LABCONNECT

CENTRAL LABORATORY MANUAL

United States

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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CONTACT INFORMATION

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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.

US Holidays

US Holidays	2025		2026	
	Day	Date	Day	Date
New Year's Day (January 1)	Wed	Jan 1	Thurs	Jan 1
Martin Luther King Jr. Day (Third Monday of January)	Mon	Jan 20	Mon	Jan 19
Memorial Day (Last Monday of May)	Mon	May 26	Mon	May 25
Independence Day (July 4)	Fri	Jul 4	Sat	Jul 4
Labor Day (First Monday of September)	Mon	Sep 1	Mon	Sep 7
Thanksgiving (Last Thursday of November)	Thurs	Nov 27	Thurs	Nov 26
Day after Thanksgiving (Last Friday of November)	Fri	Nov 28	Fri	Nov 27
Christmas Eve (December 24)	Wed	Dec 24	Thurs	Dec 24
Christmas Day (December 25)	Thurs	Dec 25	Fri	Dec 25

LABCONNECT

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]	12.0	A	A[3]		A	A	A	A	A
Hematology[2]	3.0	A	A[3]		A	A	A	A	A
Urinalysis[2]		A	A[3]		A	A	A	A	A
Total IgE[4]	3.5		B		B	B	B	B	B
PK[4]	2.0		C	C	C	C	C	C	C
ADA/nAb[4]	3.0		D			D	D	D	D
Biomarker Sample[4]	6.0		E		E	E	E	E	E
Total Blood Draw Per Visit (mL)		15.0	29.5	2.0	26.5	29.5	29.5	29.5	29.5
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(AM)
B	IgE(AM)
C	PK(AM)
D	ADA/nAb(AM)
E	Biomarker Sample(AM)

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. 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.

