

STUDY COORDINATOR & PHARMACIST BREAKOUT SESSION





LABORATORY OVERVIEW

Morgan Gapara Central Lab Lead







aboratories Involved in sample management
upply Management
ow to Perform a Lab Visit
ouriers
eporting
2 ResultView Overview
est Practice Summary
ow to contact Q ² Solutions

Labs involved in samples processing GSK × ViiV



SAMPLED 30 Knightsbridge Road Building 3 Dock 3 Piscataway, NJ 08854

Healthcare

Monogram Biosciences Inc. 345 Oyster Point Boulevard South San Francisco, CA 94080, USA

Q Squared Solutions (Quest) LLC 27027 Tourney Road, Suite 2E Valencia, CA 91355, USA

Nichols Institute & **Quest Diagnostics** Infectious Diseases 33608 Ortega Highway San Juan Capistrano, CA 92675-2042, USA

Acetaminophen Toxicity **Diagnostics Pediatric** Pharmacology and **Toxicology** Sturgis Building Room S2409 Arkansas Children's Hospital 1 Children's Way Little Rock, AR 72202, USA

Labcorp Early Development Laboratories Inc. Sample Management – Bioanalytical (Room IS 160) 3301 Kinsman Boulevard Madison, WI 53704, USA

GlaxoSmithKline BIB Sample Management, Attn Cryolab UP2-1003, 1250 S. Collegeville Rd., Collegeville, PA 19426

> PPD 2246 Dabney Road Richmond, VA 23230 USA

> > Storage vendor

Labs – Scope of responsibilities

GSK ×

Healthcare





Central Lab





GSK × VIIV Samples flow and participating labs







The Starter Pack





- Investigator Manual
- transport materials
- Specific Material / Bulk Supplies



Reordering Supplies



Reordering Supplies

Q (Q² So	lutions								
			ABC P	HARMA P	ROTOCOL 123	4567 - REORDER - GL	OBAL KITS			
ACC	T#	INVENTO	DRY#		Q SQUARED SOLUTIO	INS USE ONLY:	** Pre-Lacel Study **			
SHI	P TO:	REQNUS			ORDER #:	DATE:				
A00 A00	12				OE PROCESSOR	DATE:				
			ST/	ATECIP	PR ORDER:	DATE:				
AFA	×				PR ASSEMBLE: .		DATE:			
Form Rev/	n Name: 7 1: 17 Dec	NO2A 2015			PR QC:		DATE:			
INSTR 1. Per	RUCTIONS: son ordering	Please indicate : g supplies	the following infor 2. 0	mation: Date of order su	omission	3. Date supplies requested by				
Faxth	e complete	d form to our dec	ficated fax for cile	nt reorders at +	1-404-393-6240					
Berti	poly orders	will be shipped a	eithin 5 working d	avs from receipt	t of request for terms or	e-impitted on this document. Please a	itse for transitions and			
oustor	ns clearanc	e (if applicable) p	prior to receipt of	requested supp	sies. Thank you.					
QDO	CT Use C	Only: No Nee	idle Countrie	s: NA						
QTY	UNITS	US ITEM Needle	EU ITEM	US ITEM No Nee Se	REQ	LAEORATORY KITS				
	Bags	515583V			7NOA	Screen Visit 1				
	Bags	516089V			7NOBA/XGSSE	Visit2/Day 1 XGS ACCT:	ACCT			
_	Bags	515585V 516088V	•		ZNODA	Visit 4/Day 14 & Visit 5/Day 28 Visit 6/Day 42	,			
-	Bags	515582V			TNOE	Early Withdrawal				
	Bags	516087V			7NOL	Initial Liver Event				
	Bags	516086V	-		7NOFL	Montoring/Follow Up				
	Bags	515589V			1	Unscheduled/Retest Visit	NOTE: The unscheduled			
	Bags	•		•	7NOU	Unscheduled Requisition Form	the kit. Reorder as needed			
	Caron	-	-	SUPPLEM	ENTAL SUPPLIES	House Form - Global Kas				
	Each	64376	30771	Living Collin	Tion Cure 7					
-	Each	36162	28984	Urine Colle	ction lid - When	n reordering order both the cup and lid				
	Each	508290	65167	HCG Urine	Pregnancy Test St	rios				
	Each	158851	80129	Oragene D	NA Self Collection	ka				
	Each	63141		BBL Cultur	e Swab Amies Gel	w/o Charocal				
	Each	53792	28878	21G Butter	fy Needle					





1 Form for Lab Kits 1 Form for Logistics Supplies



Reorder via fax, phone or e-mail



Allow 5-7 working days to reorder



Investigator Manual



Refer to your study specific investigator laboratory manual for instructions on sample collection and preparation

Reference Ranges for all tests performed by Q² Solutions

Lab Certification links



Requisition Forms



다 Q ² Solutions							
ABC PH	ARMA - PROT	TOCOL 1234567 S	CREEN VISI	F 1			
ACCT NO. REQ NO. ACCTNUM REQNUM C	KIT NO. KITNUM	Complete all boxes in	MOGRAPHI this section, fails	C SECTION are to do so will delay r	eports.		
		Subject Number:					
ADDR ADDR2 CITY STAT	120	Gender:	Male	Female			
FADOR		Date of Birth:	DAY M 30 & Jun will be	ONTH YEAR imputed by Quest Disgreat	10		
STUDY ID: STUDYID FORM CODE: PNAME		Collection Date:					
CENTER: INVID Issued: 19 Oct 2015 by ESR		Fasting:	Ves Required to				
Refer to sample bandling mideling	s in the investigato	r manual for complete si		YZ/YA223	3566AU)1	1
Visit: X2	Visit 2	/or/ 2	Visit 2	ABC/1234	1-567		
Required Text(s)		Snaciman / Tre		Subject #			
PT/INR		1 ml. Plasma 3.5 m	I. Sarster Vi	SBCTCC	BC	Q01	5
C Estendial		T the Planta, 2.2 h	2. 38 100		1 1		
For famales of childbaring potential only, check how if required		1 mL Serum, Clear	Push Cap Tub		FR		
Chemistry		1 mL Serum, White	Cap Tube				//
C- Reactive Protein		1 mL Serum, White	Cap Tube				
HIV 1/2 Ab w/reflex to WB		2 mL Serum, EU W US C	thite Cap Tube lear Push Cap 1	lube			
Folate		1 mL Serum, White	Cap Tube		FR		
Hematology		2 mL Whole Blood,	Lavender Tub	e	RT		
Glucose Predose Time: 24 hours		1 mL Plasma, White	e Cap Tube		RT		
Glucose 1 Hr Postdose Time 24 hours		1 mL Plasma, White	e Cap Tube		RT		
Urinalysis	10 ml	L Urine, Yellow Urinal	ysis Tube w/pre	servative	RT		
IMPORTANT: All labels are custo Make sure to other	mized per test, plea	se complete subject / patie	ent identifier on a	every label.			
PLANE MILE IN ADDRESS	** NO TESTE	NG OUTSIDE OF PR	OTOCOL **				
** OUT OF PRO Test Name:	TOCOL TESTE Approv	NG ALLOWED WIT	II SPONSOR	APPROVAL ONLY Date:	**		
White Copy - Room Ter	mperature (RT)	Blue Copy - Froren (Fl	0 Yellow	Copy - Site Record	-		

