

Central Laboratory Services Manual

Roche Products Limited

Protocol: WO43571

Labcorp Project #: 211285

Region: EMEA

Version: 4.0.0

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14 April 2022

Manual Revised:

06 September 2023

labcorp
Drug Development

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Investigator
Support

Since 2021, Covance has been known globally as Labcorp. Although our name changed, your studies continue to be delivered by the same talented, committed teams, on the same scientific instruments, with the same tireless commitment to patients.

We are still phasing out any remaining items that have the Covance name and logo. During this transition period, you may still receive some items with the Covance name and logo in combination with our Labcorp branding and logo. Over time, new items will fully transition to the new branding and bear the new name and logo.

Have additional questions? Contact our Investigator Support team
[Labcorp Central Laboratory Services Investigator Support Team](#)

History of Change

Project	Work Type	DateCreated/ Revised	Description	Standard Page
211285	New Manual	14-Apr-22	New Manual	0
211285	Mod. Manual	20-Jul-22	Updated: Version Number from 1.0.0 to 2.0.0 (cover page) Added: Manual revised date (cover page) Updated: History of Change (Manual) Added: Test groups FSH MN, ESTRADIOL MN (VTS, SPC, REQ) Updated: Occurrence for visit Cycle 2, 6 Day 1 and Cycle n day 1 (VTS) Added: Required testing for groups SM12 PLASMA RHUPH20 ADA, SM13 SERUM PERTUZUMAB ADA, SM14 SERUM TRASTUZUMAB ADA for visit Treatment Discontinuation (VTS, SPC, REQ) Updated: Standard page to WO43571_Roche Standardized Tissue Collection Instruction_v2_2022-06-28 (MANUAL)	0
211285	Mod. Manual	30-Aug-22	Updated: Version number from 2.0.0 to 2.1.0 (Cover). Updated: Revision Date (Cover). Updated: History of Change (Manual). Updated: SM5 SERUM PERTUZUMAB ADA PRE & SM13 SERUM PERTUZUMAB ADA test groups to have their own Narrative tabel (SPC). Updated: Specialty Visit Definition (VTS) Added: Label line for the visit CHEMISTRY MIN and COAGULATION MIN test groups (SPC) Updated: Collection narrative, shipping address, shipping frequency, collection vial for all applicable test groups (SPC, All Applicable Reqs) Updated: NCR, Legends, AD notes, optional testing table (All Applicable Reqs)	0
0	Mod. Std Page	28-Dec-22	Updated: annual holiday dates	CustomClosed_EMEA
0	Mod. Std Page	16-Jan-23	Updated: typo "circum-stances" to correctly read as "circumstances" under "Courier Pick-up Information" section.	GeneralInformationPackagingShipping_ContRed
0	Mod. Std Page	3-Feb-23	Updated: ISO15189 certification Updated: Dr. Lewest CV	EURLaboratoryCertifications
211285	Mod. Manual	20-Mar-23	Updated: Version Number from 2.1.0 to 3.0.0 (cover page) Updated: Manual revised date (cover page) Updated: History of Change (Manual) Updated: SM3 SERUM PERTU/TRASTU PK PRE, SM4 PLASMA RHUPH20 ADA PRE, SM5 SERUM PERTUZUMAB ADA PRE, SM6 SERUM TRASTUZUMAB ADA PRE For visits Cycle 1 Day 1 Arm A, Cycle 1 Day 1 no WGS/WES Arm A (VTS, SPC, REQS) Updated: SPECIALTY VISIT DEFINITIONS (VTS) Added: New Visits Treatment Discontinuation Arm A V3 & Treatment Discontinuation Arm B V3 (Manual) Updated: AD notes, conditional testing tables (All applicable Reqs) Updated: Visit names from Treatment Discontinuation , Follow up Month 3, 12 and 24 , Cycle 4 Day 1 Arm A to Treatment Discontinuation V2, Follow up Month 3, 12 and 24 V2, Cycle 4 Day 1 Arm A Protocol V2 (Manual)	0
0	Mod. Std Page	5-Jul-23	Updated: Xcelerate Welcome letter to replace "Xcelerate" with "Labcorp" Updated: footer formatting on subsequent pages to match the first page	XcelerateWelcomeLetter
0	Mod. Std Page	20-Jul-23	Updated: CAP certification	EURLaboratoryCertifications
211285	Mod. Manual	6-Sep-23	Updated: Version Number from 3.0.0 to 4.0.0 (cover page) Updated: Manual revised date (cover page) Updated: History of Change (Manual) Updated: Collection/return container for test group FRESH TISSUE BLOCK from Y6OP to OE6P & for test group ARCHIVAL TISSUE BLOCK from OC6P to OE6P for visit Tissue Sample Collection (SPC, REQ)	0

Definitions of Abbreviations:

A2=Appendix 2: CCLS & CVCL Contacts

A3=Appendix 3: Courier Information

A5=Appendix 5: Revision History

AD=Administrative statement or question.

DEMO=Demographics

DOC=Day of collection

GIP=General Information Pages

REQ or REQS=Requisition(s)

SH=Sample Handling

SIG=Signature Page

SPC=Specimen collection (page(s) with collection narrative)

TOC=Table of contents

UDS=Urine drug screen

VTS=Visit test schedule

Note: Reference Ranges, Alerts and Flagging standard modifications listed above are Covance-driven modifications and may not apply to project-specific reference range sets. Please discuss reference ranges, alerts and flags with your project manager.

Labcorp CLS Version Control Process

Labcorp CLS currently uses a 3 decimal version control process (1.0.0) where:

- The first digit indicates a sponsor driven modification (1.0.0)
- The second digit indicates a Labcorp driven modification (1.1.0)
- The third digit indicates a standard page update (1.1.1)

All digits after the first digit will restart with a new sponsor driven modification (2.0.0)

Privacy Notice

At Labcorp Central Laboratory Services, we understand the importance of protecting our partner's personal information. That's why we have a comprehensive privacy statement that outlines how we collect, use, and protect the personal information you provide us.

Our privacy statement explains the types of personal information we collect, how we use it and how we ensure its security and confidentiality. It also provides information about your rights, such as the right to access, modify or delete your personal information.

We believe that transparency is key when it comes to data privacy, which is why we encourage you to review our privacy statements in our website: <https://drugdevelopment.labcorp.com/customers/investigators/investigator-study-team.html>



Privacy Statement
Institution



Privacy Statement
Investigator



Privacy Statement
Study Staff

Have additional questions? Contact our Investigator Support team
[Labcorp Central Laboratory Services Investigator Support Team](#)

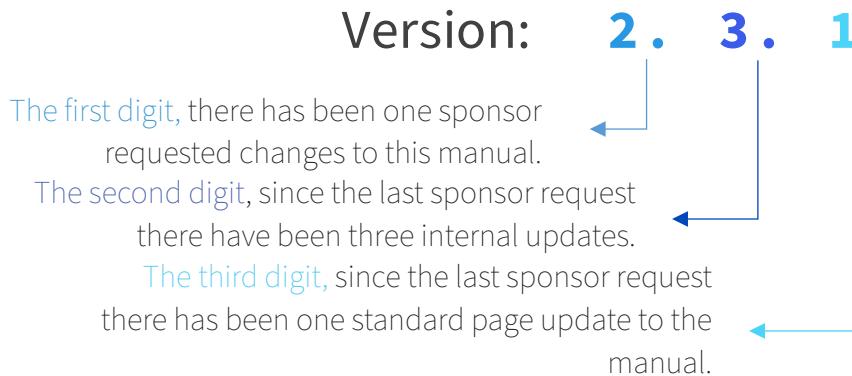
Version Control Process

This version system takes sponsor requested updates, internally requested updates, and standard page updates into account.

Labcorp CLS has a **three-digit version system** in place for our laboratory manuals:



- All digits after the first digit will restart with a new sponsor driven modification (2.0.0)
- With the above as an explanation, **here is an example:**



- All changes will be accompanied by a Manual Revised date change. This information will be present on the cover of the manual as well as the footer on all pages of the manual.

SECTION BREAK

Labcorp Investigator Portal



Investigator Support

Our portal provides all the information you need. On-screen results, lab reports, alerts, eQueries, Kit Inventory Summary, training materials and communications are all available and easy to find.

- To access our portal go to <https://xip.labcorp.com>
- If you need to **change your password** visit: <https://ddaccess.labcorp.com/web/ups/passwordmanager>
- Don´t forget to **change your password every 90 days**.
- If you don´t have an account or access to a study please contact your Sponsor or CRO to request it.

In the portal, you can keep track of your kit inventory at all times to manage patient visits effectively. To ensure accurate inventory, please inform Labcorp of expired, lost, damaged, or transferred kits by going to the **Kit Inventory Website**: <https://drugdevelopment.labcorp.com/kitordering>

Still need Support?
Visit the Application Training* for quick guides or contact the [Investigator Support Team](#) through the chat or contact numbers.

Quick Overview - Home Page / Dashboard

Provides access to study-specific information via study cards.

The screenshot shows the Labcorp Investigator Portal dashboard. At the top right are 'User Settings' and a 'Logout' button. Below is a section titled 'Non Study-specific' with links to 'General Communications', 'General Lab Manuals', 'General Training Materials', and 'Application Training'. Further down are sections for 'Announcements' (with a Japanese demo notice) and 'Common Links' (including a calendar and privacy statement). The main area features 'Study Cards' for 'Central Labor...' and 'Unread Documents' (2). A 'User Settings' sidebar on the right includes links for 'General Manuals', 'General Communications', 'General Training Materials', 'Application Training', and 'Announcements' (6).

Study Cards (1)
Provides access to study-specific data and documents

Unread Documents (2)
The number of unread documents at the site level will display on the study card.

Non Study-specific
General Communications,
General Lab Manuals,
General Training Materials
and Application Training

User Settings
Edit and modify your settings, including notifications

***Application Training**
How to navigate and quick reference guides

Important Announcements
Maintenance releases, reminders, and frequently used links

Shipping Considerations Holidays

To avoid delays when shipping during the holiday season, we recommend that you plan ahead and follow these recommendations.

Local courier service (pickup and delivery) may be limited prior to, during and following observed holidays in the country to which you are shipping specimens. It is imperative that you check local service schedules in advance of the holiday.

Important considerations when planning your patient visits during the holidays.

- Your courier service reserves the right to observe earlier than usual pick-up times during the holidays. Call your courier service for local pick-up schedules.
- During the December/National holidays, schedule your pickups in advance of the holiday where possible.
- Call early in the day to schedule your pickup.
- When a holiday is observed on Monday, avoid laboratory collections on the preceding Saturday (i.e. Labor Day).*
- Frozen specimens should NOT be shipped on the day before the observed holiday. Send frozen specimens on the next available business day.*
- If shipping specimens on Friday, mark airway bill for Saturday delivery.*
- Specimens with short stabilities (eg. lymphocyte subsets, reticulocyte counts, etc.) should not be collected on the day prior to the holiday.*
- For sites with 24 hours delivery time to Labcorp Central Laboratory Services, do not schedule any shipment 24 hours before one of the dates on the next pages.*
- For sites with 48 hours delivery time to Labcorp Central Laboratory Services, do not schedule any shipment 48 hours before one of the dates on the next pages.*

* Not applicable for Japan

Holiday reminders are also available on the website:

<https://drugdevelopment.labcorp.com/customers/investigators/investigator-study-team.html>

Labcorp Central Laboratory Services Observed Holidays

EUROPE, MIDDLE EAST AND AFRICA (SPECIMENS SENT TO GENEVA)

2023	2024	2025	
01 January	01 January	01 January	New Year's Day
07 April ¹	29 March ¹	18 April ¹	Good Friday
10 April	01 April	21 April	Easter Monday
18 May	09 May	29 May	Ascension Day
29 May	20 May	09 June	Whit Monday
01 August	01 August	01 August	Swiss National Day
07 September	05 September	11 September	Jeûne Genevois
25 December	25 December	25 December	Christmas Day
31 December	31 December	31 December	Restauration de la République

¹ Limited operations within Labcorp Central Laboratory Services this day due to Easter Good Friday period.

CONTACT NUMBERS TO CALL LABCORP CENTRAL LABORATORY SERVICES



To call Labcorp Central Laboratory Services in Geneva from:

Monday - Friday: 8h00 - 19h00 (Geneva time = GMT +1)

Saturday: 10h00 - 17h00 (Geneva time = GMT +1)

If you need urgent assistance outside of Geneva working hours you may call

Investigator Support in Indianapolis at +1 317 271 1200 (then press 1)

Austria	Hungary	Portugal	+ 800 88 77 44 11 (Tel) + 800 88 77 44 22 (Fax)
Belgium	Ireland	Slovakia	
Bulgaria	Israel	Slovenia	
Cyprus	Italy Liechtenstein	Spain	
Denmark	Luxemburg	Sweden	
France	Netherlands	Switzerland	
Germany	Norway	United Kingdom	

Croatia + 800 8877 4411 (Tel) or
0800 223061 (Tel)
0800 22 30 60 (Fax)

Czech Republic 800 142 083 (Tel)
800 142 787 (Fax)

Finland 990 800 88 77 44 11 (Tel)
990 800 88 77 44 22 (Fax)

Greece 00 800 4112 871 141 (Tel)
00 800 4112 871 140 (Fax)

Latvia 800 031 43 (Tel)
800 031 01 (Fax)

Lithuania 8800 30262 (Tel)
8800 30124 (Fax)

Monaco 800 93 185 (Tel)
800 93 184 (Fax)

Poland +800 8877 4411 (Tel) or
0-0800 4111 231 (Tel)
+800 8877 4422 (Fax) or
0-0800 4111 230 (Fax)

Romania 08008 9 52 14 (Tel)
08008 9 52 13 (Fax)

Russia 8 800 333 73 39 (Tel) or
8 800 201 71041 (Tel)
8 800 333 73 38 (Fax) or
8 800 201 81041 (Fax)

Ukraine 0800504643 (Tel)
0800504642 (Fax)

CONTACT NUMBERS TO CALL LABCORP CENTRAL LABORATORY SERVICES



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If you need urgent assistance outside of Geneva working hours you may call
Investigator Support in Indianapolis at +1 317 271 1200 (then press 1)

South Africa

00 800 88 77 44 11 (Tel) or
0800998424 (Tel)
800 88 77 44 22 (Fax)

Turkey

00 800 419 871 141 (Tel)
00 800 419 871 140 (Fax)

Callers in countries that do not have a LCLS Toll Free Line, please call +41 58 822 7901 (Fax +41 58 822 7521) OR ask your local telephone operator for a collect call to
+41 58 822 7000.

Courier Contact information can be found on the Investigator & Study Staff Website, along with Dangerous Goods
Training requirements and other important information:

<https://drugdevelopment.labcorp.com/customers/investigators/investigator-study-team.html>

Kit Information

Our pre-labeled and prepared collection kits alleviate logistical burdens, ensuring accuracy and efficiency during each patient visit.

Follow these instructions to avoid delays on your results.



- To obtain the highest quality specimens possible, store all collection supplies between 4°C to 25°C (39°F to 77°F). If an incident occurs where the storage conditions for a lab kit are in question, contact your study Monitor or CRA.
- Kits are protocol, investigator and visit specific. Select the correct kit accordingly by checking the information printed on the outside of each kit box.
- **Check the expiration dates** on the outside of the box before using the kit as some tubes have expiration dates defined by their manufacturers, and the kit's expiration date corresponds to the shortest expiration date of the tube(s) within it.
- **Collecting a specimen in an expired container that has an additive may result in inaccurate or invalid test results.** The sample will be cancelled and marked as "Sample drawn in expired tube: Testing not performed."
- A unique accession number is assigned to each kit and its requisition form. Within the kit, specimen container s and the requisition have the same accession number (bar code). **Do not interchange the tubes and/or requisition forms between kits.**
- If you have expired tubes, please use the online web tool at or call Labcorp to have these kits replaced and your inventory updated.
- Each container label is pre-printed with a barcode and an accession number.
- Complete the labels with appropriate identifiers (screening number and/or patient number) using a blue or black ball point or indelible ink pen. Errors in specimen labeling cause delays in reporting patient results and in some cases require testing to be cancelled.
- Bulk Supplies: Depending on your protocol, additional items may be provided. For some studies, no bulk supply is provided.
- We collect information about site performance in connection with use and return of kits to help sponsors and sites evaluate clinical studies and identify areas for improvement.

Update your kit inventory or replace kits:

<https://drugdevelopment.labcorp.com/customers/investigators/order-a-kit.html>

The following page is for all visits except for:

Tissue Sample Collection

Cycle 1 Day 1 Arm A

Cycle 1 Day 1 Arm B

Retest

Cycle 1 Day 1 no WGS/WES Arm A

Cycle 1 Day 1 no WGS/WES Arm B

Retest without WGS/WES

Safety Mobile Nursing

Treatment Discontinuation Arm A V3

Treatment Discontinuation Arm B V3

Treatment Discontinuation V2

Cycle 4 Day 1 Arm A Protocol V2

Follow up Month 3, 12 and 24 V2 and B V2

Automatic Kit Supply and Resupply 1/2



Investigator
Support

Our innovative kit service and automated resupply processes are quick and efficient, reducing the burden on your investigator site staff.

In your initial shipment, you will receive a start-up supply of collection kits and shipping boxes/documents specific to your site and this trial.

For Required Scheduled Visits

- 1.** When you use the first collection kit and complete the requisition, this becomes a patient-specific kit
- 2.** Upon receipt of each of your patients' first visit kit/samples, our automatic resupply system sets up a future kit resupply schedule based on the visit testing schedule provided to us by your sponsor
- 3.** This schedule is set up to "trigger" a resupply of kits approximately 21 days prior to the need at your site. This will allow for production and delivery time (within 7 days of visit) to your site
- 4.** The auto resupply system reviews our record of your site inventory each day for any activity, (e.g., kits sent in, or kits shipped out)

Important Considerations

- Accurate site inventory in our database is vital for optimal automatic resupply success
- It is important that you keep us informed of inventory changes such as lost, damaged or expired kits
- Visits that contain all frozen batch shipped samples (e.g., monthly or end of study, instead of day of collection) should be monitored closely. The Labcorp Central Laboratory Services database does not recognize that the kit has been used until it is received at Labcorp Central Laboratory Services
- We recommend using our website for all kit ordering, questions, and inventory updates

For Other Visits

Some kits cannot be automatically resupplied based on the visit test schedule, for example, visits that occur within the first week of the study or those that are unscheduled: Retest or Early Termination kits.

- 1.** These visits would be resupplied based on a minimum/maximum schedule. For example Visit 1 could be defined with a minimum of 3 and maximum of 5
- 2.** When your site inventory for Visit 1 falls below 3 kits in our database, the auto resupply system would generate a "trigger" order to build your inventory back up to 5

Continue to next page...

Automatic Kit Supply and Resupply 2/2



Investigator
Support

The pre-defined levels can be customized for your site by contacting the Investigator Support Center. If your site is a high enroller or slow enroller, we can adjust the resupply to work more efficiently for your needs.

Automatic Supply Exceptions

- Shipping supplies need to be ordered and are not automatically resupplied
- There is no automatic resupply for Russia, Ukraine, Belarus, and Moldova, due to Import regulations
- There is no supply of shipping boxes for Israel and Africa provided by Labcorp Central Laboratory Services. Investigators in these countries are kindly requested to order shipping boxes from the courier each time they request a pick-up

To request additional supplies

- Web Resupply is the preferred method
- For sites in Europe, Middle East and Africa contact Kit Inventory Center in Geneva
- Phone: Please find your country contact number in this Manual in the How to Contact Us page, in the General Information Section or in this link
<https://drugdevelopment.labcorp.com/customers/investigators/investigator-study-team.html>

Delivery days and Turn around times

- Refer to your Web resupply form for delivery days
- Please note there will be an expedited fee for orders requested with less than the standard turn around time
- If you are located in an extended delivery area your delivery may take longer than the standard turn around time

To update your kit inventory or replace kits:

<https://drugdevelopment.labcorp.com/kitordering>

If you have questions related to kits or supplies use the chat or contact numbers:

<https://drugdevelopment.labcorp.com/customers/investigators/investigator-study-team.html>



The following page is for only:

Tissue Sample Collection

Cycle 1 Day 1 Arm A

Cycle 1 Day 1 Arm B

Retest

Cycle 1 Day 1 no WGS/WES Arm A

Cycle 1 Day 1 no WGS/WES Arm B

Retest without WGS/WES

Safety Mobile Nursing

Treatment Discontinuation Arm A V3

Treatment Discontinuation Arm B V3

Treatment Discontinuation V2

Cycle 4 Day 1 Arm A Protocol V2

Follow up Month 3, 12 and 24 V2 and B V2

Supply/No Automatic Resupply



Investigator
Support

Resupply

There is no automatic resupply for this study. All material (kits, shipping material and documents, bulk supplies, etc...) needed for the laboratory visits must be ordered using the Web Resupply form.

There is no supply of shipping boxes for Israel and Africa. Investigators in these countries are requested to order boxes from their couriers each time they request a pick-up.

To request additional supplies, please contact the appropriate Kit Inventory Center listed below:

For sites in Europe, Middle East and Africa contact Kit Inventory Center in Geneva

Web Resupply: <http://www.drugdevelopment.labcorp.com/kitordering>

Phone: Please refer to Section 1 (Toll Free Contact Numbers) of this Labcorp Central Laboratory Services.

All supply orders need to be ordered by 12:00 p.m. local time in order to be processed. Orders received after 12:00 p.m. local time will be processed the following business day (Monday - Friday)

Refer to your Web resupply form for delivery days.

- Please note there will be an expedited fee for orders requested with less than the standard turn around time.
- Reminder: If you are located in an extended delivery area your delivery may take longer than the standard turn around time.

**PLEASE NOTE: The preferred method of communication for all kit ordering, questions and kit inventory updates included, is through the website. Go to the above link, select your region, complete ALL of Section A, comment box (for questions) and security check. Section B only needs to be completed for kit orders. Labcorp Central Laboratory Services is able to reply to your comments within the web based tool. **

Kit Order Notifications



Investigator Support

We provide a notification service to ensure you are well informed regarding the status of your kit orders.

Email Notifications

For each kit order, either from our automatic resupply system or via a site request, a notification email will be sent to the receiving site's supply recipient at the following times:

- Confirmation that an order has been created. This email will provide a listing of the materials included in the order
- Confirmation that an order has been shipped from Labcorp Central Laboratory Services. This email will include courier information that will allow tracking of the shipment
- For Japan Sites: Confirmation email notifications will only be sent for Orders Created and Orders Cancelled

If kits are sent to your site via an import broker, the shipment confirmation e-mail will not be sent to you; shipment details will be communicated from the broker.

Order Cancellation

In the event that an order is cancelled, a notification email will also be sent. Please note, the Investigator Order Notification emails as well as other important Labcorp Central Laboratory Services communications will arrive in your inbox from Labcorp Central Laboratory Services Communications@labcorp.com

Opt-out Option

Additionally, the notification system has been designed with an opt-out option, which will allow recipients to decline receipt of the emails if not wanted. If you do not wish to receive these email notifications in the future, please send an email to: OrderNotificationOptOut@labcorp.com

This mailbox is designed solely for stopping emails from being sent to a particular email recipient and not monitored for questions.

If you need support, please contact your local [Labcorp Central Laboratory Services Investigator Support Team](#)

SECTION BREAK

LABORATORY VISIT SCHEDULE FOR PROTOCOL WO43571
Roche Products Limited

		Screening	Induction Therapy Phase	Maintenance Therapy Phase Arm A				Maintenance Therapy Phase Arm B	
Protocol Visit Name	Screening	Induction Therapy Cycle 1 Day 1	Cycle 1 Day 1		Cycle 2, 6 Day 1 and Cycle n day 1	Cycle 4 Day 1	Cycle 1 Day 1		
LabCorp Kit Name	Tissue Sample Collection	Induction Therapy Cycle 1 Day 1	Cycle 1 Day 1 Arm A	Cycle 1 Day 1 no WGS/WES Arm A	Cycle 2, 6 Day 1 and Cycle n day 1	Cycle 4 Day 1 Arm A Protocol V2	Cycle 1 Day 1 Arm B	Cycle 1 Day 1 no WGS/WES Arm B	
VISIT TYPE <i>(RQ=Required, Opt=Optional, U=Unscheduled)</i>	U	RQ	RQ	RQ	U	RQ	RQ	RQ	
OCCURRENCE	Screening	Induction Therapy Phase Cycle 1 Day 1 prior Randomization	Time windows of 7 days after Induction Therapy (at least 4 cycles)	Time windows of 7 days after Induction Therapy (at least 4 cycles)	Day 1 of Cycle 2 and 6 and then Day 1 of every 4th Cycle thereafter for the first 2 years (i.e. 10th, 14th, 18th Cycle etc.) and then every 6th Cycle up to 4 years of maintenance treatment	Cycle 4 Day 1 (+/- 3 Days)	Time windows of 7 days after Induction Therapy (at least 4 cycles)	Time windows of 7 days after Induction Therapy (at least 4 cycles)	
KIT TYPE	T-6	1	2	4	T-1	6	3	5	
Service(s)	Specimen Type								
SM1 BIOMARKER BLOOD	Whole Blood			X	X		X	X	
SM2 BIOMARKER PLASMA	Plasma		X	X	X		X	X	
SM3 SERUM PERTU/TRASTU PK PRE	Serum		X	C	C		X	X	
SM4 PLASMA RHUPH20 ADA PRE	Plasma		X	C	C		X	X	
SM5 SERUM PERTUZUMAB ADA PRE	Serum		X	C	C		X	X	
SM6 SERUM TRASTUZUMAB ADA PRE	Serum		X	C	C		X	X	
SM7 PLASMA GIREDESTRANT PK PRE	Plasma						X	X	
SM8 PLASMA GIREDESTRANT PK 3HR	Plasma						X	X	
SM9 RBR BLOOD	Whole Blood			C	C		C	C	
SM10 WGS/WES BLOOD	Whole Blood			X			X		
SM11 SERUM PERTU/TRASTU PK	Serum								
SM12 PLASMA RHUPH20 ADA	Plasma								
SM13 SERUM PERTUZUMAB ADA	Serum								
SM14 SERUM TRASTUZUMAB ADA	Serum								
<i>Test/Kit Build Only</i>									
FRESH TISSUE BLOCK	Block	paraffin block (preferred) or at least 20 slides *							
FRESH TISSUE SLIDE	Slides								
ARCHIVAL TISSUE BLOCK	Block								
ARCHIVAL TISSUE SLIDE	Slides								
CHEMISTRY MN	Serum								
COAGULATION MN	Plasma								
HEMATOLOGY MN	Whole Blood								
URINALYSIS MN	Urine								
FSH MN	Serum								
ESTRADIOL MN	Serum								

X Mandatory testing

O Optional testing

C Conditional testing

LABORATORY VISIT SCHEDULE FOR PROTOCOL WO43571
Roche Products Limited

Protocol Visit Name	Maintenance Therapy Phase Arm B		Discontinuation and follow-up									Safety Mobile Nursing			Retest	
	Cycle 2, 6 Day 1 and Cycle n day 1	Cycle 4 Day 1	Treatment Discontinuation other than Progression of Disease				Disease Progression				Follow up Month 3, 12 and 24					
LabCorp Kit Name	Cycle 2, 6 Day 1 and Cycle n day 1	Cycle 4 Day 1 Arm B	Treatment Discontinuation V2	Treatment Discontinuation Arm A V3	Treatment Discontinuation Arm B V3	Treatment Discontinuation V2	Treatment Discontinuation Arm A V3	Treatment Discontinuation Arm B V3	Tissue Sample Collection	Follow up Month 3, 12 and 24 V2	Safety Mobile Nursing	Retest	Retest without WGS/WES			
(RQ=Required, Opt=Optional, U=Unscheduled)	U	RQ	U	U	U	U	U	U	U	U	U	U	U	U	U	U
OCCURRENCE	Day 1 of Cycle 2 and 6 and then Day 1 of every 4th Cycle thereafter for the first 2 years (i.e 10th, 14th.... until 34th) and then every 6th Cycle up to 4 years (Cycle 70) of maintenance treatment	Cycle 4 Day 1 (+/- 3 Days)	28 (+/-3) days after the final dose of Phesgo	within 40 days after disease progression or prior to start next systemic anti-cancer therapy, whichever is sooner.	28 (+/-3) days after the final dose of Phesgo	28 (+/-3) days after the final dose of Phesgo	within 40 days after disease progression or prior to start next systemic anti-cancer therapy, whichever is sooner.	28 (+/-3) days after the final dose of Phesgo	Disease Progression	Follow up visit 3, 12 or 24 months after last dose of Phesgo.	-	-	-	-	-	-
KIT TYPE	T-1	7	T-2	T-7	T-8	T-2	T-7	T-8	T-6	T-3	T-4	U	T-5			
Service(s)	Specimen Type															
SM1 BIOMARKER BLOOD	Whole Blood														O	O
SM2 BIOMARKER PLASMA	Plasma	X		X	X	X	X	X							O	O
SM3 SERUM PERTU/TRASTU PK PRE	Serum		X												O	O
SM4 PLASMA RHUPH20 ADA PRE	Plasma		X												O	O
SM5 SERUM PERTUZUMAB ADA PRE	Serum		X												O	O
SM6 SERUM TRASTUZUMAB ADA PRE	Serum		X												O	O
SM7 PLASMA GIREDESTRANT PK PRE	Plasma		X												O	O
SM8 PLASMA GIREDESTRANT PK 3HR	Plasma		X												O	O
SM9 RBR BLOOD	Whole Blood														O	O
SM10 WGS/WES BLOOD	Whole Blood														O	
SM11 SERUM PERTU/TRASTU PK	Serum				X			X			X				O	O
SM12 PLASMA RHUPH20 ADA	Plasma			X		X		X			X				O	O
SM13 SERUM PERTUZUMAB ADA	Serum			X		X		X			X				O	O
SM14 SERUM TRASTUZUMAB ADA	Serum			X		X		X			X				O	O
<i>Test/Kit Build Only</i>																
FRESH TISSUE BLOCK	Block														paraffin block (preferred) or at least 15 slides	
FRESH TISSUE SLIDE	Slides															
ARCHIVAL TISSUE BLOCK	Block															
ARCHIVAL TISSUE SLIDE	Slides															
CHEMISTRY MN	Serum														X	
COAGULATION MN	Plasma														X	
HEMATOLOGY MN	Whole Blood														X	
URINALYSIS MN	Urine														X	
FSH MN	Serum														X	
ESTRADIOL MN	Serum														X	

X Mandatory testing
 O Optional testing
 C Conditional testing

LABORATORY VISIT SCHEDULE FOR PROTOCOL WO43571

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SPECIALTY VISIT DEFINITIONS:

Kit - Induction Therapy Cycle 1 Day 1

This kit should be used to collect PK, ADA and Biomarker samples at Cycle 1 Day 1 of Induction Therapy Phase (Day 1 of 1st cycle in the study).

