Quanterix	Work Instruction	
	Document No: WI-1364 **Name:** Lysate Diluent D	Revision No: 03 Effective: 08 Apr 2019 Page 1 of 11

LABELING INFORMATION

Component name	Lysate Diluent D
Lot number	210922 (1)
Item number – Bulk	102915
☑ Item number – Reagent (30 mL)	102914
☐ Item number – Reagent (400mL)	103361
Operator	Nathaniel Richardson
Manufacturing date	26May2022
Batch size (kg)	0.032
Reviewer	Michael P. Coffey
Expiration date (12 months from DOM)	19Apr2023 (1)
Storage conditions	2-8°C

Released

1. PURPOSE

This procedure describes the preparation of Lysate Diluent D (0.2% BSA, 0.5% NCS, pH 8.0). The buffer is composed of 50 mM Tris, 450 mM NaCl, 0.2% BSA, 0.5% Newborn Calf Serum, 0.5% Brij L23, 0.5% Tergitol NP-40, 0.05% ProClin 300, and pH 8.0. The reagent fill volume is 30 mL or 400 mL.

2. REFERENCE DOCUMENTS

Description	Document #
Quanterix Biosafety Manual	PROC-0003
Quanterix Chemical Hygiene Plan	PROC-0004
pH meter and probe	SOP-0029
Pipetting equipment	SOP-0030
Filtration equipment	SOP-0031
Mixing equipment	SOP-0032
Weighing equipment	SOP-0033
Gowning	SOP-0034
DI water	SOP-0036
Deviations	SOP-0053
Non – Conforming Material	SOP-0091

Release

(1) Fill from lot # 210906, EXP: 19Apr2022

3. SAFETY AND ENVIRONMENTAL INFORMATION

3.1 Waste Handling and Disposal

3.1.1 This product is suitable for drain disposal. Solutions containing biological substances must be decontaminated prior to disposal.

4. EQUIPMENT

Description	Equipment #
pH meter and probe	
Pipetting equipment	N/A NTR 26 May 2022
Filtration equipment	
Mixing equipment	
Weighing equipment	AST-10613
DI Water	N/A NTR 26 May 2022

5. MATERIALS

Description	Item #	Storage Location
Trizma base, ⩾ 99.9%	100024	Room temp
Trizma hydrochloride, reagent grade	100242	Room temp
Sodium chloride	100025	Room temp
Brij L23 solution, 30 %	102906	Room temp
TERGITOL NP-40 solution, 70%	102905	Room temp
Albumin from bovine serum (BSA)	100015	2°–8°C
Newborn calf serum (NCS)	100011	-20 °C
ProClin 300	100182	Room temp
Sodium hydroxide solution – 1.0 M NaOH	100183	Room temp
Hydrochloric acid solution – 1.0 M HCl	100173	Room temp
Bottle, 30-mL	100449	Room temp
Bottle, 500-mL	101398	Room temp
0.2-micron filter appropriate for batch size	N/A	N/A

Released

6. PROCEDURE

6.1 Component Addition

6.1.1 Determine the batch size, round up to the nearest tenth.

☐ N/A For 30 mL reagent preparation use table below to calculate batch size

Number of Reagents		Fill Volume		Excess		mL to kg Conversion		Batch size
1	×	30.0 mL	×	1.05	/	984.252	=	0.032 kg

Note: 1L = 1.016kg

☑ N/A For 400 mL reagent preparation use table below to calculate batch size

Number of Reagents		Fill Volume		Excess		mL to kg Conversion		Batch size
	×	400 mL	×	1.05	/	984.252	=	kg

Note: 1L = 1.016kg

☑ N/A For bulk preparation indicate the batch size below

Batch Size
kg

6.1.2 Place 70% Tergitol NP-40 and 30% Brij L23 solutions in a water bath heated to 45° C for a minimum of 20 minutes. Stir each bottle 10 times with a fresh serological pipette after removing from water bath and prior to measuring to ensure homogenous composition. Serological pipette used can be used for aspirating required amount for batch.

Time placed in water bath	Time removed from water bath	Total time
AM/PM N/A NTR26May2022	AM/PM	

Note: Terigtol's melting point is 39° C, therefore Tergitol should be measured immediately after removing from water bath.

6.1.3 Calculate and record the amount needed of each component in the table below. Verify all calculations before proceeding.