MULTI-PAGE FORM:



White copy is to be sent with ambient samples

λ

Blue copy is to be sent with frozen samples



 \mathbf{Z}

Yellow copy is to be retained at site

Pre-labelled return tubes



Requisition Forms





- ✓ Correct
 Visit
- Incorrect Visit = potential sample being drawn in error, therefore missing data points





Required Test(s)	Specimen / Transport Tube	Ship				
PT/INR	1 mL Plasma, 3.5 mL Sarstedt Vial	FR				
Estradiol For females of childbearing potential only, check box if required	1 mL Serum, Clear Push Cap Tube	FR				
Chemistry	1 mL Serum, White Cap Tube					
C- Reactive Protein	1 mL Serum, White Cap Tube	рт				
HIV 1/2 Ab w/reflex to WB	2 mL Serum, EU White Cap Tube US Clear Push Cap Tube	RT				
Folate	1 mL Serum, White Cap Tube	FR				
Hematology	2 mL Whole Blood, Lavender Tube	RT				
Glucose Predose Time: 24 hours	1 mL Plasma, White Cap Tube	RT				
Glucose 1 Hr Postdose Time: 24 hours	1 mL Plasma, White Cap Tube	RT				
Urinalysis 10 mL Urine, Yellow Urinalysis Tube w/preservative						
MPORTANT: All labels are custo Make sure to adhere	mized per test, please complete subject / patient identifier on every label. the correct label on the samples sent to the Central Lab	\sim				
	** NO TESTING OUTSIDE OF PROTOCOL **	>				

Ensure you draw and ship only the required tests

Complete optional test check box

Ship at the correct temperature







Impact of an Incorrectly Completed Requisition

KELLOGG MD, WELLVILLE CE BATTLE CREEK	JOHN NTER I, NY					Q ² Solutions a Quintiles Quest Joint Venture			
Patient Name		Patient ID		Age	Sex	Collection Date & Time			
000213				66	F	17 Dec 2015 (Local Time)			
Page	Requis	ition #	Login Date	e		Report Date & Time			
1 of 5	of 5 376518			2015 (GMT	-8)	20 Dec 2015 02:39(GMT-8)			
Remarks:					Kit Number:				
64187	178 3	76518 8			YH376518				

Laboratory Report

Report Status: Temporary

emographics				
SPONSOR:	ABC PHARMA			
PROTOCOL:	1234567	* * * *	* * * * * * * * * * * * * * *	*
STUDY ID:	1YZ	* Note:	Critical data from the	*
CENTER:	219839	*	requisition are missing,	*
PGX ACCOUNT	84552082	*	incomplete, or inconsistent	*
		*	with previous records. Thus,	*
		*	interpretation and critical	*
		*	value flagging of lab results	*
		*	are not possible.	*
		*	Please call Q ² Solutions, a	*
		*	Quintiles Quest Joint Venture	*
		*	immediately.	*
		* * * *	* * * * * * * * * * * * * *	*

Samples drawn in error, missing samples

Delay of results , NO final report

NO protocol specific flagging, No calculated results Sponsor is charged for transferring results to the correct protocol

CRF discrepancies







* LIPID PANEL: FOR FASTING LIPIDS ASSESSMENTS, AN OVERNIGHT FAST IS PREFERRED; HOWEVER, A MINIMUM OF A 6-HOUR FAST IS ACCEPTABLE FOR PARTICIPANTS WITH AFTERNOON APPOINTMENTS.









	PRIMARY C United States Puerto Rico (M	OURIER (Mon-Fri) Ion-Thurs)	BACKUP COURIER United States (Weekend & After Hours) Puerto Rico (Friday, Weekend & After Hours			
COUNTRY	ROOM TEMPERATURE	FROZEN	ROOM TEMPERATURE	FROZEN		
United States, Puerto Rico	FedEx	FedEx	Marken	Marken		

IMPACT :

Please note using BACK UP premium couriers for standard shipments is very expensive and will impact the study budget.

Sites must use couriers as directed in the Contact and Shipping Appendix



GSK

Couriers

telephone numbers

booking

Failure to adhere to these times will impact the transit time. Record the booking reference, date/time of the call, and the name of the person contacted

The Site Specific Summary provided in your Starter Pack indicates when to use the

primary and backup couriers, and provides you with site-specific courier contact

Contact your local courier office for package pickup cut-off times and shipment





- Dry ice can be supplied by the courier upon request of the investigator
- One or two day notice is required (depending on country)
 - > See instructions provided in Contact and Shipping Information Appendix provided with the Starter Pack



Ambient Sample Shipment Preparation



Commercial Couriers

GSK ×



Slide each sample vial into absorbent tube shuttle.

Place folded requisition, printed side out, into back pouch of specimen transport bag.



Roll up absorbent tube shuttle and slide into specimen transport bag.



Follow closure instructions on bag when sealing.

PACKING THE ROOM TEMPERATURE SHIPPER:

Recommended maximum of two transport bags per shipping box

Place specimen transport bag(s) on top of one air pillow*, and place second air pillow* on top of specimen transport bag(s).

No more than two patients' specimens can be shipped together.

Close box flaps in numbered order. Remove adhesive strip from flap #3, and press down on flap #4 firmly to seal box.

Air Pillow/ Gel Wrap Specimen(s) Air Pillow/ Gel Wrap

*Gel wraps should replace air pillows to surround specimens when outside temperatures are below -10°C/14°F or above 34°C/93°F.



ADDRESSING AND DOCUMENTING THE ROOM TEMPERATURE SHIPPER: Place shipping documents in pouch on top flap of package.

Address the outside of package.





				Laborat	tory Rep	port
KELLOGG ME WELLVILLE 15 MEDICAI BLACK CREE	D, JOHN CENTER WAY EK NY 20	120				Q ² Solutions
Patient Name		Patient ID		Age	Sex	Collection Date & Time
059734				72	м	23 Jan 2015 (Local Time)
Page	Requis	uisition # Login Date		gin Date		Report Date & Time
1 of 4	96537	4	24 Jan	2015 (G	er-8)	24 Jan 2015 22:07 (GMT-8)
Remarks:						Kit Number:
641	70606 9	65374 8				YE965374