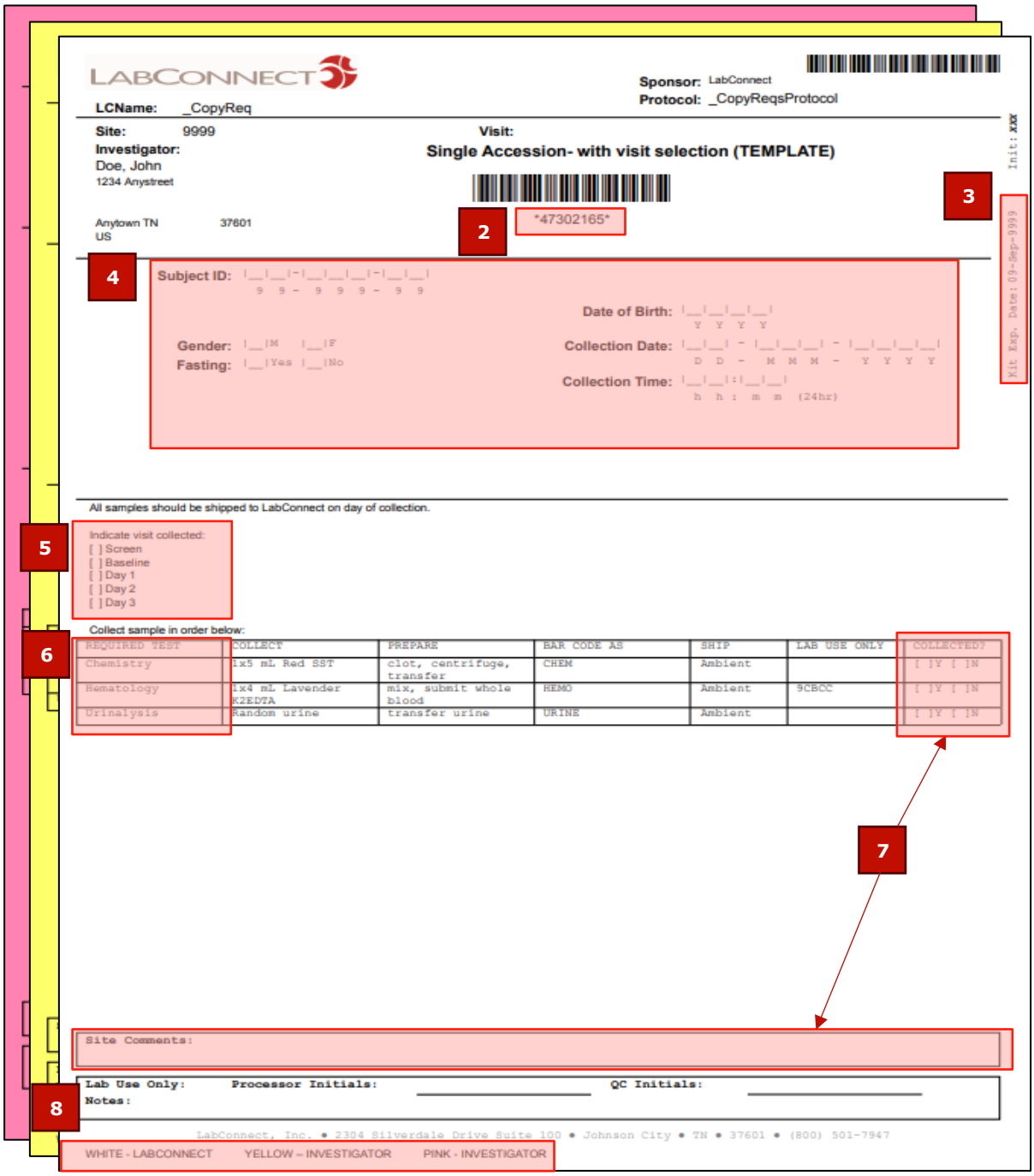
Requisition Copy Guide

Kit Name	White Copy	Yellow Copy	Pink Copy
A: Safety(AM)	LabConnect Cleveland	Investigator	Investigator
B: IgE(AM)	LabConnect Cleveland	Investigator	Investigator
C: PK(AM)	LabConnect Cleveland*	LabConnect Cleveland**	Investigator
D: ADA/nAb(AM)	LabConnect Cleveland*	LabConnect Cleveland**	Investigator
E: Biomarker Sample(AM)	LabConnect Cleveland*	LabConnect Cleveland**	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.)

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

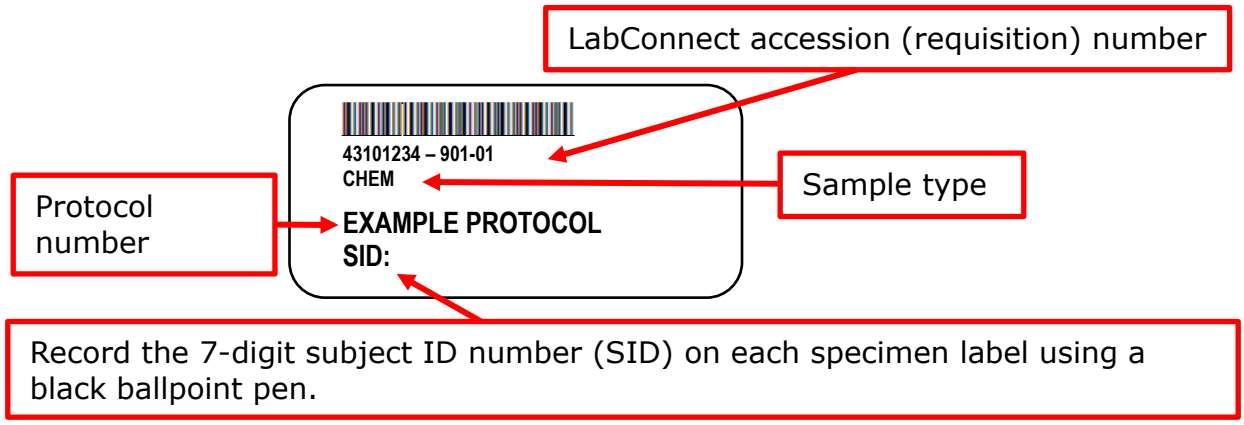


2. Ensure 8-digit requisition/accession number matches number on specimen labels
3. Enter kit expiration date and initial entry, if blank
4. Enter Subject ID, subject demographics, and date/time of specimen collection, as applicable
5. Indicate visit being collected, as applicable
6. Collect samples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

