

Quanterix	Form	
	Document No: FRM-0108	Revision No: 08 Effective: 11 Jun 2019 Page 1 of 6
	Name: Component Labeling and Filling Record	

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 Bead Diluent (500mL)	MG 17 May 2021	PBP 17 May 2021
Part Number:	101362		
Lot Number:	110119		
Expiration Date:	11 Apr 2022 ^①		
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	MG 17 May 2021	PBP 17 May 2021

2. Label Inspection, completed by Verifier (Mfg)

2.1. Verifier attach label below, initial and date label

Simoa Homebrew Bead Diluent (500 mL)

REF 101362	2-8°C		LBL-181-60 Rev 2.0
LOT 110119			
Exp 11-Apr-2022	Quanterix Corp.		
For Research Use Only			
PBP 17 May 2021			

Released

① Fill Form lot 110115. MG 17 May 2021.

<h1>Quanterix</h1>	Form	
	Document No: FRM-0108	Revision No: 08
	Name: Component Labeling and Filling Record	Effective: 11 Jun 2019 Page 2 of 6

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	MG 17 May 2021	PBP 17 May 2021
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		

Label Amount and Quality Verified by (Quality Control):	Print Name	Signature	Date
	N/A	MG 17 May 2021	

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	MG 17 May 2021	PBP 17 May 2021
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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	MG 17 May 2021	PBP 17 May 2021
Material & Paperwork 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		
Equipment within calibration	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

Released

Quanterix	Form	
	Document No: FRM-0108	Revision No: 08
	Name: Component Labeling and Filling Record	Effective: 11 Jun 2019 Page 3 of 6

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	500 mL	Target Fill	500g	Filling Equipment	N/A
Top of range 2%					
Target Fill		Factor		2% of Top range	
500 g	X	0.02	=	10 g	
Target Fill		2% of Top range		Top of range	
500 g	+	10 g		510 g	

Bottom of range 2%					
Target Fill		Factor		2% of Bottom range	
500g	X	0.02	=	10 g	
Target Fill		2% of Bottom range		Bottom of Range	
500g	-	10g		490g	
Performed By: (Mfg) Initial/Date	MG 17 May 2021			Verified By: (Mfg) Initial/Date	PBP 17 May 2021

Released

<h1>Quanterix</h1>	Form	
	Document No: FRM-0108	Revision No: 08
	Name: Component Labeling and Filling Record	Effective: 11 Jun 2019 Page 4 of 6

Table: Weight Check Calculation

	Bottle Number	Gross weight	Tare Weight	Net weight	Target Range	Net Weight Meets Target Range
Beginning Bottle	1	575.1	67.7 g	507.4	490-510g	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Middle Bottle 1	7	568.2	67.5g	500.7		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Middle Bottle 2		N/A	MG 17 May 2021			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Middle Bottle 3						<input type="checkbox"/> Pass <input type="checkbox"/> Fail
End Bottle	15	574.3	67.5g	506.8		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail

Performed By (Mfg) Initial/Date: <u>MG 17 May 2021</u>	Verified By (Mfg) Initial/Date: <u>BB 17 May 2021</u>
--	---

6. Kitting: Line Clearance (Quality Control)

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

Item # verified	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	<input type="checkbox"/> N/A	Performed by (QC): Initial/Date: <u>N/A MG 17 May 2021</u>
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	

Released

Quanterix	Form	
	Document No: FRM-0108	Revision No: 08
	Name: Component Labeling and Filling Record	Effective: 11 Jun 2019 Page 5 of 6

7. Label Accountability

		Quantity:	Performed By: (Mfg) Initial/Date	Verified By: (Mfg) Initial/Date
A	Total number of Bottles/Kits Labeled:	① 215	MG 17 May 2021	BB 17 May 2021
B	Total number of Labels on Form:	1		
C	Total number of Labels (A+B):	16		
D	Number of Labels Requested:	20		
E	Calculate difference (D-C):	4		
F	Number of Labels Destroyed:	4		
G	Calculate Label Reconciliation (F-E):	0		

Label Accountability	Print name	Signature	Date
Verified by (Quality Control):	N/A	MG 17 May 2021	

8. Final Document Review Signatures

	Print name	Signature	Date
Reviewed by	Jen Patman		23 May 2021
QA Reviewed By	Linda Carr		24 May 2021

Released

① Entry Error. MG 17 May 2021

Quanterix	Form	
	Document No: FRM-0108 Name: Component Labeling and Filling Record	Revision No: 08 Effective: 11 Jun 2019 Page 6 of 6

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

Released

Product Number:	101362
Lot Number:	110119
Expiration:	11-Apr-2022
Storage:	2-8°C

Laboratory Analysis

Characteristic	Result
pH Measurement	PASS

Review/Approval

Shivani Goel

QC Manager

Shivani Goel 24 May 2021

Name

Title

Signature/Date