Report Status: Final						
Demographics						
SPONSOR :	ABC PHARMA					
PROTOCOLI	1234567					
STUDY ID:	1YZ					
CENTER	010886					
SUBJECT NUMBER:	059734					
BIRTHDATE:	30 Jun 1942					
VISIT:	VISIT 1 SCR	SEN				
PGX ACCOUNT	84549639					
Results						
		Re	sult		Reference	Site
Test	Flag	In Range	Out of Range	Units	Range	Code
HEMATOLOGY						¥7
UEMOGLOBIN	103		11.0	G /DT.	11.8-16.8	14
UPMATOCRIT	**		64.4	8	36.0-49.0	
DLATELET COUNT		182000		DEB CIMM	120 000-400 000	
WUITE CELL COINT		8 7		THOU /MCL	3 8-10 8	
TOTAL NEITROBULLS	10	5.84		THOU/MCL	1 80-8 00	
NEITFORUTI, SEGS	o no	67 A		3	40 0-75 0	
DACODUTI.C		0.5		3	0.0-2.0	
FOSTNOPUTLS		6.4		3	0.0-7.0	
FOSTNOPHILS ABSOL	עייינ		0.56	THOU/MCL	0.05-0.55	
LYMPHOCYTES	JOIN	19.0	0.20	*	16.0-46.0	
MONOCYTERS		6.7		3	0.0-12.0	
RED CELL COUNT		3.8		MILL/MCL	3.7-5.5	
TOTAL NEUTROPHILS		67.4		8	40.0-75.0	
NEUTROPHILS ABSOL	UTE	5.84		THOU/MCL	1.80-8.00	
BASOPHILS ABSOLUT	E	0.04		THOU/MCL	0.00-0.20	
LYMPHOCYTES ABSOL	UTE	1.65		THOU/MCL	0.85-4.10	
MONOCYTES ABSOLUT	E	0.58		THOU/MCL	0.20-1.10	
				,		
CHEMISTRY						YZ
ALBUMIN		4.1		G/DL	3.2-5.0	
ALKALINE PHOSPHAT	TASE E		203	0/L	20-125	
ALAT (SGPT)		37		U/L	0-48	
ASAT (SGOT)	_	34		U/L	0-55	
BILIRUBIN, DIRECT	C .	0.1		MG/DL	0.0-0.4	
BILIRUBIN, INDIRE	CT	0.3		MG/DL	0.0-1.3	
BILIRUBIN, TOTAL		0.4		MG/DL	0.0-1.3	

Reports sent via Fax and / or Email

Information you may find on your report

- **Sponsor-defined Alert:** a customized flag will appear on the report. Site will receive a phone call from Q² Solutions
- **Telephone Alert: life threatening values as defined by Q² Solutions or sponsordefined alerts will be called to the investigator
- Exclusion Alert: a flag of 'E' will appear on the report. No other notification will be provided.





OUT OF RANGE	ANALYTES	CLINI	CALLY SIGNI	REFERENCE RANGE		
HEMATOLOGY	HC	11 0	NO	VEC		
IEROGLOBIN	110	11.0	NO	_165 G/DL	11.8-16	8
HEMATOCRIT	**	64.4	NO	YES	11.0 10.	
					36.0-49.	0
EOSINOPHILS ABS	OLUTE	0.56	NO	YES		-
				THOU/MCL	0.05-0.5	5
CHEMISTRY						
ALKALINE PHOSPH	ATASE E	203	NO	_YES		
				U/L	20-125	
GT		86	NO	_YES	0.75	
THOORE		210	NO	U/L VPC	0-75	
PUCOPE		210	NO	_IES	70 125	
				MG/ DL	70-125	
				ከአጥም-		>
TNURSTICATOR OF				DATE:		
INVESTIGATOR S	IGNATURE:					
INVESTIGATOR S	IGNATURE:					
UNVESTIGATOR S	HE QUICK T	REND REPO		AIN TRUNCATE	D TEXT RESULT	ī (5)!
INVESTIGATOR S Quick Trend NOTE: TH PLEAS	HE QUICK T	REND REPO O THE ACTU @ DENO	ORT MAY CONT JAL LAB REPO TES ABNORMA	AIN TRUNCATE RT FOR COMPLI AL RESULTS	D TEXT RESULT ETE RESULT(S)	(S)!
INVESTIGATOR S Quick Trend NOTE: TI PLEAS	HE QUICK T	REND REPO O THE ACTU @ DENO	ORT MAY CONT JAL LAB REPO TES ABNORMA	AIN TRUNCATE RT FOR COMPLI AL RESULTS	D TEXT RESULT ETE RESULT(S)	ī(S)!
INVESTIGATOR S Quick Trend NOTE: TI PLEAS	HE QUICK T SE, REFER T Req#: 28	REND REPO O THE ACTU @ DENO 01343	ORT MAY CONT/ JAL LAB REPOI TES ABNORMA 633856	AIN TRUNCATE RT FOR COMPLI LL RESULTS 922847	D TEXT RESULT ETE RESULT(S) 922856	922828
INVESTIGATOR S Quick Trend NOTE: TI PLEAS	HE QUICK T SE, REFER T Req#: 28 it Date: 01 Visit: 95	REND REPO O THE ACTU @ DENO 31343 . Dec 2014	ORT MAY CONT JAL LAB REPO TES ABNORMA 633856 29 Dec 2014 28	AIN TRUNCATE RT FOR COMPLI AL RESULTS 922847 12 Jan 2015 48	D TEXT RESULT ETE RESULT(S) 922856 09 Feb 2015 88	922828 09 Mar 20 128
INVESTIGATOR S Quick Trend NOTE: TH PLEAS Vis Vis	HE QUICK T SE, REFER T Req#: 28 it Date: 01 Visit: SE it Type:	REND REPO O THE ACTU @ DENO 31343 . Dec 2014	AT MAY CONT/ JAL LAB REPO TES ABNORMA 633856 29 Dec 2014 28	AIN TRUNCATE RT FOR COMPLI LL RESULTS 922847 12 Jan 2015 4B	922856 09 Feb 2015 8B	922828 09 Mar 20 128
INVESTIGATOR S Quick Trend NOTE: TI PLEAS Vis ADD LIVER MON CI	HEQUICK T SE, REFER T Req#: 28 it Date: 01 Visit: SE sit Type: HEM	REND REPO O THE ACTU @ DENO 31343 : Dec 2014	ORT MAY CONTJ JAL LAB REPOI TES ABNORMA 633856 29 Dec 2014 28	AIN TRUNCATE RT FOR COMPLI LL RESULTS 922847 12 Jan 2015 48	922856 09 Feb 2015 8B	922828 922828 09 Mar 20 128
INVESTIGATOR S Quick Trend NOTE: TI PLEAS Vis ADD LIVER MON CI ALAT (SGPT)	HEQUICK T SE, REFER T Req#: 28 it Date: 01 Visit: SE sit Type: HEM	REND REPO O THE ACTU @ DENO 31343 : Dec 2014 3 87	ORT MAY CONTJ JAL LAB REPOI TES ABNORMA 633856 29 Dec 2014 28 @59	AIN TRUNCATE RT FOR COMPLI LL RESULTS 922847 12 Jan 2015 48 @78	D TEXT RESULT ETE RESULT(S) 922856 09 Feb 2015 8B @127	922828 99 Mar 20 128 @260

Information you may find on your report

- Specimen Retained
 - Storage specimen received and stored
- Clinical Significance Review (Summary)
 - Tabulation of all laboratory values that fall outside the reference ranges, sponsordefined alerts, and telephone alerts

PI must review the report, sign/date in the space provided.