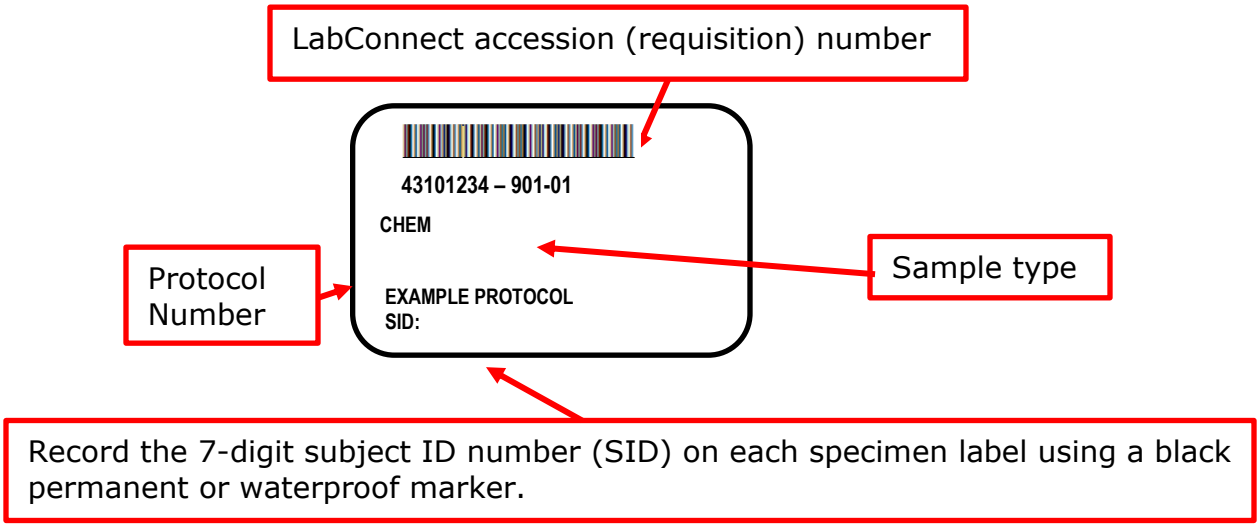
Completing Labels

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

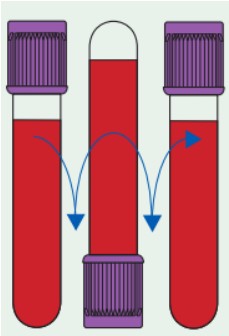
Published order of draw provided for reference: 1. No additive tube or blood culture, 2. Citrate blood, 3. Blood for serum, 4. Heparin blood for plasma, 5. EDTA blood, 6. Other tubes.

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

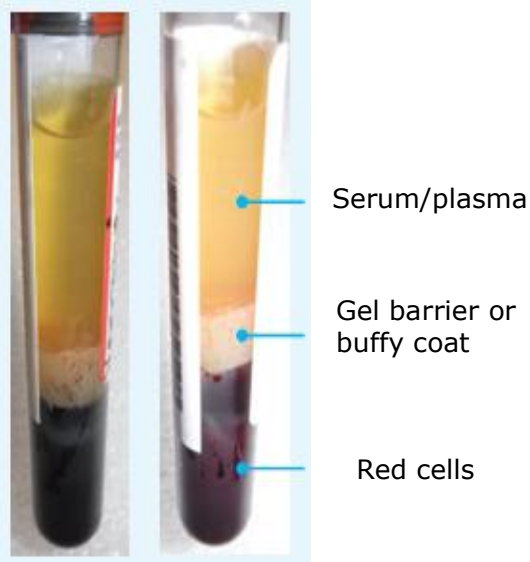
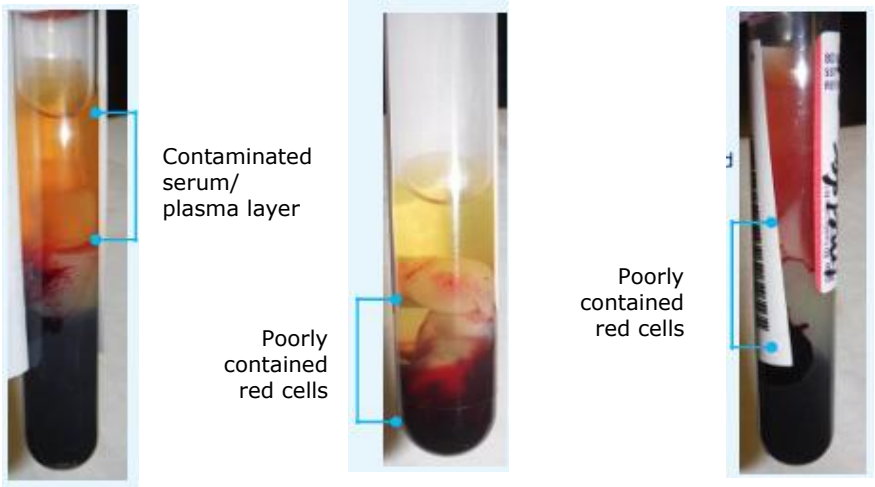


