

CENTRAL LABORATORY MANUAL

Australia

Seabreeze

STAT COPD

Protocol Title:

A Phase 2, Multi-center, 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 Participants with Chronic Obstructive Pulmonary Disease and Type 2 Inflammation

Prepared For:

Connect Biopharma
CBP-201-207

Prepared By:

LabConnect
CONN1207

Accelerating the Development of New Medicines.



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*For assistance with
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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.

Australia Holidays

Australian Holidays	2025		2026	
	Day	Date	Day	Date
New Year's Day	Wed	Jan 1	Thurs	Jan 1
Australia Day	Mon	Jan 27	Mon	Jan 26
Labour Day	Mon	Mar 10	Mon	Mar 9
Good Friday	Fri	Apr 18	Fri	Apr 3
Easter Monday	Mon	Apr 21	Mon	Apr 6
ANZAC Day	Fri	Apr 25	Mon	Apr 27
King's Birthday	Mon	Jun 9	Mon	Jun 8
AFL GF Holiday*	TBD	TBD	TBD	TBD
Melbourne Cup Day	Tue	Nov 4	Tue	Nov 3
Christmas Day	Thurs	Dec 25	Fri	Dec 25
Boxing Day	Fri	Dec 26	Mon	Dec 28

***AFL GF PUBLIC HOLIDAY IS SUBJECT TO THE AFL SCHEDULE WHICH IS RELEASED AT THE START OF EACH YEAR. THESE ARE LIKELY TO BE THE HOLIDAY DATES BUT MAY BE SUBJECT TO CHANGE.**



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	Early Termination	Unscheduled
	Visit	V1a	V2 ¹	V5	V6	V8	V9	ET	UNS
	Day	Up to 26 Weeks to D-1	0	3	7 ± 2 Days	28 ± 3 Days	56 ± 3 Days (EOT)		
	Week				1	4	9		
Lab Assessments	Draw Volume (mL)								
Chemistry, including CRP ²	8.5	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 Sample ⁵	3.5		B		B	B	B	B	B
Fibrinogen ⁵	2.7		B		B	B	B	B	B
PK ⁵	2.0		C	C	C	C	C	C	C
ADA/nAb ⁵	4.0		D		D	D	D	D	D
Biomarker Sample ⁵	6.0		E		E	E	E	E	E
Total Blood Draw Per Visit (mL)		12.5	30.7	2.0	26.7	30.7	30.7	30.7	30.7
On-Site Testing									
Urine Pregnancy			X ⁴			X	X		

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

Footnotes:

- 1 Randomization/Baseline 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 COPD exacerbation are already available within 72 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 For women of childbearing potential only if Screening and the Baseline Visit (Day 0) are not on the same day. Analyzed at a local laboratory.
- 5 On Day 0, PK and ADA/nAb samples (as well as Fibrinogen, 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.

Kit Table: Table 2

Kit Letter	Kit Name
A	Safety(AP)
B	IGE/FIBCT(AP)
C	PK(AP)
D	ADA/nAb(AP)
E	Biomarker Sample(AP)

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(AP)	LabConnect MEL-Refrigerated	Investigator	Investigator
B: IGE/FIBCT(AP)	LabConnect MEL-Refrigerated	LabConnect MEL-Frozen	Investigator
C: PK(AP)	LabConnect MEL-Primary Sample	LabConnect MEL-Backup Sample	Investigator
D: ADA/nAb(AP)	LabConnect MEL-Primary Sample	LabConnect MEL-Backup Sample	Investigator
E: Biomarker Sample(AP)	LabConnect MEL-Primary Sample	LabConnect MEL-Backup Sample	Investigator

* Please include white copy with initial sample shipments.

**Please include yellow copy with backup sample shipments.

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.)



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 REQUISITION FORM COMPLETELY.

Sponsor: LabConnect
Protocol: _CopyReqsProtocol

LCName: _CopyReq

Site: 9999
Investigator: Doe, John
1234 Anystreet

Visit:
Single Accession- with visit selection (TEMPLATE)

47302165

Anytown TN 37601
US

Subject ID: |_|_|-|_|_|-|_|_|
 9 9 - 9 9 9 9 - 9 9

Date of Birth: |_|_|-|_|_|-|_|_|
 Y Y Y Y

Gender: |_|M |_|F
Fasting: |_|Yes |_|No

Collection Date: |_|_|-|_|_|-|_|_|-|_|_|-|_|_|-|_|_|
 D D - M M M - Y Y Y Y

Collection Time: |_|_|:|_|_|-|_|_|
 h h : m m (24hr)

Init: xxx
Kit Exp. Date: 09-Sep-9999

All samples should be shipped to LabConnect on day of collection.