Quick Trend

 Summary of test results.
 Baseline results appear in the left column, followed by consecutive visits





Result View is a web-enabled portal from Q2 solutions

ResultViewTM System

> Result\View[™] System is a web-based tool to query, print, and save clinical study data extracted from a secured database at Q² Solutions.

Result\View™ System will allow you to view the laboratory result for each patient and to monitor patient recruitment at each site

> 24 hours a day, 7 days a week from any location

Data secured & refreshed every two hours

Privileged access to users on an ongoing basis





Q2 ResultView portal



embrace

GSK × VIIV Q2 ResultView portal



a Durches Gass? Joint Hectare	Quick	Inquiry												
ultView	Monitor	~ =	List	[ALL]	~		Re	q/Kit # 🗸	-			Note		~
ab anotany. De suite	Investig	ator 🗸 =	List	[ALL]	~ (L.	Init	tials 🗸	-		And and	Review	/-	~
Ouick Inquin	Subject ID 💙 =		List [ALL]		~ 0	2	Sit	Site Acct. # 💙 =				- Req. St	tatus	V
Management Reports	Visit	~ =	List	[ALL]	~		Vis	it Code 🗸	-	ALL STORES	1123	- Counu	<u>y</u>	Ť
Protocol Enrollment	Visit Typ	pe 🗸 =	List	[ALL]	~			Date: Colle	ctod	V From:	(dd-mon-	-уууу)	To: (d	d-mon-yyyy)
New Activity	Blindin	g: 🗹 Spor		Investigator	Units:	As Reporte	d 🗸			PRINT ALL	>>>>	VIEW		CLEAR
Flagged Results	200		200	×		<u> </u>	2	500	\bigcirc	2			×15.	<u> </u>
Sample Storage	Lab Or	der Select	ion List									Click on	heading	below to s
Missing Subject Visit	Note	SAVE Review	Anv	Study ID	Account	Rea #		Received®	Initials	Subi, ID	Sec. ID	<u>Visit</u> Name	Visit Type	Reported
Missing Order Unit	ω			DTTS2	84501939	111110	2	09/15/2015	****			1		09/15/201
Lab Order Notes	88		1	DTTS2	00000085	011110	×	03/23/2012	****			1		03/23/201
AP Inventory	ω		V	DTTS2	00000085	080108	2	08/10/2011	****	_	-	1		08/10/201
Inbound Batch Counts	ω		1	DTTS2	00000085	080107	2	08/10/2011	****			1		08/10/201
Juery Builder	Ξ		\checkmark	DTTS2	00000085	080106	2	08/10/2011	****	-		1		08/10/201
New Query					00000085	080105	×	08/10/2011	****		1.1	1		08/10/201
My Queries	CI	ick o	n th	le	00000085	080104	Æ	08/10/2011		-		1		
Shared Queries	ro	quici	tion	#	000 2085	080103	2-	08/10/2011	****	-	1.1	1		
Preferences	Tee	quisi	lior	. #		080102	⊁	08/10/2011		-		1		
Investigator Filtering	in (in	blue	2)			080101	r	08/10/2011	****	-	-	1		
	to	view	the		5 000	042813	×	04/28/2011		-		1		04/29/201
					0000085	042812	1	04/28/2011	****	-	-	1		11/13/201
	lar	o rep	ort		00000085	042811	25	04/28/2011	****	-	-	1		11/13/201
					00000085	042809	×	04/28/2011	****	-	-	1		11/13/201
	E			DTTS2	00000085	042807	<u>*</u>	04/28/2011	****	-		1		04/29/201
	æ			DTTS2	00000085	042806	۶	04/28/2011		-	-	1		04/28/201

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Q2 ResultView portal



Section: Top Demographics L Clinical Significance Re	Section: <u>op Demographics Lab Results</u> Linical Significance Review		SAVE	My Note Reviewe	s: d By:	Share: 🗌 Me 🗌	Anyone 🗖			
				CREATE	Full Quick	frend:	HTML 🗸	Output Format		
Blinded By:	Sponsor	🖌 Inv	estigator	Un	its: As Reported 💊		VIEW	PRINT	ZPREV	NEXT
Requisition:	020307		R	eport Statu	s: Fina	1				/
Investigator PLEASE GIVE RE QUEST DIAGNOST 125-135 STAINES HOUNSLOW HOUNSLOW TW3 : UNITED KINGDOM	PORT TO CATHY I TCS CLINICAL TRIA ROAD 33F, I	Kermer Als	Patient Patient Name: Patient Age: Sex:	DCMT Id: M						
Collection Date & Login Date: Report Date & Tim	Time: 01/31/2 02/03/2 1e: 02/03/2	011 (Local T 011 (GMT-8 011 10:15 (Fime) 3) 3GMT-8)							
Remarks:	0000006	56 020307 6	;							
Demographics	DER TEXT COMPLE	TE FIELD.	Study I VISIT S STUDY CENTEI VISIT: FASTIN	D: 3EQUENCE: #: R #:	DTTS1 00 Testing Protocol 23 1 NO					
Results										
Test	Flag	Re In Range	suit Out Of Range	Units	Reference Range	Site Code				
COMPLETE BLOOD (HEMOGLOBIN HEMATOCRIT RED CELL COUNT MCV MCH MCHC WHITE CELL COUNT RDW MYELOCYTES METAMYELOCYTES NEUTROPHIL, SEGS NEUTROPHIL, BANDS	G0 G0	**150 BLINDED 4.5 90 32.0 330 BLINDED 10.0 40	**3 **3 10	G/L TI/L FL PG G/L % % % %	138-172 M: 4.4-5.8 80-100 27.0-33.0 320-360 9.0-15.0 0 40.0-75.0 0.0-8.0	нз				



Q2 ResultView portal





Q2 ResultView portal Access Request

Beault/View Access Berusat Form v6 A



Q² Solutions PM: Alexia Baillie Sponsor: GSK Protocol: 209978 Q² Solutions Study ID: 9JK Date: * Required for BP upload.						ports, query builder. tigator site only. ers (submit multiple ticke	ets if needed).					
* Last Name	* First Name	* E-Mail Address (max char 80)	* Country Code (ex:49)	* Area Code (ex:201)	* Phone Number (ex:7232405)	Country	y	User Company (if investigator site not needed)	Access: (Sponsor or Investigator)	Level of access: Site,Country,All	Account Number	Site Number
							ı					
Site level	access	s can be p	rovide	d only	post the	site ha	is k	een initiate	d in Q2			

database



Q2 ResultView



Result\View™ Quick Reference

Result\View[™] is a state-of-the-art Web-based tool that gives you the ability to access important study data in a secure environment. Result\View[™] makes study monitoring more efficient by allowing you to view and print patient reports, track clinical study data, produce management reports and run queries, globally, 24 hours a day, seven days a week.