Image: Improperly Centrifuged Blood Specimen



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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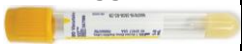
Specimen Collection Table

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	3 x 4 mL Red SSTs  **CHEM 1**  **CHEM 2**  **CHEM 3**	1. Invert 5 times to mix. 2. Clot. 3. Centrifuge at 1800-2200 g for 10-15 minutes 4. Transfer a minimum of **1.0 mL** of serum to tube labeled **CK/LD6**. 5. Transfer a minimum of **1.5** mL to tube labeled **CMP/CRP/GGT.** 6. Transfer a minimum of **2.0 mL** to tube labeled **CHOL/TRIG/URIC/DBIL.** 7. Refrigerate until ready for shipment.	3 x 4 mL Transport Tubes  **CK/LD6**  **CMP/CRP/GGT**  **CHOL/TRIG/URIC/DBIL**	Refrigerated	CK/LD6: 4 days CMP/CRP/GGT: 72 hours after separation from cells CHOL/TRIG/URIC/DBIL: 7 days	1 business day
Total IgE	1 x 3.5 mL Gold SST  **Immuno**	1. Invert 5 times to mix. 2. Clot. 3. Centrifuge at 1800-2200 g for 10-15 minutes. 4. Transfer a minimum of **0.50 mL** of serum and refrigerate until ready for shipment.	1 x 4 mL Transport Tube  **IgE**	Refrigerated	30 days	1-3 business days
ADA/nAb	1 x 3 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
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

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Test	Collection Device	Preparation Instructions	Transport Container	Temperature	Stability	TAT
Hematology Panel	1 x 3 mL Lavender K2 EDTA  **CBCDIF**	1. Invert 8 – 10 times. *Hematology specimen must be analyzed within 2 days of collection. Make every effort to ship the sample on the same day as collection.*	None – transport primary collection container	Refrigerated	48 hours	1.5 days
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
Urinalysis Panel	Fresh Random Urine 	1. Transfer urine. 2. Invert 8-10 times.	1 x 8 mL Red/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

Test	Collection Device	Preparation Instructions	Transport Container	Temperature	Stability	TAT
						

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(AM)	Refrigerated	Day of Collection	LabConnect Cleveland
B: IgE(AM)	Refrigerated	Day of Collection	LabConnect Cleveland
C: PK(AM)	Frozen	Primary: Next planned frozen shipment (PK 1) Back-up: Next planned frozen shipment after primary shipment (PK 2)	LabConnect Cleveland
D: ADA/nAb(AM)	Frozen	Primary: Next planned frozen shipment (ADA/nAb 1) Back-up: Next planned frozen shipment after primary shipment (ADA/nAb 2)	LabConnect Cleveland
E: Biomarker Sample(AM)	Frozen	Primary: Next planned frozen shipment (BS 1-2) Back-up: Next planned frozen shipment after primary shipment (BS 3-4)	LabConnect Cleveland

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 – LabConnect Provided

Each shipper will have a pre-addressed airway bill attached to the outside of the cardboard shipping container. The bottom portion of the return airway bill with the tracking number can be found inside each shipper and is provided for specimen tracking. The bottom portion should be retained for your records and shipment tracking purposes.

Additional airway bills can be ordered from LabConnect. Airway bills must be ordered prior to the subject visit.

Image: Example Ambient Airway Bill

Image: Example Frozen Airway Bill

Tracking Number

Shipment Booking

UPS – United States Domestic

Contact UPS for pickup **1-844-4UPS-LAB (1-844-487-7522).**

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

Note: Please use Fed-Ex for Sunday Shipments. Saturday shipments are not accepted.

LabConnect's pre-addressed airway bills include the option for Saturday delivery.

FedEx Same Day Booking Instructions

(US ONLY, Sunday Shipments**)**

FedEx booking email address: SPS_US-TC@fedex.com

Latest Call Time: 4 hours advance notice required. Two cutoff times:

- Schedule by 10:00 am for courier pickup by 2:00 pm and delivery by Monday at 8:00 am.
- Schedule by 2:00 pm for courier pickup by 6:00 pm and delivery by Monday at 3:00 pm.