Indicate visit collected:

Screen
 Baseline
 Day 1
 Day 2
 Day 3

Collect sample in order below:

REQUIRED TEST	COLLECT	PREPARE	BAR CODE AS	SHIP	LAB USE ONLY	COLLECTED?
Chemistry	1x5 mL Red SST	clot, centrifuge, transfer	CHEM	Ambient		Y N
Hematology	1x4 mL Lavender K2EDTA	mix, submit whole blood	HEMO	Ambient	9CBCC	Y N
Urinalysis	Random urine	transfer urine	URINE	Ambient		Y N

Site Comments:

Lab Use Only: _____

Processor Initials: _____

QC Initials: _____

Notes: _____

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WHITE - LABCONNECT YELLOW - INVESTIGATOR PINK - INVESTIGATOR

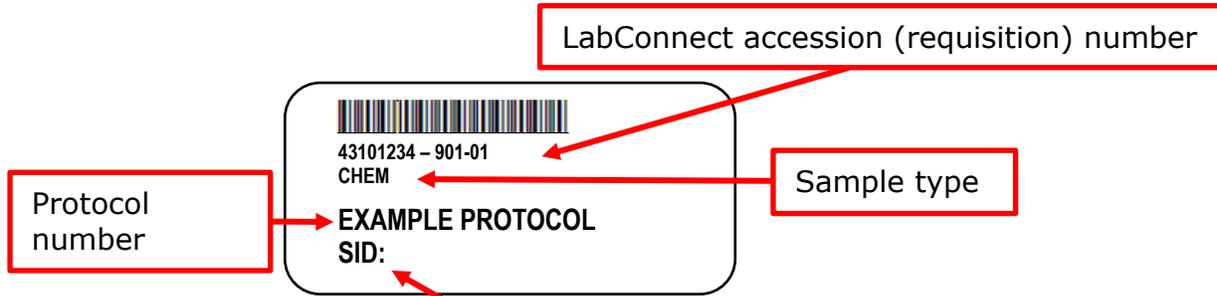
2. Ensure 8-digit requisition/accession number matches number on specimen labels
3. Enter kit expiration date and initial entry, if blank
4. Enter Subject ID, subject demographics, and date/time of specimen collection, as applicable
5. Indicate visit being collected, as applicable
6. Collect samples 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

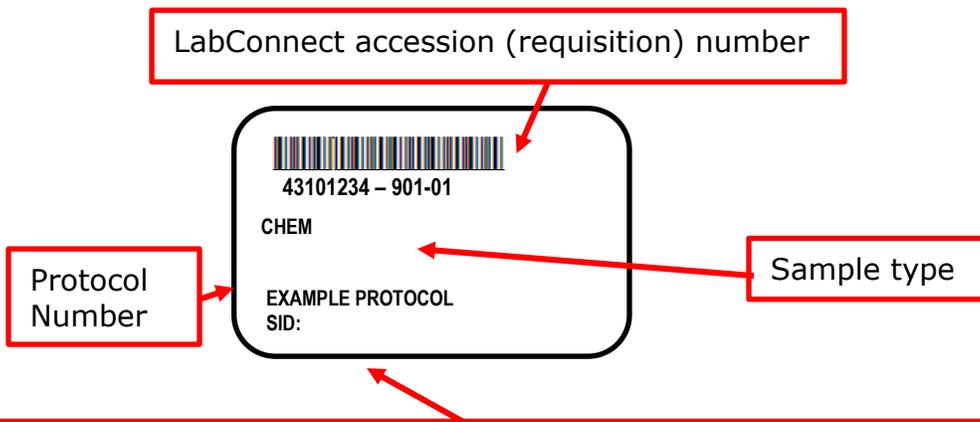
Complete each specimen label appropriately by adding SID and visit type, if applicable, to the pre-printed collection or transport device labels. Do not use a gel pen on specimen labels.

Pre-printed Specimen Label Example



Record the 7-digit subject ID number (SID) on each specimen label using a black ballpoint pen.

Pre-printed Specimen LN2/Frozen Label Example*



Record the 7-digit subject ID number (SID) on each specimen label using a black permanent or waterproof marker.

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



Important Information

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).

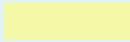
General Collection and Processing Guidance

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

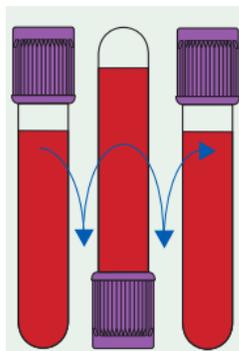
Published order of draw provided for reference: 1. No additive tube or blood culture, 2. Citrate blood, 3. Blood for serum, 4. Heparin blood for plasma, 5. EDTA blood, 6. Other tubes.