Logaing on to Result\View™

 Click the link provided in either of the confirmation emails containing your Username and Password or enter the following URL into your browser: <u>https://resultview.questdiagnostics.com/resultv</u> <u>iew/logon/logon.jsp</u>

Note: Be sure to save the site as a favorite.

 For best results, copy and paste the Username and Password from the confirmation emails into the appropriate fields.

Note: You will be asked immediately to change the password to something unique, known only by you. If you can't find the confirmation emails or you can't remember your username or password, contact your local Result\View[™] Help Desk.

 Read the User Agreement and click the checkbox to agree to the terms and conditions.

HELP DESK INFORMATION

America/Australia: +1 913-674-8584 Europe/Asia: +44(0) 1184 506039

Email: globalitservicedesk@guintilesims.com

Please be sure to mention that you are calling in regards to Result\View™ when contacting the Help Desk

	Image: Comparison of the study of study crosp Image: Comparison of the study crosp Image: Comparison of the study of the study crosp Image: Comparison of the study of the study crosp Image: Comparison of the study of the study crosp Image: Comparison of the study of the study crosp Image: Comparison of the study of the study crosp Image: Comparison of the study of the study crosp Image: Comparison of the study of the study crosp Image: Comparison of the study crosp				
Laboratory Results Metric Reports Global Monitoring	cs Data Loaded 3 Data Type Month				
Supplies Manaacoment Reports Cuery Builder Metrics Admin Preterences	Main Menu Screen Options 1 The Study or Study Group – used as the basis for generating inquiries, reports, and queries – is selected here.				
	 2 Result\View[™] Menu: Laboratory Results – Quick Inquiry screen is used to generate a Lab Order Selection List through various sort and filtering options. From this list patient lab reports can be viewed and printed. 				
	Metric Reports screens are used to generate, view, print and/or export metrics data for budget, data transmissions, first kit to site TATs, and TNPs. Each screen provides multiple sort and filtering options.				
	Global Monitoring screens are used to generate, view, print and/or export monitoring reports on study enrollment, inbound batches, supplies, and courier usage.				
	Management Reports screens are used to generate, view, print and/or export management and study data. Each screen provides multiple sort and filtering options.				
3584	 Query Builder is used to perform, save, and share ad hoc queries. The queries can be run across multiple studies. 				
39	3 Metric Data displays only for those who have access to the Metric Reports. Internal users see the dates the most current data was loaded. External users see the dates the information was approved for viewing purposes.				
ng in regards to	 4 Log Off is used to log out of the system. 5 Help is used to view online below 				
elp Desk	 6 Customer Service is used to update your profile or obtain contact information for the Help Desks and Technical Support. 				





KEY MESSAGE

PLEASE REMEMBER : Site compliance with Q² Solutions requirements is essential for the success of the study

- The Starter Pack
 - Contains everything needed for sample collection including the Investigator Laboratory Manual

Kits and additional supplies management

- The site is responsible for proper kit management to ensure readiness for the patient enrolment and conducting during the study. This includes review of expired kits and reordering.
- Sample labelling and Requisition Forms
 - MUST be completed correctly to avoid delay in reporting
- Specimen Collection and Preparation / Logistics
 - Please review investigator Laboratory manual for instructions before specimen collection.
 - Please review Shipping Appendix for packing and courier information
- The Reorder Form
 - Supply levels are site responsibility. Please re-order at least 5-7 working days in advance



Client Response Center





E-MAIL: <u>ctcrc@q2labsolutions.com</u> Toll free numbers can be found in the investigator manual



RAMOS - IWRS

Viviana Wilches Study Delivery Lead







- GSK Accounts and Access
- RAMOS NG System Review
- Supplies and Shipments
- Subject Visits recorded in RAMOS NG
- Screenfail and Withdrawal of Subjects
- Replacing a Container
- Confirmation Reports
- Helpdesk and Tips
- Questions





GSK Accounts and Access





- Access:
 - Ensure your site Monitor has initiated process for obtaining GSK ID for site staff, including Principal Investigator and site personnel. Monitors can provide **1:1 training** as needed
 - Respond to email invitation to open RAMOS NG & Activate Account.
 - Bookmark **RAMOS NG Direct link** : <u>https://ramosng.gsk.com</u>
- Important Note: If the user has a GSK account then they have access to RAMOS NG. Access is
 specific to the user's site. It is recommended all users login and check their access as soon as their
 site is activated.
- Documentation you will receive before Study goes live:
 - Pharmacy Manual
 - **RAMOS NG Study Specific User Guide** will be distributed once the study has been configured and RAMOS NG system is Live in Production.
- Do not wait until you have your first subject to try to log into the system the first time





RAMOS NG system review







- The Registration and Medication Ordering
 System Next Generation (RAMOS NG) is GSK's interactive web-based application for registering and enrolling subjects and managing drug supplies
- It will allow a site to:
 - Screen Subjects
 - Enroll (Randomize) subjects
 - Dispense study medication
 - Unblind subjects in an emergency situation
 - Manage study medication supply
 - Confirm receipt of Investigational Product





Home Page

- After you log in you will go to the **Home page**. This page will display a hyperlink to your study site.
- Most sites will only have a single **site**.

RAMOS NG 🕬	uation				Language: English 🗸			
Change View					Welcome, Michelle Doherty Logout Help			
					Time Zone: UTC			
CHANGE VIEW (CENTRE / DEPOT / STUDY)								
CHOOSE CENTRE								
Centre +	Study +	Study Status 🕈	Centre Status 🕈	Investigator +	Number Of Subjects +			
012345	212548v001	OPEN	OPEN	Jazz Patel	2			
111222	212548v001	OPEN	OPEN	Michelle Doherty	41			
213400_TestSiteUS	213400v001	OPEN	OPEN	FN_TestUS LN_TestUS	28			




Home Page

CLITI	E SUMMARY	SUBJECT SUMN	1ARY	CENTRE	INVENTORY
MOS NG Evalu ne Subjects Supply St y Code: 212548v001 > Centre: 012345	Jatic hipm : Change View				dy Documentation Language: Eng Welcome, Michelle Doherty Logou Tim
CENTRE SUMMARY	012345 212548v001	Enrolled Registration	1 0	K	×
Status nvestigator Name	OPEN Jazz Patel	Screen Failed	0 Per	nding	10
ctudy Code itatus nvestigator Name CENTRE MONITORING ubierts Missed Window	OPEN Jazz Patel	Screen Failed Unblind Withdrawn	0 Pei 1 In 1 0 Tot	nding fransit al	10 40 50