Kit - Cycle 1 Day 1 Arm A

Sites under protocol version 2

This kit should be used to collect PK, ADA and Biomarker samples at Cycle 1 Day 1 during Maintenance Therapy Phase after Randomization, in **Arm A only**.

Sites under protocol version 3

This kit should be used to collect Biomarker samples at Cycle 1 Day 1 during Maintenance Therapy Phase after Randomization, in **Arm A only**. Pertuzumab, Trastuzumab, and RHuPH20 PK and ADA samples are not applicable to **Arm A version 3**.

Kit - Cycle 1 Day 1 Arm B

This kit should be used to collect PK, ADA and Biomarker samples at Cycle 1 Day 1 during Maintenance Therapy Phase after Randomization, in **Arm B only**.

GIREDESTRANT PK samples are applicable to subject in treatment **Arm B only**.

Kit - Cycle 1 Day 1 no WGS/WES Arm A

Sites under protocol version 2

This kit should be used to collect PK, ADA and Biomarker samples at Cycle 1 Day 1 during Maintenance Therapy Phase after Randomization, in **Arm A only**. This kit will be used by sites not collecting WGS/WES samples.

Sites under protocol version 3

This kit should be used to collect samples at Cycle 1 Day 1 during Maintenance Therapy Phase after Randomization, in **Arm A only**. Pertuzumab, Trastuzumab, and RHuPH20 PK and ADA samples are not applicable to **Arm A version 3**. This kit will be used by sites not collecting WGS/WES samples.

Kit - Cycle 1 Day 1 no WGS/WES Arm B

This kit should be used to collect PK, ADA and Biomarker samples at Cycle 1 Day 1 during Maintenance Therapy Phase after Randomization, in **Arm B only**. This kit will be used by sites not collecting WGS/WES samples.

GIREDESTRANT PK samples are applicable to subject in treatment **Arm B only**.

Kit - Cycle 4 Day 1 Arm A Protocol V2

Only Applicable to Protocol Version 2

This kit should be used to collect PK and ADA samples at Cycle 4 Day 1 during Maintenance Therapy Phase after Randomization, in **Arm A only**.

Kit - Cycle 4 Day 1 Arm B

This kit should be used to collect PK and ADA samples at Cycle 4 Day 1 during Maintenance Therapy Phase after Randomization, in **Arm B only**.

GIREDESTRANT PK samples are applicable to subject in treatment **Arm B only**.

LABORATORY VISIT SCHEDULE FOR PROTOCOL WO43571

Roche Products Limited

SPECIALTY VISIT DEFINITIONS:

Kit - Cycle 2, 6 Day 1 and Cycle n day 1

This kit should be used to collect Biomarker plasma samples at the following visits during Maintenance Therapy phase:

- Cycle 2 Day 1
- Cycle 6 Day 1
- **Day 1 of every 4th cycle for the first 2 years**
- Cycle 10 Day 1
- Cycle 14 Day 1
- Cycle 18 Day 1
- Cycle 22 Day 1
- Cycle 26 Day 1
- Cycle 30 Day 1
- Cycle 34 Day 1
- **Day 1 of Every 6th Cycle from 2 years up to 4 years of the maintenance treatment.**
- Cycle 40 Day 1
- Cycle 46 Day 1
- Cycle 52 Day 1
- Cycle 58 Day 1
- Cycle 64 Day 1
- Cycle 70 Day 1

Kit - Treatment Discontinuation V2

Only Applicable to Protocol Version 2 (for Arm A and B)

This kit should be used for **Treatment Discontinuation** 28 (+/-3) day after the final dose of study treatment to collect Biomarker Plasma Samples in case of discontinuation treatment for any reason other than Disease Progression.

If treatment is discontinued due to **Disease Progression**, this kit should be used in combination with Tissue samples collection kits to assess Tumor tissue samples. The Biomarker plasma sample collection at **Disease Progression** should occur within 40 days after **Disease Progression** or prior to start of the next systemic anti-cancer therapy, whichever is sooner.

Kit - Treatment Discontinuation Arm A V3

Applicable to Arm A protocol version 3

This kit could be used for **Treatment Discontinuation** 28 (+/-3) day after the final dose of study treatment to collect Biomarker Plasma Samples in case of discontinuation treatment for any reason other than **Disease Progression**.

If treatment is discontinued due to Disease Progression, this kit should be used in combination with Tissue samples collection kits to assess Tumor tissue samples. The Biomarker plasma sample collection at **Disease Progression** should occur within 40 days after **Disease Progression** or prior to start of the next systemic anti-cancer therapy, whichever is sooner.

Kit - Treatment Discontinuation Arm B V3

Applicable to Arm B protocol version 3

- **Treatment Discontinuation** 28 (+/-3) day after the final dose of study treatment to collect PK, ADA and Biomarker plasma samples in case of discontinuation treatment for any reason other than Disease Progression.
- **Disease Progression:** if treatment is discontinued due to disease progression, this kit should be used in combination with Tissue samples collection kits to assess Tumor tissue samples. The Biomarker plasma sample collection at **Disease Progression** should occur within 40 days after **Disease Progression** or prior to start of the next systemic anti-cancer therapy, whichever is sooner.

LABORATORY VISIT SCHEDULE FOR PROTOCOL WO43571

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SPECIALTY VISIT DEFINITIONS:

Kit - Follow up Month 3, 12 and 24 V2

Only Applicable to Protocol Version 2

This kit should be used to collect samples at the following "Follow-Up" visits:

- Follow-Up Month 3
- Follow-Up Month 12
- Follow-Up Month 24

Please note that Follow-up visits are based on the date of the last dose of Phesgo and not on treatment discontinuation visit.

Kit - Tissue Sample Collection

This kit can be used at the following visits for Archival of Fresh tumor tissue collection:

- **Screening:**

Archival tumor tissue samples from primary (preferred) and/or metastatic sites obtained during screening for confirmation of HER2 positivity , for retrospective ER and PgR status assessment, and for further research on exploratory biomarkers.

A representative FFPE tumor specimen in a paraffin block (preferred) or at least 20 slides containing unstained, freshly cut 4 μ M serial sections mounted on positive charged glass slides must be submitted prior to study enrollment. In exceptional circumstances, 11 to 19 slides are acceptable provided that other eligibility requirements are met. For China, the number of slides required for eligibility will be based on HGRAC specifications.

- **Disease Progression:**

A representative FFPE tumor specimen in a paraffin block (preferred) or at least 15 slides containing unstained, freshly cut 4 μ M serial sections mounted on positive charged glass slides should be submitted at the time of **Disease Progression**. Biopsies at the time of progression should be performed within 40 days after progression or prior to the next anti-cancer therapy, whichever is sooner.

Kit - Retest

This kit can be used:

- to collect Biomarker Blood, WGS/WES Blood or RBR Blood at any time during the study in case missed during Cycle 1 Day 1 in Maintenance Therapy phase.
- for repeat or follow-up testing.
- to recollect analyses at any time during the trial or
- to substitute for any kit except Tissue Sample Collection, if you do not have the appropriate kit in stock. If so, please cross through "Retest" and write the visit name on the requisition form.
- Make sure that you order all tests required for the visit being performed.

Kit - Retest without WGS/WES

This kit can be used:

- to collect Biomarker Blood or RBR Blood at any time during the study in case missed during Cycle 1 Day 1 in Maintenance Therapy phase.
- for repeat or follow-up testing.
- to recollect analyses at any time during the trial or
- to substitute for any kit except Tissue Sample Collection, if you do not have the appropriate kit in stock. If so, please cross through "Retest" and write the visit name on the requisition form.

Make sure that you order all tests required for the visit being performed.

Kit - Safety Mobile Nursing

This kit should be used to collect Safety testing at patient home.

LABORATORY VISIT SCHEDULE FOR PROTOCOL WO43571

Roche Products Limited

STUDY SPECIFIC NOTES:

- Sponsor is collecting 01-Jan and the subject's birth year as the date of birth (DOB) for all subjects in this study. Labcorp CLS reference ranges, alerts, flags and age-dependent calculations will be based on the generic DOB provided by the investigator. It is the responsibility of the investigator to ensure these parameters are aligned with the real subject age and that the subject meets the age requirement for the study.
- On treatment days, all assessments should be performed prior to dosing, unless otherwise specified.
- Pertuzumab, Trastuzumab, and RHuPH20 PK and ADA samples are not applicable to Arm A version 3 during maintenance phase
- GIREDESTRANT PK samples are applicable to subject in treatment **Arm B only**.
- Tissue Sample Collection kit should be ordered manually by site where Tissue collection samples occur.
- Treatment in both study treatment arms will continue until Disease Progression, unacceptable toxicity, withdrawal of consent, death or predefined study end, whichever occurs first.

Instructions ONLY for Global Care for Mobile Nursing Visits

Applicable kits:

Safety Mobile Nursing

Kit ordering:

Contact the appropriate Kit Inventory Center listed below:

Web Resupply (preferred method):

<https://drugdevelopment.labcorp.com/customers/investigators/order-a-kit.html>

Phone: Please refer to Section 6 (Toll Free Contact Numbers) of the LabCorp Central Laboratory Manual

Requisition completion:

Write the full subject ID in the demographics field and document the site number to which the patient belongs in the field 'Site Number', printed on the requisition.

Shipping instructions:

Refer to shipping instructions in the Manual for mobile nursing visit.

SPECIMEN COLLECTION PROCEDURES FOR PROTOCOL WO43571

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Some immunoassay tests may exhibit interference when samples are collected from a person who is consuming a supplement with a high dose of biotin (also termed as vitamin B7 or B8, vitamin H, or coenzyme R). It is recommended to ask patients about biotin supplementation. Physicians should be aware that high levels of biotin supplementation may have an impact over a period of at least 72 hours. See the list of assays with potential interference immediately following the specimen collection procedures.

SERUM

TESTS	VISITS	COLLECT	RETURN	
SM3 SERUM PERTU/ TRASTU PK PRE	Induction Therapy Cycle 1 Day 1, Cycle 1 Day 1 Arm A*, Cycle 1 Day 1 no WGS/WES Arm A*, Cycle 4 Day 1 Arm A Protocol V2, Cycle 1 Day 1 Arm B, Cycle 1 Day 1 no WGS/WES Arm B, Cycle 4 Day 1 Arm B, Retest*, Retest without WGS/WES*	 1x 3.5 mL gold top serum separation tube	2 mL	FROZEN -70°C OR BELOW DAY OF COLLECTION OR WITHIN 24hr TO: LABCORP CLS
SM11 SERUM PERTU/ TRASTU PK	Treatment Discontinuation Arm B V3*, Follow up Month 3, 12 and 24 V2, Retest*, Retest without WGS/WES*		1x cryovial	

1. One 3.5 mL gold top serum separator tube.
 2. Draw blood into a 3.5 mL serum separator tube (SST) using standard venipuncture techniques.
 3. Mix the blood with the clotting activation agent by gently inverting tube 10 times.
 4. Place the serum separator tube upright to clot at room temperature for 30 minutes until centrifugation.
 5. Centrifuge for 15 minutes at 1500-2000 x g at 4°C within 60 minutes of blood collection. (Centrifugation is the same if no refrigerated centrifuge is available).
 6. Separate serum from blood sample within 20 minutes of the end of centrifugation.
 7. Use provided pipette to transfer all of the serum into the appropriately labeled tube (~1.75 mL of serum).
 8. Immediately freeze and store the samples upright at or below -70°C until shipment to Central Lab Services (if no -70°C freezer, use -20°C) . Ship samples FROZEN on day of collection or within 24hr.

* Optional/Conditional testing or All testing Optional/Conditional at Visit; ** Reflex testing
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SPECIMEN COLLECTION PROCEDURES FOR PROTOCOL WO43571

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SERUM

TESTS	VISITS	COLLECT	RETURN	
SMS SERUM PERTUZUMAB ADA PRE	Induction Therapy Cycle 1 Day 1, Cycle 1 Day 1 Arm A*, Cycle 1 Day 1 no WGS/WES Arm A*, Cycle 4 Day 1 Arm A Protocol V2, Cycle 1 Day 1 Arm B, Cycle 1 Day 1 no WGS/WES Arm B, Cycle 4 Day 1 Arm B, Retest*, Retest without WGS/WES*	 1x 3.5 mL gold top serum separation tube	 2 mL 1x cryovial	FROZEN -70°C OR BELLOW DAY OF COLLECTION OR WITHIN 24hr TO: LABCORP CLS
	Treatment Discontinuation V2*, Treatment Discontinuation Arm B V3*, Follow up Month 3, 12 and 24 V2, Retest*, Retest without WGS/WES*			
<ol style="list-style-type: none"> 1. One 3.5 mL gold top serum separator tube. 2. Draw blood into a 3.5 mL serum separator tube (SST) using standard venipuncture techniques. 3. Mix the blood with the clotting activation agent by gently inverting tube 10 times. 4. Place the serum separator tube upright to clot at room temperature for 30 minutes until centrifugation. 5. Centrifuge for 15 minutes at 1500-2000 x g at 4°C within 60 minutes of blood collection. (Centrifugation is the same if no refrigerated centrifuge is available). 6. Separate serum from blood sample within 20 minutes of the end of centrifugation. 7. Use provided pipette to transfer all of the serum into the appropriately labeled tube (~1.75 mL of serum). 8. Immediately freeze and store the samples upright at or below -70°C until shipment to Central Lab Services (if no -70°C freezer, use -20°C). Ship samples FROZEN on day of collection or within 24hr 				

SERUM

TESTS	VISITS	COLLECT /	RETURN	
CHEMISTRY MN	Safety Mobile Nursing	 2x 2.5 mL red top serum separation tubes	 3.5 mL	AMBIENT DAY OF COLLECTION TO: INVESTIGATOR SITE LABS
Mobile Nursing kit for safety testing.				
PLEASE FOLLOW SEPARATE INSTRUCTIONS.				
SHIP AMBIENT ON DAY OF COLLECTION TO THE INVESTIGATOR SITE LABS. DO NOT SHIP TO LABCORP.				

* Optional/Conditional testing or All testing Optional/Conditional at Visit; ** Reflex testing

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SPECIMEN COLLECTION PROCEDURES FOR PROTOCOL WO43571

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SERUM

TESTS	VISITS	COLLECT	RETURN	
SM6 SERUM TRASTUZUMAB ADA PRE	Induction Therapy Cycle 1 Day 1, Cycle 1 Day 1 Arm A*, Cycle 1 Day 1 no WGS/WES Arm A*, Cycle 4 Day 1 Arm A Protocol V2, Cycle 1 Day 1 Arm B, Cycle 1 Day 1 no WGS/WES Arm B, Cycle 4 Day 1 Arm B, Retest*, Retest without WGS/WES*	 1x 3.5 mL gold top serum separation tube	2 mL 	FROZEN -70°C OR BELOW DAY OF COLLECTION OR WITHIN 24hr
SM14 SERUM TRASTUZUMAB ADA	Treatment Discontinuation V2*, Treatment Discontinuation Arm B V3*, Follow up Month 3, 12 and 24 V2, Retest*, Retest without WGS/WES*		1x Cryovial	TO: LABCORP CLS
<ol style="list-style-type: none"> 1. One 3.5 mL gold top serum separator tube. 2. Draw blood into a 3.5 mL serum separator tube (SST) using standard venipuncture techniques. 3. Mix the blood with the clotting activation agent by gently inverting tube 10 times. 4. Place the serum separator tube upright to clot at room temperature for 30 minutes until centrifugation. 5. Centrifuge for 15 minutes at 1500-2000 x g at 4°C within 60 minutes of blood collection. (Centrifugation is the same if no refrigerated centrifuge is available). 6. Separate serum from blood sample within 20 minutes of the end of centrifugation. 7. Use provided pipette to transfer all of the serum into the appropriately labeled tube (~1.75 mL of serum). 8. Immediately freeze and store the samples upright at or below -70°C until shipment to Central Lab Services (if no -70°C freezer, use -20°C). Ship samples FROZEN on day of collection or within 24hr. 				

SERUM

TESTS	VISITS	COLLECT /	RETURN	
			AMBIENT DAY OF COLLECTION	
FSH MN, ESTRADIOL MN	Safety Mobile Nursing	 1x 2.5 mL red top serum separation tube	5 mL  1x plastic vial FSH MN LOCAL TESTING ONLY	TO: INVESTIGATOR SITE LABS
Mobile Nursing kit for safety testing. PLEASE FOLLOW SEPARATE INSTRUCTIONS. SHIP AMBIENT ON DAY OF COLLECTION TO THE INVESTIGATOR SITE LABS. DO NOT SHIP TO LABCORP.				

* Optional/Conditional testing or All testing Optional/Conditional at Visit; ** Reflex testing
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SPECIMEN COLLECTION PROCEDURES FOR PROTOCOL WO43571

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PLASMA

TESTS	VISITS	COLLECT	RETURN	
SM2 BIOMARKER PLASMA	Induction Therapy Cycle 1 Day 1, Cycle 1 Day 1 Arm A, Cycle 1 Day 1 no WGS/WES Arm A, Cycle 2, 6 Day 1 and Cycle n day 1, Cycle 1 Day 1 Arm B, Cycle 1 Day 1 no WGS/WES Arm B, Treatment Discontinuation V2, Treatment Discontinuation Arm A V3, Treatment Discontinuation Arm B V3, Retest*, Retest without WGS/WES*	 2 x 10.0 mL lavender top EDTA tubes	5 mL  2x Corning cryovials	FROZEN -70°C DAY OF COLLECTION (DOC) OR THE FOLLOWING DAY TO: LABCORP CLS

1. Record the subject ID (Patient ID) on the label of all the tubes.
2. Draw 20 mL of blood into 2 x 10 mL K2 EDTA blood collection tubes.
3. Within 60 minutes of collection, centrifuge the blood collection tubes for 10 min at 1,600 x g at 4°C to separate the plasma.
4. Transfer the supernatant plasma from each collection tube into a single 15 mL centrifuge tube for a second spin.
NOTE: Always place the pipette at the top of the plasma layer and stop aspirating 1/4" (5 mm) above the buffy coat (cellular layer) in order to avoid contaminating the plasma with cells.
5. Centrifuge the tube containing plasma for 10 min at 1,600 x g at 4°C.
6. Aliquot plasma into 2 x 5 mL cryovials.
7. Discard the blood collection tubes and the intermediate tube.
8. Immediately store the samples upright at -70°C until shipment (if -70°C is not available, -20°C is also accepted).
9. Ship FROZEN to Labcorp on dry ice the day of collection (DOC) or the following day if DOC is not possible.

PLASMA

TESTS	VISITS	COLLECT	RETURN	
COAGULATION MN	Safety Mobile Nursing	 2x 1.8 mL 3.2% blue top sodium citrate tubes	3.5 mL  1x plastic vial, COAGULATION MN LOCAL TESTING ONLY	AMBIENT DAY OF COLLECTION TO: INVESTIGATOR SITE LABS

Mobile Nursing kit for safety testing.

PLEASE FOLLOW SEPARATE INSTRUCTIONS.

SHIP AMBIENT ON DAY OF COLLECTION TO THE INVESTIGATOR SITE LABS. DO NOT SHIP TO LABCORP.

* Optional/Conditional testing or All testing Optional/Conditional at Visit; ** Reflex testing
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SPECIMEN COLLECTION PROCEDURES FOR PROTOCOL WO43571

Roche Products Limited

PLASMA

TESTS	VISITS	COLLECT	RETURN	
SM4 PLASMA RHUPH20 ADA PRE	Induction Therapy Cycle 1 Day 1, Cycle 1 Day 1 Arm A*, Cycle 1 Day 1 no WGS/WES Arm A*, Cycle 4 Day 1 Arm A Protocol V2, Cycle 1 Day 1 Arm B, Cycle 1 Day 1 no WGS/WES Arm B, Cycle 4 Day 1 Arm B, Retest*, Retest without WGS/WES*		2 mL 	FROZEN -70°C DAY OF COLLECTION OR WITHIN 24 HR
SM12 PLASMA RHUPH20 ADA	Treatment Discontinuation V2*, Treatment Discontinuation Arm B V3*, Follow up Month 3, 12 and 24 V2, Retest*, Retest without WGS/WES*			TO: LABCORP CLS
<ol style="list-style-type: none"> 1. Collect blood sample using the 2.0 mL K3EDTA collection tube. 2. After obtaining the blood sample, invert the tube gently 8-10 times until the anticoagulant is mixed well with the blood. 3. Samples should be stored on ice until centrifugation. Centrifugation must happen within 30 minutes of collection. 4. Place the blood tube into the centrifuge and spin at 1500g (minimum 1000 g) and approximately 4°C for 10-15 minutes. 5. Use the standard laboratory technique to transfer the plasma into the appropriately labeled cryovial. 6. Store the plasma sample upright at approximately -70°C freezer until shipment. 7. Ship frozen plasma sample to Central Lab Services (CLS) on the day of collection or within 24 hours of collection with enough dry ice to ensure samples remain frozen for at least 72 hours. 				

TESTS	VISITS	COLLECT	RETURN	
SM7 PLASMA GIREDESTRANT PK PRE	Cycle 1 Day 1 Arm B, Cycle 1 Day 1 no WGS/WES Arm B, Cycle 4 Day 1 ARM B, Retest*, Retest without WGS/WES*		2 mL 	FROZEN -70°C DAY OF COLLECTION OR WITHIN 24 HR
SM8 PLASMA GIREDESTRANT PK 3HR	Cycle 1 Day 1 Arm B, Cycle 1 Day 1 no WGS/WES Arm B, Cycle 4 Day 1 ARM B, Retest*, Retest without WGS/WES*		1x cryovial	TO: LABCORP CLS
<ol style="list-style-type: none"> 1. Collect blood sample using the 3.0 mL- K2EDTA draw tube (using standard venipuncture techniques). 2. After obtaining the blood sample, mix collection tube thoroughly by slowly inverting the collection tube 8-10 times. 3. Place the collection tube in an ice/water bath and maintain chilled until centrifugation. 4. Within 60 minutes of collection, process collection tubes in a refrigerated centrifuge set at approximately 2000 x g for 15 minutes. PK samples need to be placed on wet ice immediately following blood draw and then centrifuged in a refrigerated centrifuge and then returned to wet ice for aliquoting. 5. Use the standard laboratory technique to transfer the plasma into appropriately labeled cryovials. 6. Store plasma aliquot samples in a freezer (not frost free) set to maintain a temperature of -70 °C until shipped for analysis. Plasma samples must be processed and stored within two (2) hours of blood collection. If a -70 °C freezer is not available, samples may be stored at -20 °C for up to one week. 7. Ship Frozen PK samples to Central Lab Services on the day of collection or within 24 hr of collection with enough dry ice to maintain samples frozen for at least 72 hours. 				

* Optional/Conditional testing or All testing Optional/Conditional at Visit; ** Reflex testing

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SPECIMEN COLLECTION PROCEDURES FOR PROTOCOL WO43571

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WHOLE BLOOD

TESTS	VISITS	COLLECT / RETURN	
SM1 BIOMARKER BLOOD	Cycle 1 Day 1 Arm A, Cycle 1 Day 1 no WGS/WES Arm A, Cycle 1 Day 1 Arm B, Cycle 1 Day 1 no WGS/WES Arm B, Retest*, Retest without WGS/WES*	 1x 6.0 mL lavender top EDTA tube	FROZEN -70°C DAY OF COLLECTION (DOC) OR THE FOLLOWING DAY TO: LABCORP CLS

* If missed on Cycle 1 Day 1, this blood sample can be collected at any point in the study.

1. Record the subject ID (Patient ID) on the label of the tube.
2. Draw 6 mL of blood into lavender top, K2 EDTA vacutainer tube using standard venipuncture techniques.
Fill tube completely.
3. Invert the tube gently 8-10 times. One complete inversion is to turn the filled tube upside-down and return it to upright position.
Note: Do not shake. Inadequate mixing may result in platelet clumping, clotting and/or incorrect test results.
4. Immediately store the samples upright at -70°C until shipment (if -70°C is not available, -20°C is also accepted).
5. Ship FROZEN to Labcorp on dry ice the day of collection (DOC) or the following day if DOC is not possible.

TESTS	VISITS	COLLECT / RETURN	
SM9 RBR BLOOD*	Cycle 1 Day 1 Arm A, Cycle 1 Day 1 no WGS/WES Arm A, Cycle 1 Day 1 Arm B, Cycle 1 Day 1 no WGS/WES Arm B, Retest, Retest without WGS/WES	 1x 6.0 mL lavender top EDTA tube	FROZEN -70°C DAY OF COLLECTION (DOC) OR THE FOLLOWING DAY TO: LABCORP CLS

IMPORTANT:

- * Before collecting this sample, ensure the patient has signed the optional RBR consent.
- * If the patient has agreed to the RBR sample collection, kindly note that this sample must only be taken after the patient is randomized into the study.

