LABCONNECT

CENTRAL LABORATORY MANUAL

Europe

Seabreeze

STAT ASTHMA

Protocol Title:
A Phase 2, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled Trial to Evaluate the Efficacy and Safety of Rademikibart as an Add-on Treatment for Acute Exacerbation in Adult and Adolescent Participants with Asthma and Type 2 Inflammation

Prepared For:
Connect Biopharma
CBP-201-206

Prepared By:
LabConnect
CONN1206

Accelerating the Development of New Medicines.

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REGIONAL HOLIDAYS

Holidays will affect specimen shipment/delivery and resupply order requests. Please **DO NOT** ship specimens on or around the holidays listed below. If resupply orders are placed, account for delay in shipment/delivery of kits. If patient visits cannot be scheduled on alternative dates, consult with your LabConnect Project Manager.

NOTE: LOCALLY OBSERVED HOLIDAYS MAY DISRUPT COURIER SERVICE WITHIN YOUR AREA. PLEASE CALL YOUR COURIER IN ADVANCE FOR LOCAL PICKUP SCHEDULES.

Germany Holidays

Germany Holidays	2025		2026	
	Day	Date	Day	Date
New Year's Day (January 1)	Wed	Jan 1	Thurs	Jan 1
Good Friday (Friday immediately preceding Easter Sunday)	Fri	Apr 18	Fri	Apr 3
Easter Monday (Monday after Easter Sunday)	Mon	Apr 21	Mon	Apr 6
Labour Day (May 1)	Thurs	May 1	Fri	May 1
Ascension Day (39 days after Easter)	Thurs	May 29	Thurs	May 14
Whit Monday (50 days after Easter)	Mon	Jun 9	Mon	May 25
Corpus Christi Day (60 days after Easter)	Thurs	Jun 19	Thurs	Jun 4
German Unity Day (October 3)	Fri	Oct 3	Sat	Oct 3
All Saints Day (November 1)	Sat	Nov 1	Sun	Nov 1
Christmas Day (December 25)	Thurs	Dec 25	Fri	Dec 25
2nd Day of Christmas (December 26)	Fri	Dec 26	Sat	Dec 26

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Netherlands Holidays (kit shipment)

Netherlands Holidays	2025		2026	
	Day	**Date**	**Day**	**Date**
New Year's Day (January 1)	Wed	Jan 1	Thurs	Jan 1
Good Friday (Friday immediately preceding Easter Sunday)	Fri	Apr 18	Fri	Apr 3
Easter Sunday	Sun	Apr 20	Sun	Apr 5
Easter Monday (Monday after Easter Sunday)	Mon	Apr 21	Mon	Apr 6
King's Day (April 27)	Sat	Apr 26	Mon	Apr 27
Liberation Day (May 5)	Mon	May 5	Tue	May 5
Ascension Day (39 days after Easter)	Thurs	May 29	Thurs	May 14
Pentecost (49 days after Easter)	Sun	Jun 8	Sun	May 24
Whit Monday (50 days after Easter)	Mon	Jun 9	Mon	May 25
Christmas Day (December 25)	Thurs	Dec 25	Fri	Dec 25
2nd Day of Christmas (December 26)	Fri	Dec 26	Sat	Dec 26

UK Holidays

UK Holidays	2025		2026	
	Day	Date	Day	Date
New Year's Day	Wed	Jan 1	Thurs	Jan 1
New Year's Day Observed				
Good Friday	Fri	Apr 18	Fri	Apr 3
Early May Bank Holiday	Mon	May 5	Mon	May 4
Spring Bank Holiday	Mon	May 26	Mon	May 25
Christmas day	Thurs	Dec 25	Fri	Dec 25
Boxing Day	Fri	Dec 26	Sat	Dec 26
Substitute Bank Holiday for Christmas Day				
Substitute Bank Holiday for Boxing Day			Mon	Dec 28

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Georgia Holidays

Georgia Holidays	2025		2026	
	Day	Date	Day	Date
New Year's Day	Wed	Jan 1	Thurs	Jan 1
New Year's (Day 2)	Thurs	Jan 2	Fri	Jan 2
Orthodox Christmas Day	Tues	Jan 7	Wed	Jan 7
Orthodox Epiphany	Sun	Jan 19	Mon	Jan 19
Mother's Day	Mon	Mar 3	Tues	Mar 3
International Women's Day	Sat	Mar 8	Sun	Mar 8
Independence Restoration Day	Wed	Apr 9	Thurs	Apr 9
Orthodox Good Friday	Fri	Apr 18	Fri	Apr 10
Orthodox Holy Saturday	Sat	Apr 19	Sat	Apr 11
Orthodox Easter Sunday	Sun	Apr 20	Sun	Apr 12
Orthodox Easter Monday	Mon	Apr 21	Mon	Apr 13
Victory Day	Fri	May 9	Sat	May 9
St Andrew's Day	Mon	May 12	Tues	May 12
Day of Family Purity and Respect for Parents	Thurs	May 17	Sun	May 17
Independence Day	Mon	May 26	Tues	May 26
Day of the Assumption of Mary	Thurs	Aug 28	Fri	Aug 28
Svetitskhovloba	Tues	Oct 14	Wed	Oct 14
St George's Day	Sun	Nov 23	Mon	Nov 23

Serbia Holidays

Serbia Holidays	2025		2026	
	Day	Date	Day	Date
New Year's Day	Wed	Jan 1	Thurs	Jan 1
New Year's (Day 2)	Thurs	Jan 2	Fri	Jan 2
Orthodox Christmas Day	Tues	Jan 7	Wed	Jan 7
Orthodox Epiphany	Sun	Jan 19	Mon	Jan 19
Mother's Day	Mon	Mar 3	Tues	Mar 3
International Women's Day	Sat	Mar 8	Sun	Mar 8
Independence Restoration Day	Wed	Apr 9	Thurs	Apr 9
Orthodox Good Friday	Fri	Apr 18	Fri	Apr 10
Orthodox Holy Saturday	Sat	Apr 19	Sat	Apr 11
Orthodox Easter Sunday	Sun	Apr 20	Sun	Apr 12
Orthodox Easter Monday	Mon	Apr 21	Mon	Apr 13
Victory Day	Fri	May 9	Sat	May 9
St Andrew's Day	Mon	May 12	Tues	May 12
Day of Family Purity and Respect for Parents	Thurs	May 17	Sun	May 17
Independence Day	Mon	May 26	Tues	May 26
Day of the Assumption of Mary	Thurs	Aug 28	Fri	Aug 28
Svetitskhovloba	Tues	Oct 14	Wed	Oct 14
St George's Day	Sun	Nov 23	Mon	Nov 23

LABCONNECT SCHEDULE OF EVENTS AND VISITS

LabConnect Event Schedule: Table 1

NOTE: Local labs to be collected per protocol on Visit 1b are not detailed in this table.

	Phase	Screening	Randomization /Baseline	Post-IP Treatment Assessment			Follow-up	Unscheduled	Early Termination
	Visit	V1a	V2[1]	V5	V6	V8	V9	UNS	ET
	Day	Up to 26 Weeks to D-1	0	3	7 (Week 1)	28 (Week 4)	56 (EOT/Week 8)		
	Window				±2 days	±3 days	±3 days		
Lab Assessments	Draw Volume (mL)								
Chemistry, including CRP[2]	5.0	A	A[3]		A	A	A	A	A
CK[2]	2.5	A	A[3]		A	A	A	A	A
Hematology[2]	4.0	A	A[3]		A	A	A	A	A
Urinalysis[2]		A	A[3]		A	A	A	A	A
Total IgE[4]	2.5		B		B	B	B	B	B
PK[4]	2.0		C	C	C	C	C	C	C
ADA/nAb[4]	4.0		D			D	D	D	D
Biomarker Sample[4]	6.0		E		E	E	E	E	E
Total Blood Draw Per Visit (mL)		11.5	26.0	2.0	22.0	26.0	26.0	26.0	26.0
On Site Testing									
Urine Pregnancy			X[5]			X	X		

ADA = anti-drug antibodies; EOT = End of Trial; ET = Early Termination; nAb = neutralizing antibody; PK = Pharmacokinetic; V = visit

Footnotes:

[1] Randomization/Baseline/Administration Visit is defined as Day 0 (V2). Screening V1b and Day 0 (V2) may be the same day or up to 48 hours apart. All assessments at Visit 2 (Day 0) are to be conducted pre-IP dose administration with the exception of the assessment of SC injection sites and post-IP administration vital sign measurements.

[2] Hematology, clinical chemistry, and urinalysis parameters are provided in Appendix C of the protocol.

[3] Screening V1b: Due to the short screening window, local laboratory results will be used for the purpose of determining the participant's eligibility for randomization. Local laboratory samples should be taken at Screening V1b and the results should be received and reviewed prior to randomization to allow review of the applicable eligibility criteria. If local laboratory results from the assessment of the current asthma exacerbation are already available within 48 hours prior to Screening V1b, these results can be used for determination of participant's eligibility. For all randomized participants, a sample for central laboratory analysis should be obtained before IP administration on Day 0 as baseline.

[4] On Day 0, PK and ADA/nAb samples (as well as IgE and Biomarker samples) will be collected prior to administration of IP. On days when PK and ADA/nAb sample collection are coinciding, the samples can be taken at the same time.