R	RAMOS	NC Evaluat								Study Documentation Language: English 🗸
ł	tine you	to register a	new subj	n enaples ect.						Welcome, Michelle Doherty Logout Help
5	itudy Code: 212548v0	01 _2								Time Zone: BST
2	SUBJECTS									
Ľ	Screening [one Export To	CSV File R	efresh						Enable Filter
	Subject ID \$	Status \$	Rand No \$	Enroll Date \$	Last Visit ¢	Last Visit Date \$	Registration Date \$	Last Dispensed	Cohort \$	
	000999	ENROLLED	1005	20-Jul-2020	Day 1 R	20-Jul-2020	20-Jul-2020	20-Jul-2020	Cohort 1	^
	000998	ENROLLED	2003	20-Jul-2020	Day 1 R	20-Jul-2020	20-Jul-2020	20-Jul-2020	Cohort 2	
	000997	SCREENED			Screening	20-Jul-2020	20-Jul-2020			
	000996	BB-DROPPED	1007	20-Jul-2020	Day 1 R	20-Jul-2020	20-Jul-2020	20-Jul-2020	Cohort 1	
	000995	BB-DROPPED	1008	20-Jul-2020	Day 1 R	20-Jul-2020	20-Jul-2020	20-Jul-2020	Cohort 1	
Г	000994	BB-DROPPED	1009	20-Jul-2020	Day 1 R	20-Jul-2020	20-Jul-2020	20-Jul-2020	Cohort 1	
	000993	SCREENED			Screening	20-Jul-2020	20-Jul-2020			
	000992	P-DROPPED	2005	20-Jul-2020	Day 1 R	20-Jul-2020	20-Jul-2020	20-Jul-2020	Cohort 2	
	000991		2006	20-lul-2020	Day 1 R	20-Jul-2020	20-Jul-2020	20-Jul-2020	Cohort 2	
	Clickin ⁰⁰⁰ REGIS subjec	ig on the SU TRATION ID :t's page.	BJECT takes yo	u to that	Screening	20-Jul-2020	20-Jul-2020			~





Supplies and Shipments

GSK × VIIV DRUG SUPPLIES FOR STUDY 209639



- An initial shipment will be initiated once the first subject at site has completed screening. Shipments will be processed within 3 to 5 working days
- Resupply of medication will be automatic through RAMOS NG.
- IMPORTANT: If your site has several subjects coming within a short period of time (exceeding 3 subjects), please call the GSK Clinical Support Helpdesk. Investigative sites will NOT have the capability of ordering supplies in the RAMOS NG IRT
- If there is a temperature excursion, please contact the helpdesk. Do not report the temperature excursion in RAMOS.

GSK × VIIV RECEIVING AND REQUESTING SHIPMENTS



Please refer to your Study Specific User Guide which will show you all steps needed to Receive and request shipments

To receive a shipment, click on the hyperlink and complete the steps

Click on Shipments – New Request to order additional supplies

RAMOS NG Evaluat	ion					Study Documentation Languag	;e:English 🗸
Home Subjects Supply Shipr	nents Change View					Welcome, Michelle Doherty	Logout Help
Study Code: 204691v001 > Centre: 101							Time Zone: JS
CENTRE SUMMARY		SUBJECT SUMMARY			CENTRE INVENTORY SUMMARY		
Centre Study Code Status Investigator Name CENTRE MONITORING Subjects Missed Window Subjects By Strata Summary Centre Dispense Report Centre Summary Report Inventory Report	101 204691/V001 OPEA Monib INV View Generate Generate Generate Generate	Enrolled Registration Screen Failed Unblind Withdrawn Com plete Total New Subject		0 2 4 0 7 13	Bulk Damaged Pending Available In Transit Total	2 77 58 30 167	
		Electric d	Town i			Blanned Amiusl	
7554	ess order ID e	RELEASED	204691EVAL1.01_JPN_DPT		204691v001:101	Planned Amval e	
7567		RELEASED	204691EVAL1.01_JPN_DPT		204691v001:101		
7577		RELEASED	204691EVAL1.01_JPN_DPT		204691v001:101		
14025		RELEASED	204691EVAL1.01_JPN_DPT		204691v001:101		
83605		SHIPPED	204691EVAL1.01_JPN_DPT		204691v001:101	21-Aug-2020	





Subject Visits Recorded in RAMOS NG





Subject's Screening Visit

New Subjects can be processed by selecting the SCREENING VISIT on the Home page

RAMOS NG 👁	valuation					Study Documentation Langu	age: English 🗸	
Home Subjects Supply	Shipments Change View					Welcome, Kevin Clear	Logout Help	
Study Code: 209639v001 > Centre: 209	y Code: 209639v001 > Centre: 209639_TextSiteUSA Time Zone: UTC							
CENTRE SUMMARY		SUBJECT SUMMARY			CENTRE INVENTORY SUMMARY			
Centre Study Code Status Investigator Name	209639_TestSiteUSA 209639v001 OPEN TestinvFN TestinvLN	Enrolled Registration Screen Failed		18 6 0	Bulk Pending	20		
CENTRE MONITORING Subjects Missed Window Subjects By Strata Summary Centre Dispense Report Centre Summary Report	View View Generate Generate	Unblind Withdrawn Complete Total Screening		0 0 2 26	Dispensed Available Total	434 366 820		
	Generate	Clabur -	From A	70.		Blanned Artivel		
227172	Afress order to a	RELEASED	RTP	209639v001:209639_TestSitel	USA	Plaimed Arrival e		
227173		RELEASED	RTP	209639v001:209639_TestSitel	USA			

New Subjects can be also processed by selecting the Subjects Tab on Home page





Subject's Screening Visit

Enter a six digit Subject ID number provided to the site







Subject's Screening Visit

Enter a six-digit Subject ID number provided to the site

	Study Documentation Language: English 🗸
Home Subjects Supply Shipments Change View	Welcome, Kevin Clear Logout Help
Study Code: 209639v001 > Centre: 209639_TestSiteUSA	Time Zone: UTC
ENTER SUBJECT ID	
Enter Subject ID Done Cancel	

Select the demographic information

		Study Documentation Language: English 🔽
Home Subjects Supply Shipments Change View		Welcome, Kevin Clear Logout Help
Study Code: 209639v001 > Centre: 209639_TestSiteUSA > Subject: 000031 > Visit: Screening		Tíme Zone: UTC
COLLECT SUBJECT DATA		
Sex (at study entry) *	- Select - 🔽	CLETOM DATA
Race*	Select 🗸	CUSTOM DATA
Ethnicity (please refor to RAMOS NG User Guide for more details)*	- Select -	CLISTOM DATA
Next Cancel		





Randomize a Subject

Select Randomization button to randomize the subject.







Randomize a Subject

Select the stratification factor and weight.







Subject Visits

Select an answer for the oral bridging question

RAMOS NG Evaluation		Study Documentation Language: English 🗸
Home Subjects Supply Shipments Change View		Welcome, Kevin Clear Logout Help
Study Code: 209639v001 > Centre: 209639_TestSiteUSA > Subject: 000031 > Visit: Month 1		Time Zone: UTC
COLLECT SUBJECT DATA		
Is Cabotegravir oral bridge therapy needed? *	– Select – 🔽	QUESTION
Next Cancel		

If oral bridging is selected, select a quantity.