* If missed on Cycle 1 Day 1, this blood sample can be collected at any point in the study.

1. Record the subject ID (Patient ID) on the label of the tube.
2. Draw 6 mL of blood into lavender top, K2 EDTA vacutainer tube using standard venipuncture techniques.
Fill tube completely.
3. Invert the tube gently 8-10 times. One complete inversion is to turn the filled tube upside-down and return it to upright position.
Note: Do not shake. Inadequate mixing may result in platelet clumping, clotting and/or incorrect test results.
4. Immediately store the samples upright at -70°C until shipment (if -70°C is not available, -20°C is also accepted).
5. Ship FROZEN to LabCorp on dry ice the day of collection (DOC) or the following day if DOC is not possible.

	VISITS	COLLECT / RETURN	
SM10 WGS/WES BLOOD	Cycle 1 Day 1 Arm A, Cycle 1 Day 1 Arm B, Retest*	 1x 6.0 mL lavender top EDTA tube	FROZEN -70°C DAY OF COLLECTION (DOC) OR THE FOLLOWING DAY TO: LABCORP CLS

IMPORTANT:

- * Before collecting this sample, ensure your site has been granted approval for WGS or WES.
- * If your site has been granted approval for WGS or WES, kindly note that this sample must only be taken after the patient is randomized into the study.

* If missed on Day 1, this blood sample can be collected at any point in the study.

1. Record the subject ID (Patient ID) on the label of the tube.
2. Draw 6 mL of blood into lavender top, K2 EDTA vacutainer tube using standard venipuncture techniques.
Fill tube completely.
3. Invert the tube gently 8-10 times. One complete inversion is to turn the filled tube upside-down and return it to upright position.
Note: Do not shake. Inadequate mixing may result in platelet clumping, clotting and/or incorrect test results.
4. Immediately store the samples upright at -70°C until shipment (if -70°C is not available, -20°C is also accepted).
5. Ship FROZEN to Labcorp on dry ice the day of collection (DOC) or the following day if DOC is not possible.

* Optional/Conditional testing or All testing Optional/Conditional at Visit; ** Reflex testing

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SPECIMEN COLLECTION PROCEDURES FOR PROTOCOL WO43571

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WHOLE BLOOD

TESTS	VISITS	COLLECT / RETURN	AMBIENT DAY OF COLLECTION
HEMATOLOGY MN	Safety Mobile Nursing	 1x 2.0 mL lavender top EDTA tube	TO: INVESTIGATOR SITE LABS

Mobile Nursing kit for safety testing.

PLEASE FOLLOW SEPARATE INSTRUCTIONS.

SHIP AMBIENT ON DAY OF COLLECTION TO THE INVESTIGATOR SITE LABS. DO NOT SHIP TO LABCORP.

URINE

TESTS	VISITS	COLLECT /	RETURN	AMBIENT DAY OF COLLECTION
URINALYSIS MN	Safety Mobile Nursing	Standard urine collection cup	 1x 10.0 mL yellow top conical tube URINALYSIS MN LOCAL TESTING ONLY	TO: INVESTIGATOR SITE LABS

Mobile Nursing kit for safety testing.

PLEASE FOLLOW SEPARATE INSTRUCTIONS.

SHIP AMBIENT ON DAY OF COLLECTION TO THE INVESTIGATOR SITE LABS. DO NOT SHIP TO LABCORP.

* Optional/Conditional testing or All testing Optional/Conditional at Visit; ** Reflex testing
 English_Specimen Collection Procedures_Update: 20220830

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SPECIMEN COLLECTION PROCEDURES FOR PROTOCOL WO43571

Roche Products Limited

BLOCK

TESTS	VISITS	COLLECT / RETURN	AMBIENT DAY OF COLLECTION
FRESH TISSUE BLOCK	Tissue Sample Collection*	 1x yellow biopsy tissue cassette, 1x bubble bag, 1x biohazard bag, 1x label Except Korea 1x 60 mL blue cap specimen container, 1x 60 mL orange cap specimen container with AP bar	TO: CELLCARTA NV ATTN. SAMPLE RECEPTION TEAM – P2040 SINT-BAVOSTRAAT 78 2610 WILRIJK BELGIUM

For instructions on how to collect the biopsy sample, please refer to the document **WO43571 TISSUE COLLECTION INSTRUCTIONS** at the end of this section.

Please make sure to properly identify the eForm printed from EDC RAVE system using the labels provided in the kit.

Do not ship to LabCorp – **Ship ambient directly to CellCarta on day of collection or at the earliest possible date.**

TESTS	VISITS	COLLECT / RETURN	AMBIENT DAY OF COLLECTION
ARCHIVAL TISSUE BLOCK	Tissue Sample Collection*	 1x bubble bag, 1x biohazard bag, 1x 60 mL orange cap specimen container with AP bar, 1x label	TO: CELLCARTA NV ATTN. SAMPLE RECEPTION TEAM – P2040 SINT-BAVOSTRAAT 78 2610 WILRIJK BELGIUM

For instructions on how to collect the biopsy sample, please refer to the document **WO43571 TISSUE COLLECTION INSTRUCTIONS** at the end of this section.

Please make sure to properly identify the eForm printed from EDC RAVE system using the labels provided in the kit.

Do not ship to LabCorp – **Ship ambient directly to CellCarta on day of collection or at the earliest possible date.**

* Optional/Conditional testing or All testing Optional/Conditional at Visit; ** Reflex testing

English_Specimen Collection Procedures_Update: 20230906

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SPECIMEN COLLECTION PROCEDURES FOR PROTOCOL WO43571

Roche Products Limited

SLIDES

TESTS	VISITS	COLLECT / RETURN	AMBIENT DAY OF COLLECTION
FRESH TISSUE SLIDE	Tissue Sample Collection*	 1x 25 count slide mailer, 1x label, 1x yellow biopsy tissue cassette, 1x biohazard bag, 1x foam sheet Except Korea 1x 60 mL blue cap specimen container	TO: CELLCARTA NV ATTN. SAMPLE RECEPTION TEAM – P2040 SINT-BAVOSTRAAT 78 2610 WILRIJK BELGIUM

For instructions on how to collect the biopsy sample, please refer to the document **WO43571 TISSUE COLLECTION INSTRUCTIONS** at the end of this section.

Please make sure to properly identify the eForm printed from EDC RAVE system using the labels provided in the kit.

Do not ship to LabCorp – **Ship ambient directly to CellCarta on day of collection or at the earliest possible date.**

TESTS	VISITS	COLLECT / RETURN	AMBIENT DAY OF COLLECTION
ARCHIVAL TISSUE SLIDE	Tissue Sample Collection*	 1x 25 count slide mailer, 1x label, 1x biohazard bag, 1x foam sheet	TO: CELLCARTA NV ATTN. SAMPLE RECEPTION TEAM – P2040 SINT-BAVOSTRAAT 78 2610 WILRIJK BELGIUM

Refer to the document **WO43571 TISSUE COLLECTION INSTRUCTIONS** in the manual.

Please make sure to properly identify the eForm printed from EDC RAVE system using the labels provided in the kit.

Do not ship to LabCorp – **Ship ambient directly to CellCarta on day of collection or at the earliest possible date.**

* Optional/Conditional testing or All testing Optional/Conditional at Visit; ** Reflex testing
English_Specimen Collection Procedures_Update: 20220830

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Shipping material for biopsies

<u>Standard courier set-up for the site: Items to order from LabCorp</u>	
Shipping box for ambient samples (SD0R - referral shipper without LabCorp logo) Make sure not to cover regulatory marking.	
Airwaybill for CellCarta (AR0A) Make sure not to use documents for shipment to LabCorp CLS	
Proforma invoice for CellCarta (C0RA) Needed for all sites located in a different country than destination laboratory.	
<u>Premium courier set-up for the site</u>	
Material and shipping documents will be provided by the courier shipping boxes to be ordered to LabCorp	

Book a pick-up at least 48 hours prior to the visit. Please make sure you use appropriate courier and indicate the 'Ship To' destination. Make sure to contact courier in case no confirmation or incorrect confirmation is received for the pick-up request.

The shipping material should be ordered any time needed on
<https://drugdevelopment.labcorp.com/customers/investigators/order-a-kit.html>

Please indicate destination laboratory name when ordering shipping material for samples not returned to LabCorp CLS.

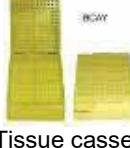
Tissue collection requirements

Description of biopsy collection requirements and kits to use

Version with no Ethanol Provided

Archival Tumor FFPE Collection		
ARCHIVAL BLOCK FFPE (not applicable to China)		
Item in the kit	Item in bulk supplies (order separately)	Item to download from EDC RAVE
 <p>Free label ARCHIVAL BLOCK WO43571 AMB TO CC</p>  <p>Free Label EFORM</p>	 <p>Biohazard bag (<u>ZPLB</u>)</p>  <p>Bubble bag (BBPB/8BBG)</p>  <p>Orange top container (<u>OC6P/8OCP</u>) to label ARCHIVAL BLOCK WO43571 AMB TO CC. For sites in EMEA: Specimen Jar, 60mL, orange cap-AP BAR LABEL, CE, <u>OE6P</u>.</p>	<p>Tissue sample collection form to label TISSUE EFORM*</p> 
ARCHIVAL TISSUE SLIDE		
Item in the kit	Item in bulk supplies (order separately)	Item to download from EDC RAVE
 <p>Free label ARCHIVAL SLIDE WO43571 AMB TO CC</p>  <p>Free Label EFORM</p>	 <p>25 slot slide mailer with 25 Superfrost+ slides (<u>S25S</u>) to label ARCHIVAL SLIDE WO43571 AMB TO CC</p>  <p>Biohazard bag (<u>ZPLB</u>)</p>	 <p>FMST</p> <p>Foam padding (FMST - pack of 5)</p> <p>Tissue sample collection form to label TISSUE EFORM*</p> 

The kits and supplies for tumor biopsies should be ordered any time they are needed on
<https://drugdevelopment.labcorp.com/customers/investigators/order-a-kit.html>

Tumor FFPE Collection			
FRESH TISSUE BLOCK (not applicable to China)			
Item in the kit	Item in bulk supplies (order separately)	Item to download from EDC RAVE	
 <p>Free label FRESH BLOCK WO43571 AMB TO CC</p>  <p>Free Label EFORM</p>	 <p>10% neutral buffered formalin (PC40/8F35)</p>  <p>Biohazard bag (ZPLB)</p>  <p>Bubble bag (BBPB/8BBG)</p>	 <p>Tissue cassette (BCAY/8BCY)</p>  <p>Yellow top container (Y60P/8C6A) to label FRESH BLOCK WO43571 AMB TO CC. For sites in EMEA: <u>OE6P</u></p>	<p>Tissue sample collection form to label TISSUE EFORM*</p> 
FRESH TISSUE SLIDE			
Item in the kit	Item in bulk supplies (order separately)	Item to download from EDC RAVE	
 <p>Free label FRESH SLIDE WO43571 AMB TO CC</p>  <p>Free Label EFORM</p>	 <p>10% neutral buffered formalin (PC40/8F35)</p>  <p>25 slot slide mailer with 25 Superfrost+ slides (S25S) to label FRESH SLIDE WO43571 AMB TO CC</p>	 <p>Tissue cassette (BCAY/8BCY)</p>  <p>Foam padding (FMST - pack of 5)</p>  <p>Biohazard bag (ZPLB)</p>	<p>Tissue sample collection form to label TISSUE EFORM*</p> 

**The kits and supplies for tumor biopsies should be ordered any time they are needed on
<https://drugdevelopment.labcorp.com/customers/investigators/order-a-kit.html>**

Study requirements

Screening sample

General:

- This study requires a formalin-fixed and paraffin embedded (FFPE) tumor specimen: Block (preferred) or at least 20 slides.
- Slides should be unstained, freshly cut, serial sections (4 μ m) mounted on positively charged glasses (Superfrost® Plus)
- In exceptional circumstances, 11-19 slides are acceptable provided that other eligibility requirements are met;
- **For China**, the number of slides required for eligibility will be based on HGRAC specifications and are contingent on the approval by the IRB or EC and, if applicable, an appropriate regulatory body; We recommend for any samples submitted from China to cut 15 consecutive slides: 9 slides for the main part and 6 slides for the exploratory part of the WO43571 study. During the period where only main HGRAC approval was received please ship 9 slides and provide the remaining 6 slides in a second shipment once exploratory HGRAC approval was obtained. Once HGRAC approval was obtained from the main and exploratory part, please ship all 15 slides in 1 shipment.
- Samples must be fixed in a formalin-based fixative (10% NBF for 6 - 72 hours). Samples fixed in Z5, Prefer, AFA, and other alcohol-based fixatives are not acceptable.
- Archival blocks are preferred over slides.
- Primary sample is preferred over metastatic sample
- Tumor tissue must have been evaluated for HER2 expression prior to enrollment
- Local ER positivity should be preferentially assessed on the same lesion

Specimen requirements:

- Tumor tissue should be of good quality based on total and viable tumor content. Samples must contain a minimum of 50 viable tumor cells that preserve cellular context and tissue architecture regardless of needle gauge or retrieval method.
- Samples collected via resection, core needle biopsy (preferably with at least three cores, embedded in a single paraffin block), or excisional, incisional, punch, or forceps biopsy are preferred. Fine-needle aspiration, brushing, cell pellets from pleural effusion, bone metastases, and lavage samples are not acceptable.
- If archival tissue is insufficient, the patient may undergo a fresh pretreatment resection, core needle biopsy (preferably with at least three cores, embedded in a single paraffin block), or excisional, incisional, punch, or forceps biopsy of the tumor.
- Fresh tissue biopsies should be processed as detailed in the sample processing section

Disease recurrence (mandatory if deemed clinically feasible by the investigator)

- In case of disease recurrence, a tissue sample needs to be collected 40 days after recurrence or prior to start of the next systemic anti-cancer therapy (whichever is sooner)
- A representative FFPE tumor specimen in a paraffin block (preferred) or at least 15 slides containing unstained, freshly cut, serial sections needs to be submitted.

PROTOCOL WO43571 TISSUE COLLECTION INSTRUCTIONS

- Samples can be collected via resection, core needle biopsy (preferably with at least three cores, embedded in a single paraffin block), or excisional, incisional, punch, or forceps biopsy. Fine-needle aspiration, brushing, cell pellets from pleural effusion, bone metastases, and lavage samples are not acceptable.

Important considerations for fresh tissue biopsies:

- Avoid delayed fixation: the biopsy samples must be fixed immediately after collection.
- Avoid over-fixation: only 10% NBF for 6 - 72 hours is acceptable.

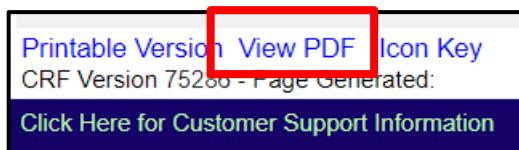
Instructions for creating tissue documents

Tissue Laboratory Requisition Form = print-out of the Tissue Sample Collection eForm from RAVE

- Enter EDC RAVE and complete the **Tissue Sample Collection eForm**. Please ensure that all fields are completed.
- Collection date MUST be accurate. The collection date refers to when the tissue was collected from the patient during a medical procedure (it is not equivalent to date of archival slide sectioning or date tissue block arrives at the site or is shipped to another lab).
- If archival tissue is insufficient and a fresh pretreatment biopsy is collected, choose the fresh biopsy kit and select the "fresh biopsy" box on the eForm.

**** Please note that incomplete requisitions will likely delay sample testing****

- To print the eForm, click on '**View PDF**' at the end of the eForm



- This will give you a printable PDF form (Tissue eForm), which needs to be included in the shipment
- Label the Tissue eForm with the label EFORM provided in the LabCorp kit

Documentation for Multiple Blocks or Slide sets

Each sample (block/slide set) should be

- collected using **separate** LabCorp Tissue kits (one sample per LabCorp accession number)
- completed **separately** in EDC RAVE
- accompanied by a **separate** tissue eForm

Sample Processing Guidelines

ARCHIVAL TISSUE KIT

Archival FFPE Tissue Block Preparation Instructions

Reminder: Plastic containers are provided in bulk.

- As soon as the patient has provided written informed consent for the study, archival tissue must be requested. Sites are required to secure the release of the archival tumor sample from the pathology lab (onsite or from outside facility). Please ask the pathology lab to confirm that there is sufficient tissue of good quality remaining in the block before submitting.
- Complete the Tissue eForm in eCRF and print a copy. Attach one of the LabCorp barcode labels to the eForm and make a copy for your records. The LabCorp barcode labels are provided in the collection kits.
- Ensure the block is labeled with the tumor block ID and the ID matches the block ID in the eForm
- Place the FFPE tumor tissue block in the container (provided in bulk) and identify the container with the label ARCHIV FFPE BLOCK / WO43571.
- Write the Screening ID and RRID on the label.
- Follow shipment instructions and ship the block as soon as possible

Archival Tissue Slide Preparation Instructions

A slide mailer with slides that have been validated for the required tests are provided either in the kit or as bulk supplies. **Please use the provided Superfrost Plus positively Charged Microscope slides for tissue.**

Slides should be submitted **within 72 hours after sectioning**. Please note that only freshly cut slides can be tested

- Label the slides in a solvent resistant manner (e.g. pencil or diamond etching) with the study ID (WO43571) patient Screening Number, Block ID and Sequential Slide Number. If space allows please also add the RRID ID. Please do not use adhesive labels as these will be removed by the testing facility upon receipt.
- Section paraffin block at 4 μ m.
- Mount **20** serially cut (consecutive) sections onto the provided positively charged Superfrost slides. **For China**, the number of slides required will be based on HGRAC specifications: 9 slides for the main part and 6 slides for the exploratory part of the WO43571 study.

PROTOCOL WO43571 TISSUE COLLECTION INSTRUCTIONS

If the provided Superfrost® Plus slides were not used, please ensure that the slides are positively charged and have a “+” mark from the manufacturer or indicate on the comments section on the eForm that the slides are positively charged.

- Slides should be **air-dried** for at least 1 hour. **The slides should NOT be baked.** Ship immediately after drying.

Ensure slides are completely dry and place the labeled slides in the provided slide mailer. Transcribe the Patient ID onto the label attached to the slide mailer.

FRESH TISSUE KIT

Fresh Tissue Biopsy at Baseline or Disease Progression

Tissue cassette, plastic container and 10% Neutral Buffered Formalin (10% NBF) are provided in bulk.

- Fresh biopsies should be obtained as per your institution's procedures.
- **Immediately** after obtaining the tumor sample, the sample should be placed into the provided tissue cassette for fixation steps.
- Place the cassette into the provided 10% NBF and ensure that the tissue is completely submerged.
- Fix the tissue sample in 10% NBF for 6-72 hours.
- The sample should be embedded in paraffin according to your institution's procedures.
- After embedding, please label the paraffin block with the tumor block ID and the patient's screening number or patient ID.
- Place the FFPE tumor tissue block in the container and identify the container with the label FRESH FFPE BLOCK/ WO43571.
- Write the screening or Patient ID on the label.
- Complete the Tissue eForm in eCRF and print a copy. Attach one of the LabCorp barcode labels to the eForm and make a copy for your records. The LabCorp barcode labels are provided in the collection kits.
- Ensure the block ID matches the block ID in the eForm
- Follow below shipment instructions and ship the block as soon as possible

Recommendations for fresh tissue biopsy:

1. If sending core biopsies, 3-5 cores aligned and embedded into a single block.
2. Surface area of at least 5 x 5 mm (25 mm²).
3. Sample volume of 1 mm³, total depth of at least 40 microns.
4. Tumor sample contains at least 30,000 cells but preferably 75,000 to 150,000 cells with at least 80% of cells being nucleated.
5. Sample has at least 20% of cells being malignant cells

PROTOCOL WO43571 TISSUE COLLECTION INSTRUCTIONS

FRESH TUMOR FFPE SLIDES Sample Instructions

Slide mailers with slides that have been validated for the required tests are provided in bulk. Please use the provided Superfrost Plus Charged Microscope slides for tissue.

If the provided Superfrost® Plus slides were not used, please ensure that the slides are positively charged and have a “+” mark from the manufacturer or indicate on the comments section on the eForm that the slides are positively charged.

- Label the slides in a solvent resistant manner (e.g. pencil or diamond etching) with the study ID (WO43571) patient Screening Number or patient ID, Block ID and Sequential Slide Number. If space allows please also add the RRID ID. Please do not use adhesive labels, as these will be removed by the testing facility upon receipt.
- Section paraffin block at 4µm.
- Mount at least 15 serially cut (consecutive) sections onto the provided positively charged Superfrost slides.
For China: Only applicable for sites participating in exploratory analysis
- Slides should be **air-dried** for at least 1 hour. Ensure slides are completely dry and place the labeled slides in the provided slide mailer. **Do not bake the slides.**
- Write the Patient ID or Screening ID onto the label (FRESH FFPE SLIDES/ WO43571) to be attached to the slide mailer.
- Follow below shipment instructions and ship the slides as soon as possible

REMINDERS

Make sure to include in the shipment:

- Tissue specimen
- Printed copy of EDC RAVE tissue eForm with LabCorp label "EFORM" stuck on it.
- Please ensure **all fields** are completed

Missing information may delay the reporting of eligibility results.

Tissue kits are not on automatic resupply. Please reorder at www.covance.com/kitordering

Note: Please indicate destination laboratory name when ordering shipping material for samples not returned to LabCorp CLS.

Shipment Instructions

SHIP DIRECTLY TO CellCarta (formerly HistoGenex)

(Address below - **do not ship back to LabCorp**)

Slide Mailers: Place the foam sheet on top of slides. Close the slide mailer and put the slide mailer or box in the bubble bag. If the slide mailer or box doesn't fit into the bubble bag, wrap the slide mailer with the bubble bag and secure it with tape or rubber band. Place inside the largest compartment of specimen biohazard bag and seal.

Tissue Blocks: Place block in plastic bubble wrap padding cut to size. Place wrapped block in 60 mL plastic orange top container. Place inside the largest compartment of specimen biohazard bag and seal.

PROTOCOL WO43571 TISSUE COLLECTION INSTRUCTIONS

- Insert the print-out of the completed tissue eForm in the outer pocket of the specimen biohazard bag and seal bag.
- Use provided foam padding to package the sealed specimen biohazard bag into the **AMBIENT** shipping container.
- Use the pre-printed air waybill (provided with supplies) to ship the sample.

For Japanese sites only:

- Retrieve the cover page of the paper included within the LabCorp kit (1st page).
- Fold this cover page and insert it visibly in the pouch of the shipping box, together with the completed eForm print-out.
- This cover page will allow BML courier drivers to identify the accession # of the samples prepared, which is required for proper pick-up

Use courier designated by LabCorp

Ship to:

CellCarta
Attn. Sample Reception Team – P2040
Sint-Bavosstraat 78
2610 Wilrijk
Belgium
Email: trialsANT1@cellcarta.com
Tel: +32 3 502 0625

Clinical sites from mainland China only will ship samples to:

CellCarta Medical Science and Technology (Shandong) Ltd.,
Attn. Sample Reception, P2040
3rd floor, No.1 Building, Information and Industrial Park,
No. 8 Lianhua Road, High-tech Zone,
Jining, Shandong Province, PRC.
China

Email: trialsJIN1@cellcarta.com
Tel: + 86-0537-2392466

RESULTS REPORTING

CellCarta will transfer the HER2 status to the IxRS provider, which will then determine if the patient is eligible for the study. CellCarta will report results to the sites through the CellCarta (HistoGeneX) Customer Portal.

In case of issues with the sample, the Site contacts, Study Coordinator and Monitor, will be notified by e-mail that a Data Clarification Form (DCF) was posted on the CellCarta (HistoGeneX) Customer Portal for the site personnel to follow-up.

PROTOCOL WO43571 TISSUE COLLECTION INSTRUCTIONS

Turnaround time (TAT) at CellCarta after the sample has been released for testing or after resolution of critical queries:

HER2 testing = 3-5 working days

The first business day after accessioning of the samples will be the first day of the TAT for testing. If samples are placed on hold, the first day of the TAT for testing will be the first business day after samples are released for analysis (after critical query resolution). **Testing begins after resolution of any critical queries in case of issues with samples.**

The status of the sample processing and reporting can be checked via the status tracker available on the CellCarta portal and updated daily.

Centrifuge Instructions

Guidelines for the conversion of Relative Centrifugal Force (g) to RPM (Rotations per Minute)

Caution: Tubes requiring centrifugation must rest on the bottom of the centrifuge bucket. If the tube does not rest on the bottom of the centrifuge bucket, the cap may loosen or come off during centrifugation. A spacer provided by the centrifuge vendor should be inserted if your tube does not rest on the bottom of the centrifuge bucket.

Calculating the Centrifuge Speed from the Required g Force

In general, Labcorp CLS recommends serum and plasma samples centrifuge at 1500 to 2000 x g for 15 minutes at room temperature. Any deviations to these recommendations will be listed in your laboratory requisitions.

Labcorp CLS provides the gravitational force (g) or relative centrifugal force (RCF) with the collection narrative. However, many centrifuges require the operator to electronically input or “dial in” the desired speed of the centrifuge, not the g force. In order to input the correct speed, two pieces of information are needed: the desired gravitational force (g) and the radius of the centrifuge. The radius of your centrifuge can be obtained from your operator’s manual or by calling the customer service representative from the manufacturer/supplier of your centrifuge. If you are unable to obtain this information, the radius can be found by measuring in centimeters (cm) the distances between the center of the rotation and the bottom of the tube in the rotor.

Finding the necessary speed to enter on your centrifuge can be done in several ways. One way to obtain this information is:

Equation for calculating the centrifuge speed

F = gravitational force (g)

R = Radius (in cm)

N: Speed of centrifuge rotator (RPM)

$$N = \sqrt{\frac{F}{0.00001118(R)}}$$

Example

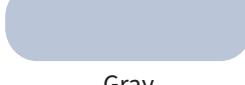
With a centrifuge radius of 10cm and 1000g the required speed (RPM) is:

$$N = \sqrt{\frac{1000}{0.00001118(10)}}$$

$$N = 2990 \text{ rpm}$$

Draw Order

Blood samples must be drawn in a specific order to avoid cross-contamination of the sample by additives found in different collection tubes.

CLSI Recommended Order of Draw for Tube Collections (CLSI GP41, 5th edition)		
Draw First	Standard Cap Color	Collection Tube
	 Yellow	Blood Cultures
	 Blue	Citrate Tube* <small>*When using a winged blood collection set (butterfly needle with the attached tubing) for venipuncture and a coagulation (citrate) tube is the first tube needed, first draw a discard tube using a non-additive tube. The discard tube need not be filled completely.</small>
	 Orange or Red	Serum Tube
	 Green	Heparin Tube
	 Purple	EDTA
Draw Last	 Gray	Fluoride (Glucose) Tube

Important: Always follow your facility's recommendation or SOP for order of draw should they differ from the above.

Blood Smear Preparation



Proper blood smear preparation is crucial for reliable results.
Please read the following indications.

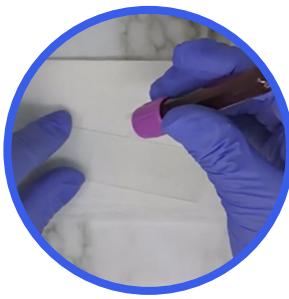
Collection
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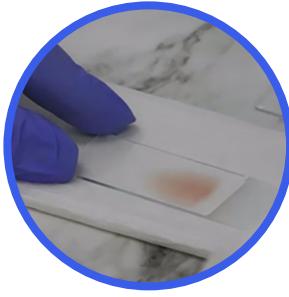
1. Write the accession number and Subject ID on the frosted end of the slide using a pencil. Properly identified slides allow appropriate sample tracking.