[5] For women of childbearing potential only if Screening V1b and the Baseline Visit (Day 0) are not on the same day. Analyzed at a local laboratory.

Kit Table: Table 2

Kit Letter	Kit Name
A	Safety(EU)
B	IgE(EU)
C	PK(EU)
D	ADA/nAb(EU)
E	Biomarker Sample(EU)

Shipping Temperature:

Refrigerated:	X
Frozen:	X

Retest

Retesting is a repeat of a panel or test associated with a scheduled visit. Please utilize the Retest kit or select the Retest visit on applicable requisitions.

Unscheduled

Unscheduled testing occurs when a subject completes a visit at a time that is not on the regular event schedule. Please select the Unscheduled visit on applicable requisitions.

IMPORTANT VISIT PREPARATION

In Advance of Patient Visit

At least **15 DAYS BEFORE ANY COLLECTION PROCEDURES**, please check expiration dates on all laboratory supplies. If supplies are past the expiration date, please re-order additional supplies using the supply reorder form immediately. Kit expirations can be found on the kit label for each kit (see below images).

Image: Bagged Kit Label

Image: Absorbent Wrap and Tubes

Ensure shipping materials are available and shipments are appropriately scheduled for specimen shipping.

Cool/Freeze gel packs as instructed to ensure they are appropriately suited for temperature-controlled shipments.

Please procure dry ice for shipment of frozen samples (provided by courier). See Airway Bill on shipping box (LabConnect provides) for weight of dry ice needed per box. Refer to Shipment Preparation Section of this document for sample picture of AWB.

Day of Patient Visit

Always check that the correct kit is being used for the visit being completed and confirm that the provided requisition number matches the pre-labeled tubes in the kit.

COMPLETING REQUISITIONS AND LABELS

The first 8-digits of the barcoded accession number on the specimen label MUST match the 8-digit barcoded requisition number listed on the requisition. Please ensure the subject ID is recorded on the requisition and the tubes submitted. An overview of the labels and requisitions is provided on the following pages of the lab manual.

If any requisition is returned incomplete, or if information is missing or inconsistent, LabConnect Customer Service will contact the investigator site for clarification. Additional information on the LabConnect Query process can be found in this document in the Laboratory Queries and Reporting section.

Please use the proper format when recording the subject ID number: XXXXYYY (2 digit country code, plus 2 digit site identifier, followed by 3 digit subject number).

A COPY OF THE REQUISITION FORM MUST ACCOMPANY ALL SPECIMEN SHIPMENTS.

Completing Requisitions

The requisition is a 3-part carbonless form. The requisition contains the same unique identifier as the specimen labels. When writing on the form, align all pages properly and press firmly with a ballpoint pen.

ALL FIELDS ON THE REQUISITION MUST BE COMPLETED.

DO NOT pre-fill your requisitions. All data must be documented contemporaneously as required by FDA predicate rule, ALCOA, GDP, and requirements of ICH E6 R2 for GCP. ***Failure to complete all fields will delay results.*** The information must be recorded completely, accurately, and legibly. Demographic information should remain consistent for each subject.

Requisition Copy Guide

Kit Name	White Copy	Yellow Copy	Pink Copy
A: Safety(EU)	LabConnect GmbH-Refrigerated	LabConnect GmbH-Frozen	Investigator
B: IgE(EU)	LabConnect GmbH-Refrigerated	Investigator	Investigator
C: PK(EU)	LabConnect GmbH-Primary Sample	LabConnect GmbH-Backup Sample	Investigator
D: ADA/nAb(EU)	LabConnect GmbH-Primary Sample	LabConnect GmbH-Backup Sample	Investigator
E: Biomarker Sample(EU)	LabConnect GmbH-Primary Sample	LabConnect GmbH-Backup Sample	Investigator

Please note that the picture below is an example of a requisition and may differ from actual requisitions designed for a specific study. (ex. Subject ID format, Visits, and Sample Collections.)

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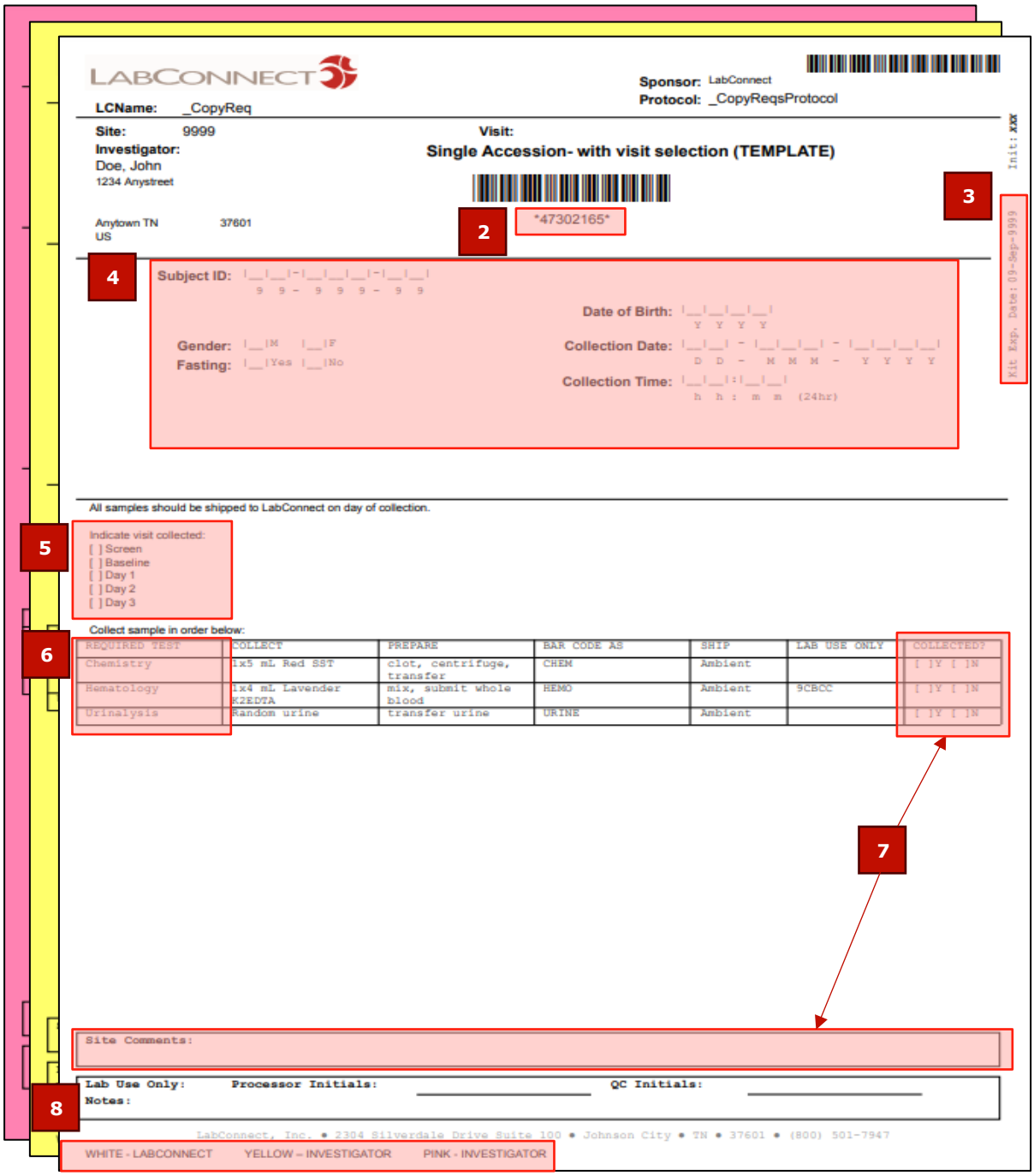
Non-Digital Requisition Example and Steps

1 ***ENSURE ALL PAGES ARE ALIGNED AND PRESS FIRMLY WITH A NON-GEL BALLPOINT PEN TO FILL OUT THE REQUISITON FORM COMPLETELY.***

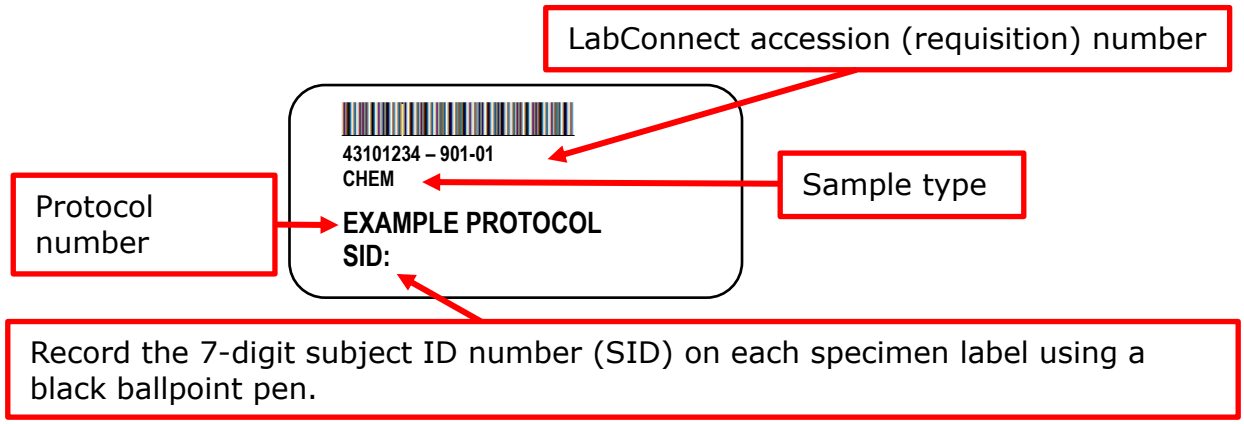


2. Ensure 8-digit requisition/accession number matches number on specimen labels
3. Enter kit expiration date and initial entry, if blank
4. Enter Subject ID, subject demographics, and date/time of specimen collection, as applicable
5. Indicate visit being collected, as applicable
6. Collect samples in order on requisition form
7. If specimen is collected, indicate so by marking the box next to Y. If a specimen is not collected, indicate so by marking the box next to N. The reasons for a specimen not being collected should be recorded in the Site Comments section of the form
8. Separate and distribute copies as per the instructions on the bottom of each requisition form