****Record Booking No. to identify shipment****

Email Subject Line Format: - LabConnect Study Name and Site No. / LabConnect Pick up (Town & State) / delivering to (Town & State), 5/27 (Date)

Ex: CONN1206 Site 1901 / LabConnect Pick up (Honolulu, HI) / Delivering to (Cleveland, OH), 5/27

Pickup/Delivery Details:

- Complete pick up address (Dept/Floor)
- Contact name & Phone ****MUST be a direct contact knowledgeable of the pickup to avoid any delays with completing the collection****
- Complete delivery address:
  - LabConnect Cleveland
  - 3201 Carnegie Avenue Cleveland, OH 44115
  - Attn: Gabriella Sanchez
  - +1 216-930-9021
  - gsanchez@labconnect.com
- No. of Pieces
- Weight
- Dimensions (Ex Refrigerated Shipper provided by LabConnect : L= 19 in x W =12 in x H= 12 in)
- Description of goods
- Dangerous good (Y/N)
- Pickup and delivery date

Note: Please select appropriate shipper provided by LabConnect and remove UPS air waybill. Vendor will provide air waybill required for shipment.

Samples will be tracked by booking number.

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

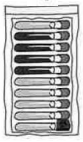
1 Ambient Gel Wrap

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

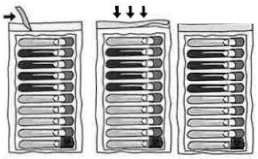
2 Ambient Gel Wraps

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

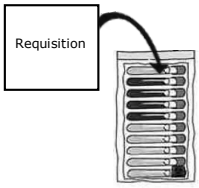
3 **Insert samples into the sample sleeve inside the Sample Bag**



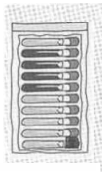
4 **Peel off the inner tape liner to expose the adhesive and fold, pressing firmly from the center to the end closing the bag**



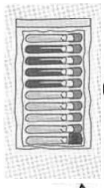
5 **Place the appropriate copy of the requisition(s) in the pouch on the Sample Bag**



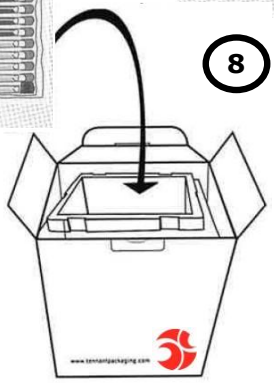
6 **Insert Sample Bag into the Bubble Bag**



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

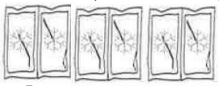


8 **Insert one foam pad over the Bubble Bag**



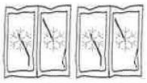
9 **Insert the season-appropriate number of conditioned (frozen) Gel Wraps over the foam pad**

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

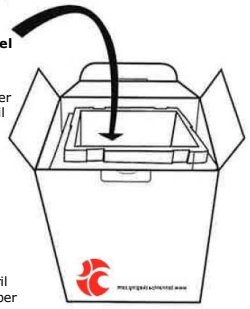


Freeze 3 Gel Wraps for at least 24 hours in at least -18°C or -4°F before use

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

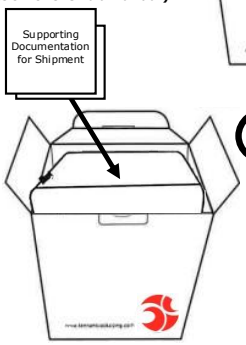


Freeze 2 Gel Wraps for at least 24 hours in at least -18°C or -4°F before use

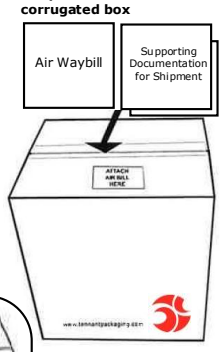


10 **Replace foam lid on EPS Molded Cooler securing the inner box**

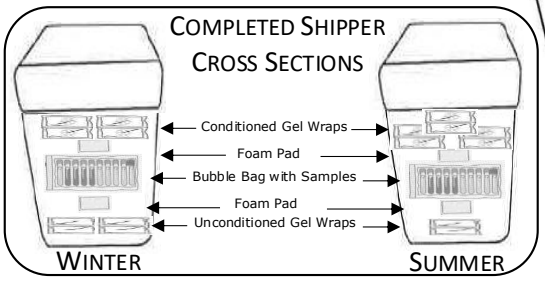
11 **Place a copy of each Supporting Documentation for Shipment atop the foam lid of the EPS Molded Cooler (list of required documents supplied in the Supporting Documentation for Shipment section of the Lab Manual)**