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

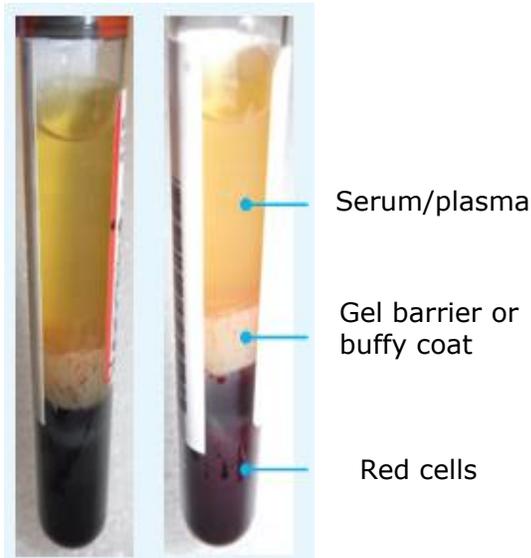
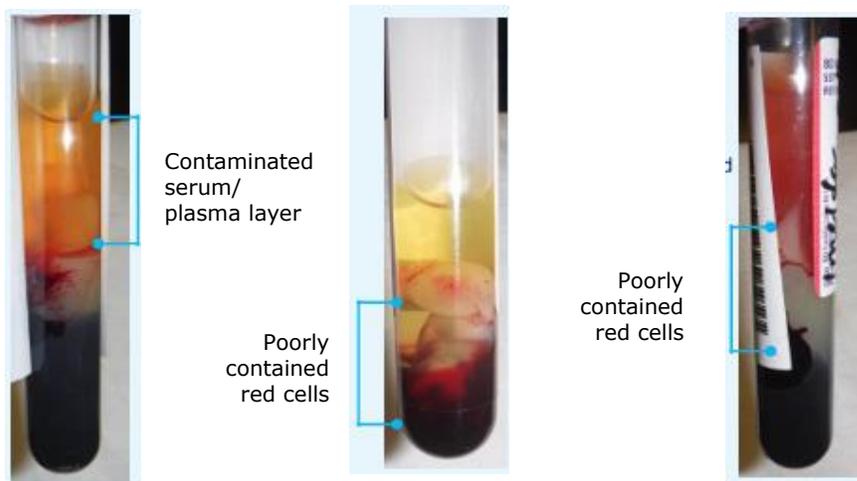


Image: Improperly Centrifuged Blood Specimen





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)

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
Fibrinogen	1 x 2.7 mL Blue Sodium Citrate  Fibrinogen	<ol style="list-style-type: none"> When using a butterfly needle, a discard tube (non-additive tube) should be used before specimen collection (no need to fill discard completely). Invert 3-4 times to mix immediately following collection. Clot. Centrifuge at 2000-2500g for 15 minutes. Transfer all plasma, minimum of 0.9 mL Freeze immediately until ready for shipment. 	1 x 10 mL Transport Tube  FIBCT	Frozen	2 weeks	1 business day (Mon-Fri.)
Chemistry Panel	1 x 8.5 mL Gold SST  CHEM 1	<ol style="list-style-type: none"> Invert 5 times to mix. Clot. Centrifuge at 1800-2200 g for 10-15 minutes Transfer all serum, minimum of 4 mL Refrigerate until ready for shipment 	1 x 4 mL Transport Tube  CHEM	Refrigerated	3 days	1 business day
Total IgE	1 x 3.5 mL Red SST  Immuno	<ol style="list-style-type: none"> Invert 5 times to mix. Clot. Centrifuge at 1800-2200 g for 10-15 minutes. Transfer all serum, minimum of 1.7 mL Refrigerate until ready for shipment. 	1 x 4 mL Transport Tube  IgE	Refrigerated	48 hours	1 business day
ADA/nAb	1 x 4 mL Red No Gel  ADA/nAb	<p><i>Note: Sponsor-provided instructions</i></p> <ol style="list-style-type: none"> Invert 5 times to mix. Clot for at least 30 min. Centrifuge at 1300 ±20g for 10 minutes at Room Temperature within 120 min after collection. 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 2 mL 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  Biomarkers	<p><i>Note: Sponsor-provided instructions</i></p> <ol style="list-style-type: none"> Invert 5 times to mix. Clot for at least 30 min. Centrifuge at 1300 ±20g for 10 minutes at Room Temperature within 120 min after collection. 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). 	6 x 2 mL Cryovials  BS 1  BS 2  BS 3  BS 4  BS 5  BS 6	Frozen	To be assessed	N/A
Hematology	1 x 4 mL Lavender K2 EDTA  HEMO	<ol style="list-style-type: none"> Invert 8 – 10 times <p><i>Hematology specimen must be analyzed within 3 days of collection. Make every effort to ship the sample on the same day as collection"</i></p>	None – transport primary collection container	Refrigerated	72 hours	1 business day
PK	1 x 2 mL Lavender K2 EDTA  PK	<p><i>Note: Sponsor-provided instructions</i></p> <ol style="list-style-type: none"> After collection, gently invert 10 times and then store upright in an ice cold water bath to maintain ~4°C until centrifugation. Centrifuge at 2000 ±20g for 10mins at 4°C for 10 minutes within 120 min after collection and then place in ice water bath for aliquoting. 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). Note: it is important to avoid hemolysis which impacts the assay (send regardless) 	2 x 2 mL Cryovials  PK 1  PK 2	Frozen	746 days	N/A