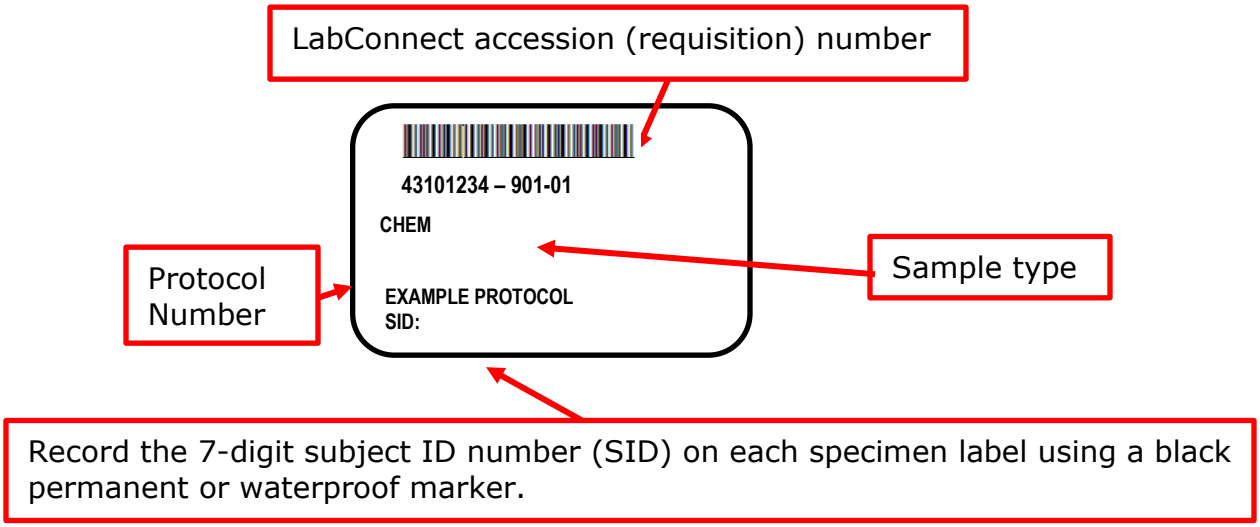
Completing Labels

Complete each specimen label appropriately by adding SID and visit type, if applicable, to the pre-printed collection or transport device labels. Do not use a gel pen on specimen labels.

Pre-printed Specimen Label Example



Pre-printed Specimen LN2/Frozen Label Example *



**LN2 labels are smaller labels that are specifically designed for samples requiring frozen or Liquid Nitrogen storage.*

If a specimen collection device or transport vial is defective or is missing, utilize available additional supplies or the correct supply item from another collection kit.

Follow the steps outlined below to label the supply item to ensure the accession number matches the kit accession number:

- Defective tube (damaged or expired):
  - Carefully remove the label from the defective tube
  - Apply the removed label to the replacement tube
  - Ensure the label is securely adhered to the new tube (apply scotch tape if necessary)
  - Notate the tube exchange on the requisition (example: Expired chemistry test collection tube was replaced with a new SST tube with expiry date 01Jan2024).
- Missing tube:
  - Writing directly on the collection/transport tube or on a securely adhered paper label, record the following data on the collection/transport tube:
    - Protocol number
    - Accession number
    - Sample name
    - Subject ID

If a requisition is missing or does not match the kit/tube, contact order_admin@labconnect.com for the correct replacement requisition.

SPECIMEN COLLECTION AND PREPARATION

General Specimen Preparation Information

To ensure the accuracy of test results, careful consideration of collection technique and sample preparation is required. Specimen requirements for each test are listed in this section. Specimen volume requirements must be adhered to. All specimens received must be properly identified with the specimen label and subject identifier. **UNLABELED SPECIMENS WILL NOT BE TESTED.**

Preparation Instructions

1. Perform venipuncture and other specimen collection procedures according to site protocols.
2. Collect specimens in the order listed, using the collection devices(s) outlined in the Specimen Collection Table(s) below.
    a. DO NOT send extra tubes as they will be destroyed upon receipt. If a specimen is not defined in the Specimen Collection Table(s), it cannot be accepted for this study.
3. Prepare the specimen(s) for transportation and/or analysis by following the instructions in the Specimen Collection Table(s) below (Preparation Instructions field).
4. Store specimen(s) at the appropriate temperature (Temperature field in Specimen Collection Table(s)) until scheduled transport/shipment.
5. Complete the requisition(s) associated with each specimen. **A copy of the requisition MUST be included in each specimen shipment**. *Please refer to Requisition Copy Guide above.*
6. Transport/ship specimen(s) according to the shipping frequency defined in the Specimen Collection Tables(s).

General Collection and Processing Guidance

Follow the recommended collection parameters and instructions in the Specimen Collection Table (s) to prevent specimen rejection at the testing laboratory. The table and instructions below outline the parameters for specimen collection that may vary from site collection protocols.

Recommended Order of Draw

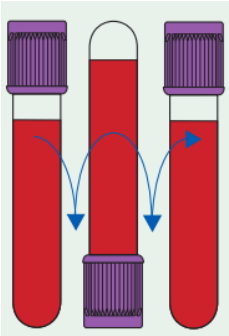
Published order of draw provided for reference: 1. No additive tube or blood culture, 2. Citrate blood, 3. Blood for serum, 4. Heparin blood for plasma, 5. EDTA blood, 6. Other tubes.

Always follow your site procedures for order of draw if tubes are not documented in the below image or in the Specimen Collection table(s).

Closure Color	Collection Tube	Mix by Inverting
	Blood Cultures	8 to 10 times
	Serum (glass tube)	—
	Citrate	3 to 4 times
	BD SST™ Gel Separator Tube	5 times
	BD SST Gel Separator Tube	"
	Serum (plastic tube)	"
	Heparin	8 to 10 times
	BD PST™ Gel Separator Tube With Heparin	"
	EDTA	8 to 10 times
	Fluoride (glucose tube)	8 to 10 times

Inversion Guidelines

Below images shows one *(1) complete inversion.* Please complete as many inversions as needed per tube, according to the order of draw instructions and below Specimen Collection table(s). Invert gently and do not shake.



Centrifugation Guidelines

All specimens should be centrifuged within one (1) hour of collection, unless otherwise specified. General guidelines for centrifuging samples are as follows: centrifuge 10-15 minutes between 1300 – 1800 g (see APPENDIX B: NOMOGRAM FOR CONVERTING RCF TO RPM for conversion factors). *Specific centrifuge instructions will be provided in the below Specimen Collection Table and should be followed.*

Properly separated blood will show clear separation of serum/plasma, buffy coat, gel barrier (if applicable), and red blood cells.

Improper centrifugation will not allow for complete separation resulting in contaminated serum/plasma layer, broken gel barrier (if applicable), and/or poorly contained red cells (examples provided below). If serum/plasma and cells do not completely separate, re-centrifuge for an additional 6-8 minutes or until separation is complete. Note: hemolyzed specimens will not achieve complete separation due to the destruction of red blood cells.