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



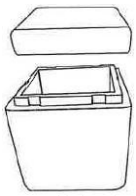
LABCONNECT

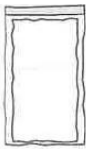
VV-QUAL-03688 Reference Document – Shippers & Temp Loggers v1

FROZEN (DRY ICE) SHIPPER WITH TUBE/VIAL SPECIMEN TYPES

CONTENTS


Corrugated box

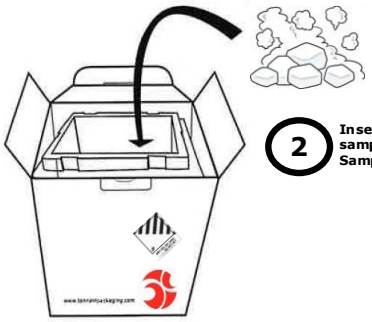

EPS Molded Cooler


95kPa Sample Bag with absorbent sleeve

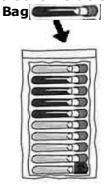

Dry Ice

The weight of the dry ice added to the shipper at time of shipment ***MUST*** match the preestablished weight determined on the Air Waybill (AWB) in kilograms.
DO NOT change the AWB or the AWB weight.
DO NOT over pack or under pack the dry ice.

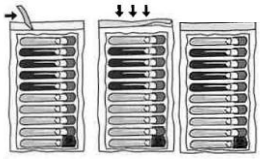
1 **Insert 50% of the AWB determined dry ice into the EPS Molded Cooler inside the Corrugated box**



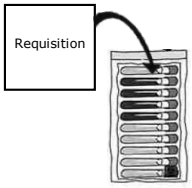
2 **Insert samples into the sample sleeve inside the Sample Bag**



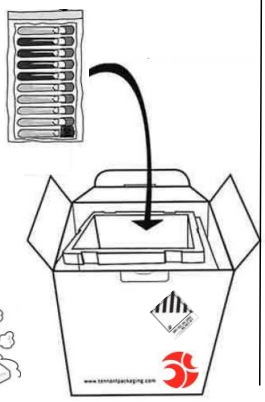
3 **Peel off the inner tape liner to expose the adhesive and fold, pressing firmly from the center to the end closing the bag**



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



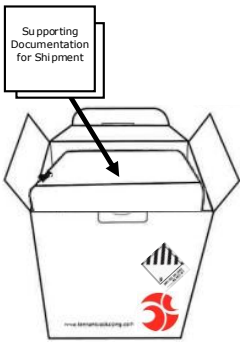
5 **Insert Sample Bag over top the packed dry ice**



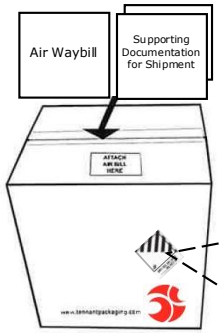
6 **Insert the remaining 50% of the AWB determined dry ice into the EPS Molded Cooler inside the Corrugated box**

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

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

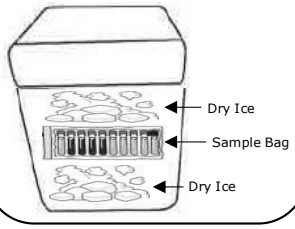


9 **Seal corrugated box and insert copy of air waybill (if not previously affixed to shipper) and a copy of each Supporting Documentation for Shipment in the pouch affixed to the corrugated box**