2. After mixing the hematology tube, insert the Diff-Safe dispenser into the rubber stopper.



3. Turn the tube upside down and press the Diff-Safe dispenser against the slide, 0.5 cm from the frosted end. Discontinue pressure the instant the drop appears*.



5. Allow the droplet to draw completely across the edge of the slide. Gently push the second slide forward, only allowing the weight of the slide to be applied on the glass surface.

6. Repeat the process for the other slide. Allow the slides to air dry while lying flat. Return slides to plastic mailer(s) for shipment. Ship the tube with the hematology slides.

Blood Smear Preparation And Diff-Safe Safety Tips

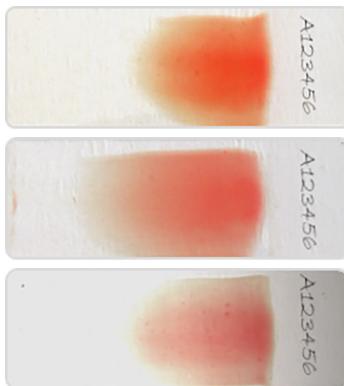


Proper blood smear preparation is crucial for reliable results.
Please read the following indications.

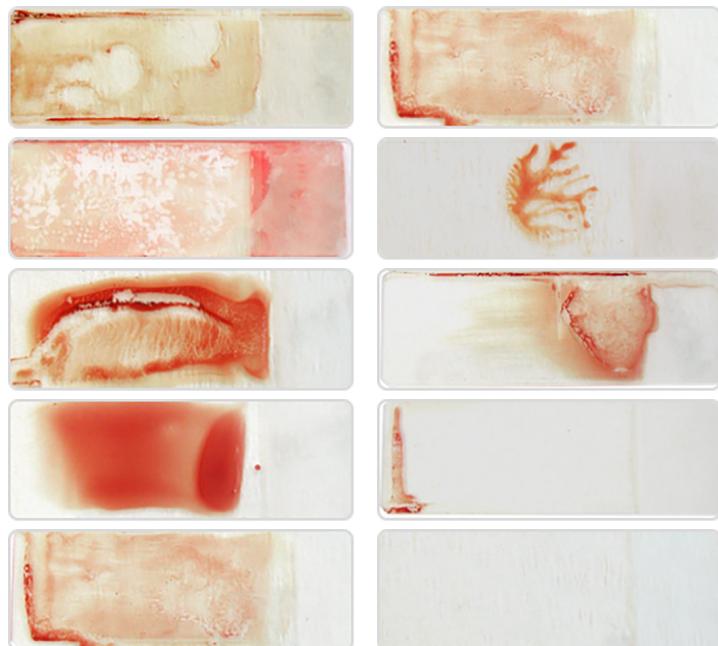
Collection
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Blood Smears

Examples of well-made slides:



Examples of incorrect slides:

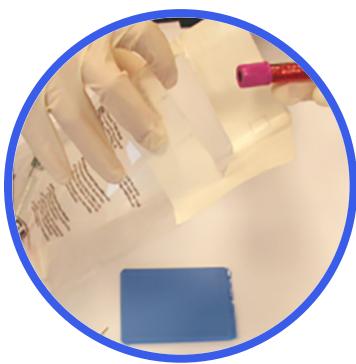


Diff-Safe

Important instructions for use:



After the blood smear preparation, please remove the Diff-Safe from the tube.



Place tube into the specimen collection bag without the Diff-Safe.



If the Diff-Safe is not removed properly, the blood will spill into the specimen collection bag, and the samples will be useless.

Please remove the Diff-Safe from the tube.

Single Use Needle Protection Device Instructions

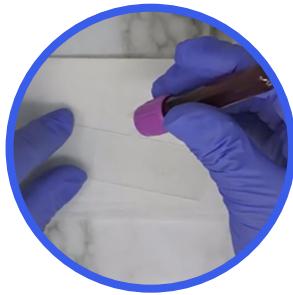


Proper blood smear preparation is crucial for reliable results.
Please read the following indications.

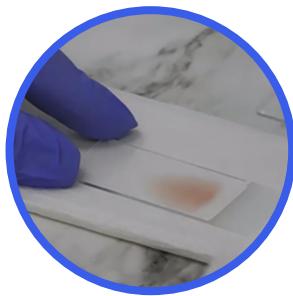
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videos



1. Write the accession number and Subject ID on the frosted end of the slide using a pencil. Properly identified slides allow appropriate sample tracking.



3. Turn the tube upside down and press the Diff-Safe dispenser against the slide, 0.5 cm from the frosted end. Discontinue pressure the instant the drop appears*.



5. Allow the droplet to draw completely across the edge of the slide. Gently push the second slide forward, only allowing the weight of the slide to be applied on the glass surface.

2. After mixing the hematology tube, insert the Diff-Safe dispenser into the rubber stopper.

4. Holding the second slide at a 30° angle, pull the slide towards the drop of blood until contact is made.

6. Repeat the process for the other slide. Allow the slides to air dry while lying flat. Return slides to plastic mailer(s) for shipment. Ship the tube with the hematology slides.

Blood Smear Preparation And Diff-Safe Safety Tips



Proper blood smear preparation is crucial for reliable results.
Please read the following indications.

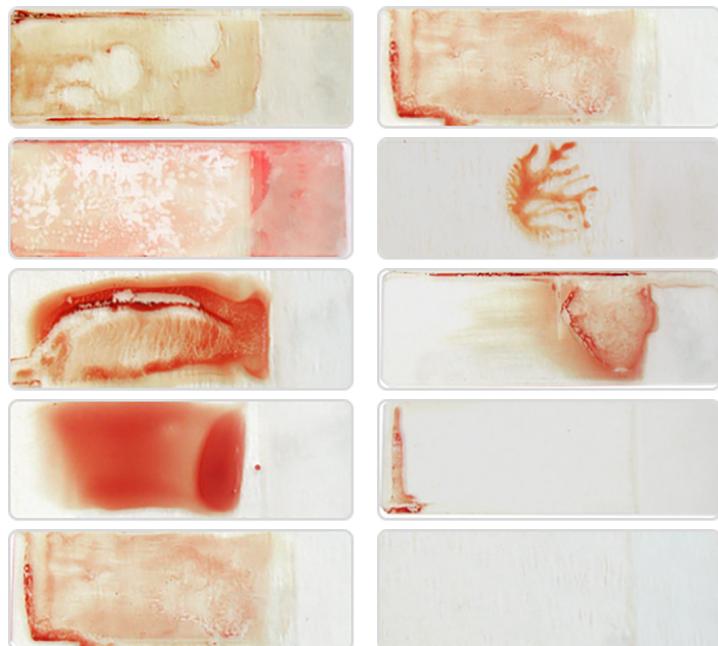
Collection
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Blood Smears

Examples of well-made slides:



Examples of incorrect slides:

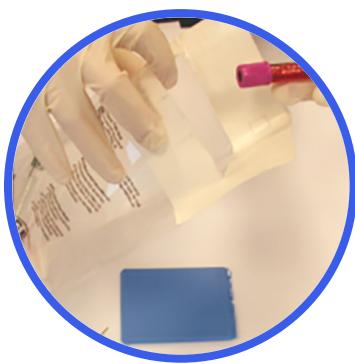


Diff-Safe

Important instructions for use:



After the blood smear preparation, please remove the Diff-Safe from the tube.



Place tube into the specimen collection bag without the Diff-Safe.



If the Diff-Safe is not removed properly, the blood will spill into the specimen collection bag, and the samples will be useless.

Please remove the Diff-Safe from the tube.

Procedure For Sarstedt Monovette® Drawing System (1/2)



Monovette® Tube

Monovette® tubes are collection containers that behave similarly to vacuum tubes. However, they have a unique appearance and differences in handling such as: vacuum must be manually created, an adaptor must be used, and Monovette tubes use a turn and lock system.

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procedures
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Items needed to perform blood draw using a butterfly needle and Monovette Tube



Butterfly assembly with multi-adapter



Monovette® tube



1. Prepare the Monovette® tubes by pulling back the plunger until it firmly locks into place and an audible click is heard. Break off the plunger. This creates the vacuum for the tubes.
2. Attached the Monovette® adapter by screwing it onto the butterfly needle.
3. For small volume Monovette tubes, Labcorp Central Laboratory Services will provide a clear discard tube. After performing the venipuncture, insert and push the clear Monovette® discard tube onto the adapter and turn clockwise to lock. Allow the line to fill with blood. It is not necessary to fill the discard tube. This step is simply needed to prime the butterfly line. Once the line is primed, remove the tube by twisting it counterclockwise. Discard this tube according to your sites' biohazard procedures.
4. Fill the remaining Monovette® tubes as directed.



Procedure For Sarstedt Monovette® Drawing System (2/2)

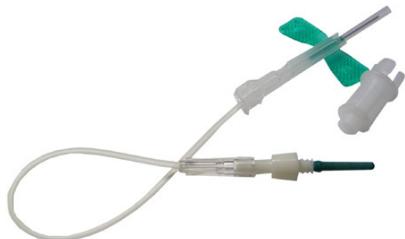


Non-Monovette® Tube

Monovette® tubes can be used with other vacuum tubes in a single stick. The transition between these tubes is quick and easy. This process is described below.

Collection
procedures
videos

Items needed to perform blood draw using a butterfly needle and non-Monovette® Tube.



Butterfly assembly with multi-adapter



Vacutainer Holder



Non-Monovette® Tube



1. Unscrew the adapter from the butterfly needle.



2. Screw the needle of the butterfly assembly into the standard needle holder.



3. Insert non-Monovette® tube(s) into holder; blood will flow into the tube until the vacuum is filled.

Biotin Interference

Biotin (Vitamin B7) May Interfere with Lab Tests

Labcorp Central Laboratory Services would like to make Clinicians aware that some assays can be affected by high levels of biotin in a patient's serum/plasma. High dose biotin may be prescribed in the treatment of multiple sclerosis or dermatologic conditions. Thinking it is a contributor to keratin, some people take biotin supplements hoping to improve their hair, skin and nails. Over-the-counter formulations are available under a variety of names including Vitamin B7, Vitamin H and coenzyme R. These may contain nearly 1,000 times the Institute of Medicine-recommended daily dose of 30 mcg.

Many laboratory immunoassays utilize the interaction of biotin with streptavidin. Patient samples with high levels of biotin can interfere with these tests, causing falsely high or falsely low results depending on the assay mechanism. Physicians should be aware that high levels of biotin supplementation may have an impact over a period of at least 72 hours.

The following are some recommendations for Health Care Providers from the FDA Safety Communication on Biotin:

- Talk to your patients about any biotin supplements they may be taking, including supplements marketed for hair, skin, and nail growth.
- Be aware that many lab tests, including but not limited to cardiovascular diagnostic tests and hormone tests, that use biotin technology are potentially affected, and incorrect test results may be generated if there is biotin in the patient's specimen.
- If a lab test result doesn't match the clinical presentation of your patient, consider biotin interference as a possible source of error.
- Know that biotin is found in multivitamins, including prenatal multivitamins, biotin supplements, and dietary supplements for hair, skin, and nail growth in levels that may interfere with lab tests.
- Report to the lab test manufacturer and the FDA if you become aware of a patient experiencing an adverse event following potentially incorrect laboratory test results due to biotin interference.

IMMUNOASSY TESTS WITH POTENTIAL INTERFERENCE BY BIOTIN SUPPLEMENTATION

Note: This list is subject to change as new assays are validated.

Assay	Assay	Assay
Adrenocorticotropic hormone (ACTH)	Free T4	Interleukin-6 (IL-6)
Amyloid beta 1-42	Gastrin	N Terminal ProBNP (NT proBNP)
Anti-cyclic citrullinated peptides (CCP)	Hepatitis A antibody Total (HAVt)	Osteocalcin
Anti-Hepatitis B e-antigen (a-Hbe)	Hepatitis B core Antibody (HBc Ab)	Parathyroid Hormone (PTH),Intact
Anti-Mullerian Hormone (AMH)	Hepatitis B Core IgM Antibody (HBc IgM Ab)	Placental Growth Factor (PIGF)
Anti-thyroglobulin antibody, quantitative (ATG)	Hepatitis B e Antigen (HBe Ag)	Procalcitonin
Anti-thyroid peroxidase (ATPO), quant	Hepatitis B surface Antibody Qual (anti-HBs II)	Procollagen I Intact N-Terminal (P1NP)
Beta2 Microglobulin	Hepatitis B surface Antibody Quant (HBs Ab Quant)	Prolactin
Beta-crosslaps	Hepatitis B Surface Antigen (HBs Ag)	Sex hormone-binding globulin (SHBG)
CA 19-9	Hepatitis C Antibody (HCV)	Soluble fms-like tyrosine kinase-1 (sFlt-1)
CA15-3	HIV Ag/Ab combo (cHIV)	Thyroglobulin
CA19-9	Homocysteine	Total T3
Calcitonin	Human Chorionic Gonadotropin (beta-hCG)	Total Tau
C-peptide	Inhibin A	Troponin I Ultra
Creatine Kinase (CK)MB	Insulin	Troponin T
Direct Renin	Insulin-Like Growth Factor 1 (IGF-1)	Troponin T, Gen 5
Estradiol	Insulin-Like Growth Factor Binding Protein 3 (IGFBP-3)	Troponin T-hs

SPECIMEN COLLECTION PROCEDURES FOR URINE PREGNANCY TEST

SAS™ Pregnancy Urine

READ ALL INSTRUCTIONS
BEFORE BEGINNING THE ASSAY

INTENDED USE

SAS™ Pregnancy Urine is a visual and rapid test for the qualitative determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. This test is for professional use only.

SUMMARY AND EXPLANATION

The detection of hCG (human chorionic gonadotropin) in serum and urine has proven valuable in the presumptive diagnosis of pregnancy. This glycoprotein hormone is secreted by the developing placenta after fertilization. The hCG hormone doubles approximately every 2.2 days during the 1st trimester.¹ Detectable levels start at 5 mIU/mL during the first week of gestation and rise to 100,000 mIU/mL at 2 to 3 months. A slower rise may be associated with high risk abortions.² Values decline between 10% and 15% of peak concentrations during the 2nd and 3rd trimesters.³ False results may occur due to certain pathological conditions. See "Limitations of the Procedure."

PRINCIPLE OF THE TEST

SAS™ Pregnancy Urine is a rapid qualitative test to detect the presence of hCG in urine. The test utilizes a combination of monoclonal and polyclonal antibody reagents to selectively detect elevated levels of the hCG in urine. The assay is conducted by the addition of a urine specimen into the test device sample well and observing for the formation of colored lines. The specimen migrates via capillary action along the membrane and reacts with the colored conjugate. A positive specimen reacts with the hCG-specific antibody colored conjugate and forms a colored line in the T (test) window. Absence of this colored line suggests a negative result. To serve as a control for the procedure, a colored line in the C (control) window will always appear regardless of the presence or absence of hCG.

REAGENTS

Test device containing monoclonal mouse-hCG colored conjugate and hCG antibody coated on a membrane.

PRECAUTIONS

1. For *In-Vitro* diagnostic use only.
2. The test device should be discarded in a proper biohazard container after testing.
3. Do not use kit beyond expiration date.
4. The test device should remain in the sealed pouch until ready for use.

STORAGE AND STABILITY

The test kit is to be stored at room temperature (15° - 30°C) for the duration of the shelf-life. The test device must remain "sealed" in the pouch until ready for use.

SPECIMEN COLLECTION AND PREPARATION

The urine specimen must be collected into a clean, dry container, either plastic or glass. Specimens collected at random may be used; however, the first morning urine generally contains the highest concentration of hormone. A urine sample exhibiting visible precipitates should be filtered, centrifuged, or allowed to settle (obtaining clear aliquots) before testing. Gross hematuria may prevent an accurate reading of test results by masking the positive line.

Specimen Storage-Urine specimens may be refrigerated (2° - 8°C) and stored up to 72 hours prior to assay. If specimens are refrigerated, they must be equilibrated to room temperature (15° - 30°C) before testing.

PROCEDURE

Materials Provided

1. Test device containing monoclonal mouse-hCG colored conjugate hCG antibody coated on a membrane.
2. Disposable specimen dropper.

Materials Required But Not Provided

Specimen collection container.

Directions For Use

The pouch must be at room temperature before opening to avoid condensation of moisture on the membrane. Allow specimen and/or controls to reach room temperature prior to testing.

1. Remove the test device from the protective pouch and place it on a flat surface. Label the device with patient or control identifications.
2. Dispense 4 drops (approximately 0.15 mL) of urine into the round sample well (see illustration below). Wait for colored lines to appear.
3. Read results at 4 minutes. Positive results may be observed in as short as 30 seconds depending on the concentration of hCG. The presence of the control line is not indicative of the test being completed. Wait the entire 4 minutes for the completion of the test. **READ UNDER DIRECT LIGHT TO AVOID INTERFERENCE OF SHADOWS IN THE T AND C WINDOWS.**



INTERPRETATION OF RESULTS

Negative Results

The test is negative if a colored line appears only in the C (control) window. (See illustration).

Positive Results

The test is positive if one colored line appears in the T (test) window and one colored line appears in the C (control) window (See illustration). Any colored line in the T (test) window should be considered positive. Colored lines may be lighter or darker than each other. Specimens with hCG levels near the threshold of the test may develop color (faint lines) overtime after the 4 minute reading. In such cases another test should be performed with a new specimen in 48-72 hours. A line that appears after 15 minutes should be ignored.

Invalid Results

The test is invalid if no colored line appears in the C (control) window even if a colored line appears in the T (test) window. If no colored line appears in the C (control) window, add 1 to 2 additional drops of urine and wait an additional 4 minutes. If colored line still does not appear in the C (control) window, the test is invalid and should be repeated using another test device.



NEGATIVE

POSITIVE

SPECIMEN COLLECTION PROCEDURES FOR URINE PREGNANCY TEST

QUALITY CONTROL

Each test device includes a built-in procedural control. The appearance of a Control Line in the C region of the assay is a positive procedural control. Correct procedural technique, specimen flow and assay performance is confirmed when a colored line appears in the C (control) area of the cassette. If the colored line fails to appear in the C (control) area, the test result is invalid. A clear background is an internal negative procedural control. The background color should be white to light pink and should not interfere with the reading of the test result. If a more intensely red background color appears, it may interfere with the ability to read the test result, therefore the test should be repeated. Users should follow their state and local regulations and guidelines regarding GLP requirements.

LIMITATIONS OF THE PROCEDURE

1. False negative results may occur when levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
2. Elevated levels of hCG may be found in trophoblastic disease, choriocarcinoma, and embryonal cell carcinoma. Islet cell tumors may also produce hCG as well as other carcinomas.⁴
3. Detectable levels of hCG may remain several weeks following normal pregnancy, delivery by cesarean section, spontaneous or therapeutic abortion.⁵
4. Ectopic pregnancies may produce very low levels of hCG. A negative test therefore does not exclude ectopic pregnancy.⁶ If this condition is suspected, further testing using a quantitative test may be desirable. Abnormally high levels of hCG may be seen in molar pregnancies. Samples from abnormal pregnancies are beyond the intended use for qualitative hCG tests.
5. Approximately one third of all conceptions end in natural termination.⁷ This may produce positive results when testing early in the pregnancy, followed by negative results after the natural termination. Low positive results may be confirmed by retesting with a first morning urine specimen collected 48 hours later.
6. This test provides a presumptive diagnosis for pregnancy. Physicians should evaluate all clinical and laboratory findings before making a definitive diagnosis.
7. A viscous specimen (high specific gravity) may exhibit a slower flow rate, therefore requiring more time for the test to be completed.
8. A high dose "hook effect" may occur where the intensity of sample line decreases as the concentration of hCG increases. If a "hook effect" is suspected, dilution of specimens may increase color intensity of the sample line.⁸
9. This test is designed to be a qualitative test only and does not correlate directly to quantitative hCG tests. The intensity of color in a positive line should not be evaluated as "quantitative or semiquantitative".
10. Sensitive immunoassays may demonstrate false positive results with specimens containing heterophilic antibodies. Assays may also exhibit false-positive or false negative results with specimens containing human anti-mouse antibodies. These specimens may come from patients receiving preparations of mouse monoclonal antibodies for diagnosis or therapy or have been exposed to mice. If the qualitative interpretation is inconsistent with the clinical evaluation, results should be confirmed by an alternate hCG method.^{9,10}

EXPECTED VALUES

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present. The amount will vary with gestational age and between patients. SAS™ Pregnancy Urine can detect hCG levels as low as 25 mIU/mL in urine.

PERFORMANCE CHARACTERISTICS

Accuracy by Comparison

A total of 111 blind clinical samples from suspected pregnant women were studied by different clinics and laboratories. Samples were assayed with SAS™ Pregnancy Urine and another commercially available one-step membrane test according to assay procedure. Both methods showed 43 positive and 68 negative results. The results demonstrated a 100% overall accuracy of SAS™ Pregnancy Urine compared to the other commercially available test.

Sensitivity & Specificity

SAS™ Pregnancy Urine detects hCG concentrations of 25 mIU/mL and greater in urine. It has been standardized to World Health Organization Third International

Standard (75/537). The addition of LH (300 mIU/mL), FSH (1000 mIU/mL), and TSH (1000 µIU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) urine showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) urine samples:

Acetaminophen	20 mg/dL
Acetylsalicylic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL
Atropine	20 mg/dL
Caffeine	20 mg/dL
Gentisic Acid	20 mg/dL
Glucose	2 g/dL
Hemoglobin	1 mg/dL
Bilirubin	2 mg/dL
Triglycerides	450 mg/dL

None of the substances at the concentration tested interfered in the assay.

REFERENCES

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70-pi-sas-pu
Revised 10-14

Authorised Representative
MegaCor GmbH,
Europaplatz 1
88131 Lindau
GERMANY



Requisition Completion



To help prevent a delay in your results being reported, please follow carefully the instructions below.

- It is required that you complete all questions and fill out all information on all pages for sample processing.
- Use a black ball pen and use leading zeros when applicable.
Use the correct format when marking the boxes.
- When pulling a kit off the shelf, review the label on the box and the contents on the kit. Ensure the accession number on the requisition and on the containers match. Ensure the patient identifiers on the specimen container match the identifiers on the requisition.

Find the requisition forms for this study in the Requisition Forms Section.



Labcorp Central Laboratory Services Sàrl,
Rue Mous-Marches 7
1217 Meyrin Geneva Switzerland
Tel: 0041 58 823 7901
Fax: 0041 58 823 7521

Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.
Page 2 of 2

«Bar_req»

Return this page with Samples

Laboratory Requisition Form
2-part
SPONSOR NAME
Protocol: PROTOCOL NUMBER
Investigator: «Inv_n»

Instructions:
Complete all boxes on this requisition with a blue or black ball point pen. Failure to complete all boxes will delay reports.

Please check that all patient identifiers are complete, consistent and correct, and that each container has the same accession number, when packing specimens for shipment!

Does Subject have UTI?
(Check one or mandatory)

OPTIONAL TESTING - Please mark the box(es) or to ensure proper ordering of optional test(s)!
If you fail to mark the checkbox, testing may be ordered per Labcorp policy without investigator notification.

CHEMISTRY PANEL
 SERUM BETA HCG
 HEMATOLOGY/DIFFERENTIAL PANEL
 FSH
 COAGULATION GROUP
 HEPATITIS B CORE ANTIBODY and HEPATITIS B SURFACE ANTIGEN
(Internal note: also order SM109734)

For Labcorp Use Only					
Employee Visa	Tube Count			Validation	Internal Comments
	Amb	Frt	Refng		
WHITE COPY-LABCORP «Bar_req» U-1 299999 AUTHORIZATION IS REQUIRED FOR ADDITIONAL TESTING PLEASE DO NOT RETURN EMPTY CONTAINERS TO LABCORP.					
PINK COPY-INVESTIGATOR «33AF_TCQ1» SHA 230112					

Example with consolidation

Site must tick the appropriate box (If applicable)

Patient Demographics

If incomplete, a system hold will be placed causing a delay in the results reporting.

Collection Date

Be careful not to confuse the patient's birth date with the collection date
The day and month will be hardcoded, only birth year should be recorded.

Use a 24 hour clock to record collection time.

Optional testing

Check appropriate box (If applicable)

Internal use only

Do not write in this section

Site personnel

Record full names in capital letters
We utilize this field to resolve any questions related to requisitions, if incomplete, this could result in delay of resolution.

Administrative Questions

Have several purposes including triggering testing.





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1217 Meyrin Geneva Switzerland
Tel: 0041 58 822 7901
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«Requisition_n»

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«Bar_req»

Page 1 of 2
2-part

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

VISIT: INDUCTION THERAPY CYCLE 1 DAY 1

DO NOT RETURN THIS PAGE

Testing For This Visit

Please refer to the Laboratory Manual for detailed sample collection, preparation, and handling instructions.

Associated Test Group(s)	Draw Container	Return Container	Shipment Condition
SM2 BIOMARKER PLASMA	2x 10.0 mL lavender top EDTA tubes	2x Corning cryovials	Frozen
SM3 SERUM PERTU/TRASTU PK PRE	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM4 PLASMA RHUPH20 ADA PRE	1x 2.0 mL lavender top K3 EDTA tube	1x cryovial	Frozen
SM5 SERUM PERTUZUMAB ADA PRE	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM6 SERUM TRASTUZUMAB ADA PRE	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen

All samples should be collected prior any drug administration.

No NCR
1

«Label_6»
211285

Keep on file for your records. DO NOT return to Labcorp.

«Bar_req»
APN 220830



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Laboratory Requisition Form
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Investigator : «Inv_n»

Page 2 of 2
2-part

Instructions:

Complete all boxes on this requisition with a blue or black ball point pen. Failure to complete all boxes will delay reports.

Please check that all patient identifiers are complete, consistent and correct, and that each container has the same accession number, when packing specimens for shipment!

Accession No.
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THE ACCESSION NUMBER IS THE
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VISIT: INDUCTION THERAPY CYCLE 1 DAY 1 SUBJECT/PATIENT INFORMATION

Patient Number

Birthdate Day Month Year
Complete year 0 1 J A N

Sex Male Female

COLLECTION INFORMATION

Collection Date Day Month Year
Complete month field in English
(Example: 01 JAN 2001)

Collection Time 24 Hour Clock
(Record Midnight as 23:59) :

THIS SECTION TO BE COMPLETED BY SITE PERSONNEL ONLY

Requisition Completed by

Full name in capital letters

Phone number

Of the person completing the requisition

Collection Date
(DD-MMM-YYYY)

Collection Time
(24 hr clock)

Not
Collected

SM2 BIOMARKER PLASMA	SM3 SERUM PERTU/TRASTU PK PRE	SM4 PLASMA RHUPH20 ADA PRE	SM5 SERUM PERTUZUMAB ADA PRE	SM6 SERUM TRASTUZUMAB ADA PRE
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

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Employee Visa	Tube Count				Validation	Internal Comments:	
	Amb	Frz	Refrig	Slides			

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Page 1 of 3
2-part

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

VISIT: CYCLE 1 DAY 1 ARM A

DO NOT RETURN THIS PAGE

Testing For This Visit

Please refer to the Laboratory Manual for detailed sample collection, preparation, and handling instructions.

Associated Test Group(s)	Draw Container	Return Container	Shipment Condition
SM1 BIOMARKER BLOOD	1x 6.0 mL lavender top EDTA tube		Frozen
SM2 BIOMARKER PLASMA	2x 10.0 mL lavender top EDTA tubes	2x Corning cryovials	Frozen
SM3 SERUM PERTU/TRASTU PK PRE *	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM4 PLASMA RHUPH20 ADA PRE *	1x 2.0 mL lavender top K3 EDTA tube	1x cryovial	Frozen
SM5 SERUM PERTUZUMAB ADA PRE *	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM6 SERUM TRASTUZUMAB ADA PRE *	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM9 RBR BLOOD *	1x 6.0 mL lavender top EDTA tube		Frozen
SM10 WGS/WES BLOOD	1x 6.0 mL lavender top EDTA tube		Frozen

*Conditional

Sites under protocol version 2

This kit should be used to collect PK, ADA and Biomarker samples at Cycle 1 Day 1 during Maintenance Therapy Phase after Randomization, in **arm A only**.