Image: Properly Centrifuged Blood Specimen

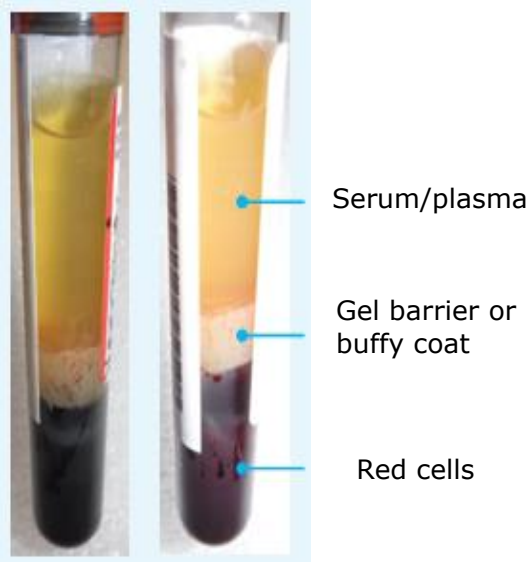
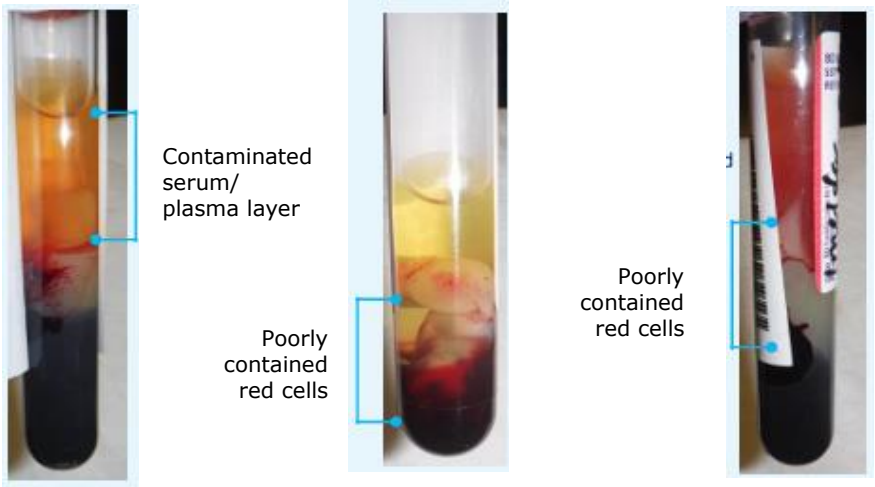


Image: Improperly Centrifuged Blood Specimen



Additional Preparation Guidelines

When preparation instructions in the table indicate the following, utilize this guidance:

- **CLOT**: place tube in standing upright position. Do not disturb the tube for 30 minutes (maximum 60 minutes) while the blood clots.
- **CENTRIFUGE:** Centrifuge within 1 hour of collection. If serum/plasma and cells do not completely separate, re-centrifuge for an additional 6-8 minutes or until separation is complete.
- **TRANSFER**: Using a transfer pipette or transfer device, transfer the preferred volume (larger volume is acceptable) required into the defined transport tube.

COLLECTION TUBES MUST BE FILLED COMPLETELY (UNTIL THE VACUUM IS EXHAUSTED)

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Specimen Collection Table

Color and shape of collection devices shown below may vary depending on manufacturer. Due to supply shortages, Sponsor approved substitutions may be provided in place of collection or transport devices shown below. Specimen Collection table is in recommended order of draw for this clinical trial. Result turnaround time listed below is in business days from receipt at testing laboratories.

Test	Collection Device	Preparation Instructions	Transport Container	Temperature	Stability	TAT
Chemistry Panel	1 x 5 mL Red SST  **CHEM 1**	1. Invert 5 times to mix. 2. Clot. 3. Centrifuge at 1800-2200 g for 10-15 minutes 4. Transfer all serum, minimum of 2mL serum 5. Refrigerate until ready for shipment	1 x 5 mL Transport Tube **CHEM**	Refrigerated	3 days	1 business day
CK	1 x 2.5 mL Red SST  **CK 1**	1. Invert 5 times to mix 2. Clot 3. Centrifuge at 1800-2200 g for 10-15 minutes 4. Transfer all serum, minimum of 1mL serum 5. Freeze -20C until ready for shipment	1 x 5 mL Transport Tube **CK**	Frozen	1 month	1 business day
Total IgE	1 x 2.5 mL Red SST  **Immuno**	1. Invert 5 times to mix. 2. Clot. 3. Centrifuge at 1800-2200 g for 10-15 minutes. 4. Transfer all serum, minimum of 1mL serum 5. Refrigerate until ready for shipment	1 x 5 mL Transport Tube **IgE**	Refrigerated	7 days	1 business day
ADA/nAb	1 x 4 mL Red No Gel  **ADA/nAb**	*Note: Sponsor-provided instructions* 1. Invert 5 times to mix. 2. Clot for at least 30 min. 3. Centrifuge at 1300 ±20g for 10 minutes at Room Temperature, within 120 min after collection. 4. Transfer a minimum of **0.50 mL** of serum to each cryovial and freeze immediately until ready for shipment (-70°C or -80°C preferred, -20°C acceptable).	2 x 2mL Cryovials  **ADA/nAb 1**  **ADA/nAb 2**	Frozen	Indefinite	N/A

Test	Collection Device	Preparation Instructions	Transport Container	Temperature	Stability	TAT
Biomarkers	1 x 6 mL Red No Gel  **BS**	*Note: Sponsor-provided instructions* 1. Invert 5 times to mix. 2. Clot for at least 30 min. 3. Centrifuge at 1300 ±20g for 10 minutes at Room Temperature within 120 min after collection. 4. Transfer a minimum of **0.50 mL** of serum to each cryovial and freeze immediately until ready for shipment (-70°C or -80°C preferred, -20°C acceptable).	4 x 2mL Cryovials  **BS 1**  **BS 2**  **BS 3**  **BS 4**	Frozen	To be assessed	N/A
Hematology Panel	1 x 4 mL Lavender K2 EDTA  **HEMO**	1. Invert 8 – 10 times.	None – transport primary collection container	Refrigerated	72 hours	1 business day
PK	1 x 2 mL Lavender K2 EDTA  **PK**	*Note: Sponsor-provided instructions* 1. After collection, gently invert 10 times and then store upright in an ice cold water bath to maintain ~4°C until centrifugation. 2. Centrifuge at 2000 ±20g at 4°C for 10 minutes within 120 min after collection and then place in ice water bath for aliquoting. 3. Transfer a minimum of **0.30 mL** of plasma to each cryovial and freeze immediately until ready for shipment (-70°C or -80°C preferred, -20°C acceptable). 4. Note: it is important to avoid hemolysis which impacts the assay (send regardless)	2 x 2mL Cryovials  **PK 1**  **PK 2**	Frozen	746 days	N/A

Test	Collection Device	Preparation Instructions	Transport Container	Temperature	Stability	TAT
Urinalysis Panel	Fresh Random Urine 	1. Transfer urine. 2. Invert 8-10 times.	1 x 8 mL Clear tube (yellow top) with preservative  **UAWMIC**	Refrigerated	72 hours	1 business day
On-Site Testing						
Urine Pregnancy	Fresh Random Urine  	Follow package insert instructions provided in Appendix E.	N/A	N/A	N/A	N/A

For on-site testing provided by LabConnect, please go to the Appendix for instructions if necessary.

SHIPMENT PREPARATION

Specimen Shipment Guide

Kit/Sample Name	Required Shipper	Frequency of Shipment	Destination
A: Safety(EU)	Refrigerated	Day of Collection	LabConnect GmbH
A: Safety(EU)-**CK**	Frozen	Day of Collection	LabConnect GmbH
B: IgE(EU)	Refrigerated	Day of Collection	LabConnect GmbH
C: PK(EU)	Frozen	Primary: Next planned frozen shipment (PK 1) Back-up: Next planned frozen shipment after primary shipment (PK 2)	LabConnect GmbH
D: ADA/nAb(EU)	Frozen	Primary: Next planned frozen shipment (ADA/nAb 1) Back-up: Next planned frozen shipment after primary shipment (ADA/nAb 2)	LabConnect GmbH
E: Biomarker Sample(EU)	Frozen	Primary: Next planned frozen shipment (BS 1-2) Back-up: Next planned frozen shipment after primary shipment (BS 3-4)	LabConnect GmbH

Shipment Documentation

Each of the documents outlined below must be included with every specimen shipment. Placement of each document is outlined in the Shipping Materials & Packaging Instructions section below. Original documents should be provided to the courier representative.

Airway Bill – Courier Provided

Contact your courier to obtain air waybills prior to the subject visit. Please reference the starter packs provided via email by your courier to order airway bills or airway bills provided with starter pack.

Commercial Invoice-UK, Serbia, Georgia Sites

A commercial invoice (CI) is a required document for the export and import clearance process. A commercial invoice must be included with all international shipments (sample shipments shipping to any facility outside their country of collection).

Commercial Invoice templates and instructions are provided electronically separate from the Lab Manual. To request electronic copies, contact your LabConnect Project Manager or Logistics Coordinators at logisticscoordinator@labconnect.com.

Commercial Invoices must be completed per the instructions to satisfy International Air Transport Association (IATA) and Department of Transportation (DOT) requirements and regulations.

Shipment Booking

UPS – UK Sites (Mon-Thu shipments)

Note: UK sites will use Marken for sample pickups Fri-Sun. (instructions to follow). Note: Shipments are not delivered on Sundays and will be not be received until Monday.

Refer to the Courier Instruction sheet for all booking instructions. The Courier Instruction sheets are provided by the courier via email to the Site Coordinator.

SHIPMENTS VIA UPS SHOULD STANDARDLY BE SCHEDULED MONDAY THROUGH THURSDAY FOR ARRIVAL ON WEDNESDAY THROUGH SATURDAY.

Cryostore – UK site Frozen Shipments

CryoStore is an ISO 9001:2015 certified LabConnect company. The shipment of dry ice to sites is arranged through CryoStore and delivered by courier.

Shipments should standardly be scheduled Monday through Friday only. Orders for delivery/pick-up must be placed, at minimum, the day before the shipment at 13:00 CET.

If you have questions concerning shipping with CryoStore, please contact CryoStore: +31 513 41 72 80 or CryoStore@labconnect.com.