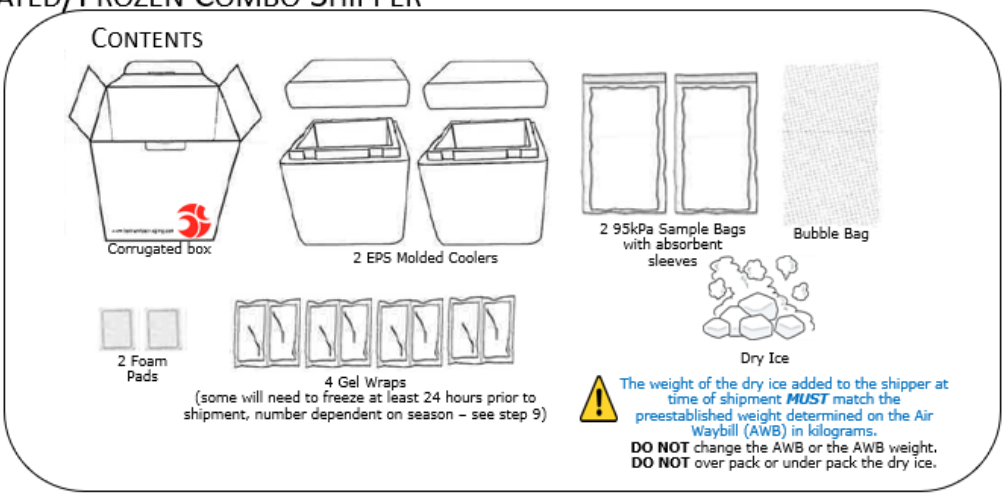
10 **Write the weight of the dry ice used in kilograms on the space provided on the Class 9 place card located on the outside of the corrugated box. This weight should match what is determined on the AWB.**

COMPLETED SHIPPER CROSS SECTIONS



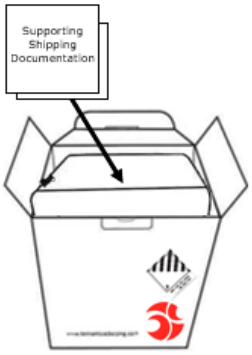
Refrigerated/Frozen Combo Shipper Instructions

REFRIGERATED/FROZEN COMBO SHIPPER

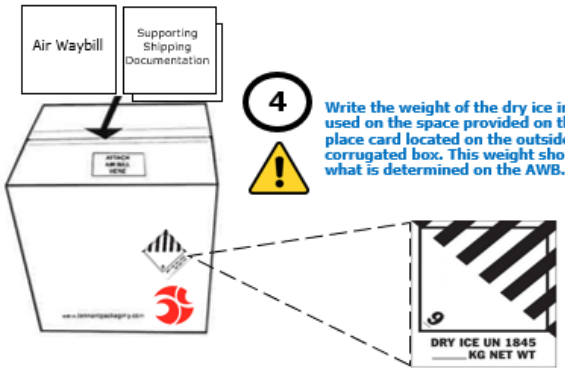


REFRIGERATED/FROZEN COMBO SHIPPERS ARE A FROZEN AND REFRIGERATED SHIPPER SIDE-BY-SIDE.

1. **Pack each shipper per the individual instructions up to and including placing the lid back on the EPS Molded Cooler**
2. **Place a copy of each Supporting Shipping Documents atop the foam lid of the EPS Molded Cooler (list supplied in the Supporting Documentation for Shipment section of the Lab Manual)**



3. **Seal corrugated box and insert copy of air waybill and a copy of each Supporting Shipping Documents in the pouch affixed to the corrugated box**



4. **Write the weight of the dry ice in kilograms used on the space provided on the Class 9 place card located on the outside of the corrugated box. This weight should match what is determined on the AWB.**

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:

- WorkOrders@labconnect.com
  - LabConnect US **DOES NOT** process orders between December 18th and December 31st each year. To have orders fulfilled in December, orders must be received by December 9th (if December 9th falls on a weekend, orders must be received the Friday prior).
  - For expedited shipments call Clinical Trial Materials at 1-800-501-7947 ext. 2 (additional fees apply for expedited shipments). There may be restrictions on expedited shipments depending on the size of the request.