Sites under protocol version 3

This kit should be used to collect Biomarker samples at Cycle 1 Day 1 during Maintenance Therapy Phase after Randomization, in **Arm A only**. Pertuzumab, Trastuzumab, and RHuPH20 PK and ADA samples are not applicable to Arm A version 3.

-All samples should be collected prior any drug administration.

- SM9 RBR BLOOD samples are only collected at participating sites if the patient has signed the optional RBR consent.

No NCR
2

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Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

Page 2 of 3
2-part

Instructions:

Complete all boxes on this requisition with a blue or black ball point pen. Failure to complete all boxes will delay reports.

Please check that all patient identifiers are complete, consistent and correct, and that each container has the same accession number, when packing specimens for shipment!

Accession No.
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VISIT: CYCLE 1 DAY 1 ARM A

SUBJECT/PATIENT INFORMATION

Patient Number

--	--	--	--	--

Birthdate

Complete year

0	1	J	A	N			
---	---	---	---	---	--	--	--

Sex

Male

Female

COLLECTION INFORMATION

Collection Date

Complete month field in English
(Example: 01 JAN 2001)

Day	Month	Year

Collection Time

(Record Midnight as 23:59)

24 Hour Clock

:

THIS SECTION TO BE COMPLETED BY SITE PERSONNEL ONLY

Requisition Completed by

Full name in capital letters

Phone number

Of the person completing the requisition

Collection Date
(DD-MMM-YYYY)

Collection Time
(24 hr clock)

Not Collected

SM1 BIOMARKER BLOOD

SM2 BIOMARKER PLASMA

SM3 SERUM PERTUZUMAB ADA PRE

SM4 PLASMA RHUPH20 ADA PRE

SM5 SERUM PERTUZUMAB ADA PRE

SM6 SERUM TTRASTUZUMAB ADA PRE

SM9 RBR BLOOD

SM 10 WGS/WES BLOOD

:

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Tube Count

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Refrig

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Validation

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ADDITIONAL TESTING IS NOT ALLOWED

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VISIT: CYCLE 1 DAY 1 ARM A

*Return this page
with Samples*

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

Page 3 of 3
2-part

Patient Number

--	--	--	--	--

Collection Date

Day	Month	Year

Complete month field in English
(Example: 01 JAN 2001)

CONDITIONAL TESTING - Please mark the box(es) or to ensure proper ordering of test(s)!
If you fail to mark the checkbox, testing may be ordered per Labcorp policy without investigator notification.

Condition	Sample
Not applicable for a site that has not been granted approval for RBR sampling. Performed only for patients at participating sites who have provided written informed consent to participate. Mark this box if SM9 RBR BLOOD sample is submitted.	<input type="checkbox"/> SM9 RBR BLOOD and SM9 RBR BLOOD COLL D/T
This samples should only be collected if site is under protocol version 2. Mark this box if SM3 SERUM PERTU/TRASTU PK PRE, SM4 PLASMA RHUPH20 ADA PRE, SM5 SERUM PERTUZUMAB ADA PRE and SM6 SERUM TRASTUZUMAB ADA PRE ADA sample is submitted.	<input type="checkbox"/> SM3 SERUM PERTU/TRASTU PK PRE and SM3 SERUM P/T PK PRE COLL D/T and SM4 PLASMA RHUPH20 ADA PRE and <input type="checkbox"/> SM4 PLS RHU ADAPRE COLL D/T and SM5 SERUM PERTUZUMAB ADA PRE and SM5 SER PERTU ADAPRE COLL D/T and SM6 SERUM TRASTUZUMAB ADA PRE and SM6 SER TRAS ADAPRE COLL D/T

Comments:

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Employee Visa	Tube Count				Validation	Internal Comments:
	Amb	Frz	Refrig	Slides		

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Page 1 of 3
2-part

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

VISIT: CYCLE 1 DAY 1 NO WGS/WES ARM A

DO NOT RETURN THIS PAGE

Testing For This Visit

Please refer to the Laboratory Manual for detailed sample collection, preparation, and handling instructions.

Associated Test Group(s)	Draw Container	Return Container	Shipment Condition
SM1 BIOMARKER BLOOD	1x 6.0 mL lavender top EDTA tube		Frozen
SM2 BIOMARKER PLASMA	2x 10.0 mL lavender top EDTA tubes	2x Corning cryovials	Frozen
SM3 SERUM PERTU/TRASTU PK PRE*	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM4 PLASMA RHUPH20 ADA PRE*	1x 2.0 mL lavender top K3 EDTA tube	1x cryovial	Frozen
SM5 SERUM PERTUZUMAB ADA PRE*	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM6 SERUM TRASTUZUMAB ADA PRE*	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM9 RBR BLOOD *	1x 6.0 mL lavender top EDTA tube		Frozen

*Conditional

Sites under protocol version 2.

This kit should be used to collect PK, ADA and Biomarker samples at Cycle 1 Day 1 during Maintenance Therapy Phase after Randomization, in **Arm A only**.

This kit will be used by sites not collecting WGS/WES samples.

Sites under protocol version 3.

This kit should be used to collect samples at Cycle 1 Day 1 during Maintenance Therapy Phase after Randomization, **in Arm A only**. Pertuzumab, Trastuzumab, and RHuPH20 PK and ADA samples are not applicable to Arm A version 3.

This kit will be used by sites not collecting WGS/WES samples.

- All samples should be collected prior any drug administration.
- SM9 RBR BLOOD samples are only collected at participating sites if the patient has signed the optional RBR consent.

No NCR
4

«Label_6»
211285

Keep on file for your records. DO NOT return to Labcorp.

«Bar_req»
CS 230320



Labcorp Central Laboratory Services S.à.r.l.
Rue Moïse-Marcinhes 7
1217 Meyrin Geneva Switzerland
Tel: 0041 58 822 7901
Fax: 0041 58 822 7521

*Return this page
with Samples*

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

Page 2 of 3
2-part

Instructions:

Complete all boxes on this requisition with a blue or black ball point pen. Failure to complete all boxes will delay reports.

Please check that all patient identifiers are complete, consistent and correct, and that each container has the same accession number, when packing specimens for shipment!

Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

VISIT: CYCLE 1 DAY 1 NO WGS/WES ARM A
SUBJECT/PATIENT INFORMATION

Patient Number

Birthdate Day Month Year
Complete year 0 1 J A N

Sex Male Female

COLLECTION INFORMATION

Collection Date Day Month Year
Complete month field in English
(Example: 01 JAN 2001)

Collection Time 24 Hour Clock
(Record Midnight as 23:59) :

THIS SECTION TO BE COMPLETED BY SITE PERSONNEL ONLY

Requisition Completed by

Full name in capital letters

Phone number

Of the person completing the requisition

Collection Date (DD-MMM-YYYY)	Collection Time (24 hr clock)	Not Collected	SM1 BIOMARKER BLOOD	SM2 BIOMARKER PLASMA	SM3 SERUM PERTUZUMAB ADA PRE	SM4 PLASMA RHUPH20 ADA PRE	SM5 SERUM PERTUZUMAB ADA PRE	SM6 SERUM TRASTIZUMAB ADA PRE	SM9 RBR BLOOD
<input type="text"/>	:	<input type="checkbox"/>	X	X	X	X	X	X	X

For Labcorp Use Only

Employee Visa	Tube Count				Validation	Internal Comments:
	Amb	Frz	Refrig	Slides		

WHITE COPY- LABCORP

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«Bar_req» 4	«Label_6» 211285	ADDITIONAL TESTING IS NOT ALLOWED PLEASE DO NOT RETURN EMPTY CONTAINERS TO LABCORP.	«Bar_req» CS 230320
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Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
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«Bar_req»

VISIT: CYCLE 1 DAY 1 NO WGS/WES ARM A

*Return this page
with Samples*

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

Page 3 of 3
2-part

Patient Number

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Collection Date

Day	Month	Year

Complete month field in English
(Example: 01 JAN 2001)

CONDITIONAL TESTING - Please mark the box(es) or to ensure proper ordering of test(s)!

If you fail to mark the checkbox, testing may be ordered per Labcorp policy without investigator notification.

Condition	Sample
Not applicable for a site that has not been granted approval for RBR sampling. Performed only for patients at participating sites who have provided written informed consent to participate. Mark this box if SM9 RBR BLOOD sample is submitted.	<input type="checkbox"/> SM9 RBR BLOOD and SM9 RBR BLOOD COLL D/T
This samples should only be collected if site is under protocol version 2. Mark this box if SM3 SERUM PERTU/TRASTU PK PRE, SM4 PLASMA RHUPH20 ADA PRE, SM5 SERUM PERTUZUMAB ADA PRE and SM6 SERUM TRASTUZUMAB ADA PRE ADA sample is submitted.	<input type="checkbox"/> SM3 SERUM PERTU/TRASTU PK PRE and SM3 SERUM P/T PK PRE COLL D/T and SM4 PLASMA RHUPH20 ADA PRE and SM4 PLS RHU ADAPRE COLL D/T and SM5 SERUM PERTUZUMAB ADA PRE and SM5 SERUM PERTUZUMAB ADA PRE and SM6 SERUM TRASTUZUMAB ADA PRE and SM6 SERUM TRASTUZUMAB ADA PRE and SM6 SER TRAS ADAPRE COLL D/T

Comments:

For Labcorp Use Only						
Employee Visa	Tube Count				Validation	Internal Comments:
	Amb	Frz	Refrig	Slides		

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«Bar_req» 4	«Label_6» 211285	ADDITIONAL TESTING IS NOT ALLOWED PLEASE DO NOT RETURN EMPTY CONTAINERS TO LABCORP.	«Bar_req» CS 230320
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THE ACCESSION NUMBER IS THE
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«Bar_req»

Page 1 of 2
2-part

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

VISIT: CYCLE 2, 6 DAY 1 AND CYCLE N DAY 1

DO NOT RETURN THIS PAGE

Testing For This Visit

Please refer to the Laboratory Manual for detailed sample collection, preparation, and handling instructions.

Associated Test Group(s)	Draw Container	Return Container	Shipment Condition
SM2 BIOMARKER PLASMA	2x 10.0 mL lavender top EDTA tubes	2x Corning cryovials	Frozen

SM2 BIOMARKER PLASMA samples should be collected prior any drug administration.

No NCR
T-1

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211285

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APN 220830



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with Samples*

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

Page 2 of 2
2-part

Instructions:

Complete all boxes on this requisition with a blue or black ball point pen. Failure to complete all boxes will delay reports.

Please check that all patient identifiers are complete, consistent and correct, and that each container has the same accession number, when packing specimens for shipment!

Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

VISIT: CYCLE 2, 6 DAY 1 AND CYCLE N DAY 1

VISIT (CHECK ONE OR)

VISIT: See table below
Check one or

SUBJECT/PATIENT INFORMATION

Patient Number

Birthdate
Complete year Day Month Year
01 JAN

Sex Male Female

COLLECTION INFORMATION

Collection Date
Complete month field in English
(Example: 01 JAN 2001) Day Month Year

Collection Time
(Record Midnight as 23:59) 24 Hour Clock
 :

THIS SECTION TO BE COMPLETED BY SITE PERSONNEL ONLY

Requisition Completed by

Full name in capital letters

Phone number

Of the person completing the requisition

VISIT:

Cycle 2 Day 1 (PVC=C2D1)

Cycle 6 Day 1 (PVC=C6D1)

Cycle 10 Day 1 (PVC=C10D1)

Cycle 14 Day 1 (PVC=C14D1)

Cycle 18 Day 1 (PVC=C18D1)

Cycle 22 Day 1 (PVC=C22D1)

Cycle 26 Day 1 (PVC=C26D1)

Cycle 30 Day 1 (PVC=C30D1)

Cycle 34 Day 1 (PVC=C34D1)

Cycle 40 Day 1 (PVC=C40D1)

Cycle 46 Day 1 (PVC=C46D1)

Cycle 52 Day 1 (PVC=C52D1)

Cycle 58 Day 1 (PVC=C58D1)

Cycle 64 Day 1 (PVC=C64D1)

Cycle 70 Day 1 (PVC=C70D1)

Collection Date
(DD-MMM-YYYY)

Collection Time
(24 hr clock)

Not Collected

Biomarker
Plasma

: X

For Labcorp Use Only

Employee
Visa

Tube Count

Amb

Frz

Refrig

Slides

Validation

Internal Comments:

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«Bar_req»

«Label_6»

T-1

211285

ADDITIONAL TESTING IS NOT ALLOWED

PLEASE DO NOT RETURN EMPTY CONTAINERS TO LABCORP.

«Bar_req»

CS 220414



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«Bar_req»

Page 1 of 2
2-part

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

VISIT: CYCLE 4 DAY 1 ARM A PROTOCOL V2

DO NOT RETURN THIS PAGE

Testing For This Visit

Please refer to the Laboratory Manual for detailed sample collection, preparation, and handling instructions.

Associated Test Group(s)	Draw Container	Return Container	Shipment Condition
SM3 SERUM PERTU/TRASTU PK PRE	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM4 PLASMA RHUPH20 ADA PRE	1x 2.0 mL lavender top K3 EDTA tube	1x cryovial	Frozen
SM5 SERUM PERTUZUMAB ADA PRE	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM6 SERUM TRASTUZUMAB ADA PRE	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen

Only Applicable to Protocol Version 2

-This kit should be used to collect PK and ADA samples at Cycle 4 Day 1 during Maintenance Therapy Phase after Randomization, in **Arm A only**.

-All samples should be collected prior any drug administration.

No NCR
6

«Label_6»
211285

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CS 220414



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VISIT: CYCLE 4 DAY 1 ARM A PROTOCOL V2

*Return this page
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Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

Instructions:
Complete all boxes on this requisition with a blue or black ball point pen. Failure to complete all boxes will delay reports.

Please check that all patient identifiers are complete, consistent and correct, and that each container has the same accession number, when packing specimens for shipment!

SUBJECT/PATIENT INFORMATION				
Patient Number				
Birthdate	Day	Month	Year	
Complete year	0	1	J	A
Sex	Male	Female		
COLLECTION INFORMATION				
Collection Date	Day	Month	Year	
Complete month field in English (Example: 01 JAN 2001)				
Collection Time	24 Hour Clock			
(Record Midnight as 23:59)	:			
THIS SECTION TO BE COMPLETED BY SITE PERSONNEL ONLY				
Requisition Completed by				
Full name in capital letters				
Phone number				
Of the person completing the requisition				

Collection Date (DD-MMM-YYYY)	Collection Time (24 hr clock)	Not Collected	SM3 SERUM PERTU/TRASTU PK PRE	SM4 PLASMA RHUPH20 ADA PRE	SM5 SERUM PERTZUMAB ADA PRE	SM6 SERUM TRASTZUMAB ADA PRE
	:	<input type="checkbox"/>	X	X	X	X

For Labcorp Use Only							
Employee Visa	Tube Count				Validation	Internal Comments:	
	Amb	Frz	Refrig	Slides			

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«Bar_req» 6	«Label_6» 211285	ADDITIONAL TESTING IS NOT ALLOWED PLEASE DO NOT RETURN EMPTY CONTAINERS TO LABCORP.	«Bar_req» CS 220414
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«Requisition_n»

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«Bar_req»

Page 1 of 3
2-part

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

VISIT: CYCLE 1 DAY 1 ARM B

DO NOT RETURN THIS PAGE

Testing For This Visit

Please refer to the Laboratory Manual for detailed sample collection, preparation, and handling instructions.

Associated Test Group(s)	Draw Container	Return Container	Shipment Condition
SM1 BIOMARKER BLOOD	1x 6.0 mL lavender top EDTA tube		Frozen
SM2 BIOMARKER PLASMA	2x 10.0 mL lavender top EDTA tubes	2x Corning cryovials	Frozen
SM3 SERUM PERTU/TRASTU PK PRE	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM4 PLASMA RHUPH20 ADA PRE	1x 2.0 mL lavender top K3 EDTA tube	1x cryovial	Frozen
SM5 SERUM PERTUZUMAB ADA PRE	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM6 SERUM TRASTUZUMAB ADA PRE	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM7 PLASMA GIREDESTRANT PK PRE	1x 3.0 mL lavender top EDTA tube	1x cryovial	Frozen
SM8 PLASMA GIREDESTRANT PK 3HR	1x 3.0 mL lavender top EDTA tube	1x cryovial	Frozen
SM9 RBR BLOOD *	1x 6.0 mL lavender top EDTA tube		Frozen
SM10 WGS/WES BLOOD	1x 6.0 mL lavender top EDTA tube		Frozen

*Conditional

-This kit should be used to collect PK, ADA and Biomarker samples at Cycle 1 Day 1 during Maintenance Therapy Phase after Randomization, in Arm B only.

-Except SM8 PLASMA GIREDESTRANT PK 3HR (+/- 1 hour), all samples should be collected prior any drug administration.

- SM9 RBR BLOOD samples are only collected at participating sites if the patient has signed the optional RBR consent.

No NCR
3

«Label_6»
211285

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«Bar_req»
APN 220830



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Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

Page 2 of 3
2-part

Instructions:

Complete all boxes on this requisition with a blue or black ball point pen. Failure to complete all boxes will delay reports.

Please check that all patient identifiers are complete, consistent and correct, and that each container has the same accession number, when packing specimens for shipment!

Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

VISIT: CYCLE 1 DAY 1 ARM B

SUBJECT/PATIENT INFORMATION

Patient Number

--	--	--	--	--

Birthdate

Complete year

Day	Month	Year
01	JAN	

Sex

Male

Female

COLLECTION INFORMATION

Collection Date

Complete month field in English
(Example: 01 JAN 2001)

Day	Month	Year

Collection Time

(Record Midnight as 23:59)

24 Hour Clock

:

THIS SECTION TO BE COMPLETED BY SITE PERSONNEL ONLY

Requisition Completed by

Full name in capital letters

Phone number

Of the person completing the requisition

Collection Date (DD-MMM-YYYY)	Collection Time (24 hr clock)	Not Collected	SM3 SERUM PERTUZUMAB ADA PRE	SM4 PLASMA RHUPH20 ADA PRE	SM5 SERUM PERTUZUMAB ADA PRE	SM6 SERUM TRASTUZUMAB ADA PRE	SM7 PLASMA GIREDESTRANT PK PRE	SM8 PLASMA GIREDESTRANT PK PRE	SM1 BIOMARKER BLOOD	SM2 BIOMARKER PLASMA	SM9 RBR BLOOD	SM10 WGS/WES BLOOD
	:	<input type="checkbox"/>	X	X	X	X	X	X		X	X	X
3HR	:	<input type="checkbox"/>							X			

Mark the Not Collected box when the time point was not able to be collected.

For Labcorp Use Only

Employee Visa	Tube Count				Validation	Internal Comments:
	Amb	Frz	Refrig	Slides		

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«Bar_req» 3	«Label_6» 211285	ADDITIONAL TESTING IS NOT ALLOWED PLEASE DO NOT RETURN EMPTY CONTAINERS TO LABCORP.	«Bar_req» CS 220414
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VISIT: CYCLE 1 DAY 1 ARM B

*Return this page
with Samples*

Laboratory Requisition Form

Page 3 of 3
2-part
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

Patient Number

--	--	--	--	--

Collection Date

Day	Month	Year

Complete month field in English
(Example: 01 JAN 2001)

CONDITIONAL TESTING - Please mark the box(es) or to ensure proper ordering of test(s)!

If you fail to mark the checkbox, testing may be ordered per Labcorp policy without investigator notification.

Condition	Sample
<p>Not applicable for a site that has not been granted approval for RBR sampling. Performed only for patients at participating sites who have provided written informed consent to participate.</p> <p>Mark this box if SM9 RBR BLOOD sample is submitted.</p>	<input type="checkbox"/> SM9 RBR BLOOD and SM9 RBR BLOOD COLL D/T

Comments:

For Labcorp Use Only						
Employee Visa	Tube Count				Validation	Internal Comments:
	Amb	Frz	Refrig	Slides		

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«Bar_req» 3	«Label_6» 211285	ADDITIONAL TESTING IS NOT ALLOWED PLEASE DO NOT RETURN EMPTY CONTAINERS TO LABCORP.	«Bar_req» CS 220414
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Page 1 of 3
2-part

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

VISIT: CYCLE 1 DAY 1 NO WGS/WES ARM B

DO NOT RETURN THIS PAGE

Testing For This Visit

Please refer to the Laboratory Manual for detailed sample collection, preparation, and handling instructions.

Associated Test Group(s)	Draw Container	Return Container	Shipment Condition
SM1 BIOMARKER BLOOD	1x 6.0 mL lavender top EDTA tube		Frozen
SM2 BIOMARKER PLASMA	2x 10.0 mL lavender top EDTA tubes	2x Corning cryovials	Frozen
SM3 SERUM PERTU/TRASTU PK PRE	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM4 PLASMA RHUPH20 ADA PRE	1x 2.0 mL lavender top K3 EDTA tube	1x cryovial	Frozen
SM5 SERUM PERTUZUMAB ADA PRE	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM6 SERUM TRASTUZUMAB ADA PRE	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM7 PLASMA GIREDESTRANT PK PRE	1x 3.0 mL lavender top EDTA tube	1x cryovial	Frozen
SM8 PLASMA GIREDESTRANT PK 3HR	1x 3.0 mL lavender top EDTA tube	1x cryovial	Frozen
SM9 RBR BLOOD *	1x 6.0 mL lavender top EDTA tube		Frozen

*Conditional

This kit should be used to collect PK, ADA and Biomarker samples at Cycle 1 Day 1 during Maintenance Therapy Phase after Randomization, in **Arm B only**.

-This kit will be used by sites not collecting WGS/WES samples.

-Except SM8 PLASMA GIREDESTRANT PK 3HR (+/- 1 hour), all samples should be collected prior any drug administration.

- SM9 RBR BLOOD samples are only collected at participating sites if the patient has signed the optional RBR consent.

No NCR
5
211285

«Label_6»
Keep on file for your records. DO NOT return to Labcorp.

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Laboratory Requisition Form
Roche Products Limited
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Page 2 of 3
2-part

Instructions:

Complete all boxes on this requisition with a blue or black ball point pen. Failure to complete all boxes will delay reports.

Please check that all patient identifiers are complete, consistent and correct, and that each container has the same accession number, when packing specimens for shipment!

Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

VISIT: CYCLE 1 DAY 1 NO WGS/WES ARM B
SUBJECT/PATIENT INFORMATION

Patient Number

Birthdate
Complete year **01 JAN**

Sex Male Female

COLLECTION INFORMATION

Collection Date
Complete month field in English
(Example: 01 JAN 2001)

Collection Time
(Record Midnight as 23:59)

THIS SECTION TO BE COMPLETED BY SITE PERSONNEL ONLY

Requisition Completed by

Full name in capital letters

Phone number

Of the person completing the requisition

Collection Date
(DD-MMM-YYYY)

Collection Time
(24 hr clock)

Not
Collected

SM1 BIOMARKER BLOOD

SM2 BIOMARKER PLASMA

SM3 SERUM PERTUZYTRASTU PK PRE

SM4 PLASMA RHUH20 ADA PRE

SM5 SERUM PERTUZUMAB ADA PRE

SM6 SERUM TRASTUZUMAB ADA
PRE

SM7 PLASMA GIREDESTRANT PK PRE

SM8 PLASMA GIREDESTRANT PK

SM9 RBR BLOOD

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>									
3HR		:	:	<input checked="" type="checkbox"/>									

Mark the Not Collected box when the time point was not able to be collected.

For Labcorp Use Only

Employee Visa	Tube Count				Validation	Internal Comments:
	Amb	Frz	Refrig	Slides		

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«Bar_req» 5	«Label_6» 211285	ADDITIONAL TESTING IS NOT ALLOWED PLEASE DO NOT RETURN EMPTY CONTAINERS TO LABCORP.	«Bar_req» CS 220414
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VISIT: CYCLE 1 DAY 1 NO WGS/WES ARM B

*Return this page
with Samples*

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

Page 3 of 3
2-part

Patient Number

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Collection Date

Day	Month	Year

Complete month field in English
(Example: 01 JAN 2001)

CONDITIONAL TESTING - Please mark the box(es) or to ensure proper ordering of test(s)!

If you fail to mark the checkbox, testing may be ordered per Labcorp policy without investigator notification.

Condition	Sample
Not applicable for a site that has not been granted approval for RBR sampling. Performed only for patients at participating sites who have provided written informed consent to participate.	<input type="checkbox"/> SM9 RBR BLOOD and SM9 RBR BLOOD COLL D/T

Mark this box if SM9 RBR BLOOD sample is submitted.

Comments:

For Labcorp Use Only						
Employee Visa	Tube Count				Validation	Internal Comments:
	Amb	Frz	Refrig	Slides		

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Page 1 of 2
2-part

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

VISIT: CYCLE 4 DAY 1 ARM B

DO NOT RETURN THIS PAGE

Testing For This Visit

Please refer to the Laboratory Manual for detailed sample collection, preparation, and handling instructions.

Associated Test Group(s)	Draw Container	Return Container	Shipment Condition
SM3 SERUM PERTU/TRASTU PK PRE	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM4 PLASMA RHUPH20 ADA PRE	1x 2.0 mL lavender top K3 EDTA tube	1x cryovial	Frozen
SM5 SERUM PERTUZUMAB ADA PRE	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM6 SERUM TRASTUZUMAB ADA PRE	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM7 PLASMA GIREDESTRANT PK PRE	1x 3.0 mL lavender top EDTA tube	1x cryovial	Frozen
SM8 PLASMA GIREDESTRANT PK 3HR	1x 3.0 mL lavender top EDTA tube	1x cryovial	Frozen

-This kit should be used to collect PK and ADA samples at Cycle 4 Day 1 during Maintenance Therapy Phase after Randomization, in **Arm B only**.

- Except SM8 PLASMA GIREDESTRANT PK 3HR (+/- 1 hour), all samples should be collected prior any drug administration.

No NCR
7

«Label_6»
211285

Keep on file for your records. DO NOT return to Labcorp.

«Bar_req»
CS 220414



Labcorp Central Laboratory Services S.à.r.l.
Rue Moïse-Marcinhes 7
1217 Meyrin Geneva Switzerland
Tel: 0041 58 822 7901
Fax: 0041 58 822 7521

Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

VISIT: CYCLE 4 DAY 1 ARM B

*Return this page
with Samples*

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

Instructions:
Complete all boxes on this requisition with a blue or black ball point pen. Failure to complete all boxes will delay reports.

Please check that all patient identifiers are complete, consistent and correct, and that each container has the same accession number, when packing specimens for shipment!

Page 2 of 2
2-part

SUBJECT/PATIENT INFORMATION									
Patient Number									
Birthdate	Day	Month	Year						
Complete year	0	1	JAN						
Sex	Male	Female							
COLLECTION INFORMATION									
Collection Date	Day	Month	Year						
Complete month field in English (Example: 01 JAN 2001)									
Collection Time	24 Hour Clock								
(Record Midnight as 23:59)	:								
THIS SECTION TO BE COMPLETED BY SITE PERSONNEL ONLY									
Requisition Completed by									
Full name in capital letters									
Phone number									
Of the person completing the requisition									

Collection Date (DD-MMM-YYYY)	Collection Time (24 hr clock)	Not Collected	SM3 SERUM PERTU/TASTU PK PRE	SM4 PLASMA RHUPH20 ADA PRE	SM5 SERUM PERTUZUMAB ADA PRE	SM6 SERUM TRASTZUMAB ADA PRE	SM7 PLASMA GIREDESTRANT PK PRE	SM8 PLASMA GIREDESTRANT PK
	:	<input type="checkbox"/>	X	X	X	X	X	
3HR	:	<input type="checkbox"/>						X

For Labcorp Use Only										
Employee Visa	Tube Count				Validation	Internal Comments:				
	Amb	Frz	Refrig	Slides						

WHITE COPY- LABCORP

PINK COPY-INVESTIGATOR

«Bar_req» 7	«Label_6» 211285	ADDITIONAL TESTING IS NOT ALLOWED PLEASE DO NOT RETURN EMPTY CONTAINERS TO LABCORP.	«Bar_req» CS 220414
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Labcorp Central Laboratory Services S.à.r.l.
Rue Moïse-Marcinhes 7
1217 Meyrin Geneva Switzerland
Tel: 0041 58 822 7901
Fax: 0041 58 822 7521

Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

Page 1 of 2
2-part

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

VISIT: TREATMENT DISCONTINUATION V2

DO NOT RETURN THIS PAGE

Testing For This Visit

Please refer to the Laboratory Manual for detailed sample collection, preparation, and handling instructions.