Email CryoStore@labconnect.com with the following information to register with CryoStore:

a. Study Name
b. Site Number
c. Contact Information
    i. Name
    ii. Email
    iii. Phone Number
d. Address for delivery of shippers, dry ice and pickup of sample shipments

Ordering Dry Ice, Shippers, or Specimen Collection with CryoStore

1. Go to CryoStore's online ordering system using the study/site specific link provided at registration and provide:
    a. Date shipper needs to be delivered
    b. Delivery address for shippers
    c. Pick-up address for completed package (if different than delivery address)
    d. Number of vials/tubes and kit boxes to be shipped
    e. Email address and phone number of contact person to receive packaging and pick-up instructions
2. An email summarizing your order will be sent within 2 hours of order placement
3. A shipment notification email with tracking information will be sent when dry ice has shipped to the site
4. The day before requested delivery, instructions for shipper delivery, use, packaging and return shipping along with a copy of the airway bill will be emailed
5. Upon receipt of shipper, follow the packaging instructions found in the Shipment Preparations section of this document or provided in the shipper.

Delivery times vary by region. NOTE: The necessary courier air waybill and packing list for the shipment is already included on the shipping box. Do not place any other shipping labels on the box.

Rest of World Shipments- Marken: Serbia and Georgia Sites (Mon-Sat)

Refer to Marken Starter Pack or Courier Instruction sheet for all booking instructions. Starter Packs and Courier Instruction sheets are provided by the courier via email to the Site Coordinator.

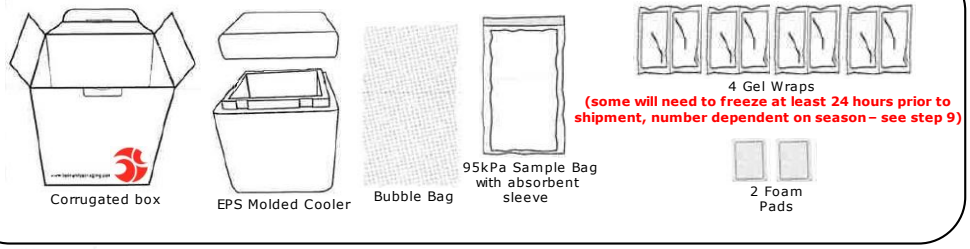
LABCONNECT

Shipment Materials and Packaging Instructions

Refrigerated Shipper Instructions-UK ONLY *(Marken providing refrigerated shippers to sites in Georgia and Serbia)*

REFRIGERATED SHIPPER WITH TUBE/VIAL SPECIMEN TYPES

CONTENTS

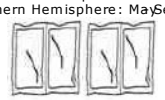


1 **Insert the season-appropriate number of unconditioned (ambient) Gel Wrap(s) into the EPS Molded Cooler inside the Corrugated box**

Summer Configuration
Northern Hemisphere: May-September
Southern Hemisphere: October-April

1 Ambient Gel Wrap

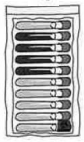
Winter Configuration
Northern Hemisphere: October-April
Southern Hemisphere: May-September



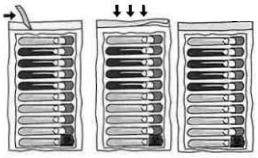
2 Ambient Gel Wraps

2 **Insert one foam pad over the Gel Wrap(s)**

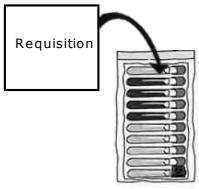
3 **Insert samples into the sample sleeve inside the Sample Bag**



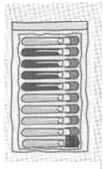
4 **Peel off the inner tape liner to expose the adhesive and fold, pressing firmly from the center to the end closing the bag**



5 **Place the appropriate copy of the requisition(s) in the pouch on the Sample Bag**

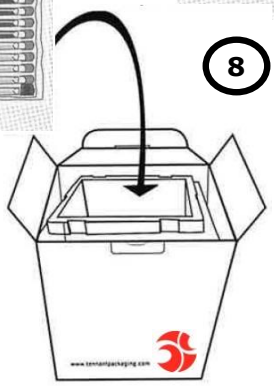


6 **Insert Sample Bag into the Bubble Bag**



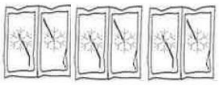
7 **Insert Bubble Bag over top the foam pad**

8 **Insert one foam pad over the Bubble Bag**



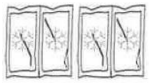
9 **Insert the season-appropriate number of conditioned (frozen) Gel Wraps over the foam pad**

Summer Configuration
Northern Hemisphere: May-September
Southern Hemisphere: October-April

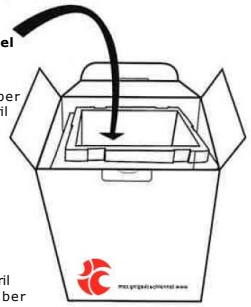


Freeze 3 Gel Wraps for at least 24 hours in at least -18°C or -4°F before use

Winter Configuration
Northern Hemisphere: October-April
Southern Hemisphere: May-September

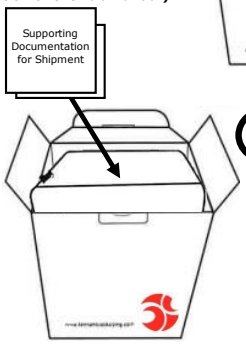


Freeze 2 Gel Wraps for at least 24 hours in at lea -18°C or -4°F before us

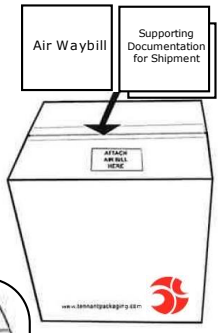


10 **Replace foam lid on EPS Molded Cooler securing the inner box**

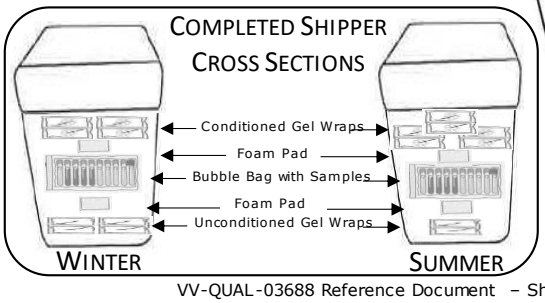
11 **Place a copy of each Supporting Documentation for Shipment atop the foam lid of the EPS Molded Cooler (list of required documents supplied in the Supporting Documentation for Shipment section of the Lab Manual)**



12 **Seal corrugated box and insert copy of air waybill (if not previously affixed to shipper) and a copy of each Supporting Documentation for Shipment in the pouch affixed to the corrugated box**



COMPLETED SHIPPER CROSS SECTIONS



LABCONNECT

VV-QUAL-03688 Reference Document – Shippers & Temp Loggers v1

Cryostore Frozen Shipper Instructions-UK Sites: Mon-Thurs

This package consists of a complete packaging system according P650 Class 9 specifications for shipping your biological material for analysis, all packed inside the outer corrugated box that you just opened.

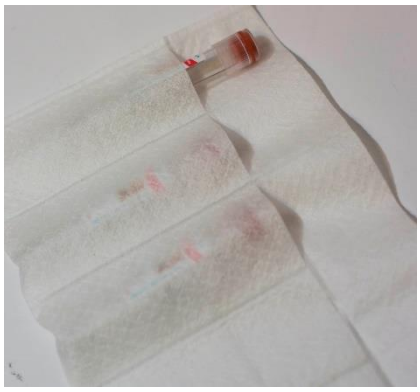
This packaging system consists of:

- Inner corrugated box, pre-labelled (addresses, UN3373, UN1845) for the return shipment
- EPS box with dry ice (provided by CryoStore) and a large 95kPA
    - Sealbag with clamp for the frozen samples

1. Open the outer box and take out the packaging system inside.

2. Only use the inner corrugated box for your shipments. Destroy the original outer box.

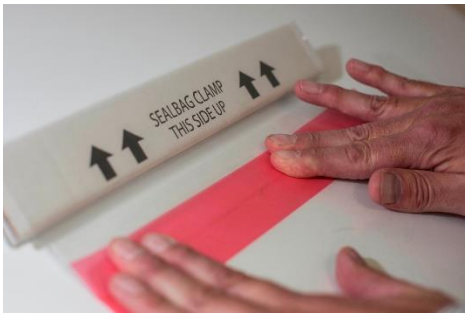
3. Take the sealbag, open the EPS box and take out the dry ice box.



4. Add samples to the sample pouch

5. Add the sample pouches or cryo box to the large sealbag with clamp

6. Remove the backing paper from the adhesive from the sealbag.



7. Stretch and flatten adhesive tape of the bag closure. Press the adhesive tape firmly from the center outwards.

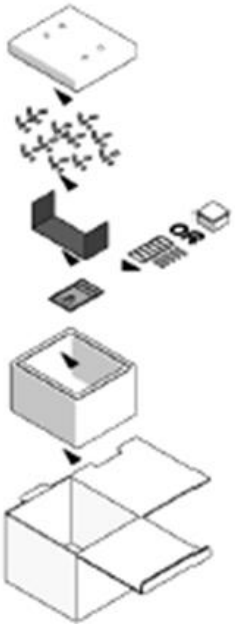
8. Place the sealbag into the EPS box and fit the cardboard clamps into the slots on the sidewalls of the box to ensure that the bag is held firmly in place.
9. Take the box with dry ice and pour the dry ice over the sealbag.