Test	Collection Device	Preparation Instructions	Transport Container	Temperature	Stability	TAT
Urinalysis with Microscopic	Fresh Random Urine 	1. Transfer urine 2. Invert 8-10 times	1 x 9 mL Clear tube (yellow top) No preservative  UAWMIC	Refrigerated	3 days	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(AP)	Refrigerated	Day of Collection	LabConnect MEL
B: IGE/FIBCT(AP)- IgE	Refrigerated	Day of Collection	LabConnect MEL
B: IGE/FIBCT(AP)- FIBCT	Frozen	Day of Collection	LabConnect MEL
C: PK(AP)	Frozen	Primary: Next planned frozen shipment (PK 1) Back-up: Next planned frozen shipment after primary shipment (PK 2)	LabConnect MEL
D: ADA/nAb(AP)	Frozen	Primary: Next planned frozen shipment (ADA/nAb 1) Back-up: Next planned frozen shipment after primary shipment (ADA/nAb 2)	LabConnect MEL
E: Biomarker Sample(AP)	Frozen	Primary: Next planned frozen shipment (BS 1-3) Back-up: Next planned frozen shipment after primary shipment (BS 3-6)	LabConnect MEL

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.

Shipment Booking

Rest of World Shipments

Refer to the courier 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.

SMARTWAYS SHIPMENTS SHOULD STANDARDLY BE SCHEDULED MONDAY THROUGH THURSDAY FOR ARRIVAL ON TUESDAY THROUGH FRIDAY.