Associated Test Group(s)	Draw Container	Return Container	Shipment Condition
SM2 BIOMARKER PLASMA	2x 10.0 mL lavender top EDTA tubes	2x Corning cryovials	Frozen
SM12 PLASMA RHUPH20 ADA*	1x 2.0 mL lavender top K3 EDTA tube	1x cryovial	Frozen
SM13 SERUM PERTUZUMAB ADA*	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM14 SERUM TRASTUZUMAB ADA*	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen

Only Applicable to Protocol Version 2 (for Arm A and B)

This kit should be used for **Treatment Discontinuation** 28 (+/-3) day after the final dose of study treatment to collect Biomarker Plasma Samples in case of discontinuation treatment for any reason other than Disease Progression.

If treatment is discontinued due to **Disease Progression**, this kit should be used in combination with Tissue samples collection kits to assess Tumor tissue samples. The Biomarker plasma sample collection at disease progression should occur within 40 days after Disease Progression or prior to start of the next systemic anti-cancer therapy, whichever is sooner.

SM12 PLASMA RHUPH20 ADA , SM13 SERUM PERTUZUMAB ADA and SM14 SERUM TRASTUZUMAB ADA should be collected at this visit if treatment is discontinued for reasons other than Disease progression.

No NCR
T-2

«Label_6»
211285

Keep on file for your records. DO NOT return to Labcorp.

«Bar_req»
CS 230320



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Rue Moïse-Marcinges 7
1217 Meyrin Geneva Switzerland
Tel: 0041 58 822 7901
Fax: 0041 58 822 7521

*Return this page
with Samples*

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

Page 2 of 2

2-part

Instructions:

Complete all boxes on this requisition with a blue or black ball point pen. Failure to complete all boxes will delay reports.

Please check that all patient identifiers are complete, consistent and correct, and that each container has the same accession number, when packing specimens for shipment!

Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

VISIT: TREATMENT DISCONTINUATION V2

VISIT (CHECK ONE OR)

VISIT: Check one <input checked="" type="checkbox"/> or <input type="checkbox"/>	Treatment Discontinuation (PVC=DISC)
	Disease Progression (PVC=DP)

SUBJECT/PATIENT INFORMATION

Patient Number

Birthdate
Complete year
01 JAN

Sex Male Female

COLLECTION INFORMATION

Collection Date
Complete month field in English
(Example: 01 JAN 2001)

Collection Time
(Record Midnight as 23:59) 24 Hour Clock :

THIS SECTION TO BE COMPLETED BY SITE PERSONNEL ONLY

Requisition Completed by

Full name in capital letters

Phone number

Of the person completing the requisition

Collection Date (DD-MMM-YYYY)	Collection Time (24 hr clock)	Not Collected	BIMARKER PLASMA	PLASMA RHUPH20 ADA	SERUM PERTUZUMAB ADA	SERUM TRASTUZUMAB ADA
<input type="text"/>	<input type="text"/> <input type="text"/> :	<input type="checkbox"/>	<input type="checkbox"/>	X	X	X

CONDITIONAL TESTING - Please mark the box(es) or to ensure proper ordering of test(s)!
If you fail to mark the checkbox, testing may be ordered per Labcorp policy without investigator notification.

Condition	Sample
This samples should be collected only if treatment is discontinued for reasons other than Disease progression, meaning that PVC=DISC. Mark this box if SM12 PLASMA RHUPH20 ADA, SM13 SERUM PERTUZUMAB ADA and SM14 SERUM TRASTUZUMAB ADA sample is submitted.	<input type="checkbox"/> SM12 PLASMA RHUPH20 ADA and SM12 PLASMA RHU ADA COL D/T <input type="checkbox"/> SM13 SERUM PERTUZUMAB ADA and SM13 SERUM PERTU ADA COL D/T <input type="checkbox"/> SM14 SERUM TRASTUZUMAB ADA and SM14 SERUM TRASTU ADA COL D/T

For Labcorp Use Only						
Employee Visa	Tube Count				Validation	Internal Comments:
	Amb	Frz	Refrig	Slides		

WHITE COPY- LABCORP

PINK COPY-INVESTIGATOR

«Bar_req» T-2	«Label_6» 211285	ADDITIONAL TESTING IS NOT ALLOWED PLEASE DO NOT RETURN EMPTY CONTAINERS TO LABCORP.	«Bar_req» CS 230320
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Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

Page 1 of 2 Laboratory Requisition Form
Roche Products Limited
2-part Protocol: WO43571
Investigator : «Inv_n»

VISIT: TISSUE SAMPLE COLLECTION

DO NOT RETURN THIS PAGE

THIS IS NOT A REQUISITION.

You should print the Tissue Sample Collection eForm from the **EDC RAVE system** and return it with the samples. On the upper right corner of the eForm, please make sure to affix the extra barcoded Covance label provided in the kit that matches the label on the samples and the pathology report (if available).

Note: a Tissue Requisition Form worksheet is provided in the lab manual in case the eForm cannot be printed. If used, please also place the extra barcoded Covance label on the printed form.

Testing For This Visit			
Please refer to the Laboratory Manual for detailed sample collection, preparation, and handling instructions.			
Associated Test Group(s)	Draw Container	Return Container	Shipment Condition
Fresh Tissue Block*	1x yellow biopsy tissue cassette, 1x bubble bag, 1x biohazard bag, 1x 60 mL blue cap specimen container, 1x 60 mL orange cap specimen container with AP bar,, 1x label		Ambient
Fresh Tissue Slides*	1x 25 count slide mailer, 1x label, 1x yellow biopsy tissue cassette, 1x 60 mL blue cap specimen container, 1x biohazard bag, 1x foam sheet		Ambient
Archival Tissue Block*	1x bubble bag, 1x biohazard bag, 1x 60 mL orange cap specimen container with AP bar, 1x label		Ambient
Archival Tissue Slide*	1x 25 count slide mailer, 1x label, 1x biohazard bag, 1x foam sheet		Ambient

* Optional

No NCR T-6 211285	«Label_6» Keep on file for your records. DO NOT return to Labcorp.	«Bar_req» CS 230906
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Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

Page 2 of 2 Laboratory Requisition Form
Roche Products Limited
2-part Protocol: WO43571
Investigator : «Inv_n»

VISIT: TISSUE SAMPLE COLLECTION

DO NOT RETURN THIS PAGE

This kit should be used to collect **fresh or archival tumor tissue** sample at **Screening** and **Disease Progression**.

- For instructions on how to collect the biopsy sample, please refer to the document **PROTOCOL WO43571 TISSUE COLLECTION INSTRUCTIONS** in the manual.

Screening Visit:

- Archival tissue sample from the primary tumor (preferred) and/or metastatic sites must be submitted to assess HER2 status to confirm eligibility. Only participants who do not have tissue specimens that meet eligibility requirements may undergo a biopsy during the screening period.
- If archival tumor tissue is unavailable or is determined to be unsuitable or insufficient for required testing, an additional pretreatment tumor sample is required, but only if the benefit of such investigations are deemed to outweigh any risk in the judgment of the investigator.

Disease Progression visit

- A representative FFPE tumor specimen in a paraffin block (preferred) or at least 15 slides containing unstained, freshly cut 4uM serial sections mounted on positive charged glass slides.
- should be submitted at the time of Disease Progression. Biopsies at the time of progression should be performed within 40 days after progression or prior to the next anti-cancer therapy, whichever is sooner.
- Tissue Sample Collection kit should be ordered manually by site where Tissue collection samples occurs.
- Do not ship to Labcorp – **Ship ambient directly to CellCarta on day of collection or at the earliest possible date.**

CellCarta NV

Attn. Sample Reception Team – P2040
Sint-Bavostraat 78
2610 Wilrijk
Belgium
Email: trialsANT1@cellcarta.com
Tel: +32 3 502 0625

No NCR
T-6

«Label_6»
211285

Keep on file for your records. DO NOT return to Labcorp.

«Bar_req»
CS 230320



Labcorp Central Laboratory Services S.à.r.l.
Rue Moïse-Marcinhes 7
1217 Meyrin Geneva Switzerland
Tel: 0041 58 822 7901
Fax: 0041 58 822 7521

Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

Page 1 of 2
2-part

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

VISIT: TREATMENT DISCONTINUATION ARM A V3

DO NOT RETURN THIS PAGE

Testing For This Visit

Please refer to the Laboratory Manual for detailed sample collection, preparation, and handling instructions.

Associated Test Group(s)	Draw Container	Return Container	Shipment Condition
SM2 BIOMARKER PLASMA	2 x 10.0 mL lavender top EDTA tubes	2 x Corning cryovials	Frozen

Applicable to Arm A protocol version 3.

This kit could be used for **Treatment Discontinuation** 28 (+/-3) day after the final dose of study treatment to collect Biomarker Plasma Samples in case of discontinuation treatment for any reason other than Disease Progression.

If treatment is discontinued due to Disease Progression, this kit should be used in combination with Tissue samples collection kits to assess Tumor tissue samples. The Biomarker plasma sample collection at Disease Progression should occur within 40 days after Disease Progression or prior to start of the next systemic anti-cancer therapy, whichever is sooner.

No NCR
T-7

«Label_6»
211285

Keep on file for your records. DO NOT return to Labcorp.

«Bar_req»
CS 230320



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Rue Moïse-Marcinhes 7
1217 Meyrin Geneva Switzerland
Tel: 0041 58 822 7901
Fax: 0041 58 822 7521

*Return this page
with Samples*
Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

Page 2 of 2
2-part

Instructions:

Complete all boxes on this requisition with a blue or black ball point pen. Failure to complete all boxes will delay reports.

Please check that all patient identifiers are complete, consistent and correct, and that each container has the same accession number, when packing specimens for shipment!

Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

VISIT: TREATMENT DISCONTINUATION ARM A V3

VISIT (CHECK ONE OR)

VISIT: Treatment Discontinuation(PVC=DISC)
Check one or Disease Progression (PVC=DP)

SUBJECT/PATIENT INFORMATION

Patient Number

Birthdate Day Month Year
Complete year 0 1 J A N

Sex Male Female

COLLECTION INFORMATION

Collection Date Day Month Year
Complete month field in English
(Example: 01 JAN 2001)

Collection Time 24 Hour Clock
(Record Midnight as 23:59) :

THIS SECTION TO BE COMPLETED BY SITE PERSONNEL ONLY

Requisition Completed by

Full name in capital letters

Phone number

Of the person completing the requisition

Collection Date (DD-MMM-YYYY)	Collection Time (24 hr clock)	Not Collected	Biomarker Plasma
<input type="text"/>	<input type="text"/> : <input type="text"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

For Labcorp Use Only						
Employee Visa	Tube Count				Validation	Internal Comments:
	Amb	Frz	Refrig	Slides		

WHITE COPY- LABCORP

PINK COPY-INVESTIGATOR

«Bar_req» T-7	«Label_6» 211285	ADDITIONAL TESTING IS NOT ALLOWED PLEASE DO NOT RETURN EMPTY CONTAINERS TO LABCORP.	«Bar_req» CS 230320
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Labcorp Central Laboratory Services S.à.r.l.
Rue Moïse-Marcinhes 7
1217 Meyrin Geneva Switzerland
Tel: 0041 58 822 7901
Fax: 0041 58 822 7521

Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

Page 1 of 2
2-part

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

VISIT: TREATMENT DISCONTINUATION ARM B V3

DO NOT RETURN THIS PAGE

Testing For This Visit

Please refer to the Laboratory Manual for detailed sample collection, preparation, and handling instructions.

Associated Test Group(s)	Draw Container	Return Container	Shipment Condition
SM2 BIOMARKER PLASMA	2 x 10.0 mL lavender top EDTA tubes	2 x Corning cryovials	Frozen
SM11 SERUM PERTU/TRASTU PK*	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM12 PLASMA RHUPH20 ADA*	1x 2.0 mL lavender top K3 EDTA tube	1x cryovial	Frozen
SM13 SERUM PERTUZUMAB ADA*	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM14 SERUM TRASTUZUMAB ADA*	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen

*Conditional

Applicable to Arm B protocol version 3.

This kit should could be used for two case scenarios:

-**Treatment Discontinuation** 28 (+/-3) day after the final dose of study treatment to collect PK, ADA and Biomarker plasma samples in case of discontinuation treatment for any reason other than Disease Progression.

-**Disease Progression:** if treatment is discontinued due to disease progression, this kit should be used in combination with Tissue samples collection kits to assess Tumor tissue samples. The Biomarker plasma sample collection at **Disease Progression** should occur within 40 days after **Disease Progression** or prior to start of the next systemic anti-cancer therapy, whichever is sooner.

No NCR
T-8
211285

«Label_6»
Keep on file for your records. DO NOT return to Labcorp.

«Bar_req»
CS 230320



Labcorp Central Laboratory Services S.à.r.l.
Rue Moïse-Marcinhes 7
1217 Meyrin Geneva Switzerland
Tel: 0041 58 822 7901
Fax: 0041 58 822 7521

*Return this page
with Samples*
Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

Page 2 of 2
2-part

Instructions:

Complete all boxes on this requisition with a blue or black ball point pen. Failure to complete all boxes will delay reports.

Please check that all patient identifiers are complete, consistent and correct, and that each container has the same accession number, when packing specimens for shipment!

Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

VISIT: TREATMENT DISCONTINUATION ARM B V3

VISIT (CHECK ONE OR)

VISIT: Check one <input checked="" type="checkbox"/> or <input type="checkbox"/>	Treatment Discontinuation (PVC=DISC)
	Disease Progression (PVC=DP)

SUBJECT/PATIENT INFORMATION

Patient Number

Birthdate Day Month Year
Complete year 0 1 J A N

Sex Male Female

COLLECTION INFORMATION

Collection Date Day Month Year
Complete month field in English
(Example: 01 JAN 2001)

Collection Time 24 Hour Clock
(Record Midnight as 23:59) :

THIS SECTION TO BE COMPLETED BY SITE PERSONNEL ONLY

Requisition Completed by

Full name in capital letters

Phone number

Of the person completing the requisition

Collection Date (DD-MMM-YYYY)	Collection Time (24 hr clock)	Not Collected	BIOMARKER PLASMA	SERUM PERTU/TRASTU PK	PLASMA RHUPH20 ADA	SERUM PERTUZUMAB ADA	SERUM TRASTUZUMAB ADA
<input type="text"/>	:	<input type="checkbox"/>	X	X	X	X	X

CONDITIONAL TESTING - Please mark the box(es) or to ensure proper ordering of test(s)!
If you fail to mark the checkbox, testing may be ordered per Labcorp policy without investigator notification.

Condition	Sample
This samples should be collected only if treatment is discontinued for reasons other than Disease progression, meaning that PVC=DISC. Mark this box if SM11 SERUM PERTU/TRASTU PK ,SM12 PLASMA RHUPH20 ADA, SM13 SERUM PERTUZUMAB ADA and SM14 SERUM TRASTUZUMAB ADA sample is submitted.	<input type="checkbox"/> SM11 SERUM PERTU/TRASTU PK and SM11 SERUM P/T PK COLL D/T SM12 PLASMA RHUPH20 ADA and SM12 PLASMA RHU ADA COLL D/T <input type="checkbox"/> SM13 SERUM PERTUZUMAB ADA and SM13 SERUM PERTU ADA COLL D/T SM14 SERUM TRASTUZUMAB ADA and SM14 SERUM TRASTU ADA COLL D/T

For Labcorp Use Only

Employee Visa	Tube Count				Validation	Internal Comments:
	Amb	Frz	Refrig	Slides		

WHITE COPY- LABCORP

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«Bar_req» T-8	«Label_6» 211285	ADDITIONAL TESTING IS NOT ALLOWED PLEASE DO NOT RETURN EMPTY CONTAINERS TO LABCORP.	«Bar_req» CS 230320
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1217 Meyrin Geneva Switzerland
Tel: 0041 58 822 7901
Fax: 0041 58 822 7521

Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

Page 1 of 2
2-part

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

VISIT: FOLLOW UP MONTH 3, 12 AND 24 V2

DO NOT RETURN THIS PAGE

Testing For This Visit

Please refer to the Laboratory Manual for detailed sample collection, preparation, and handling instructions.

Associated Test Group(s)	Draw Container	Return Container	Shipment Condition
SM11 SERUM PERTU/TRASTU PK	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM12 PLASMA RHUPH20 ADA	1x 2.0 mL lavender top K3 EDTA tube	1x cryovial	Frozen
SM13 SERUM PERTUZUMAB ADA	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM14 SERUM TRASTUZUMAB ADA	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen

Only Applicable to Protocol Version 2

This kit should be used to collect samples at the following "Follow-Up" visits:

- Follow-Up Month 3
- Follow-Up Month 12
- Follow-Up Month 24

Please note that Follow-up visits are based on the date of the last dose of Phesgo and not on treatment discontinuation visit.

No NCR
T-3
211285

«Label_6»
211285

Keep on file for your records. DO NOT return to Labcorp.

«Bar_req»
CS 230320



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1217 Meyrin Geneva Switzerland
Tel: 0041 58 822 7901
Fax: 0041 58 822 7521

*Return this page
with Samples*

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

Page 2 of 2
2-part

Instructions:

Complete all boxes on this requisition with a blue or black ball point pen. Failure to complete all boxes will delay reports.

Please check that all patient identifiers are complete, consistent and correct, and that each container has the same accession number, when packing specimens for shipment!

Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

VISIT: FOLLOW UP MONTH 3, 12 AND 24 V2

VISIT (CHECK ONE OR)

VISIT: Check one <input checked="" type="checkbox"/> or <input type="checkbox"/>	Follow-Up Month 3 (PVC= FOLLOW-3M)
	Follow-Up Month 12 (PVC= FOLLOW-12M)
	Follow-Up Month 24 (PVC= FOLLOW-24M)

SUBJECT/PATIENT INFORMATION

Patient Number

Birthdate Day Month Year
Complete year 01 JAN

Sex Male Female

COLLECTION INFORMATION

Collection Date Day Month Year
Complete month field in English
(Example: 01 JAN 2001)

Collection Time 24 Hour Clock
(Record Midnight as 23:59) :

THIS SECTION TO BE COMPLETED BY SITE PERSONNEL ONLY

Requisition Completed by

Full name in capital letters

Phone number

Of the person completing the requisition

Collection Date (DD-MMM-YYYY)	Collection Time (24 hr clock)	Not Collected	SERUM PERTU/TRASTU PK	PLASMA RHUPH20/ADA	SERUM PERTUZUMAB ADA	SERUM TRASTUZUMAB ADA
<input type="text"/>	:	<input type="checkbox"/>	X	X	X	X

For Labcorp Use Only						
Employee Visa	Tube Count				Validation	Internal Comments:
	Amb	Frz	Refrig	Slides		

WHITE COPY- LABCORP

PINK COPY-INVESTIGATOR

«Bar_req» T-3	«Label_6» 211285	ADDITIONAL TESTING IS NOT ALLOWED PLEASE DO NOT RETURN EMPTY CONTAINERS TO LABCORP.	«Bar_req» CS 230320
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Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

Page 1 of 2
2-part

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

VISIT: SAFETY MOBILE NURSING

DO NOT RETURN THIS PAGE

Testing For This Visit

Please refer to the Laboratory Manual for detailed sample collection, preparation, and handling instructions.

Associated Test Group(s)	Draw Container	Return Container	Shipment Condition
CHEMISTRY MN	2x 2.5 mL red top serum separation tubes	1 x plastic vial	Ambient
COAGULATION MN	2x 1.8 mL 3.2% blue top sodium citrate tubes	1 x plastic vial	Ambient
HEMATOLOGY MN	1 x 2.0 mL lavender top EDTA tube		Ambient
URINALYSIS MN	Standard urine collection cup	1x 10.0 mL yellow top conical tube	Ambient
FSH MN, ESTRADIOL MN	1x 2.5 mL red top serum separation tube	2 x plastic vials	Ambient

Applicable kits:

Safety Mobile Nursing

Kit ordering:

Contact the appropriate Kit Inventory Center listed below:

Web Resupply (preferred method):

<https://drugdevelopment.labcorp.com/customers/investigators/order-a-kit.html>

Phone: Please refer to Section 6 (Toll Free Contact Numbers) of the LabCorp Central Laboratory Manual

Requisition completion:

Write the full subject ID in the demographics field and document the site number to which the patient belongs in the field 'Site Number', printed on the requisition.

Shipping instructions:

Refer to shipping instructions in the Manual for mobile nursing visit.

No NCR
T-4

«Label_6»
211285

Keep on file for your records. DO NOT return to Labcorp.

«Bar_req»
HK 220720

Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

Do NOT Return to Labcorp

SCC

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

Page 2 of 2
2-part

Site Number Reassignment : (Add leading 0 if necessary)

--	--	--	--	--	--	--

ATTN: LPS Team – Site reassignment

Instructions:

Complete all boxes on this requisition with a blue or black ball point pen. Failure to complete all boxes will delay reports.

Please check that all patient identifiers are complete, consistent and correct, and that each container has the same accession number, when packing specimens for shipment!

Patient Number

--	--	--	--	--	--

Birthdate

Day	Month	Year					
Complete year							
0	1	J	A	N			

Sex

Male	Female
------	--------

COLLECTION INFORMATION

Collection Date

Day	Month	Year					
Complete month field in English (Example: 01 JAN 2001)							

Collection Time

24 Hour Clock							
(Record Midnight as 23:59)							
:							

THIS SECTION TO BE COMPLETED BY SITE PERSONNEL ONLY

Requisition Completed by

Full name in capital letters

Phone number

Of the person completing the requisition

Comments:

WHITE COPY-REFERRAL LAB
Do NOT Return to Labcorp

PINK COPY-INVESTIGATOR
Do NOT Return to Labcorp

SCC

SCC

«Bar_req» T-4 211285	«Label_6»	ADDITIONAL TESTING IS NOT ALLOWED PLEASE DO NOT RETURN EMPTY CONTAINERS TO LABCORP.	«Bar_req» CS 220414
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Labcorp Central Laboratory Services S.à.r.l.
Rue Moïse-Marcinhes 7
1217 Meyrin Geneva Switzerland
Tel: 0041 58 822 7901
Fax: 0041 58 822 7521

Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

Page 1 of 3
2-part

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

VISIT: RETEST

DO NOT RETURN THIS PAGE

Testing For This Visit

Please refer to the Laboratory Manual for detailed sample collection, preparation, and handling instructions.

Associated Test Group(s)	Draw Container	Return Container	Shipment Condition
SM1 BIOMARKER BLOOD*	1x 6.0 mL lavender top EDTA tube		Frozen
SM2 BIOMARKER PLASMA *	2x 10.0 mL lavender top EDTA tubes	2x Corning cryovials	Frozen
SM3 SERUM PERTU/TRASTU PK PRE *	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM4 PLASMA RHUPH20 ADA PRE*	1x 2.0 mL lavender top K3 EDTA tube	1x cryovial	Frozen
SM5 SERUM PERTUZUMAB ADA PRE *	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM6 SERUM TRASTUZUMAB ADA PRE *	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM7 PLASMA GIREDESTRANT PK PRE *	1x 3.0 mL lavender top EDTA tube	1x cryovial	Frozen
SM8 PLASMA GIREDESTRANT PK 3HR *	1x 3.0 mL lavender top EDTA tube	1x cryovial	Frozen
SM9 RBR BLOOD *	1x 6.0 mL lavender top EDTA tube		Frozen
SM10 WGS/WES BLOOD *	1x 6.0 mL lavender top EDTA tube		Frozen
SM11 SERUM PERTU/TRASTU PK*	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM12 PLASMA RHUPH20 ADA*	1x 2.0 mL lavender top K3 EDTA tube	1x cryovial	Frozen
SM13 SERUM PERTUZUMAB ADA*	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM14 SERUM TRASTUZUMAB ADA*	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen

*Optional

This kit can be used:

- to collect Biomarker Blood or RBR Blood at any time during the study in case missed during Cycle 1 Day 1 in Maintenance Therapy phase.
- for repeat or follow-up testing.
- to recollect analyses at any time during the trial or
- to substitute for any kit, if you do not have the appropriate kit in stock. If so, please cross through "Retest" and write the visit name on the requisition form.

Make sure that you order all tests required for the visit being performed.

No NCR
U

«Label_6»
211285

Keep on file for your records. DO NOT return to Labcorp.

«Bar_req»
APN 220830



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1217 Meyrin Geneva Switzerland
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Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

VISIT: RETEST

*Return this page
with Samples*
Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

Page 2 of 3
2-part

Instructions:

Complete all boxes on this requisition with a blue or black ball point pen. Failure to complete all boxes will delay reports.

Please check that all patient identifiers are complete, consistent and correct, and that each container has the same accession number, when packing specimens for shipment!

SUBJECT/PATIENT INFORMATION															
Patient Number															
Birthdate Complete year															
<table border="1"> <tr> <td>Day</td> <td>Month</td> <td>Year</td> </tr> <tr> <td>0</td> <td>1</td> <td>JAN</td> </tr> </table>										Day	Month	Year	0	1	JAN
Day	Month	Year													
0	1	JAN													
Sex															
<input type="checkbox"/> Male					<input type="checkbox"/> Female										
COLLECTION INFORMATION															
Collection Date															
<table border="1"> <tr> <td>Day</td> <td>Month</td> <td>Year</td> </tr> <tr> <td></td> <td></td> <td></td> </tr> </table>										Day	Month	Year			
Day	Month	Year													
Complete month field in English (Example: 01 JAN 2001)															
Collection Time															
<table border="1"> <tr> <td colspan="2">24 Hour Clock</td> </tr> <tr> <td colspan="2">(Record Midnight as 23:59)</td> </tr> <tr> <td>:</td> <td></td> </tr> </table>										24 Hour Clock		(Record Midnight as 23:59)		:	
24 Hour Clock															
(Record Midnight as 23:59)															
:															
THIS SECTION TO BE COMPLETED BY SITE PERSONNEL ONLY															
Requisition Completed by															
Full name in capital letters Phone number															
Of the person completing the requisition															

Collection Date (DD-MMM-YYYY)	Collection Time (24 hr clock)	Not Collected	SM3 SERUM PERTU/TRASTRU PK PRE	SM4 PLASMA RHUPH20 ADA PRE	SM5 SERUM PERTUZUMAB ADA PRE	SM6 SERUM TRASTUZUMAB ADA PRE	SM7 PLASMA GIREDESTRANT PK PRE	SM8 PLASMA GIREDESTRANT PK	SM1 BIOMARKER BLOOD	SM2 BIOMARKER PLASMA	SM9 RBR BLOOD	SM10 WGS/WES BLOOD	SM11 SERUM PERTU/TRASTRU PK	SM12 PLASMA RHUPH20 ADA	SM13 SERUM PERTUZUMAB ADA	SM14 SERUM TRASTUZUMAB ADA
		<input type="checkbox"/>	X	X	X	X	X		X	X	X	X	X	X	X	X
3HR	:	<input type="checkbox"/>						X								

Mark the Not Collected box when the time point was not able to be collected.

