form is used to record the required information for Bead filling operations. This document is used alongside Formulation and Label documentation to record filling for better traceability.

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3. REFERENCES

Document Number	Document title
FRM-0113	Line Clearance Checklist
SOP-0028	Quanterix Glossary
SOP-0033	Balance Operation
SOP-0034	Gowning
SOP-0039	WandMixer
SOP-0040	Cleaning Labware
SOP-0042	Zebra Label Printer Operation (ZM400)
SOP-0043	Fill Volume Information for Simoa Components
SOP-0049	Manual Filling Operation
PROC-0004	Quanterix Chemical Hygiene Plan
PROC-0003	Quanterix Biosafety Manual

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.

5. EQUIPMENT

Document Title	Equipment #
Pipetting equipment	PS4173G
Weighing equipment	28804486

6. MATERIALS

Description	Item #
Vial, 2 mL, Clear, PP, Sterile	100442
Closure, 2 mL Clear HDPE, Sterile	100443
Bottle, 4 mL, Amber, PP	100444
Closure, 4mL, White, PP	103086
Bottle and Cap, 8 mL, Clear	101394

Release

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7. PERFORMING THE FILL

- Refer to SOP-0049 for the manual filling process.

7.1. Fill Bulk Solution into Reagent Bottles

7.1.1 Print labels then adhere to the required number of reagent bottles.

7.1.2 Fill the bulk into the labeled reagent bottles then cap. Verify the fill weight throughout the filling event as specified below.

- 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.

- Record the tare weight of each bottle with a cap and record in the table below.

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

- Once a weight verification bottle is filled, stop and weigh the sample to ensure it is in the specified range.

- If bottle passes specified range continue the filling process. If bottle fails the specified range, stop the filling process and contact immediate supervisor. Document course of action in the comment section below.

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	Name: Homebrew Bead Filling Record	

☐ N/A	**4-mL Amber Vial**				
Item: Dye Encoded Homebrew Target: **1.8g - 2.0g**	Beg. Bottle 1	Middle Bottle 1 8	Middle Bottle 2 ___	Middle Bottle 3 ___	End Bottle 16
Gross weight	4.00	3.99			4.02
Tare weight	2.19	2.19			2.19
Net weight	1.81	1.80			1.85 1.83
Acceptance	☑ Pass ☐ Fail	☑ Pass ☐ Fail	☐ Pass ☐ Fail ☑ N/A	☐ Pass ☐ Fail ☐ N/A	☑ Pass ☐ Fail

☑ **N/A Comment:**

_____

_____

_____

☑ N/A	**8-mL Clear Vial**				
Item: 103207 Target: **5.0 - 5.2g**	Beg. Bottle ___	Middle Bottle 1 ___	Middle Bottle 2 ___	Middle Bottle 3 ___	End Bottle ___
Gross weight					
Tare weight					
Net weight					
Acceptance	☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail ☐ N/A	☐ Pass ☐ Fail ☐ N/A	☐ Pass ☐ Fail

☑ **N/A Comment:**

_____

_____

_____

Quanterix	**Form**	
	Document No: FRM-0081	Revision No: 03 Effective: 07 May 2018 Page 5 of 5
	Name: Homebrew Bead Filling Record	

☑ N/A	**2-mL Clear Vial**				
Item: 103206 **Target:** **1.5g - 1.7g**	Beg. Bottle ___	Middle Bottle 1 ___	Middle Bottle 2 ___	Middle Bottle 3 ___	End Bottle ___
Gross weight					
Tare weight					
Net weight					
Acceptance	☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail ☐ N/A	☐ Pass ☐ Fail ☐ N/A	☐ Pass ☐ Fail

☑ N/A Comment:

_____

_____

_____

7.1.3   Document number of vials filled, QC samples, and amount for inventory.

Vials filled	QC Samples	Inventory (Filled-QC)
16	0	16

7.1.4   Store filled reagent bottles at 2–8°C.

8.   DOCUMENTATION/RECORDS MANAGEMENT

8.1.   Completed records must be submitted to Quality Control for review and archival.
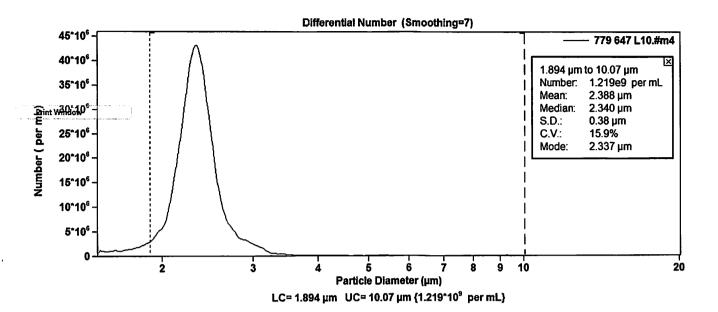
9.   REVISION HISTORY