10. Close the lid of the EPS box.
11. Close the corrugated box.

The box is ready for pick-up. The shipping labels are already on the box. Please check the shipping labels.

Pickup by the courier is already arranged. Place the box at the pickup location. Never change AWB labels or use this box for other shipments

In case of any issues, problems, question or need to change delivery or pick up, please contact CryoStore at: Cryostore@labconnect.com or Tel: +31 513 417280



Dry Ice:
Minimum required for 72hr duration = 5.9 kg
Maximum dry ice capacity in empty cooler = 11.3 kg

When utilizing a Marken Frozen Shipper, Marken will provide dry ice. Sites will need to place the 95 kPa bag with samples in the shipper and verify that the airway bill destination matches the required sample destination.

LABORATORY SUPPLIES

Please note, there is no automatic shipment of kit resupplies. Sites are responsible for ordering kits on-time for subject visits.

It is the responsibility of the investigator sites to rotate laboratory supplies and use kits prior to their expiration dates.

Upon receipt of all kit orders, investigator sites should inspect all kits for completeness and ensure kits and supplies are maintained at an ambient temperature as a standard. If any material is shipped frozen or refrigerated, the temperature must be sustained throughout storage until use.

Additional Supplies

In addition to the specimen collection kits, LabConnect will provide investigative sites with the following:

- Phlebotomy Supply Kit
- Urine Pregnancy Kit (N/A for Georgia sites)
- Urine Collection Cups with Lids
- 2 mL Cryoboxes
- 23G Butterfly Needles

Ordering Kits and Additional Supplies

Note: Copy the Supply Reorder form(s)provided in this Lab Manual prior to use. A laminated copy of the Reorder form is also provided.

Standard kit delivery timelines are up to **10 BUSINESS DAYS PLUS TRANSIT** and may be extended during times of peak demand or supply chain impacts.

Additional laboratory collection kits may be ordered by scanning and emailing a Supply Reorder Form (provided in the Appendices) to:

- EMEA-workorders@labconnect.com

EXPIRED KITS SHOULD BE DISCARDED IN ACCORDANCE WITH YOUR SITE'S STANDARD OPERATING PROCEDURE(S) (SOP). DO NOT RETURN TO LABCONNECT.

AT STUDY TERMINATION, PLEASE DISCARD THE FOLLOWING SUPPLIES IN ACCORDANCE WITH YOUR SITE'S STANDARD OPERATING PROCEDURE(S) (SOP) – DO NOT RETURN TO LABCONNECT:

Airway bills
Tubes and other collection devices
Transport tubes
Shippers

LABORATORY QUERIES AND REPORTING

Query Process

If a requisition is received with incomplete or incorrect information, LabConnect will contact the site for clarification. Queries should be answered promptly without delay.

DELAYS IN RESPONSE TO QUERIES MAY JEOPARDIZE TESTING.

Situations that may prompt a query from LabConnect include, but are not limited to:

- Missing demographic data
- Data on requisition is inconsistent with other visits
- Illegible writing
- Missing or questionable collection date or time
- Missing samples
- Receipt of extra specimens
- Unclear visit type
- Missing requisition
- Missing visits
- Mislabeled specimens
- Site number and subject ID mismatch
- Protocol mismatch
- Mismatch requisition number on requisition form and specimen labels
- Additional data requested on the requisition form is missing

If you have questions concerning a query, please contact Customer Service:
+49 221 8282 9540
Customerserviceemea@labconnect.com

Non-Digital Query Process

1. Customer Service will send an email to the site coordinator (1st attempt)
2. If a response is not received, Customer Service will send a follow up email the next morning (2nd attempt) and again the next morning if still no response (3rd attempt)

If a response is not received within 3 days, the query will be escalated to the Project Manager, or designee, to contact the Sponsor/CRO for resolution.

To respond to a query, reply to the email or call Customer Service.

Laboratory Report Access

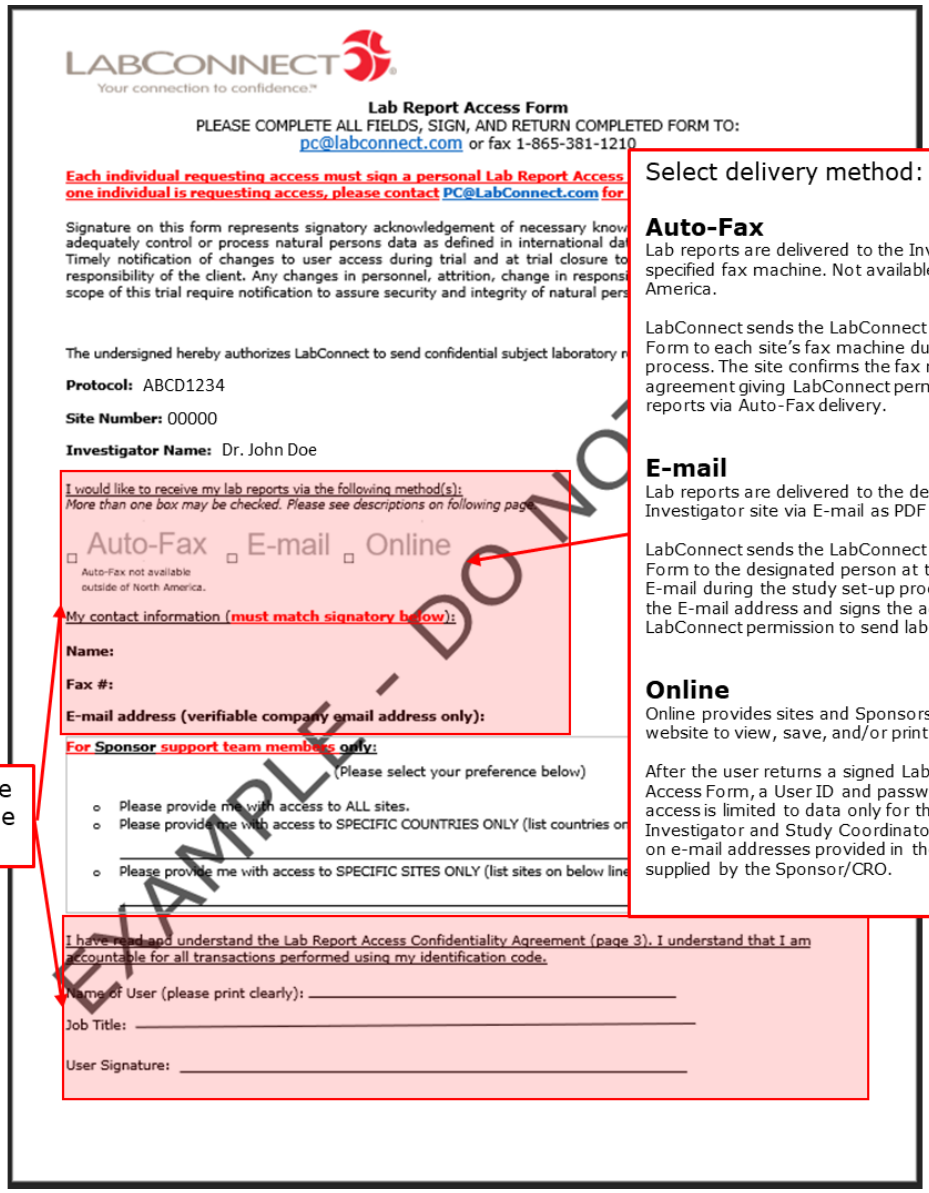
Contacts listed on the Site List will automatically receive a Lab Report Access request form. If a site contact is not listed on the Site List, request a Lab Report Access Form from Project Coordinators at PC@labconnect.com. NOTE: Each individual requesting access must sign a personal Lab Report Access Form.

If you have questions concerning report access, please contact Project Coordinators: PC@labconnect.com

LABCONNECT

Laboratory Report Access Form Example

! *Complete all fields on the form, sign, and return completed form to PC@labconnect.com.*



LABCONNECT
Your connection to confidence.™

Lab Report Access Form
PLEASE COMPLETE ALL FIELDS, SIGN, AND RETURN COMPLETED FORM TO:
pc@labconnect.com or fax 1-865-381-1210

Each individual requesting access must sign a personal Lab Report Access
one individual is requesting access, please contact PC@LabConnect.com for

Signature on this form represents signatory acknowledgement of necessary know
adequately control or process natural persons data as defined in international da
Timely notification of changes to user access during trial and at trial closure to
responsibility of the client. Any changes in personnel, attrition, change in respons
scope of this trial require notification to assure security and integrity of natural pers

The undersigned hereby authorizes LabConnect to send confidential subject laboratory r

Protocol: ABCD1234

Site Number: 00000

Investigator Name: Dr. John Doe

I would like to receive my lab reports via the following method(s):
More than one box may be checked. Please see descriptions on following page

☐ Auto-Fax ☐ E-mail ☐ Online
Auto-Fax not available outside of North America.

My contact information (must match signatory below):

Name:

Fax #:

E-mail address (verifiable company email address only):

For Sponsor support team members only:
(Please select your preference below)

- Please provide me with access to ALL sites.
- Please provide me with access to SPECIFIC COUNTRIES ONLY (list countries or
- Please provide me with access to SPECIFIC SITES ONLY (list sites on below line

I have read and understand the Lab Report Access Confidentiality Agreement (page 3). I understand that I am accountable for all transactions performed using my identification code.