Subject Visits – Months 4, 8, 12, and every multiple of 4

Select a weight if prompted

		Study Documentation Language: English 🗸
Home Subjects Supply Shipments Change View		Welcome, Kevin Clear Logout Help
Study Code: 209639v001 > Centre: 209639_TestSiteUSA > Subject: 000031 > Visit: Month 4		Time Zone: UTC
COLLECT SUBJECT DATA		
Please select the participant's weight range.* Next Cancel	- Select - >=50kg to <=51kg >51kg to <=58kg >66kg to <=73kg >73kg to <=80kg >80kg to <=88kg >88kg to <=95kg	QUESTION
	>95kg to <=102kg >102kg to <=110kg >110kg to <=115kg	





Screenfail and Withdrawal of Subjects





Screen Failure / Withdrawal of a Subject

Click on Screen fail if subject in screened status or Withdraw if subject is enrolled.

		Study Documentation Language: English 🔽				
Home Subjects Supply Shipments Change View		Welcome, Kevin Clear Logout Help				
dy Code: 209639v001 > Centre: 209639_TestSiteUSA > Subject: 000017						
SUBJECT						
DETAIL DATA						
Subject ID 000017 Status SCREENED						
Study : Centre 209639v001 : 209639_TestSiteUSA Rand ID						
Registration Date 27-Jul-2023 Enroll Date						
Randomization Screen Fail Replace Container Done						
Visit Date Type	Drug Assigned	Notes				
Visit Screening - 27-jul-2023						

	Study Documentation Language: English 🗸
Home Subjects Supply Shipments Change View	Welcome, Kevin Clear Logout Help
Study Code: 209639v001 > Centre: 209639_TestSiteUSA > Subject: 000031	Time Zone: UTC
SUBJECT	
DETAIL DATA STRATA DOSING FACTORS	
Subject ID 000031 Status ENROLLED	
Study: Centre 209639v001 : 209639_TestSiteUSA Rand ID 2008 Treatment Group D1 [VH3810109 IV infusion]	
Registration Date 28-jul-2023 Enroll Date 28-jul-2023	
Month 5 Withdraw R splace Container Done	





Screen Failure / Withdrawal of a Subject

Select the reason and then click on Confirm.

RAMOS NG Evaluation	Study Documentation Language: English 🗸
Home Subjects Supply Shipments Change View	Welcome, Kevin Clear Logout Help
Study Code: 209639v001 > Centre: 209639_TestSiteUSA > Subject: 000017	Time Zone: UTC
SCREEN FAIL CONFIRM	
Please confirm you wish to screen fail subject: 000017 Choose a reason	
- Select Reason Screen Fail Subject	
Or input reason*	
WARNINGI Subject will no longer be eligible to participate in the study.	
Confirm Cancel	









Replacing a Container





Replacing a Container

The **REPLACE CONTAINER** function allows the user to replace the container. The replace container functionality will only replace containers for the subject's last dispensing.

RAMOS NG Evaluation				Study Documentation Language: English 🗸			
Home Subjects Supply Shipments	Change View			Welcome, Kevin Clear Logout Help			
Study Code: 209639v001 > Centre: 209639_TestSiteUS	5A > Subject: 000031			Time Zone: UTC			
SUBJECT							
DETAIL DATA STRATA DOSING FACTO	IRS						
Subject ID 000031 Status ENROLLED Study : Centre 209 [9v001 : 209639_TestSiteUSA Rand II 2008 Treatment Group D1 [VH3810109 IV infusion] Registration Date 28 Ju-2022 Executive te 28 Jul-2023 Month S Withdraw Replace Container Done							
Visit	Date	Туре	Drug Assigned	Notes			
Visit Screening - 28-Jul-2023							
Visit Randomization - 28-Jul-2023	Visit Randomization - 28-jul-2023						
Visit Month 1 - 28-Jul-2023	Visit Month 1 - 28-jul-2023						
Visit Month 3 - 28-Jul-2023							
Visit Month 4 - 28-Jul-2023							





Confirmation Reports





Confirmation Reports

To generate a report click on the Regenerate Report Tab and then click on the Regenerate button on the required visit. Confirmation emails are sent to the study contacts if they are set up to receive when visits occur.

RAMOS NG (Evaluation		Study Documentation Language: English
Home Subjects Supply	Shipments Change View		Welcome, Kevin Clear Logout Hel
Study Code: 209639v001 > Centre: 2	09639_TestSiteUSA > Subject: 000031		Time Zone: UT
SUBJECT			
DETAIL DATA STRATA	DOSING FACTORS		
Subject ID 000031 Study : Centre 209639v001 : Registration Date 28-jul-2023	Status ENROLLED 209639_TestSiteUSA Rand ID 2008 T Enroll Date 28-Jul-2021	represent Group D1 [VH3810109 IV infusion]	
Month 5 Withdraw F	Replace Container Do		
Visit	Date	Туре	
Screening	28-jul-2023	Register Subject	<study> - Site: <site -="" <subjectid="" subject:=""> - Visit Confirmation Regenerate Repor</site></study>
Randomization	28-Jul-2023	Enroll Subject	<study> - Site: <sil> - Subject: <subjectid> - Visit Confirmation Regenerate Report</subjectid></sil></study>
Month 1	28-Jul-2023	Dispense Drug	<study> - Site: <site> - Subject: <subjectid> - Visit Confirmation Regenerate Report</subjectid></site></study>
Month 3	28-Jul-2023	Dispense Drug	<study> - Site: <site> - Subject: <subjectid> - Visit Confirmation</subjectid></site></study>
Month 4	28-Jul-2023	Dispense Drug	<study> - Site: <site> - Subject: <subjectid> - Visit Confirmation Regenerate Report</subjectid></site></study>





Confirmation Reports

A pdf formatted report will be displayed.



Transaction Date: 28-Jul-2023 18:42:37 GMT

Study:	209639v001
Study Centre:	209639_TestSiteUSA
Investigator:	TestInvFN TestInvLN
Performed by:	kwc16755@gsk.com

Subject 000031 Information

Subject Status:	SCREENED
Register Date:	28-Jul-2023
Visit:	Screening
Visit Description:	Screening

Subject Data Details

Ethnicity (please refor to RAMOS NG User Guide for	Hispanic / Latinx	
more details): Race:	Black	
Sex (at study entry):	Female	





Helpdesk and Tips





GSK Clinical Support Helpdesk

- Available 24/7
- Toll free phone: http://www.clinicalsupporthd.gsk.com/contact.html
- eMail: <u>GSKClinicalSupportHD@gsk.com</u>
- Information to provide to the GSK Clinical Support Helpdesk:
 - Study Number 209639
 - Study is a RAMOS NG study
 - Site Number
 - Investigator Name
 - Person's name and contact information who is calling the helpdesk
 - Subject number (CRF number)
 - Brief summary of the issue





- Log into RAMOS NG to check your access.
- To assist with access issues, please contact your site monitor or the GSK Clinical Support Helpdesk.
- Please review the HOME page to confirm any inbound orders.
- Upon shipment receipt, please follow the temp monitoring instructions in each shipment before confirming in RAMOS NG.
- Carefully review all data that is being input into the system prior to confirming it.