For Labcorp Use Only															
Employee Visa	Tube Count				Validation	Internal Comments:									
	Amb	Frz	Refrig	Slides											

WHITE COPY- LABCORP

PINK COPY-INVESTIGATOR

«Bar_req» U	«Label_6» 211285	ADDITIONAL TESTING IS NOT ALLOWED PLEASE DO NOT RETURN EMPTY CONTAINERS TO LABCORP.	«Bar_req» CS 220414
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Labcorp Central Laboratory Services S.à.r.l.
Rue Moïse-Marcinhes 7
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Tel: 0041 58 822 7901
Fax: 0041 58 822 7521

Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

VISIT: RETEST

*Return this page
with Samples*

Laboratory Requisition Form

Page 3 of 3
2-part
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

Patient Number

Collection Date

Day	Month	Year
Complete month field in English (Example: 01 JAN 2001)		

OPTIONAL TESTING - Please mark the box(es) or to ensure proper ordering of optional test(s)!
If you fail to mark the checkbox, testing may be ordered per Labcorp policy without investigator notification.

<input type="checkbox"/>	SM1 BIOMARKER BLOOD and SM1 BIOMARKER BLOOD COLL D/T	<input type="checkbox"/>	SM2 BIOMARKER PLASMA and SM2 BIOMARKER PLASMA COLL D/T	<input type="checkbox"/>	SM3 SERUM PERTU/TRASTU PK PRE and SM3 SERUM P/T PK PRE COLL D/T
<input type="checkbox"/>	SM4 PLASMA RHUPH20 ADA PRE and SM4 PLS RHU ADAPRE COLL D/T	<input type="checkbox"/>	SM5 SERUM PERTUZUMAB ADA PRE and SM5 SER PERTU ADAPRE COLL D/T	<input type="checkbox"/>	SM6 SERUM TRASTUZUMAB ADA PRE and SM6 SER TRAS ADAPRE COLL D/T
<input type="checkbox"/>	SM7 PLASMA GIREDESTRANT PK PRE and SM7 PLS GIRED PKPRE COLL D/T	<input type="checkbox"/>	SM8 PLASMA GIREDESTRANT PK 3HR and SM8 PLS GIRED PK3HR COLL D/T	<input type="checkbox"/>	SM9 RBR BLOOD and SM9 RBR BLOOD COLL D/T
<input type="checkbox"/>	SM10 WGS/WES BLOOD and SM10 WGS/WES BLOOD COLL D/T	<input type="checkbox"/>	SM12 PLASMA RHUPH20 ADA and SM12 PLASMA RHU ADA COLL D/T	<input type="checkbox"/>	SM13 SERUM PERTUZUMAB ADA and SM13 SERUM PERTU ADA COLL D/T
<input type="checkbox"/>	SM11 SERUM PERTU/TRASTU PK and SM11 SERUM P/T PK COLL D/T	<input type="checkbox"/>	SM14 SERUM TRASTUZUMAB ADA and SM14 SERUM TRASTU ADA COLL D/T		

Comments:

For Labcorp Use Only

Employee Visa	Tube Count				Validation	Internal Comments:
	Amb	Frz	Refrig	Slides		

WHITE COPY- LABCORP

PINK COPY-INVESTIGATOR

«Bar_req» U	«Label_6» 211285	ADDITIONAL TESTING IS NOT ALLOWED PLEASE DO NOT RETURN EMPTY CONTAINERS TO LABCORP.	«Bar_req» APN 220830
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Labcorp Central Laboratory Services S.à.r.l.
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Tel: 0041 58 822 7901
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Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

Page 1 of 3
2-part

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

VISIT: RETEST WITHOUT WGS/WES

DO NOT RETURN THIS PAGE

Testing For This Visit			
Please refer to the Laboratory Manual for detailed sample collection, preparation, and handling instructions.			
Associated Test Group(s)	Draw Container	Return Container	Shipment Condition
SM1 BIOMARKER BLOOD*	1x 6.0 mL lavender top EDTA tube		Frozen
SM2 BIOMARKER PLASMA *	2x 10.0 mL lavender top EDTA tubes	2x Corning cryovials	Frozen
SM3 SERUM PERTU/TRASTU PK PRE *	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM4 PLASMA RHUPH20 ADA PRE*	1x 2.0 mL lavender top K3 EDTA tube	1x cryovial	Frozen
SM5 SERUM PERTUZUMAB ADA PRE *	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM6 SERUM TRASTUZUMAB ADA PRE *	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM7 PLASMA GIREDESTRANT PK PRE *	1x 3.0 mL lavender top EDTA tube	1x cryovial	Frozen
SM8 PLASMA GIREDESTRANT PK 3HR *	1x 3.0 mL lavender top EDTA tube	1x cryovial	Frozen
SM9 RBR BLOOD *	1x 6.0 mL lavender top EDTA tube		Frozen
SM11 SERUM PERTU/TRASTU PK*	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM12 PLASMA RHUPH20 ADA*	1x 2.0 mL lavender top K3 EDTA tube	1x cryovial	Frozen
SM13 SERUM PERTUZUMAB ADA*	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen
SM14 SERUM TRASTUZUMAB ADA*	1x 3.5 mL gold top serum separation tube	1x cryovial	Frozen

*Optional

This kit can be used:

- to collect Biomarker Blood or RBR Blood at any time during the study in case missed during Cycle 1 Day 1 in Maintenance Therapy phase.
- for repeat or follow-up testing .
- to recollect analyses at any time during the trial or
- to substitute for any kit, if you do not have the appropriate kit in stock. If so, please cross through "Retest" and write the visit name on the requisition form.

Make sure that you order all tests required for the visit being performed.

No NCR
T-5

«Label_6»
211285

Keep on file for your records. DO NOT return to Labcorp.

«Bar_req»
APN 220830



Labcorp Central Laboratory Services S.à.r.l.
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*Return this page
with Samples*

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

Page 2 of 3
2-part

Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

VISIT: RETEST WITHOUT WGS/WES

SUBJECT/PATIENT INFORMATION

Patient Number

Birthdate
Complete year **01 JAN**

Sex Male Female

COLLECTION INFORMATION

Collection Date
Complete month field in English
(Example: 01 JAN 2001)

Collection Time
(Record Midnight as 23:59) **:**

THIS SECTION TO BE COMPLETED BY SITE PERSONNEL ONLY

Requisition Completed by

Full name in capital letters

Phone number

Of the person completing the requisition

Collection
Date
(DD-MMM-
YYYY)

Collection Time
(24 hr clock)

:

Not
Collected

SM1 BIOMARKER BLOOD	SM2 BIOMARKER PLASMA	SM3 SERUM PERTU/TRASTU PK PRE	SM4 PLASMA RHUPH20 ADA PRE	SM5 SERUM PERTUZUMAB ADA PRE	SM6 SERUM TRASTUZUMAB ADA PRE	SM7 PLASMA GIRDESTRANT PK PRE	SM8 PLASMA GIRDESTRANT PK PRE	SM9 RBR BLOOD	SM11 SERUM PERTU/TRASTU PK PRE	SM12 PLASMA RHUPH20 ADA	SM13 SERUM PERTUZUMAB ADA	SM14 SERUM TRASTUZUMAB ADA
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				X	X	X	X	X		X	X	X	X
3HR			:	<input type="checkbox"/>						X			

Mark the Not Collected box when the time point was not able to be collected.

For Labcorp Use Only

Employee Visa	Tube Count				Validation	Internal Comments:
	Amb	Frz	Refrig	Slides		

WHITE COPY- LABCORP

PINK COPY-INVESTIGATOR

«Bar_req» T-5	«Label_6» 211285	ADDITIONAL TESTING IS NOT ALLOWED PLEASE DO NOT RETURN EMPTY CONTAINERS TO LABCORP.	«Bar_req» CS 220414
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Labcorp Central Laboratory Services S.à.r.l.
Rue Moïse-Marcinhes 7
1217 Meyrin Geneva Switzerland
Tel: 0041 58 822 7901
Fax: 0041 58 822 7521

Accession No.
«Requisition_n»

THE ACCESSION NUMBER IS THE
REFERENCE NUMBER FOR
COMMUNICATION WITH LABCORP.

«Bar_req»

VISIT: RETEST WITHOUT WGS/WES

*Return this page
with Samples*

Laboratory Requisition Form
Roche Products Limited
Protocol: WO43571
Investigator : «Inv_n»

Page 3 of 3
2-part

Patient Number

Collection Date

Day	Month	Year
Complete month field in English (Example: 01 JAN 2001)		

OPTIONAL TESTING - Please mark the box(es) or to ensure proper ordering of optional test(s)!
If you fail to mark the checkbox, testing may be ordered per Labcorp policy without investigator notification.

<input type="checkbox"/>	SM1 BIOMARKER BLOOD and SM1 BIOMARKER BLOOD COLL D/T	<input type="checkbox"/>	SM2 BIOMARKER PLASMA and SM2 BIOMARKER PLASMA COLL D/T	<input type="checkbox"/>	SM3 SERUM PERTU/TRASTU PK PRE and SM3 SERUM P/T PK PRE COLL D/T
<input type="checkbox"/>	SM4 PLASMA RHUPH20 ADA PRE and SM4 PLS RHU ADAPRE COLL D/T	<input type="checkbox"/>	SM5 SERUM PERTUZUMAB ADA PRE and SM5 SER PERTU ADAPRE COLL D/T	<input type="checkbox"/>	SM6 SERUM TRASTUZUMAB ADA PRE and SM6 SER TRAS ADAPRE COLL D/T
<input type="checkbox"/>	SM7 PLASMA GIREDESTRANT PK PRE and SM7 PLS GIRED PKPRE COLL D/T	<input type="checkbox"/>	SM8 PLASMA GIREDESTRANT PK 3HR and SM8 PLS GIRED PK3HR COLL D/T	<input type="checkbox"/>	SM9 RBR BLOOD and SM9 RBR BLOOD COLL D/T
<input type="checkbox"/>	SM11 SERUM PERTU/TRASTU PK and SM11 SERUM P/T PK COLL D/T	<input type="checkbox"/>	SM12 PLASMA RHUPH20 ADA and SM12 PLASMA RHU ADA COLL D/T	<input type="checkbox"/>	SM13 SERUM PERTUZUMAB ADA and SM13 SERUM PERTU ADA COLL D/T
<input type="checkbox"/>	SM14 SERUM TRASTUZUMAB ADA and SM14 SERUM TRASTU ADA COLL D/T				

Comments:

For Labcorp Use Only

Employee Visa	Tube Count				Validation	Internal Comments:
	Amb	Frz	Refrig	Slides		

WHITE COPY- LABCORP

PINK COPY-INVESTIGATOR

«Bar_req» T-5	«Label_6» 211285	ADDITIONAL TESTING IS NOT ALLOWED PLEASE DO NOT RETURN EMPTY CONTAINERS TO LABCORP.	«Bar_req» CS 220414
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SECTION BREAK

General Information for Packaging and Shipping



Courier
contact
information

Good shipping and packaging procedures are crucial for keeping the samples safe.

Please read carefully all the instructions and tips to ensure you package and ship your samples safely, safeguarding they reach their destination undamaged.

- To comply with international cargo rules and regulations, promote safety and optimize efficient operations, all Labcorp CLS shipping material is designed in accordance with IATA regulations.
- Air waybills and shipping labels may only be used one time.
- Material Safety Data Sheets can be accessed at the following website: covancesearch.complyplus.com



MSDS

Courier Pick-up

- Prior to shipping your first specimens, we recommend that you call the courier to define your site as a new pickup location for shipments to Labcorp CLS. This will facilitate the process when you are ready for your first shipment.
- Labcorp CLS will be billed directly for all transportation costs.
- Please be sure to inquire about your local service schedules and the latest time of day that you can call to arrange for a pick-up. Timely pick-ups will ensure samples are shipped within stability for testing.

Shipping boxes (Countries except Japan when BML takes care of the sample pick-up)

- Containers must be securely packed in their shipping box. Please check by gently shaking the box after packaging. If the containers are loose, repack the box by filling the empty spaces with paper.

Samples not collected the same day of collection

While most samples are specified to be shipped day of collection, we realize there are times when circumstances do not permit this to occur.

- Late afternoon sample collection after last call-in or pick-up availability for courier service
- Dry ice may not be available the same day as frozen sample collection
- Pick-up is missed by courier service
- In the event that samples cannot be shipped the day of collection, they should be stored under the condition they are to be shipped and then be shipped the very next day of availability.



AMBIENT

Samples should remain at ambient temperature – Do not refrigerate



REFRIGERATED

Samples should remain between 2°C and 8°C



FROZEN

Samples should remain frozen at the appropriate temperature

For Latin America, Australia, New Zealand and Asia (except Japan):

When contacting courier, also inquire about local export requirements.



General Information for Packaging and Shipping



Packaging and shipping videos

Consolidating your sample shipments is a way to save you and your staff time by reducing the number of shipping cartons prepared for shipment to Labcorp. Your sponsor also benefits by reduced transportation cost for protocols.

Key Considerations

- Send samples for more than one patient and/or more than one sponsor or protocol in a single shipment
- Always consolidate patient sample shipments by condition: ambient, refrigerated, or frozen
- Be sure each patient's samples and the completed requisition for that patient are packaged together in their own Specimen Collection Bag, by shipping condition
- The Ambient shipping box will hold 2 to 4 lab kits containing ambient samples
- The Frozen shipping box will hold 1 to 2 Specimen Collection Bags of samples per frozen shipment
- Be sure to allow ample space for dry ice in your frozen shipments as you will need 3 kg of dry ice per shipment (2 Kg for North America) when using Labcorp supplied packaging. Use of courier supplied packaging may require more dry ice. Please follow your courier recommendation for the amount of dry ice to use
- Use the appropriate air waybill depending on sample condition (ambient/refrigerated or frozen)
- Please ensure the outer packaging used for transport of any Biological Substance, Category B material is marked and labeled according to the ICAO/IATA requirements

Patient samples can only be shipped back to Labcorp with the appropriate outer carton.



Contact us to inquire about packaging designed to send large numbers of samples per shipment if you are participating in a study with high daily patient volume.



General Information Related To The Transport Of Your Samples

For Europe, Middle East And Africa

We strongly recommend that you contact your local courier office, for TNT and Marken, or the DHL EKAS Team, a week before the first patient is due to enter the study in order to ensure that everything is settled regarding sample pick-up.

The shipping documentation enclosed as example in this manual will help you to fill in the DHL, TNT and Marken shipping documents.

Should your site be dealing with another transportation company, please follow the instructions given when the pick-up is requested or at the moment of the pick-up.

For TNT shipments when calling the courier for a pick-up, please mention that your package is a diagnostic shipment for Labcorp Central Laboratory Services (Geneva, Switzerland) on a "Receiver pays" basis.

Some Local TNT offices may require investigation centers to have a site specific account number. Please check when first contacting your TNT local station if your site should need such an account number. If so, please follow their instructions and once you have the number, write it down, next to the courier's phone number, as the account number must be quoted each time you call for a pick-up.

For DHL Shipments please contact the DHL Ekas Team as per courier arrangements provided.

Country specific information

Israel:

Labcorp Central Laboratory Services does not provide airway bills to sites located in Israel. All investigators are requested to fill in any additional documents which could be requested by the courier. Shipping boxes are also provided by the courier at the time it performs the pick-up. Please specify whether your samples are ambient and/or frozen, so the appropriate boxes are provided.

South Africa:

Shipping boxes and documents are provided by the courier at the time it performs the pick-up. Please specify whether your samples are ambient and/or frozen, so the appropriate materials are provided.

Specific Information For The Samples Pick-Up

For Europe, Middle East And Africa

Your study has standard pick-up only (Monday through Friday) except if otherwise specified. If delivery period to Labcorp Central Laboratory Services is 48 hours, please do not send any samples on Fridays.

Please note that your manual does not contain site specific pick-up information. Labcorp Central Laboratory Services will supply the relevant details by fax within 7 days. Should you need them earlier due to a patient visit or should you find that you have still not received the information after this delay, please contact Labcorp Central Laboratory Services using the toll free number supplied.

Should you identify any problems in relation to the courier, please contact Labcorp Central Laboratory Services immediately.

Packaging Procedures - All Countries

Ambient - Biological Substance, Category B



Notify your courier of your shipment!

Packaging
and shipping
videos



1. Insert the tube(s) into the Specimen Collection Bag containing an absorbent pack. Place bag on flat surface to minimize wrinkles, especially at adhesive sealing area. Remove tape liner to expose adhesive. Fold along bag opening so star is inside of box shape. Press from center to edge to seal.



3. Take a Gel Pak and fill it to the indicator line with cool tap water. Seal the bag.

2. Fold the white copy of the completed requisition form and place it into the pocket on the reverse side of the Specimen Collection Bag.
The bar code must be visible.



5. Place the Specimen Collection Bag on top of the Gel Pak. Wrap the Gel Pak around the Specimen Collection Bag, sandwiching the specimens in the middle.

Do not insert the specimen containers directly into the Gel Pak! Important: Ensure the hematology sample is placed in the fold of the Gel Pak.

4. Lightly press the absorbent pack to expel its contents. Massage the bag until water has been absorbed and a gel material has formed. Expel the air from the Gel Pak and reseal.

6. Place the Gel Pak into the white kit box. Do NOT ship sharps to Labcorp.

Packaging Procedures - All Countries

Ambient - Biological Substance, Category B



Packaging
and shipping
videos



7. Insert the kit into the zip bag.

8. Place the zip bag into the shipping carton. Fill empty spaces with cushioning material (i.e. paper). **Note:** If the kit box is too large to place in the ambient shipping carton, wrap a rubberband around the Gel Pak. Place the Gel Pak containing the specimen collection bag inside the large zip bag.



9. Seal the shipping carton securely. Affix the label with your address on the box as indicated on the picture above.

Note: Your shipment may be delayed if the label is not affixed to the box.

10. **US domestic shipments:** Complete and affix the airway bill to the designated spot on the box.

Rest of world: Insert the shipping documentation into the transparent pouch ensuring that the airway bill remains visible. Affix the pouch to the cardboard box on the "Place airway bill here" section.

Gel Pak Safety Tips



The appropriate use of Gel Pak during shipment is essential in preserving samples and maintaining a consistent temperature.

Packaging
and shipping
videos



Please take the specimen collection bag



Wrap the Gel Pak around the specimen



Do not put the specimen collection bag



Do Not put the tubes directly into the Gel Pak.

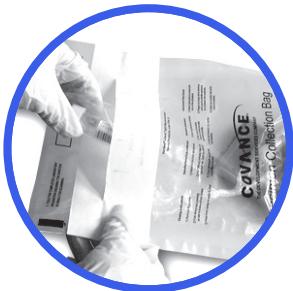
Packaging Procedures - All Countries

Frozen - Biological Substance, Category B



Notify your courier of your shipment! Ship no more than 120 mL in a Specimen Collection bag and no more than two Specimen Collection bags per 2.0 kilograms of dry ice!

Packaging
and shipping
videos



1. Insert the tube(s) into the Specimen Collection Bag containing an absorbent pack. Place bag on flat surface to minimize wrinkles, especially at adhesive sealing area. Remove tape liner to expose adhesive. Fold along bag opening so star is inside of box shape. Press from center to edge to seal.



2. Fold the white copy of the completed requisition form and place it into the pocket on the reverse side of the Specimen Collection Bag.
The bar code must be visible.



3. Fill half of the styrofoam container with dry ice and insert the Specimen Collection Bag(s). Fill the rest of the styrofoam container with dry ice.



4. Replace the styrofoam lid.



5. Seal the shipping carton securely. Affix the label with your address on the box as indicated on the picture above. **Note: Your shipment may be delayed if the label is not affixed to the box.**



6. **US domestic shipments:** Complete and affix the waybill to the designated spot on the box.
Rest of world: Insert the shipping documentation into the transparent pouch ensuring that the waybill remains visible. Affix the pouch to the cardboard box on the "Place waybill here" section.



Shipping Documents

Are Provided In Large Color-Coded Envelopes

The protocol specific shipping documents are provided in the appropriate envelope with the start-up material.
They are not automatically resupplied.

Order additional envelopes by using the web address/link <https://drugdevelopment.labcorp.com/kitordering> or by contacting Labcorp CLS.

Ambient or Refrigerated Shipments

Shipping Documents for Ambient or Refrigerated Specimens

The enclosed shipping documents must only be used when shipping ambient (room temperature) or refrigerated specimens to Covance CLS. It is very important that the enclosed shipping documents are applied to ambient or refrigerated shipping boxes. You CANNOT use an ambient shipping document for a frozen (dry ice) shipment.

Don't forget to:
1. Apply your investigator's address label
2. Complete the enclosed shipping document(s) and affix to the shipping box

* Refer to your Covance manual for detailed shipping instructions

Documentos para Remessa de Amostras à Temperatura Ambiente ou Refrigeradas*

Os documentos para remessa ameaços devem ser usados apenas para a remessa de amostras à temperatura ambiente ou refrigeradas para a Covance CLS. É muito importante que os documentos para remessa anexos sejam aplicados às caixas para remessa de material à temperatura ambiente ou refrigerado. Você NÃO PODE usar um documento para remessa de material à temperatura ambiente para enviar material congelado (gelo seco).

Não esqueça de:

1. Afixar a etiqueta com o endereço do seu investigador
2. Preencher o(s) documento(s) de remessa anexo(s) e afixa-lo(s) à caixa de remessa.

* Consulte seu manual da Covance para obter instruções detalhadas de remessa.

Document Enchant

Les documents de transport d'échantillons doivent être utilisés pour la remise de matériaux à température ambiante ou réfrigérés. Il est très important que les documents de transport soient appliqués aux boîtes de transport pour échantillons. NE POUVEZ PAS utiliser un envoi congelé (glace sèche).

N'oubliez pas de :

1. Appliquer votre étiquette
2. Compléter le (les) document(s) de transport et coller sur la boîte de transport.

* Pour les détails sur les instructions d'envoi, référez-vous au manuel Covance.

Document Mues R

Los documentos de embalaje para enviar muestras cuando se envíen muestras a temperatura ambiente. Es importante que los documentos se adhieran a las cajas de envío para usar un documento de envío congelado (hielo seco).

No olvide:
1. Aplicar la etiqueta con su dirección.
2. Completar los documentos de envío y pegarlos en la caja de envío.

* Refiérase a su manual de instrucciones para el envío.



Documentos para Remessa de Amostras Congeladas*

Os documentos para remessa anexos devem ser usados apenas para a remessa de amostras congeladas (gelo seco). É muito importante que os documentos para remessa anexos sejam aplicados às caixas para remessa de material congelado. Você NÃO PODE usar um documento para remessa de material congelado para enviar material à temperatura ambiente. O símbolo mostrado acima e em sua caixa de remessa indica que ela é destinada à remessa de materiais congelados.

Não esqueça de:

1. Afixar a etiqueta com o endereço do seu investigador
2. Preencher o(s) documento(s) de remessa anexo(s) e afixa-lo(s) à caixa de remessa.

Shipping Documents for Frozen Specimens

The enclosed shipping documents must only be used when shipping frozen (dry ice) specimens. It is very important that the enclosed shipping documents are applied to frozen shipping boxes. You CANNOT use a frozen shipping document for an ambient shipment. The symbol above and on your shipping box indicates it is designed for frozen shipments.

Don't forget to:
1. Apply your investigator's address label
2. Complete the enclosed shipping document(s) and affix to the shipping box

* Refer to your Covance manual for detailed shipping instructions

Document Enchant

Les documents de transport d'échantillons doivent être utilisés pour la remise de matériaux congelés. Il est très important que les documents de transport soient appliqués aux boîtes de transport pour échantillons.

N'oubliez pas de :

1. Appliquer votre étiquette
2. Compléter le (les) document(s) de transport et coller sur la boîte de transport.

* Pour les détails sur les instructions d'envoi, référez-vous à votre manuel Covance.

Document muest

Los documentos de embalaje para enviar muestras cuando se envíen muestras a temperatura ambiente. Es importante que los documentos se adhieran a las cajas de envío para usar un documento de envío congelado.

No olvide:
1. Aplicar la etiqueta con su dirección.
2. Completar los documentos de envío y pegarlos en la caja de envío.

* Refiérase a su manual de instrucciones para el envío.

Frozen Shipments



Documentos para Remessa de Amostras Congeladas*

Os documentos para remessa anexos devem ser usados apenas para a remessa de amostras congeladas (gelo seco). É muito importante que os documentos para remessa anexos sejam aplicados às caixas para remessa de material congelado. Você NÃO PODE usar um documento para remessa de material congelado para enviar material à temperatura ambiente. O símbolo mostrado acima e em sua caixa de remessa indica que ela é destinada à remessa de materiais congelados.

Não esqueça de:

1. Afixar a etiqueta com o endereço do seu investigador
2. Preencher o(s) documento(s) de remessa anexo(s) e afixa-lo(s) à caixa de remessa.

Miscellaneous Shipments

Shipping Documents for Miscellaneous Dangerous Goods Specimens

The enclosed shipping documents and labels must only be used when shipping miscellaneous dangerous goods (e.g. infectious, excepted quantities, limited quantities, flammable, corrosives, radioactive, etc.) specimens to Covance CLS.

Don't forget to:

1. Apply required shipping labels (if required, the labels are enclosed in this envelope)
2. Complete the enclosed shipping document(s) and insert into the plastic pouch on the shipping box

* Refer to your Covance manual for detailed shipping instructions

Documentos para Remessa de Amostras de Materiais Perigosos Diversos *

Os documentos e etiquetas para remessa anexos devem ser usados apenas para a remessa de amostras de materiais perigosos diversos (p.e., materiais infeciosos, quantidades excepcionais, quantidades limitadas, líquidos inflamáveis, materiais corrosivos, radioativos, etc.) para a Covance CLS.

Não esqueça de:

1. Afixar as etiquetas de remessa requeridas (se necessário, as etiquetas são incluídas neste envelope)
2. Preencher o(s) documento(s) de remessa anexo(s) e de colá-lo(s) dentro da bolsa de plástico na caixa de remessa

* Consulte seu manual da Covance para obter instruções de remessa detalhadas.

Documents de Transport pour Echantillons de Matières Dangereuses Diverses

Les documents de transport et les étiquettes inclus doivent être utilisés uniquement lors d'envois de matières dangereuses diverses (par exemple : infectieuses, quantités exemplaires, quantités limitées, liquides inflammables, corrosifs, radioactifs, etc.) à Covance.

Ne olvide:

1. Aplicar las etiquetas de envío requeridas (si son requeridas, las etiquetas se incluyen en este sobre)
2. Completar el (los) documento(s) de envío y de los inserir dentro de la pochette en plástico en la caja de envío.

* Pour les détails sur les instructions d'envoi, référez-vous à votre manuel Covance.

Documentos de Embarque para Muestras Variadas de Materiales Peligrosos*

Los documentos y etiquetas de embarque incluidos solo se usarán cuando se envíen muestras variadas de materiales peligrosos (ejemplo: infecciosos, cantidades aceptadas, cantidades limitadas, líquidos inflamables, corrosivos, radioactivos, etc.) a Covance CLS.

No olvide:

1. Aplicar las etiquetas de embarque requeridas (si son requeridas, las etiquetas se incluyen en este sobre)
2. Completar los documentos de embarque incluidos e insertarlos en la bolsa plástica en la caja de envío.

* Refiérase a su manual de Covance CLS para instrucciones detalladas de embarque.

Versanddokumente für Verschiedene gefährliche Güter

Versanddokumente für Verschiedene gefährliche Güter

Die beigelegten Versanddokumente und Versandetiketten sollten nur für Sendungen von verschiedenen gefährlichen Gütern (z.B. infektiöse, „excepted quantities“, in beschränkten Mengen, entzündliche Flüssigkeiten, ätzende, radioaktive, usw...) an Covance CLS verwendet werden.