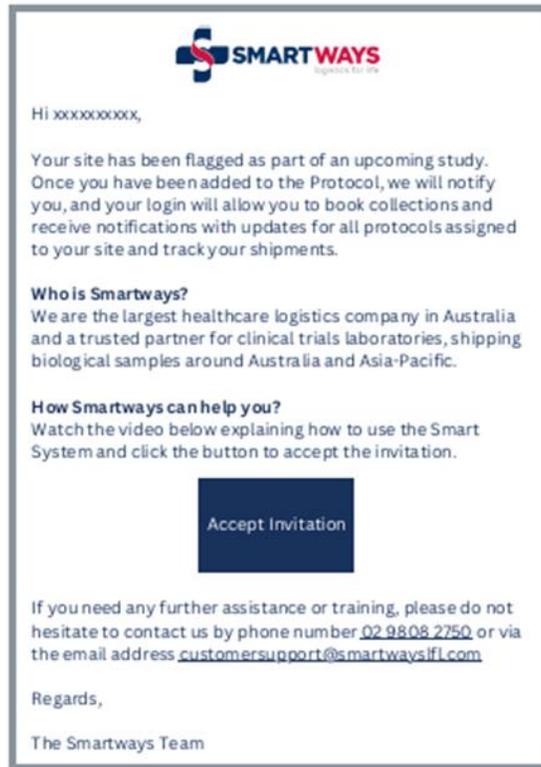
SmartClinical

A Site’s journey – From onboarding to booking shipments

Site Onboarding Email

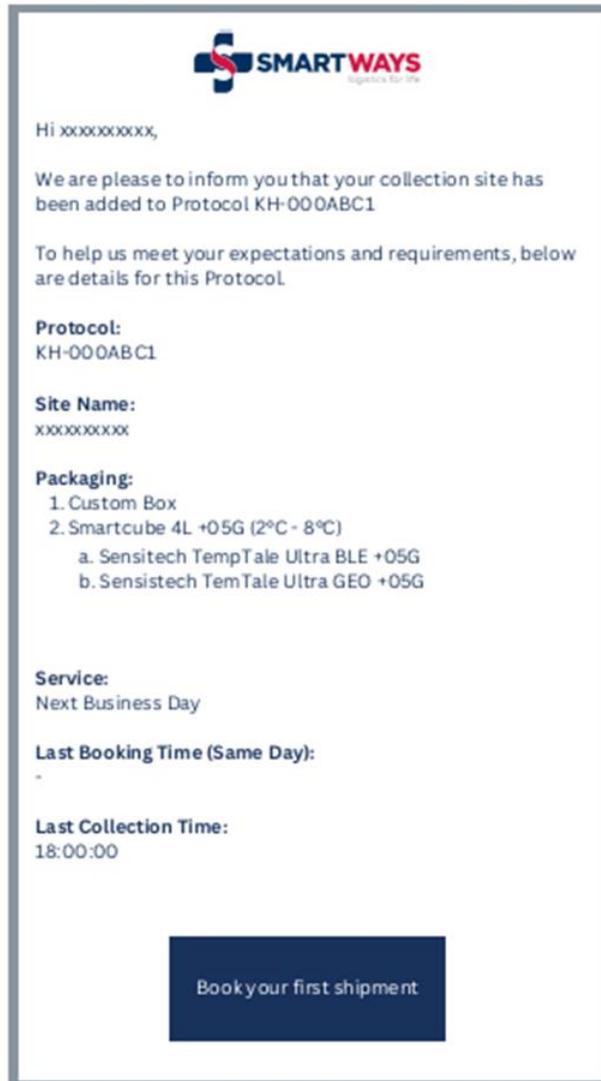
When your site is first added to the Smartways SmartClinical portal, the Site Administrator will receive an ‘Onboarding Email’ (as shown below). By clicking the ‘Accept Invitation’ button, you will be directed to another screen where you can confirm your contact details.

Accepting this invitation is crucial for gaining access to the SmartClinical portal. Afterward, you will receive notifications whenever your site is added to a specific protocol. Your login details will remain the same across all studies, even if they are contracted to different labs.



Notification of being added to a study

When your site is added to a particular protocol, you will receive a confirmation email. This email (as shown in the example below) will include the protocol number, your site name, and all study-specific requirements.





Shipment Materials and Packaging Instructions

Refrigerated Shipper Instructions

REFRIGERATED SHIPPER WITH TUBE/VIAL SPECIMEN TYPES



- 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

Requisition
- 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

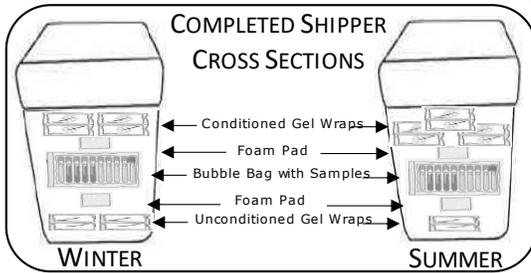
Winter Configuration
Northern Hemisphere: October-April
Southern Hemisphere: May-September

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

Supporting Documentation for Shipment
- 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

Air Waybill Supporting Documentation for Shipment

ATTACH AIR WAYBILL HERE





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
- 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:

- aus-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:

+61 3 9661 0488

sitesupportservicesMEL@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



Laboratory Report Access Form Example



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



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 Form. If one individual is requesting access, please contact PC@LabConnect.com for assistance.

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

The undersigned hereby authorizes LabConnect to send confidential subject laboratory reports to the Investigator site.

Protocol: ABCD1234
Site Number: 00000
Investigator Name: Dr. John Doe

Select delivery method:

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

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

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

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 on below line)
- 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: _____

Complete applicable fields

EXAMPLE - DO NOT

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.



Report Structure

Example Patient Report

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

STUDY SPECIFIC DETAILS



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	158E	(70 - 99)	mg/dL	JMC
Note: ----- Result value meets Exclusion Criteria.				
NA (SODIUM)	135L	(136 - 145)	mmol/L	JMC
K (POTASSIUM)	4.4	(3.5 - 5.1)	mmol/L	JMC
CL (CHLORIDE)	98	(98 - 107)	mmol/L	JMC
CO2 (CARBON DIOXIDE)	29	(22 - 32)	mmol/L	JMC
BUN (BLOOD UREA NITROGEN)	15	(6 - 20)	mg/dL	JMC
CREATININE	0.7	(0.6 - 1.1)	mg/dL	JMC
CA (CALCIUM)	10.5H	(8.6 - 10.0)	mg/dL	JMC
PHOSPHORUS	2.8	(2.4 - 4.7)	mg/dL	JMC
URIC ACID	6.5	(2.6 - 8.0)	mg/dL	JMC
AMYLASE	25L	(28 - 100)	U/L	JMC
PROTEIN TOTAL	7.0	(6.4 - 8.3)	g/dL	JMC
ALBUMIN	4.3	(3.5 - 5.2)	g/dL	JMC
BILIRUBIN TOTAL	0.3	(0.3 - 1.2)	mg/dL	JMC
ALKALINE PHOSPHATASE	81	(32 - 92)	IU/L	JMC
SGOT (AST)	17	(15 - 41)	IU/L	JMC
SGPT (ALT)	21	(17 - 69)	IU/L	JMC
IRON	48L	(50 - 170)	ug/dL	JMC
FSH	2.0	(0.4 - 8.6)	mIU/mL	JMC
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 1.8 - 9.1 mIU/mL Pregnant <0.3 mIU/mL Postmenopausal 23.0 - 116.9 mIU/mL				