Revision	Detailed Description	Date	Originator
1.0	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

End of Document

BECKMAN COULTER™

Differential Number (Smoothing=7)

779 647 L10.#m4

1.894 µm to 10.07 µm
Number:	1.219e9 per mL
Mean:	2.388 µm
Median:	2.340 µm
S.D.:	0.38 µm
C.V.:	15.9%
Mode:	2.337 µm

Number (per mL)

Particle Diameter (µm)

LC= 1.894 µm   UC= 10.07 µm {1.219*10⁹ per mL}

Quanterix

	Form	
Document No: FRM-0108		**Revision No:** 05 **Effective:** 20 Mar 2018 **Page 1 of 5**
Name: Component Labeling and Filling Record		

1. Component or Kit Information

Component Name:	Itmebrav Helper Bed 7M 1.5mL
Part Number:	105208
Lot Number:	825608
Expiration Date:	13 Mar 2019
Storage Temperature:	2-8°C
Number of labels requested:	18
Completed By:	BF
Date:	24 Sp 28
Verified by:	RM
Date:	24 Sep 2018

# of Labels Printed	Printed by	Date
18	RM	24 Sep 2018

2. Label Inspection, completed by Verifier

Print Quality	Item #	Lot #	Expiration Date	Storage Temp.	Barcode Check & Scan
☑ Pass	☑ Pass	☑ Pass	☐ Pass	☑ Pass	☐ Pass
☐ Fail	☐ Fail	☐ Fail	☐ Fail	☐ Fail	☐ Fail
☐ N/A	☐ N/A	☐ N/A	☐ N/A	☐ N/A	☑ N/A

Labels Verified by: _____   **Date:** 24 Sp 8 _____

Quanterix

Form	
Document No: FRM-0108	Revision No: 05 Effective: 20 Mar 2018 Page 2 of 5
Name: Component Labeling and Filling Record	

Homebrew Helper Bead Vial (779) 1.5mL

REF 103208 2°-8° Conc: 1.22 x10⁹ beads/ml

LOT 825608

13-Mar-2019   Quanterix Corp

For Research Use Only   LBL-181-220 Rev 1.0

BF 24 Spr 8

Verifier attach label above, initial and date label

3. Labeling Line Clearance (✓ each box)

Area clear of unrelated material	Material lot #, paperwork & labels match	Work area clean and clear of debris
✓	✓	✓

Performed by	Date
(signature)	24 Spr

4. Label Accountability

A. # of Bottles/Kits Labeled: _____ 16 _____

B. # of Labels on Form: _____ 1 _____

C. Total # of Labels (A+B): _____ 17 _____

D. # of Labels Requested: _____ 18 _____

E. Difference (D–C): _____ 18 _____

F. # of Labels Destroyed: _____ 1 _____

G. Reconciliation (F–E): _____ X0 _____

BF 24Spr

Quanterix

Form

Document No: FRM-0108

Name: Component Labeling and Filling Record

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☑ **N/A** Explain any discrepancies:

_____

_____

_____

Accountability Performed by: _____   Date: _____

5. ☑ N/A Kitting: Line Clearance

Correct Number of Individual Reagents taken out for the Number of Kits being built	Correct kitting document being used for the kit being assembled	Correct number of accessories, i.e. Insert cards, bottles, labels
☐ Pass	☐ Pass	☐ Pass
☐ Fail	☐ Fail	☐ Fail
☐ N/A	☐ N/A	☐ N/A

Performed by	Date

6. ☐ N/A Filling Line Clearance (✓ each box)

Area clear of unrelated material	Material & Paperwork match	Work area clean and clear of debris	Equipment within calibration
✓	✓	✓	✓

Performed by	Date
RM	24 Sep 2018

7. ☑ N/A **Filling Bulk Solution into Reagent Bottles**

Fill the bulk into the labeled reagent bottles then cap. Verify the fill weight throughout the filling event as specified below.

- 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.

- Record the tare weight of each bottle with a cap and record in the table below.

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

- Once a weight verification bottle is filled, stop and weigh the sample to ensure it is in the specified range.

- If bottle passes specified range continue the filling process. If bottle fails the specified range, stop the filling process and contact immediate supervisor. Document course of action in the comment section below.

- To convert target fill and target range into grams multiply by 1.02.

Vial/Bottle Size	Target Fill	Target Range	Filling Equipment

	Begin Bottle	Middle Bottle 1	☐ N/A Middle Bottle 2	☐ N/A Middle Bottle 3	End Bottle
Gross weight					
Tare Weight					
Net weight					
Acceptance	☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail
Performed by:		Date:	Verified by:		Date:

Verification Performed by (Mfg): _____ **Date:** _24Sep2018_

ljc 25Sep-2018 A
Packet Reviewed by (QC): _____ **Date:** _25 Sep 2018_

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

End of Document