Name of User (please print clearly): _____

Job Title: _____

User Signature: _____

EXAMPLE - DO NOT

Complete applicable fields

Select delivery method:

Auto-Fax
Lab reports are delivered to the Investigator site's specified fax machine. Not available outside of North America.

LabConnect sends the LabConnect Lab Report Access Form to each site's fax machine during the study setup process. The site confirms the fax number and signs the agreement giving LabConnect permission to send lab reports via Auto-Fax delivery.

E-mail
Lab reports are delivered to the designated person at the Investigator site via E-mail as PDF attachments.

LabConnect sends the LabConnect Lab Report Access Form to the designated person at the Investigator site via E-mail during the study set-up process. The site confirms the E-mail address and signs the agreement giving LabConnect permission to send lab reports via E-mail.

Online
Online provides sites and Sponsors/CROs with a secure website to view, save, and/or print laboratory data.

After the user returns a signed LabConnect Lab Report Access Form, a User ID and password is provided. Site access is limited to data only for the pertinent site. Investigator and Study Coordinator access will be based on e-mail addresses provided in the Investigator list supplied by the Sponsor/CRO.

LABCONNECT

Report Structure

Example Patient Report

SPONSOR:
PROTOCOL:
SITE#:
SUBJECT ID:
DOB:
SEX:
INITIALS:
VISIT #:
VISIT TYPE:
ACCESSION#:
PI NAME:

STUDY SPECIFIC DETAILS

LABCONNECT

2304 Silverdale Dr.
Johnson City, TN 37601

Customer Service
+1 (800) 501-7947

Collected: 7/15/13 10:00 am	Result:	Reference:	Units:	Loc:
Chemistry				
FASTING	YES			LC
GLUCOSE FASTING	158H E	(70 - 99)	mg/dL	JCMC
Note: ---------- Result value meets Exclusion Criteria.				
NA (SODIUM)	135L	(136 - 145)	mmol/L	JCMC
K (POTASSIUM)	4.4	(3.5 - 5.1)	mmol/L	JCMC
CL (CHLORIDE)	98	(98 - 107)	mmol/L	JCMC
CO2 (CARBON DIOXIDE)	29	(22 - 32)	mmol/L	JCMC
BUN (BLOOD UREA NITROGEN)	15	(6 - 20)	mg/dL	JCMC
CREATININE	0.7	(0.6 - 1.1)	mg/dL	JCMC
CA (CALCIUM)	10.5H	(8.6 - 10.0)	mg/dL	JCMC
PHOSPHORUS	2.8	(2.4 - 4.7)	mg/dL	JCMC
URIC ACID	6.5	(2.6 - 6.0)	mg/dL	JCMC
AMYLASE	25L	(28 - 100)	U/L	JCMC
PROTEIN TOTAL	7.0	(6.4 - 8.3)	g/dL	JCMC
ALBUMIN	4.3	(3.5 - 5.2)	g/dL	JCMC
BILIRUBIN TOTAL	0.9	(0.3 - 1.2)	mg/dL	JCMC
ALKALINE PHOSPHATASE	81	(32 - 92)	IU/L	JCMC
SGOT (AST)	17	(15 - 41)	IU/L	JCMC
SGPT (ALT)	21	(17 - 63)	IU/L	JCMC
IRON	48L	(50 - 170)	ug/dL	JCMC
FSH	2.0	(0.4 - 8.6)	mIU/mL	JCMC
Note: Male (>20 years) 1.4 - 18.1 mIU/mL Female (>20 years): Follicular 2.5 - 10.2 mIU/mL Mid-cycle 3.4 - 33.4 mIU/mL Luteal 1.5 - 9.1 mIU/mL Pregnant <0.3 mIU/mL Postmenopausal 23.0 - 116.3 mIU/mL				
Lipids				
CHOLESTEROL	221H	(142 - 200)	mg/dL	JCMC

Report Created: 7/17/2013 1:41:59PM EST Page 1 of 4

L=Low H=High C=Critical *=Abnormal

Alerts and Flags

Standard result alerts and flags that could appear on the report:

L Result value is below reference range.
H Result value is above reference range.
C Result value is critically low or high.
E Result value is exclusionary per protocol requirements.
* Result is abnormal or indicates reference to note.

Critical Laboratory Results

Sites are notified in the event that a critical laboratory result has been generated for a subject. This notification will be a phone call or email from the testing facility or LabConnect Customer Service to the site coordinator or designated site contact. Documentation of this notification will appear in the comments section of the laboratory report.

For projects that include harmonized chemistry ranges, critical laboratory results called or emailed by the testing laboratory will be applicable to the individual testing laboratory ranges. The final report issued by LabConnect will reflect the globally harmonized result, which may differ from the critical value notification from the testing facility. The globally harmonized result is considered the official central laboratory value.

Report Holds

Incomplete or inconsistent information on the request form and samples may cause delays in transmission of laboratory reports.

If you have questions concerning a report hold, please contact Customer Service:
+49 221 8282 9540
Customerserviceemea@labconnect.com

Cancellations

For subject safety reasons, tests may be cancelled if (please note, the following list is not exclusive):

- Samples are received at an incorrect temperature
- Quantity not sufficient (QNS) for analysis
- No sample is submitted for testing
- Samples are not properly labeled

Cancellation notifications will be sent to site contacts via portal email.

Samples tested at the LabConnect EU Wisplinghoff facility will be tested and resulted if received out of stability. A note will be added to the patient report to inform the Investigator and the client that those results may be impacted.

If you have questions concerning a cancellation, please contact Customer Service:
+49 221 8282 9540
Customerserviceemea@labconnect.com

LABCONNECT

APPENDIX A: LABCONNECT SUPPLY REORDER FORM

Complete Form and email to: EMEA-workorders@labconnect.com
ATTENTION: Standard kit and shipper delivery timelines are up to 10 business days plus transit and may be extended during times of peak demand or supply chain impacts.
Non-EU countries: Allow up to 6 days of transit time for kits and shippers from LabConnect EU, which may be extended by Customs clearance.
Expedited shipments may be accommodated but will incur additional fees.
Priority Lane Orders: Critical Patients Only; total max number per order 5, provide visit date (Date Needed*) delivery timelines are up to 4 business days plus transit.
When placing expedited orders please contact EMEA LC PM via e-mail: CS_EMEA@labconnect.com

Sponsor: Connect Biopharma **Protocol:** CBP-201-206 **LC #:** CONN1206

Site Number: _____ **Date Ordered:** _____

Investigator's Name: _____ **Date Needed:** _____
Needed for expedited shipments only, ASAP is not valid, patient visit date is required.

Requested By: _____ **Telephone Number:** _____

Any order requests for supplies **not** listed on this form will **not** be fulfilled by LabConnect

Collection Kit	Requisition Version Number	Shipper Type	Qty
A: Safety(EU)	N/A	Refrigerated** Frozen***	
B: IgE(EU)	N/A	Refrigerated**	
C: PK(EU)	N/A	Frozen***	
D: ADA/nAb(EU)	N/A	Frozen***	
E: Biomarker Sample(EU)	N/A	Frozen***	

*Shippers are not included with collection kits and **must** be ordered separately below. Please note shipper may not be required for every kit.*