6.1.4 Select an appropriate container to fit all of the components calculated in the table below (section 6.1.8).

Released

(1) Fill from lot 210906 NTR26May2022 only

6.1.5 Select a stir bar and tare the container with the stir bar on a balance. Record the weight. If not using a stir bar, tare the container without it.

Tare weight: _____kg

6.1.6 Measure DI water calculated in the table below. Dispense water into a suitably sized, and labeled container.

6.1.7 Begin mixing with a stir plate or overhead mixer.

6.1.8 Measure and add while mixing the calculated quantity of each component in the order listed in the table below. If required rinse components into container with DI water.

Material Name and Item #	Exp. Date	Batch Size (kg)		Amount Required			Amount Added	Lot #
Deionized Water	N/A		×	800 g/kg	=	g	g	N/A
Trizma base 100024			×	2.61 g/kg	=	g	g	
Trizma hydrochloride 100242			×	4.37 g/kg	=	g	g	
Sodium Chloride 100025			×	25.9 g/kg	=	g	g	
Brij L23 solution, 30% 102906			×	16.4 g/kg	=	mL	mL	
TERGITOL NP-40 solution, 70% 102905			×	7.75 g/kg	=	mL	mL	
ProClin 300 100182			×	0.492 g/kg	=	g	g	

N/A NTR 26 MAY 2022

	Print Name	Signature	Date
Performed by			
Verified by			

Released

6.1.9 Cover and mix for a minimum of 15 minutes.

Start mix time	End mix time	Total mix time
AM/PM	AM/PM	

6.2 Initial pH Measurement

6.2.1 Remove a 3-mL sample from the batch.

6.2.2 Measure and record the pH and temperature of the sample. Verify that the sample temperature is 19–25°C.

Solution temp. °C	Initial pH	Initial pH target
		7.80–8.20

If pH deviates from target range, consult with supervisor. ☐ N/A

Comment:

6.2.3 Adjust the pH to a final pH target of **7.90 – 8.10** by adding **1M NaOH** or **1M HCl** to **Lysate Diluent D** while mixing. Record the data for the pH adjustments below. Repeat until the final pH target is reached.

NOTE: If no pH adjustments are needed to achieve a pH target of **7.90 – 8.10**, N/A the table in section 6.2.3 and proceed to section 0

☐ N/A pH adjustment table

Check if N/A	pH Adjustment Solution Type Added (Circle One)		Expiration Date	Volume Added (mL)	pH Solution Lot #	Sample Temp °C (Range 19 – 25°C)	pH Reading	Target pH
	1M NaOH 100183	1M HCl 100173						
☐	1M NaOH	1M HCl						7.90–8.10
☐	1M NaOH	1M HCl						

6.3 Component Addition Table 2

6.3.1 Calculate and record the amount of NCS needed in the table below. Have all calculations verified before proceeding.

Material Name and Item #	Exp. Date	Batch Size	Amount Required				Amount Added	Lot #
NCS 100011		kg	x	4.92 g/kg	=	g	g	

	Print Name	Signature	Date
Performed by			
Verified by			

6.3.2 Measure and add NCS. Mix for 1 minute.

Start mix time	End mix time	Total mix time
AM/PM	AM/PM	

6.3.3 Stop mixing. NA MTR26May2022

6.3.4 Calculate and record the amount of BSA needed in the table below. Have all calculations verified before proceeding.

Material Name and Item #	Exp. Date	Batch Size	Amount Required				Amount Added	Lot #
BSA 100015		kg	×	1.97 g/kg	=	g	g	

	Print Name	Signature	Date
Performed by			
Verified by			

6.3.5 Measure and add BSA. Ensure that the BSA is distributed across surface of the solution. Allow to rehydrate without mixing for a minimum of 15 minutes.

Rehydration Start Time	Rehydration End Time	Total Time
AM/PM	AM/PM	

6.3.6 Cover and mix for a minimum of 15 minutes or until the BSA is completely dissolved, being sure to avoid excessive foaming.

Start mix time	End mix time	Total mix time
AM/PM	AM/PM	

6.3.7 Calculate and record below the amount of DI water required to achieve the batch size. Have all calculations verified before proceeding.