Lipids

CHOLESTEROL	221H	(143 - 200)	mg/dL	JMC
-------------	------	-------------	-------	-----

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:
+61 3 9661 0488
sitesupportservicesMEL@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
- Samples are received out of stability
- No sample is submitted for testing
- Samples are not properly labeled

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

**If you have questions concerning a cancellation, please contact Customer Service:
+61 3 9661 0488
sitesupportservicesMEL@labconnect.com**



APPENDIX A: LABCONNECT SUPPLY REORDER FORM

Complete Form and email to: aus-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.

Sites: Allow up to 6 days of transit time for kits and shippers from LabConnect, which may be extended by Customs clearance.

LabConnect Australia: Expedited shipments may be accommodated but will incur additional fees. There may be restrictions on expedited shipments depending on the size of the request. When placing expedited orders please contact sitesupportservicesMEL@labconnect.com

Sponsor: Connect Biopharma	Protocol: CBP-201-207	LC #: CONN1207
Site Number: _____	Date Ordered: _____	
Investigator's Name: _____	Date Needed: _____	
<i>Needed for expedited shipments only, ASAP is not valid, patient visit date is required.</i>		
Requested By: _____	Telephone Number: _____	

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

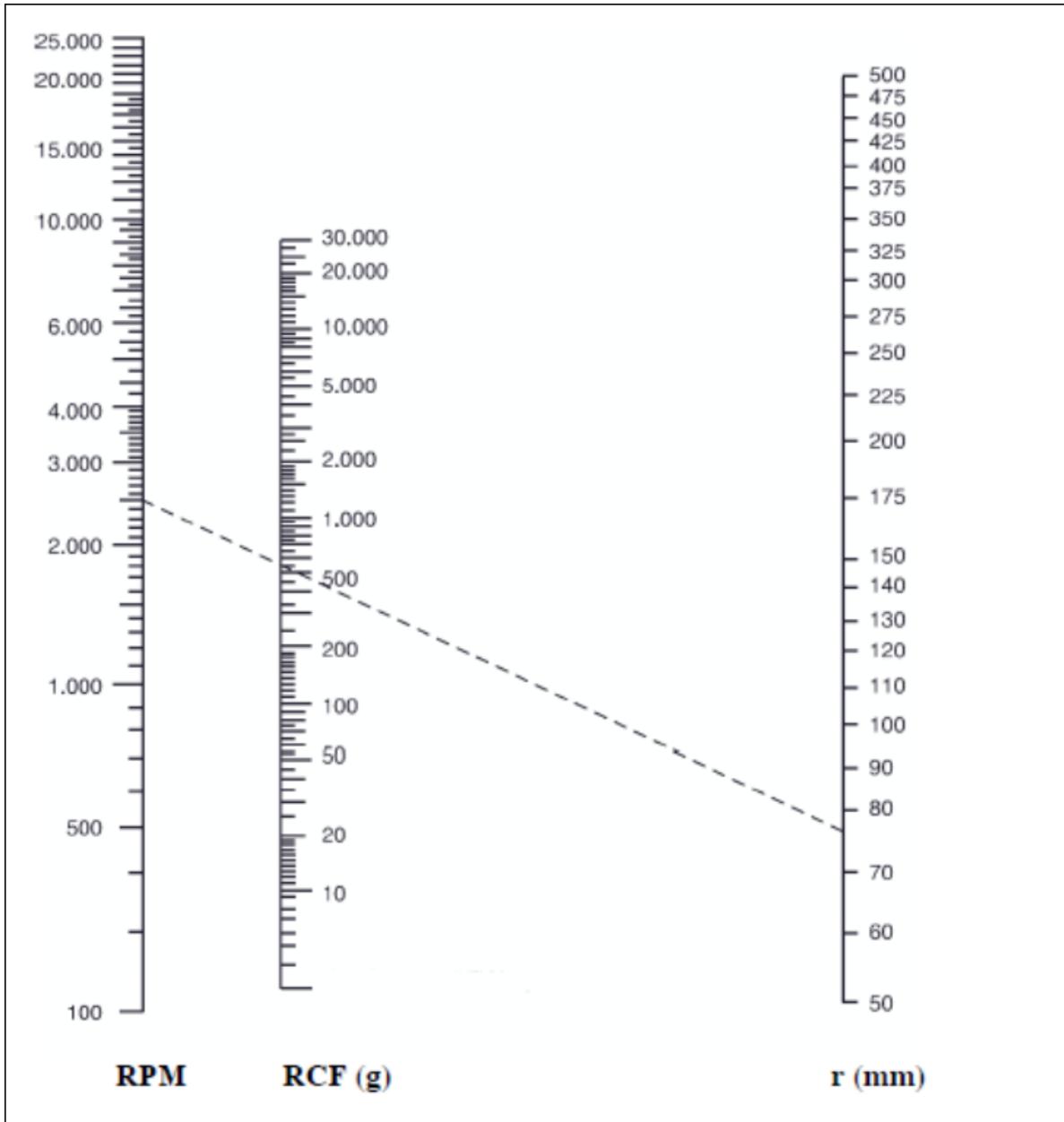
Collection Kit	Requisition Version Number	Shipper Type	Qty
A: Safety(AP)	N/A	Refrigerated	
B: IGE/FIBCT(AP)	N/A	Refrigerated Frozen**	
C: PK(AP)	N/A	Frozen**	
D: ADA/nAb(AP)	N/A	Frozen**	
E: Biomarker Sample(AP)	N/A	Frozen**	