INVESTIGATIONAL PRODUCT

Peter Leone Project Physician Lead







VH3810109A for Injection, 440mg/vial:

VH3810109A for Injection, 440mg/vial is presented as a sterile, white to yellow, uniform lyophilized powder in a 25 mL clear glass, stoppered vial. The recommended storage condition is store at 2-8°C (36-46°F), protected from light.

Recombinant Human Hyaluronidase 1mg/mL:

Each vial of Recombinant Human Hyaluronidase 1mg/mL contains 0.5 mL of rHuPH20 formulated at a concentration of 1 mg/mL (~110 000 U/mL rHuPH20) and is supplied in 2 mL glass vials as a sterile, single-dose, injectable liquid. The recommended storage condition is store at 2-8°C (36-46°F), protected from light

63





N6LS FOR IV ADMINISTRATION

N6LS 440 mg/vial should be reconstituted with **sterile Water for Injection** (WFI) and then diluted in IV bag containing compendial 5% dextrose.

- The concentration of reconstituted GSK3810109A drug product (DP) is 80 mg/mL.
- The extractable volume/vial for GSK3810109A DP is 5.5 mL (440 mg).
- The reconstituted DP is diluted to 250 mL using 5% dextrose.
- The concentration of N6LS for IV dosing can range from 3.2 mg/mL to 30 mg/mL.

N6LS dosing solutions may be stored at room temperature for up to **4 hours**.





N6LS IV dosing is a weight based dose of 60 mg/kg. Dosing is based on body weight on the day of dosing.

Determine the dose in milligrams required by the subject (weight to be rounded to one decimal point) Calculated dose (mg) = subject weight (kg) x 60 mg/kg

Calculate the required volume of reconstituted N6LS (80 mg/mL):

Required volume of reconstituted DP (mL) = Calculated dose (mg) ÷ 80mg/mL (concentration of IP)

Calculate the required number of lyophilized N6LS vials needed to prepare the dosing solutions : **Required # of lyophilized vials (round to whole number) = Required volume of reconstituted DP (mL) ÷ 5.5.ml of extractable volume**

Calculate the concentration of prepared IV dose:

Concentration of IV dosing solution (mL) = Dose (mg) ÷ 250 mL (volume of 5% dextrose injection)





- Remove the required number of vials from 2° to 8°C storage based upon the calculated dose. Allow the vial(s) to equilibrate to ambient room temperature, protected from light, for **~ 30 minutes**.
- Remove the seal. Wipe the top of the vial(s) with disinfecting tissue of isopropyl alcohol 70% or similar and allow the alcohol to dry.
- Reconstitute the vials by adding 5.2 mL of WFI to each vial (use 10 mL syringe/ 18G needle combination). Direct the stream directly onto the center of the lyophilized powder.
- Gently swirl the vial for 10 seconds with circular motion at 15-second intervals, until cake is fully dissolved, and the product is uniform in appearance. A small amount of foaming may be transiently observed during reconstitution. Allow foam to subside before withdrawing contents from vial.
- After reconstitution, visually inspect the DP vials The reconstituted DP solution should appear as a clear to opalescent; colorless to yellow or brownish yellow liquid; essentially free from visible particulates.
- If visible particles, unusual discoloration is observed, then the product should not be used.





- Reconstituted N6LS must be further diluted to 250 mL using an IV bag containing 5% dextrose.
- From a **250 mL IV bag** containing **5% dextrose** injection, **remove the required volume of the diluent to accommodate the volume of reconstituted N6LS to be added**. Add the calculated volume of the reconstituted N6LS as described in the dose calculations section. Alternatively, use an empty infusion bag and prepare the dose by adding the calculated volume of 5% dextrose injection followed by the calculated volume of reconstituted VH3810109 DP.
- Gently invert the container 5 to 10 times to ensure complete mixing. Avoid shaking or excessive agitation.
- Prior to administration, visually inspect the N6L IV dosing solution for visible particles or unusual discoloration. If unexpected visible particles, unusual discoloration, the product should not be used.





- SC dose of N6LS is 3000 mg containing approximately 1600 U/mL of rHuPH20 (60,000 u)
- The SC dosing volume calculation :
 - Dose Volume of N6LS = 3000 mg dosage volume + 4.5 mL Overfill Volume
 - Total (U) rHuPH20 = Total Volume (VH3810109) * 1600 U/mL
 - Total Volume RHUPH20 (mL) = Total (U) rHuPH20 / (110,000 U/mL)





- Remove the 8 vials of N6LS drug product from 2° to 8°C storage.
- Allow the vials to equilibrate to ambient room temperature, protected from light, for ~ 30 minutes.
- Remove the seal. Wipe the top of the vial(s) with disinfecting tissue of isopropyl alcohol 70% or similar and allow the alcohol to dry.
- Reconstitute the lyophilized vials (see dose calculation section) by adding 5.2 mL of WFI to each vial (use 10 mL syringe/ 18G needle combination). Direct the stream directly onto the center of the lyophilized powder.
- **Gently swirl** the vial for **10 seconds** with **circular motion at 15-second intervals**, until cake is fully dissolved, and the product is uniform in appearance. A small amount of foaming may be transiently observed during reconstitution. Allow foam to subside before withdrawing contents from vial.
- Remove **2 vials of PH20** solution, 110,000 U/mL, from 2°C to 8°C storage temperature.
- Allow the vials of PH20 to sit for **15 minutes to come to room temperature.**

N6LS +PH20 FOR SC ADMINISTRATION (CONTINUED) PowerPoint title (Global update in Header and Footer)



- Visually inspect the reconstituted DP and PH20 DP vials prior to SC dose solution preparation. The reconstituted N6LS solution should appear as a clear to opalescent; colorless to yellow or brownish yellow liquid; essentially free from visible particulates. The PH20 DP should appear as a clear and colorless solution. If visible particles, unusual discoloration, then the products should not be used.
- Reconstituted N6LS (42 mL) must be co-mixed with 0.6 mL of PH20 (~ 1600 U/mL)

Mixing steps are described below:

- 50mL syringe/18 G needle combination to draw a total volume of 42 mL of the reconstituted DP from 8 vials.
- Transfer 42mL of VH3810109 DP from the 50mL syringe into a single 50 or 100mL stoppered and sealed sterile glass vial. Gently swirl the solution to ensure homogeneity.
- Draw a total volume of 0.6 mL ofPH20 from 2 vials (0.3mL from each vial) using a 1mL syringe/27G needle . Transfer 0.6 mL rHuPH20 into the 50 or 100mL vial containing 42 mL GSK3910109 DP.
 Gently mix the solution to ensure homogeneity.
- Take a 50 mL syringe/18G needle combination and draw the admixture of GSK3810109 and rHuPH20 prepared in the previous step. Discard the needle and cover the end of the syringe with a cap.
- Place the 50 mL syringe in the syringe pump connect the extension set Program the pump for SC infusion of 38.1mL volume at a rate of 3mL/min.





SC ADMINISTRATION VIDEO https://vimeo.com/850628116/9a9a476f9f?share=copy



BREAK