Total Weight of Batch Container		Tare Weight		Current Batch Size
kg	-	kg	=	kg

Batch Size		Current Batch Size		Required DI	Required DI Added
kg	-	kg	=	kg	kg

	Print Name	Signature	Date
Performed by			
Verified by	N/A	NTR 26 MAY 2022	

6.3.8 Add the DI water to the batch and mix for a minimum of 15 minutes.

Start mix time	End mix time	Total mix time
AM/PM	AM/PM	

6.4 Final pH Measurement and Adjustment

6.4.1 Remove a 3-mL sample from the batch.

6.4.2 Measure and record the pH and temperature of the sample. Verify that the sample temperature is 19–25°C.

Solution temp. °C	Initial pH	pH Target
		7.90 – 8.10

6.4.3 Adjust the final pH to a target of **7.95 – 8.05** by adding **1M NaOH** or **1M HCl** to **Lysate Diluent D** while mixing. Record the data for the pH adjustments below. Repeat until the final pH target is reached.

NOTE: If no pH adjustments are needed to achieve a pH target of **7.95 – 8.05**, N/A the table in section 6.4.3 and proceed to section 6.5.

☐ N/A pH adjustment table

Check if N/A	pH Adjustment Solution Type Added (Circle One)		Expiration Date	Volume Added (mL)	pH Solution Lot #	Sample Temp °C (Range 19 – 25°C)	pH Reading	Target pH
	1M NaOH 100183	1M HCl 100173						
☐	1M NaOH	1M HCl						7.95–8.05
☐	1M NaOH	1M HCl						

N/A NTR 26 MAY 2022

6.5 **Filter**

6.5.1 Filter with the appropriate 0.2-micron filtration system for the batch size.

Filter	Item Number		Lot	

6.6 **Labeling Information**

6.6.1 Label the container and record the labeling information in the table on page 1.

7. **FILLING**

7.1 **Fill Bulk Solution into Reagent Bottles**

7.1.1 Select the appropriate 30-mL or 500-mL bottles.

Bottle Type	Item number	Indicate Selected
Bottle, 30-mL	100449	☑
Bottle, 500 mL	101398	☐

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

7.1.3 Filling Line Clearance (✓ each box)

Work area clear of unrelated material	Material lot #, paperwork & label info matches	Work area clean and clear of dust and debris	Equipment within calibration
✓	✓	✓	✓
Performed by (Signature)			Date
[signature]			26May2022

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

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

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.

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

7.1.7 Once a weight verification bottle is filled, stop and weigh the sample to ensure it is in the specified 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. Document course of action in the comment section below.

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☐ N/A For 30 mL reagent preparation use table below to calculate batch size

Target: 30.0 g Range: 29.3 – 30.7 g	Beg. Bottle	Middle Bottle 1	Middle Bottle 2	Middle Bottle 3	End Bottle
	1				
Gross weight	38,29				
Tare weight	8,25		N/A	NTR26May2022	
Net weight	30,04				
Acceptance	☑ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail ☐ N/A	☐ Pass ☐ Fail ☐ N/A	☐ Pass ☐ Fail

☑ N/A For 400 mL reagent preparation use table below to calculate batch size

Target: 408 g Range: 400 – 416 g	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:**

Only filled 1 30mL bottle NTR26May2022

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7.1.8 Total number of bottles filled, and amount inventoried.

Bottles filled	Amt. Inventoried
1	1

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

8. SIGNATURES

	Print name	Signature	Date
Performed by	Nathaniel Richardson	Nat Richardson	26 MAY 2022
Reviewed by	Michael P. COFFey	Michael Coffey	27 MAY 2022
QA Reviewed By	Linda Carr	Linda Carr	27 MAY 2022

9. REVISION HISTORY

Revision	Detailed Description	Date	Originator
01	DCR-17-1582: Initial Release	27Nov2017	L. Provencher
02	DCR-18-1200: Added a warming step for Tergitol and Brij23 in section 6.1.2. Changed measurements from volume to weight for Tergitol and Brij23 in section 6.1.8. Separated NCS and BSA component addition tables in sections 6.3.1 and 6.3.4, respectively. Updated 30mL filling target range in section 7.1.7. Added 400mL filling section in section 7.1.7.	07Nov2018	C. Tobos P. Patel
03	DCR-19-0849: Expiration date extended from 6 months after DOM to 12 months after DOM based on new shelf life data	08Feb2019	K. Bazany

End of Document

Released

Quanterix	Form	
	Document No: FRM-0108	Revision No: 09 Effective: 04 Aug 2021 Page 1 of 6
	Name: Component Labeling and Filling Record	

Use of Form: Only the Manufacturing, Kitting or 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:	Lysate Diluent D reagent	NTR26May2022	MPC 26MAY2022
Part Number:	102914		
Lot Number:	210922 (1)		
Expiration Date:	19APR2023 (1)		
Storage Temperature:	2-8°C		
Number of labels requested:	3		