*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 (IVD) (CE)	731090		SHPR: 72HR REFRIG KIT W/ LC LOGO BOX (NO AWB)	641017	
Urine Collection Cup with Lid	411071		** Frozen shipper provided by courier		
2ml Cryobox	221001				
23G butterfly needle (1 pack, 50 needles)	441030				

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

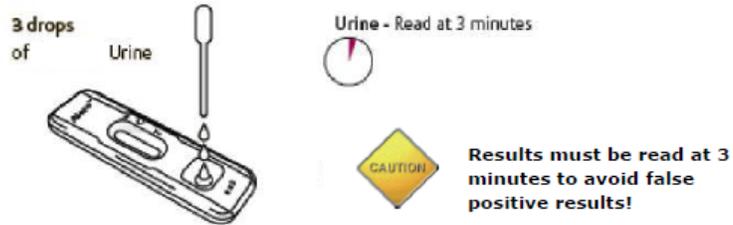
Reference ranges can be located on the laboratory report alongside the result. A comprehensive list of reference ranges will be available upon request. To request a comprehensive list of reference ranges, contact your LabConnect Project Manager.

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.

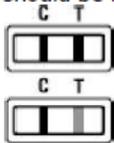
APPENDIX E: ON-SITE TESTING INSTRUCTIONS

Urine Pregnancy Instructions:

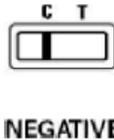


Interpretation of Results:

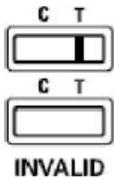
- 1. POSITIVE RESULT**- The test is positive if two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).



- 2. NEGATIVE RESULT** – The test is negative if one red line appears in the control region (C). No apparent red or pink line appears in the test region (T).



- 3. INVALID RESULT** – The test is invalid if control line fails to appear. If no colored line appears in the control region (C), the test is invalid and should be repeated using another test kit.





SPONSOR APPROVAL AND REVISION HISTORY

Sponsor Approval

Sponsor: Connect Biopharma

Protocol Number: CBP-201-207

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:

DA7DCEFC9A1D404...

Signature _____
Date 29-Jul-2025 | 10:44:25 AM PDT



Revision History

Version	Date	Details
V1.0	29-Jul-2025	Final Version

Certificate Of Completion

Envelope Id: 99CF86AD-0EE3-473D-B5D8-080A16E71FFC

Status: Completed

Subject: Complete with Docusign: CBP-201-207_LabConnect_AUS_Laboratory Manual_Final_V1.0_2025-07-29.docx

Source Envelope:

Document Pages: 34

Signatures: 1

Envelope Originator:

Certificate Pages: 4

Initials: 0

Sherry Sponsler

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2304 Silverdale Dr

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100

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Holder: Sherry Sponsler

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Timestamp

Marisa Jones

mjones@connectpharm.com

Clinical Trials Associate Manager - Connect

Biopharma

Security Level: Email, Account Authentication
(None)

Signed by:

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Signature Adoption: Pre-selected Style

Using IP Address: 184.177.166.51

Sent: 7/29/2025 1:40:52 PM

Viewed: 7/29/2025 1:44:16 PM

Signed: 7/29/2025 1:44:25 PM

Electronic Record and Signature Disclosure:

Accepted: 7/29/2025 1:44:16 PM

ID: 37915ab7-83d1-49db-bd42-7de5312d75f4

In Person Signer Events

Signature

Timestamp

Editor Delivery Events

Status

Timestamp

Agent Delivery Events

Status

Timestamp

Intermediary Delivery Events

Status

Timestamp

Certified Delivery Events

Status

Timestamp

Carbon Copy Events

Status

Timestamp

Witness Events

Signature

Timestamp

Notary Events

Signature

Timestamp

Envelope Summary Events

Status

Timestamps

Envelope Sent

Hashed/Encrypted

7/29/2025 1:40:52 PM

Certified Delivered

Security Checked

7/29/2025 1:44:16 PM

Signing Complete

Security Checked

7/29/2025 1:44:25 PM

Completed

Security Checked

7/29/2025 1:44:25 PM

Payment Events

Status

Timestamps

Electronic Record and Signature Disclosure

ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

From time to time, LabConnect Holdings, Inc. (we, us or Company) may be required by law to provide to you certain written notices or disclosures. Described below are the terms and conditions for providing to you such notices and disclosures electronically through your DocuSign, Inc. (DocuSign) Express user account. Please read the information below carefully and thoroughly, and if you can access this information electronically to your satisfaction and agree to these terms and conditions, please confirm your agreement by clicking the 'I agree' button at the bottom of this document.

Getting paper copies

At any time, you may request from us a paper copy of any record provided or made available electronically to you by us. For such copies, as long as you are an authorized user of the DocuSign system you will have the ability to download and print any documents we send to you through your DocuSign user account for a limited period of time (usually 30 days) after such documents are first sent to you. After such time, if you wish for us to send you paper copies of any such documents from our office to you, you will be charged a \$0.00 per-page fee. You may request delivery of such paper copies from us by following the procedure described below.

Withdrawing your consent

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

Consequences of changing your mind

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. To indicate to us that you are changing your mind, you must withdraw your consent using the DocuSign 'Withdraw Consent' form on the signing page of your DocuSign account. This will indicate to us that you have withdrawn your consent to receive required notices and disclosures electronically from us and you will no longer be able to use your DocuSign Express user account to receive required notices and consents electronically from us or to sign electronically documents from us.

All notices and disclosures will be sent to you electronically

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through your DocuSign user account all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

How to contact LabConnect Holdings, Inc.:

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:

To contact us by email send messages to: jcarter@labconnectllc.com

To advise LabConnect Holdings, Inc. of your new e-mail address

To let us know of a change in your e-mail address where we should send notices and disclosures electronically to you, you must send an email message to us at jcarter@labconnectllc.com and in the body of such request you must state: your previous e-mail address, your new e-mail address. We do not require any other information from you to change your email address..

In addition, you must notify DocuSign, Inc to arrange for your new email address to be reflected in your DocuSign account by following the process for changing e-mail in DocuSign.

To request paper copies from LabConnect Holdings, Inc.

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an e-mail to jcarter@labconnectllc.com and in the body of such request you must state your e-mail address, full name, US Postal address, and telephone number. We will bill you for any fees at that time, if any.

To withdraw your consent with LabConnect Holdings, Inc.

To inform us that you no longer want to receive future notices and disclosures in electronic format you may:

- i. decline to sign a document from within your DocuSign account, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;
- ii. send us an e-mail to jcarter@labconnectllc.com and in the body of such request you must state your e-mail, full name, IS Postal Address, telephone number, and account number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

Required hardware and software

Operating Systems:	Windows2000? or WindowsXP?
Browsers (for SENDERS):	Internet Explorer 6.0? or above
Browsers (for SIGNERS):	Internet Explorer 6.0?, Mozilla FireFox 1.0, NetScape 7.2 (or above)
Email:	Access to a valid email account
Screen Resolution:	800 x 600 minimum
Enabled Security Settings:	<ul style="list-style-type: none">• Allow per session cookies

- | | |
|--|---|
| | <ul style="list-style-type: none">• Users accessing the internet behind a Proxy Server must enable HTTP 1.1 settings via proxy connection |
|--|---|

** These minimum requirements are subject to change. If these requirements change, we will provide you with an email message at the email address we have on file for you at that time providing you with the revised hardware and software requirements, at which time you will have the right to withdraw your consent.

Acknowledging your access and consent to receive materials electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please verify that you were able to read this electronic disclosure and that you also were able to print on paper or electronically save this page for your future reference and access or that you were able to e-mail this disclosure and consent to an address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format on the terms and conditions described above, please let us know by clicking the 'I agree' button below.

By checking the 'I Agree' box, I confirm that:

- I can access and read this Electronic CONSENT TO ELECTRONIC RECEIPT OF ELECTRONIC RECORD AND SIGNATURE DISCLOSURES document; and
- I can print on paper the disclosure or save or send the disclosure to a place where I can print it, for future reference and access; and
- Until or unless I notify LabConnect Holdings, Inc. as described above, I consent to receive from exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to me by LabConnect Holdings, Inc. during the course of my relationship with you.