Nicht vergessen:

1. Aufzubringen die Etiketten der Remessa (wenn erforderlich, die Etiketten sind im Umschlag enthalten)
2. Beizulegen das Dokument(e) der Remessa (einschließlich der Etiketten) in die Plastiktasche in die Kiste

* Für ausführlichere Versandinstruktionen beziehen Sie bitte auf Ihr Covance Handbuch.

Documenti di trasporto per Campioni di Materie Pericolose Diverse

I documenti di trasporto e le etichette incluse devono essere utilizzate soltanto nel caso di spedizioni di materie pericolose diverse (esempio: campioni infettivi, quantità inaccettabili, quantità limitata, liquidi infiammabili, corrosivi, radioattivi ecc.) a Covance.

Non dimenticare di:

1. Attaccare le etichette per il trasporto richieste, le etichette per il trasporto saranno incluse nella busta)
2. Completare il (i) documento (i) di trasporto e inserire il(n) nell'apposita tasca di plastica sulla scatola di cartone

* Per ottenere maggiori dettagli sulle istruzioni per il trasporto, vogliate riferirvi al vostro manuale Covance.

The envelope with text in RED

contains your shipping documents for ambient, refrigerated or combo ambient-refrigerated specimens.

The envelope with text in BLUE

contains your shipping documents for frozen or combo ambient-frozen specimens.

The envelope with text in GREEN

contains your shipping documents for miscellaneous (including any special shipping documents not included in the two other envelopes) and/or dangerous goods specimens

Shipping Documents - Europe And Middle East

All Temperatures - Biological Substance, Category B

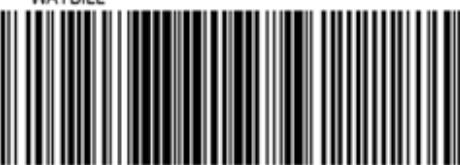
Medical Express Label

MEDICAL EXPRESS DHL 2014-04-01-10-00	WMX	
From:	Origin:	
Contact: _____		
To: Covance CLS S.A. Guy Zbinden, Dir. of Sample Handin rue Moise-Marches 7 1217 Meyrin/Geneva Switzerland	Contact: _____	
CH-GVA-GVA 1200		
C-RET-RDS	Day	Time
Ref:	Postage Weight	Price
	1.0 kg	1/1

WAYBILL



Contents: UN3373, Biological Substance, Category B




Waybill Doc Label

* ARCHIVE DOC *	Not to be attached to package	WMX	
Shipper:	Contact:		
Receiver: Covance CLS S.A. Guy Zbinden, Dir. of Sample Handin rue Moise-Marches 7 1217 Meyrin/Geneva Switzerland			
CH-GVA-GVA 1200			
Product Details: [Q] MEDICAL EXPRESS (64)	Features / Services (Service Code) Biological UN3373(HY) Data Staging 24/PW	DTP A/C:	
Payer Details: FRT A/C: 9551469/65		DTP A/C:	
Terms of Trade:			
Shipment Details:			
Ref:			
Custom Val: 5.00 USD			
Cost Decl Shpt Wgt (UOM) / Dim Wgt (UOM): 1.0 kg	Pieces 1		
Contents: UN3373, Biological Substance, Category B			
WAYBILL	Name (In Capital Letters)	Signature	Date (DD.MM.YYYY)
License Plates of pieces in shipment:			

- page 1 of 1 -

Refer to the content indicated under "Pack & Ship Instructions" to select the appropriate Airway bill for your samples (Ambient, Frozen, etc).

For MEDICAL EXPRESS LABEL:

Only attach **one shipping label, with 3 barcodes**, onto **one shipping box**.

For ARCHIVE DOC LABEL:

Place one copy into the plastic pouch that must be affixed on the shipping box with the Proforma Invoice copies
And kindly retain another copy (photocopy the waybill doc label or write the Air waybill manually) for your own reference.

PLEASE NOTE:

The DHL AWB is valid for 24 months as of their creation date. After that time, their reference number is no longer active in the DHL database, preventing the package to be inserted in the network for shipment.

We suggest that you review the DHL AWB documents you have on hand and discard any that were created more than 24 months ago. The created date can be found in the upper right hand corner of the document.

You can always order new DHL AWB via our website

(<https://drugdevelopment.labcorp.com/customers/investigators/order-a-kit.html>).

Have additional questions? Contact our Investigator Support team by using the number for your location that can be found

<https://invp.covance.com/ContactUs/contact-us.pdf>.

Shipping Documents - Europe And Middle East

All Temperatures - Biological Substance, Category B

MARKEN Time Critical Express

An MSAS Global Logistics company

ISO 9001
14001
GMS

International Waybill 1 POD

Note: The goods described below are accepted in apparent good order and condition (except where noted by shipper or noted below) for delivery to the stated consignee, subject to the standard tracing conditions set forth on the reverse side, which limit Marken's liability.

Shipper	Consignee	Reference
Reference	Telephone	Date A
Contact:	Contact	
Special Instructions		Packages
		Weight C Kgs
Contents		
FAA SECURITY ENDORSEMENT for shipments to via or originating from the USA. I certify that this shipment does not contain any unauthorised explosives, incendiaries, hazardous materials. I consent to a search of this shipment. I am aware that this endorsement and original signature, along with the shipping documents will be retained on file for at least 30 days.		
Charges at destination including Duty and Taxes to be paid by <input type="checkbox"/> Shipper <input type="checkbox"/> Consignee		
Received in good order and condition		
Signature _____ Date _____		
Print Name _____ Time _____		

Shippers Signature **B** Date **A**

Shippers Name **B** Date **A**

PHOTO ID Type

POD

Covance Central Laboratory Services Inc.

COMMERCIAL INVOICE

DATE OF EXPORTATION:	AIRWAY BILL NO.:																		
SHIPPER/EXPORTER: (complete name and address)	CONSIGNEE:																		
COUNTRY OF ULTIMATE DESTINATION: EPORT PREFERENCES:																			
<table border="1"> <thead> <tr> <th>MARKS & NUMBERS</th> <th># OF PAKGS</th> <th>COMPLETE DESCRIPTION OF GOODS</th> <th>ORG</th> <th>WEIGHT (LBS)</th> <th>QTY</th> <th>QTY UNIT</th> <th>UNIT VALUE (USD)</th> <th>TOTAL VALUE (USD)</th> </tr> </thead> <tbody> <tr> <td>E</td> <td>D</td> <td>F</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		MARKS & NUMBERS	# OF PAKGS	COMPLETE DESCRIPTION OF GOODS	ORG	WEIGHT (LBS)	QTY	QTY UNIT	UNIT VALUE (USD)	TOTAL VALUE (USD)	E	D	F						
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E	D	F																	
TOTALS: _____																			
I DECLARE ALL INFORMATION CONTAINED IN THIS INVOICE TO BE TRUE AND CORRECT.																			
SIGNATURE OF EXPORTER	(NAME AND TITLE)	DATE																	

B **A**

Marken will supply all sites with pre-printed airway bills. When shipping samples please ensure that you complete the following sections:

Information to be completed on day of collection:

- A** Date
- B** Name and/or signature
- C** Packages and weight
- D** Total weight. Mean estimated weight (average) of your parcel after sampling done:
0.8 Kg (ambient)
1.0 Kg (refrigerated)
- E** Number of boxes
- F** Quantity of Specimen collection Bags

Call your courier



Shipping Documents - Africa

All Temperatures

Marken will supply all sites with pre-printed airway bills. When shipping samples please ensure that you complete the following sections:

MARKEN Time Critical Express		INTERNATIONAL AIRWAY BILL																																														
		An MSAS Global Logistics company																																														
		ISO 9001 14001 OHSAS 18001																																														
		International Waybill 1 POD																																														
<p>Note The goods described below are accepted in apparent good order and condition (except where noted by shipper or noted below) for delivery to the stated consignee, subject to the standard trading conditions set forth on the reverse side, which limit Marken's liability.</p> <table border="1"> <tr> <td>Shipper</td> <td>Consignee</td> <td>Reference</td> </tr> <tr> <td>Reference</td> <td>Telephone</td> <td></td> </tr> <tr> <td>Contact</td> <td></td> <td></td> </tr> <tr> <td colspan="2">Special Instructions</td> <td>Contents</td> </tr> <tr> <td colspan="2"></td> <td>Value</td> </tr> <tr> <td colspan="2"></td> <td>Packages</td> </tr> <tr> <td colspan="2"></td> <td>Weight C Kgs</td> </tr> <tr> <td colspan="4"> <p>FAA SECURITY ENDORSEMENT for shipments to, via or originating from the USA. I certify that this shipment does not contain any unauthorised explosives, incendiaries, or hazardous materials. I consent to a search of this shipment. I am aware that this endorsement and original signature, along with other shipping documents will be retained on file for at least 30 days.</p> </td> </tr> <tr> <td colspan="4"> <p>Charges at destination including Duty and Taxes to be paid by <input type="checkbox"/> Shipper <input type="checkbox"/> Consignee <input type="checkbox"/></p> <p>Received in good order and condition POD</p> <table border="1"> <tr> <td>Signature</td> <td>Date</td> </tr> <tr> <td>Print Name</td> <td>Time</td> </tr> </table> </td> </tr> <tr> <td colspan="2">Shippers Signature B</td> <td colspan="2">Date A</td> </tr> <tr> <td colspan="2">Shippers Name</td> <td colspan="2"></td> </tr> <tr> <td colspan="2">PHOTO ID Type</td> <td colspan="2"></td> </tr> </table>				Shipper	Consignee	Reference	Reference	Telephone		Contact			Special Instructions		Contents			Value			Packages			Weight C Kgs	<p>FAA SECURITY ENDORSEMENT for shipments to, via or originating from the USA. I certify that this shipment does not contain any unauthorised explosives, incendiaries, or hazardous materials. I consent to a search of this shipment. I am aware that this endorsement and original signature, along with other shipping documents will be retained on file for at least 30 days.</p>				<p>Charges at destination including Duty and Taxes to be paid by <input type="checkbox"/> Shipper <input type="checkbox"/> Consignee <input type="checkbox"/></p> <p>Received in good order and condition POD</p> <table border="1"> <tr> <td>Signature</td> <td>Date</td> </tr> <tr> <td>Print Name</td> <td>Time</td> </tr> </table>				Signature	Date	Print Name	Time	Shippers Signature B		Date A		Shippers Name				PHOTO ID Type			
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Information to be completed on day of collection:

- A. Date
- B. Name and signature
- C. Packages and weight: please consign all your boxes under a same airway bill. Should you have two or more boxes, please enter the total number and total weight of all shipments on section "C" indicated in the example above.

Call Marken at phone number (27) 11 974 9798 / 1989 / 2647.

SECTION BREAK

4

Reference Ranges Alerts and Flags

There are no reference ranges/alerts and flags for this project.

SECTION BREAK

5

COLLEGE of AMERICAN
PATHOLOGISTS



CERTIFICATE OF ACCREDITATION

**Labcorp Central Laboratory Services Sarl
Meyrin-Geneva, Switzerland
Jean-Paul Lewest, MD**

CAP Number: 4658701
AU-ID: 1190700
CLIA Number: 99D2174908

The organization named above meets all applicable standards for accreditation and is hereby accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to **March 3, 2025** to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

(Signature)
Kathleen G. Beavis, MD, Accreditation Committee Chair

(Signature)
Emily Volk, MD, FCAP, President, College of American Pathologists

Current CAP certifications available at:
<https://drugdevelopment.labcorp.com/customers/investigators/accreditations-and-certifications.html>



CERTIFICATE OF ISO 15189 ACCREDITATION

Labcorp Central Laboratory Services S.a.r.l. Geneva, Switzerland

CAP # 4658701

The organization named above is granted this accreditation in accordance with the recognized International Standard ISO 15189:2012, Medical Laboratories – Requirements for quality and competence. This accreditation demonstrates competence for a defined scope and the operation of a laboratory quality management system.

Effective From October 22, 2022 through October 22, 2025

Handwritten signature of Gaurav Sharma.

Gaurav Sharma MD, FCAP
Chair, CAP 15189 Committee

The scope of this accreditation includes the Quality Management System and the disciplines of Anatomic Pathology, Chemistry, Flow Cytometry, Hematology, Immunology, Molecular Pathology and Urinalysis.

Dr. JEAN-PAUL LEWEST

Curriculum Vitae

Signature:



Date: 3-Feb-23

CONTACT

Professional address:

Labcorp Central Laboratory Services Sàrl
7, Moïse-Marcinhes
1217 Meyrin, Geneva
Switzerland

Tel: +41 58 822 7000
Fax: + 41 58 822 7584
E-mail : jean-paul.lewest@labcorp.com

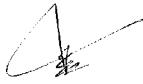
EDUCATION & QUALIFICATIONS

Higher education:

- 1982-1988** **Medical School (PCEM-DCEM) and Clinical and Therapeutic Synthesis Certificate (CSCT) at Faculty of Medicine, University of Nice-Sophia Antipolis (UNS), France**
- 1994** **Doctor of Medicine, MD State Degree at Faculty of Medicine Pitié-Salpêtrière, University Pierre & Marie Curie Paris 6 (UPMC), France**
- 1988-1994** **Specialist medical training in Medical Biology, Specialized Studies Degree (DES), University Pierre & Marie Curie Paris 6 (UPMC), France**
Internship and Residency in the Teaching Hospitals of Paris and Ile de France Region (AIHP). Certificates in Clinical Biochemistry, Parasitology-Mycology, Haematology, Immunology, and Bacteriology-Virology
12-month Military Service duty (Health Service of French Army Forces)
- 1998-1999** **University Degree in Infectious Diseases and Anti-infective Agents Chemotherapy. Faculty of Medicine, University of Claude Bernard, Lyon 1 (UCBL), France**

Dr. JEAN-PAUL LEWEST

Curriculum Vitae

Signature: 

Date: 3-Feb-23

PROFESSIONAL EXPERIENCE

Nov2009- present Labcorp Drug Development (formerly Covance), Geneva Switzerland

Current position: **Director Medical Affairs and Medical Director CLS* for Europe (CAP certificate holder) Staff Pathologist**

Duties: The Director Medical Affairs provides medical consultative and interpretive support to Labcorp Central Laboratory Services and its internal and external customers. The incumbent is responsible for medical decision-making and consultation that relate to laboratory services and clinical trials. Additional responsibilities include consulting with Quality Assurance, Safety Committee, Investigator Site Support, Project Management, Sponsors, and Investigators.

The Medical Director is the Geneva laboratory license holder and the College of American Pathologists (CAP) certificate holder. In this capacity the Medical Director provides a regulatory oversight of the laboratory activities. It encompasses medical, scientific and regulatory oversight of all areas of the laboratory including Clinical Chemistry, Haematology, Immunology, Microbiology, Histology, Flow Cytometry and Molecular Pathology. He/she is accountable for meeting requirements and retaining both CAP LAP, CLIA and ISO 15189:2012 accreditation. The Medical Director is a member of the Laboratory Senior Management team and a member of the Labcorp Geneva Executive Leadership Team.

The incumbent is the primary contact with local and federal health authorities (Cantonal Pharmacist, FOPH) for obtaining appropriate authorizations for use of controlled narcotics for scientific research purpose and use of organisms in contained environment.

*CLS – the Central Laboratory Services entity of Labcorp drug development

Nov2004- Oct2009 Labcorp Development (Asia) Pte.Ltd (formerly Covance Asia Pte.Ltd), Central Laboratory Services, Singapore

Position held: **-Director of Laboratory and Medical Director (CAP certificate holder 2006-2009)**

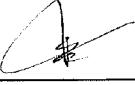
Area of expertise: Centralized Clinical Laboratory devoted to laboratory testing for pharmaceutical clinical trials. Covance Central Laboratory Services, Singapore consists of 3 Departments namely:
• Laboratory Pre-analytical services & Specimen Management
• Laboratory Operations
• Site Support Services

The Director of Laboratory is administratively responsible for all three Departments.

The Director of laboratory is licensed by the Ministry of Health and accredited by the College of American Pathologists (CAP). The laboratory also holds certification by the NGSP (National

Dr. JEAN-PAUL LEWEST

Curriculum Vitae

Signature: 

Date: 3-Feb-23

Glycated Hemoglobin Standardization Program) and the Lipid Standardization Program (LSP) of the Centers for Disease Control and Prevention–National Heart, Lung and Blood Institute (CDC-NHLBI) in the USA.

Duties:

- Member of the Senior Laboratory management team
- Ministry of Health's Private Hospitals and Medical Clinics Act License holder.
- College of American Pathologists accreditation certificate holder.
- Medical, scientific and regulatory supervision of all areas of the laboratory including Clinical Chemistry, Haematology, Immunology, Microbiology Flow Cytometry and Molecular Pathology.
- Identify and develop in coordination with Global Laboratory Heads new tests validation projects for the laboratory's testing departments.
- Accountable for Laboratory testing services quality management plan implementation and delivery.

2006-2009 Experience& Key achievements

- Led Covance Singapore Laboratory to and retained College of American Pathologists accreditation
- Supported Covance Shanghai Laboratory to College of American Pathologists accreditation (2009)
- Executed successfully a three-year multiplatform implementation plan including Laboratory expansion from 150 to 1600 sqm and a PCR laboratory renovation.
- Obtained license from MOH to provide services in Chemical Pathology, Haematology, Immunology, Medical Microbiology and HIV testing and license from Ministry of Home Affairs (Central Narcotic Bureau) to provide toxicology services as a Research Facility.
- Covance Singapore Laboratory awarded best Central Laboratory provider 2006 by Frost & Sullivan
- Plenary session Presentation at 9th Shanghai International Forum on Biotechnology& Pharmaceutical industry, July 2007, Shanghai "Understanding Across Laboratory Bias"
- Execution of fully combinable consolidated testing platform of Singapore for servicing the Asia Pacific rim including but not limited to Flow-cytometry, Coagulation, Toxicology testing, Microbiology, Protein Electrophoresis, TB Biomarker, Real time PCR and PBMC.
- Developed and led a team of 26 Scientists (Singapore) and 8 Scientists (Shanghai)
- Provided ad hoc Medical Affairs support to Asia Pacific CCLS group.

May-Nov2004 Labcorp Drug Development (formerly Covance), Geneva Switzerland

Position held: -Director of Laboratory /Laboratory Manager-General Laboratory

Area of expertise: Centralized Clinical Laboratory devoted to laboratory testing for pharmaceutical clinical trials.

Duties:

- Member of the Senior Laboratory management team
- Completed a 6-month training period and preparation prior to an international assignment to Covance CLS Asia Pte Ltd Singapore
- Reviewed of all company's specific processes in collaboration with the senior staff management team at a global level.

Dr. JEAN-PAUL LEWEST

Curriculum Vitae

Signature: 

Date: 3-Feb-23

2002-2004 Claymon Laboratories Limited, Dublin 18, Ireland (International assignment, LMM (Biomnis) group)

Position held: **-Director of Laboratory services /Pathologist**

Area of expertise:

- . Hematology (e.g. PhaselV /Pharmacovigilance monitoring for Clozapine related agranulocytosis), Blood grouping, Blood Parasitology, Haemostasis assays in development.
- . Drugs of Abuse: Toxicology Screening for Irish Prison Services and Methadone Clinics and occupational health centres.
- . Endocrinology and Clinical Chemistry service for Hospitals and Private Companies
- . Microbiology for Hospitals

Duties:

- . Member of the senior management team
- . Providing a consultation services to doctors and clients/patients
- . Maintaining and Improving quality standards of Claymon Laboratories
- . Improving efficiency, cost effectiveness, workflow management and turnaround time in the laboratory
- . Assays development

1997-2004 Biomnis-Eurofins (formerly Laboratoire Marcel Mérieux) Lyon, France

Position held: **Department of Clinical Pathology (1999-2002 and 2003-2004)**
-Consultant pathologist/Associate-Director -

Department of Clinical Pathology is located in the multidisciplinary private hospital-based clinical laboratory providing services to the Clinique du Tonkin, a 300-Bed private hospital, in Villeurbanne-Lyon, France

Area of expertise:

- . Haematology, haemostasis, clinical chemistry, transfusion, endocrinology, therapeutic drug monitoring, microbiology, and blood parasitology
- . Central Laboratory for Clinical Research Organization MC BIO and ICON (Phase III and IV studies)

Duties:

- . Supervision and training of a day and night team of 21 Medical Laboratory Scientists, 3 Seniors Medical Scientists and a Client Services Dept (4 Medical Assistants) and 4 Nurses
- . Total Quality Assurance enhancement and ISO 17025 accreditation
- . Consultation service to clinicians and discussion of results
- . Writing of technical manuals and information booklets/letters to doctors
- . Participation in on-call duties (transfusion and bacteriology emergency services) of the laboratory
- . Performance of various procedures within the Tonkin Clinic: arterial puncture, phlebotomies, capillary sampling, bleeding time, Bone marrow film
- . Method platform selections and assays development.

Dr. JEAN-PAUL LEWEST

Curriculum Vitae

Signature:



Date: 3-Feb-23

Position held: **Department of Virology and Serology (1997-1999)**
-Consultant pathologist/Associate Director

- . Supervision and medical support of the team (8 Laboratory Scientists)
- . Organization of the automated viral and bacterial serology unit (Hepatitis viruses, AIDS, Herpes, Rubella, Chlamydia) and of the specific protein assay department (interpretation of protein profiles)
- . Writing of quality procedures and method summaries.
- . Consultation service to clinicians/and laboratory clients

1994-1997 Laboratoire LABS (specialty laboratory), Nice, France

Position held: **-Associate Director -**

Responsible for the centralized immunoassay department of a group of 15 laboratories (SCM Midilab, Nice, France)

- . Immunoassay activities, including viral, parasitic and bacterial serology, tumour markers assays, hormones (thyroid, fertility), and therapeutic drug monitoring.
- . Evaluation of automated immunoassays and immunoassay methods on behalf of Midilab
- . Representative of the Midilab group in Business/Scientific Meetings
- . Supervision and Support of a small team of 3 Lab Technicians
- . Computerised cost control of laboratory testing.

1993-1994 Academic research project in the department of Medical Microbiology of Faculty of Medicine Pitié –Salpêtrière, University of Paris VI. Medicine Thesis title: «Characterization of Quinolones resistance in Enterobacteriaceae. A study of 188 strains isolated at Pitié-Salpêtrière Hospital » Faculty of Medicine Pitié-Salpêtrière, University Pierre and Marie Curie Paris 6, France (UPMC)

REGISTRATION /AFFILIATION

Authorised as Laboratory Managing Director by the Director General for Health (Geneva Canton, Switzerland)

Past Registration with the French National Medical Council as Specialist in Clinical Pathology (Medical Biology)

Past Registration with the Singapore Ministry of Health: Clinical Laboratory License Holder (PHMC Act)

Past Registration with the Medical Council of Ireland as a Medical Practitioner

ARRÊTÉ

autorisant Covance Central Laboratory Services Sàrl à exploiter un laboratoire destiné à analyser du matériel humain, sis 7, rue Moïse-Marcinhes, 1217 Meyrin, Genève

du 28 juillet 2017

LE DÉPARTEMENT DE L'EMPLOI, DES AFFAIRES SOCIALES ET DE LA SANTÉ

vu les dispositions légales en vigueur;

vu l'arrêté du Département de l'emploi, des affaires sociales et de la santé, du 9 décembre 2016, autorisant Covance Central Laboratory Services SA à exploiter un laboratoire destiné à analyser du matériel humain, sis 7, rue Moïse-Marcinhes, 1217 Meyrin, Genève;

vu les pièces constitutives du dossier;

vu l'annonce du départ de la directrice technique du laboratoire et son remplacement;

vu l'inspection des locaux par le pharmacien cantonal en date du 5 novembre 2014;

vu le préavis favorable du pharmacien cantonal, du 25 juillet 2017,

ARRÊTÉ :

Covance Central Laboratory Services Sàrl est autorisée à exploiter un laboratoire destiné à analyser du matériel humain, sis 7, rue Moïse-Marcinhes, 1217 Meyrin, Genève, conformément aux lois, règlements et instructions relatifs à cette institution, et sous les réserves exprimées par le pharmacien cantonal dans le rapport de l'inspection du 5 novembre 2014.

Il est pris acte que Monsieur Jean-Paul LEWEST, docteur en médecine, est directeur médical et directeur technique du laboratoire, à dater du 1^{er} août 2017.

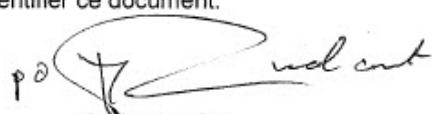
Tout changement concernant la personne précitée, ainsi que toute modification apportée aux locaux, à l'activité ou à la structure du laboratoire doit être immédiatement communiqué au pharmacien cantonal.

La conformité des locaux et des installations aux législations fédérales et cantonales, relatives au travail, à la sécurité et à la salubrité des constructions, ainsi qu'à la lutte contre l'incendie, est réservée.

Le présent arrêté annule et remplace celui du Département de l'emploi, des affaires sociales et de la santé, du 9 décembre 2016.

Seul le service du pharmacien cantonal est habilité à authentifier ce document.

Emolument : CHF 200.-.



Adrien BRON
Directeur général de la santé

Diffusion : - DEAS 1 ex.
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Direction générale de la santé – Rue Adrien-Lachenal 8 – 1207 Genève
Tél. +41 (22) 54 65 000 – Fax +41 (22) 54 65 066

REPUBLIC AND [crest] CANTON OF GENEVA

ORDER

authorising Covance Central Laboratory Services Sàrl to operate a laboratory for the analysis of human material at 7, rue Moïse-Marcinhes, 1217 Meyrin, Geneva,

of 28 July 2017

THE DEPARTMENT OF EMPLOYMENT, SOCIAL AFFAIRS AND HEALTH

having regard to current legal provisions;
having regard to the order of the Department of Employment, Social Affairs and Health of 9 December 2016, authorising Covance Central Laboratory Services SA to operate a laboratory for the analysis of human material at 7, rue Moïse-Marcinhes, 1217 Meyrin, Geneva;
having regard to the exhibits in the file;
having regard to the announcement of the departure of the technical director of the laboratory and her replacement;
having regard to the inspection of the premises by the cantonal pharmacist dated 5 November 2014;
having regard to the favourable opinion of the cantonal pharmacist of 25 July 2017,

HEREBY ORDERS:

that Covance Central Laboratory Services Sàrl is authorised to operate a laboratory for the analysis of human material at 7, rue Moïse-Marcinhes, 1217 Meyrin, Geneva, in accordance with the laws, regulations and instructions relating to this institution, and subject

Direction générale de la santé - Rue Adrien-Lachenal 8 - 1207 Geneva
Tel. +41 (22) 54 65 000 - Fax +41 (22) 54 65 066

to the reservations expressed by the cantonal pharmacist in the inspection report of 5 November 2014.

It is placed on record that Mr Jean-Paul LEWEST, doctor of medicine, is medical director and technical director of the laboratory, as from 1 August 2017.

Any change in the aforesaid person, and also any modification made to the premises, to the activity or to the structure of the laboratory must be advised immediately to the cantonal pharmacist.

The compliance of the premises and of the facilities with federal and cantonal legislation on labour, security and hygiene of the constructions, and also fire-prevention measures, is reserved.

The present order cancels and replaces that of the Department of Employment, Social Affairs and Health of 9 December 2016.

Only the cantonal pharmacist's service is empowered to authenticate this document.

Fee: CHF 200.00.

[signature]
Adrien BRON
Director-General for Health

Distribution:

- Department of Employment, Social Affairs and Health 1 copy
- Interested party 1 copy
- Santésuisse 1 copy

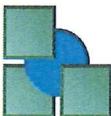
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S. J. SANDRON

Formalities Officer - UK Translation Division

I do hereby certify that this document
is signed by SABINE JOSEPH SANDRON
for and on behalf of RWS Group Ltd
at Chalfont St Peter, Buckinghamshire
on the 8th day of August 2017

PETER DAVID WILKINSON
NOTARY PUBLIC OF GERRARDS CROSS ENGLAND



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