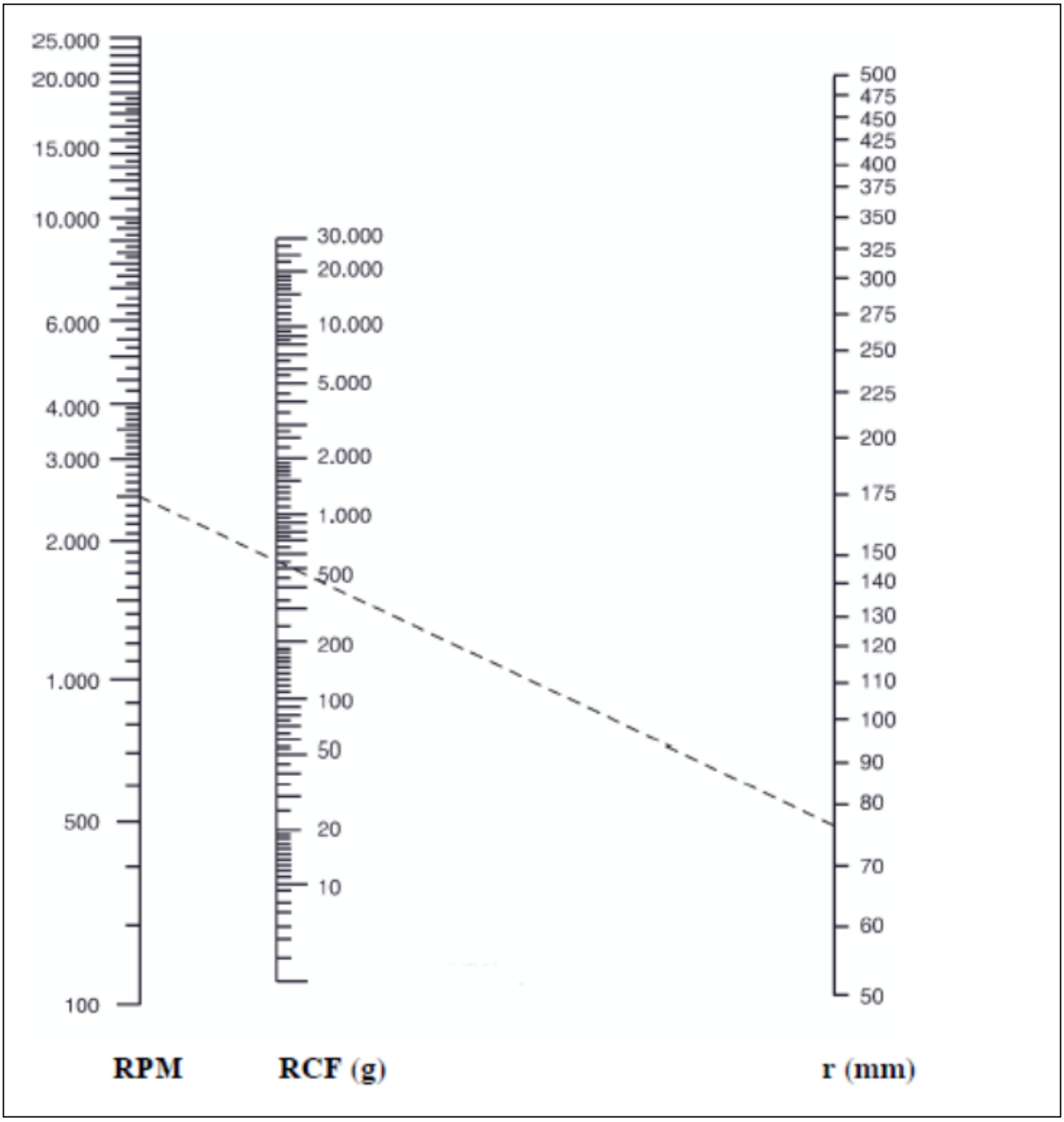
Additional Supplies	Part Number	Qty	Shippers	Part Number	Qty
Pregnancy Kit (Urine): **N/A for Georgia Sites**	731063		SHPR: 72HR REFRIG KIT W/ LC LOGO BOX (No AWB)-**UK sites only**	641017	
Urine Cup with Lid (individual)	411041		****Georgia and Serbia sites: courier is providing refrigerated shipper**		
2ml Cryobox w/ 9x9 Grid	221017		*** Frozen shipper provided by courier		
23G Butterfly Needle (1 pack, 50 butterfly needles)	441058				

LabConnect Internal Use Only

Date Order Received: _____ **SO #:** _____

Date Order Shipped **ID:**

APPENDIX B: NOMOGRAM FOR CONVERTING RCF TO RPM



Nomogram is based on the formula below, where:

- RCF= Relative centrifugal force (g)
- RPM = Centrifuge speed in revolutions per minute
- Radius = Distance in mm from center of centrifuge spindle to bottom of device when in rotor

$$\sqrt{\frac{RCF}{(1.118 \times 10^{6})(Radius\ in\ mm)}} = RPM$$

To convert maximum relative centrifugal force (RCF) to RPM:

1. Determine centrifuge's radius of rotation (in mm) by measuring distance from center of centrifuge spindle to bottom of device when inserted into rotor.
2. Using a straight-edged ruler, line up the known rotating radius on the right with the known RPM on the left.
3. Read the RCF value where the line crosses the graph in the center.

Conversely, RPM can be determined if the RCF value is known using the nomogram.

APPENDIX C: LABCONNECT SUPPLY EXPIRATION GUIDANCE

Initial kit supply orders will allow for use of materials with ≥ 6 months of shelf life, exceptions may apply if material is limited.

Resupply kit supply orders will allow for use of materials with > 4 months of shelf life.

Priority Lane orders, defined as orders to meet urgent scheduled patient visits, will allow for the use of materials with > 3 months of shelf life.

APPENDIX D: CENTRAL LAB REFERENCE RANGES AND CERTIFICATES

Reference Ranges

Reference ranges can be located on the laboratory report alongside the result. A comprehensive list of reference ranges will be available upon request. To request a comprehensive list of reference ranges, contact your LabConnect Project Manager.

Laboratory Certifications

Laboratory Certifications including, but not limited to, Laboratory Director CVs and testing laboratory CLIA, CAP, and state licenses will be provided electronically upon request. To request additional electronic copies or updated copies, contact your LabConnect Project Manager or PC@labconnect.com.

APPENDIX E: ON-SITE TESTING INSTRUCTIONS

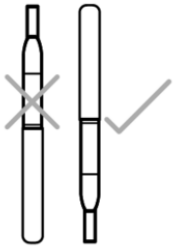
Urine Pregnancy Instructions:

Assay Procedure

Ensure all **Alere™ hCG Easy (25 mIU/mL)** devices and samples are at 18-30 °C. When ready to test, tear open the foil wrapper and remove the device.

After use of device in test, place cap over absorbent sampler.

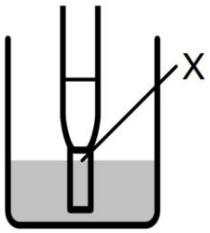
Do not invert the device during testing



Follow **one** of the following procedures:

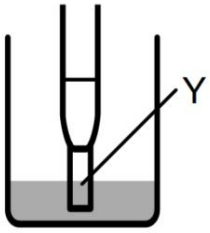
Method A – Dip

- Dip the absorbent sampler into the sample to point X, as shown in the diagram.
- **DO NOT** immerse any plastic parts in urine.
- Hold in place for 15 seconds.
- Remove the device from the sample.
- Place the cap over the absorbent sampler. **DO NOT** invert the device.
- Read result at 3-10 minutes after applying sample. It is important that the background is clear before the result is read.



Method B – Dip And Leave

- Dip **half** of the absorbent sampler into the sample to point Y, as shown in the diagram.
- Leave in place for 3 to 10 minutes.
- Remove the device from the sample.
- Place the cap over the absorbent sampler. **DO NOT** invert the device.
- Read result straight away. It is important that the background is clear before the result is read.

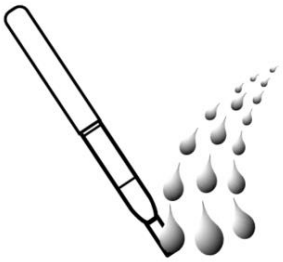


Method C – Pipette

- Place the device on a clean, dry, flat surface with the absorbent side of the sampler facing upwards.
- Pipette 100µL of the urine sample onto the absorbent sampler.
- Place the cap over the absorbent sampler. **DO NOT** invert the device.
- Read result at 3-10 minutes after applying sample. It is important that the background is clear before the result is read.

Method D – Urine Stream

- Ask the patient to hold the absorbent sampler pointing downwards in their urine stream for 3 to 7 seconds **only**.
- Place the cap over the absorbent sampler. **DO NOT** invert the device.
- Place the device on a flat surface.
- Read result at 3-10 minutes after applying sample. It is important that the background is clear before the result is read.



Interpretation of Results

The test can be read 3-10 minutes after applying the sample, regardless of which test procedure is used. See Figure 1.

- **POSITIVE: Two blue lines appear.** One line should be in the Control Line region (C) and another line should be in the Result Line region (R) of the Result Window. The color intensities of lines may vary. Therefore, any shade of color in the Result Line region (R) should be considered positive.
- **NEGATIVE: One blue line appears in the Control Line region (C).** No apparent blue line appears in the Result Line region (R) of the Result Window.
- **INVALID: Control Line (C) fails to appear.** Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new device. If the problem persists, discontinue using the kit immediately and contact your local distributor.
- Any result that appears after 10 minutes must be ignored.

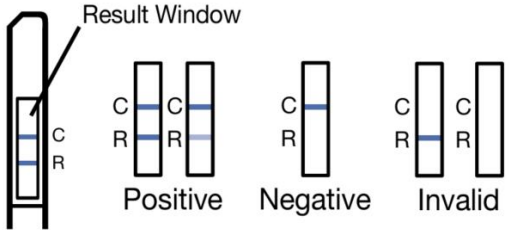


Figure 1

Quality Control

A procedural control is included in the test. A colored line appearing in the control region(C) is the internal procedural control. A clear background is an internal negative procedural control. If a background color appears in the result window and interferes with the ability to read the test result, the result may be invalid.

It is recommended that a positive hCG control (containing 25-250 mIU/mL hCG) and a negative hCG control (containing "0" mIU/mL hCG) be evaluated to verify proper test performance when a new shipment of tests are received.

SPONSOR APPROVAL AND REVISION HISTORY

Sponsor Approval

Sponsor: Connect Biopharma

Protocol Number: CBP-201-206

This document represents final approval authorizing LabConnect to activate study. Any amendments to the said Laboratory Manual require additional written authorization as such amendments affect the laboratory operations.

The contents of said material accurately reflect the parameters and requirements of our Protocol and meet my approval.

Reviewed and Approved By:

Name Marisa Jones

Title Clinical Trials Associate Manager - Connect Biopharma

Signed by:
Marisa Jones
DA7DCEFC9A1D404...

Signature

Date 13-Aug-2025 | 10:33:18 AM PDT

Revision History

Version	Date	Details
Final V2.0	13-Aug-2025	Added Clarification that LC Refrigerated Packaging instructions are for UK sites only and Marken providing refrigerated shippers to sites in Georgia and Serbia
Final V1.0	30-Jul-2025	Final Version