		Performed By: (Mfg) Initial/Date	Verified By: (Mfg) Initial/Date
Number of Labels Printed:	3	NTR26May2022	TB26May2022

2. Label Inspection, completed by Verifier (Mfg)

2.1. Verifier attach label below, initial and date label

Lysate Diluent D

REF 102914
LOT 210922
19-Apr-2023
2° 8°
Quanterix Corp.
For Research Use Only

LBL-100-74 Rev 2.0

TB26May2022

Released

(1) Fill from lot 210906

2.2. Label accuracy verification (Mfg):

		Performed By: (Mfg) Initial/Date	Verified By: (Mfg) Initial/Date
Print Quality	☑ Pass ☐ Fail	NTR26May2022	TB26May2022
Item #	☑ Pass ☐ Fail ☐ N/A		
Lot #	☑ Pass ☐ Fail ☐ N/A		
Expiration Date	☑ Pass ☐ Fail ☐ N/A		
Storage Temp.	☑ Pass ☐ Fail ☐ N/A		
Barcode Check & Scan	☐ Pass ☐ Fail ☑ N/A		

	Print Name	Signature	Date
Label Amount and Quality Verified by	Piplu Barua	Piplu Barua	26 May 2022

3. Labeling Line Clearance (✓ appropriate box)

		Performed By: (Mfg) Initial/Date	Verified By: (Mfg) Initial/Date
Area clear of unrelated material	☑ Yes ☐ No	NTR26May2022	TB26May2022
Material lot #, paperwork & labels match	☑ Yes ☐ No		
Work area clean and clear of debris	☑ Yes ☐ 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	N/A ☐ Yes ☐ No		
Material & Paperwork match	NTR26May2022 ☐ Yes ☐ No		
Work area clean and clear of debris	☐ Yes ☐ No		
Equipment within calibration	☐ Yes ☐ No		

Released

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		Factor		2% of Top range
	X	0.02	=	

Target Fill		2% of Top range		Top of range
	+		=	

Bottom of range 2%				
Target Fill		Factor		2% of Bottom range
	X	0.02	=	

Target Fill		2% of Bottom range		Bottom of Range
	-		=	

Performed By: (Mfg) Initial/Date		Verified By: (Mfg) Initial/Date	

NTR NTR26May2022

Table: Weight Check Calculation

	Bottle Number	Gross weight	Tare Weight	Net weight	Target Range	Net Weight Meets Target Range
Beginning Bottle						☐ Pass ☐ Fail
Middle Bottle 1						☐ Pass ☐ Fail
Middle Bottle 2						☐ Pass ☐ Fail
Middle Bottle 3						☐ Pass ☐ Fail
End Bottle						☐ Pass ☐ Fail

Performed By (Mfg) Initial/Date:		Verfied By (Mfg) Initial/Date:	

6. **Kitting: Line Clearance** NA NTR 26 May 2022

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

		Performed by: Initial/Date
Item # verified	☐ Pass ☐ Fail ☐ N/A	
Lot # verified:	☐ Pass ☐ Fail ☐ N/A	
Verified #. of Reagents equal to # of Kits to be built:	☐ Pass ☐ Fail ☐ N/A	
Verified correct kitting document:	☐ Pass ☐ Fail ☐ N/A	
Verified correct # of accessories (ie: insert cards, bottles, labels):	☐ Pass ☐ Fail ☐ N/A	

7. Label Accountability

		Quantity:	Performed By: (Mfg) Initial/Date	Verified By: (Mfg) Initial/Date
A	Total number of Bottles/Kits Labeled:	1	VTR26May2022	CZ26May2022
B	Total number of Labels on Form:	1		
C	Total number of Labels (A+B):	2		
D	Number of Labels Requested:	3		
E	Calculate difference (D-C):	1		
F	Number of Labels Destroyed:	1		
G	Calculate Label Reconciliation (F-E):	0		

Label Accountability Verified by	Print name	Signature	Date
	Telvin Benjamin	TBenj	26May2022

8. Final Document Review Signatures

	Print name	Signature	Date
Reviewed by	Michael P. Coffey	michael P. Coffey	27 MAY 2022
QA Reviewed By	Linda Cam	Linda Cam	27 MAY 2022

Released

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
09	DCR-21-0196: Changes per Change Control CC-21-0058	23Jul2021	R. Somogyi

End of Document