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:
+1 (800) 501-7947 ext. 3
Customerservice@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

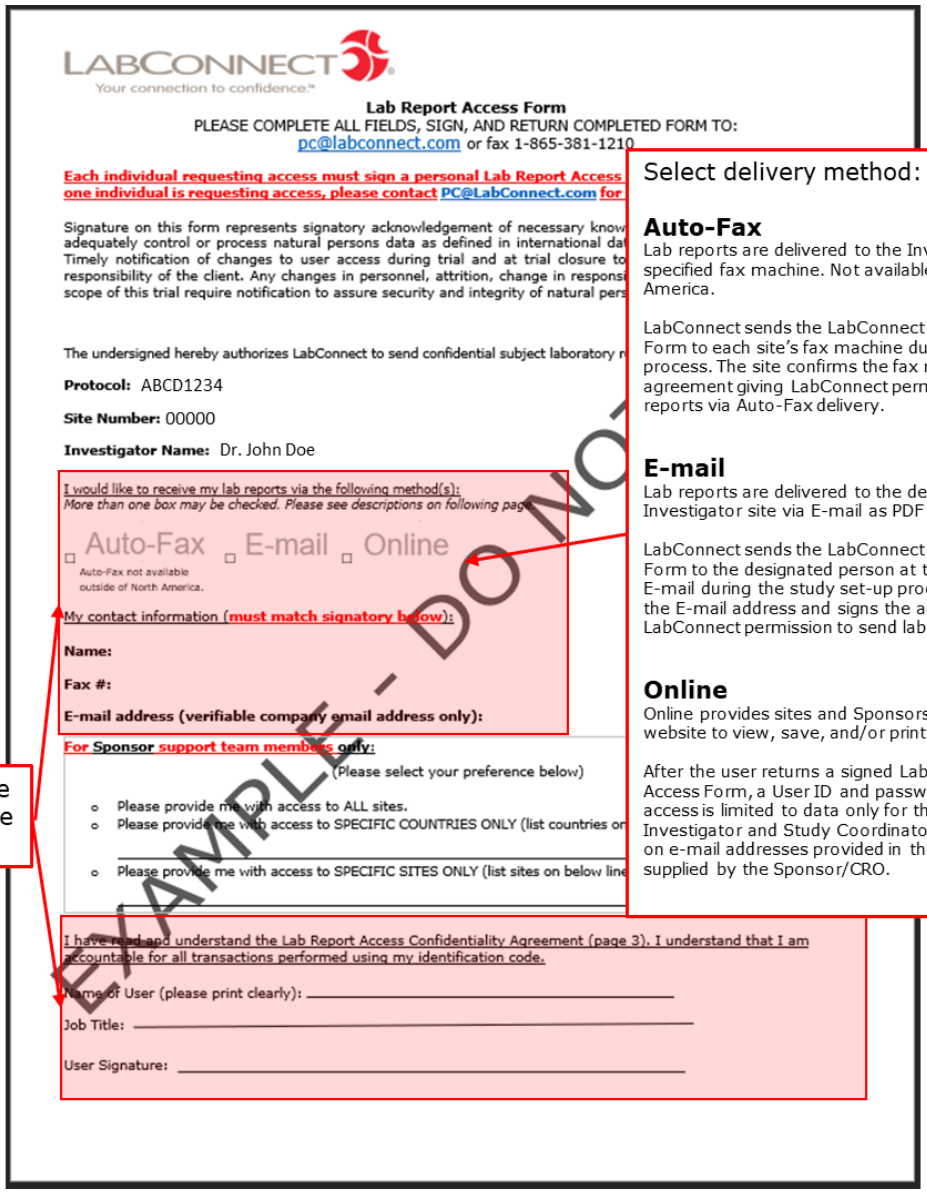
Contacts listed on the Site List will automatically receive a Lab Report Access request form. If a site contact is not listed on the Site List, request a Lab Report Access Form from Project Coordinators at PC@labconnect.com. NOTE: Each individual requesting access must sign a personal Lab Report Access 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:
+1 (800) 501-7947 ext. 3
Customerservice@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:
+1 (800) 501-7947 ext. 3
Customerservice@labconnect.com

LABCONNECT

APPENDIX A: LABCONNECT SUPPLY REORDER FORM

Complete Form and email to: 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. US Sites: Allow up to 2-5 days of transit time for kits and shippers from LabConnect US.

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

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

Investigator's Name: _____ **Date Needed:** _____

ASAP is not valid, date required

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

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

Collection Kit	Shipper Type	Qty
A: Safety(AM)	Refrigerated	
B: IgE(AM)	Refrigerated	
C: PK(AM)	Frozen	
D: ADA/nAb(AM)	Frozen	
E: Biomarker Sample(AM)	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)	731037		Combo Refrigerated/Frozen Shipper w/ UPS return AWB to LC Cleveland	641022	
Urine Cup with Lid (individual)	411071		Frozen Shipper w/ UPS return AWB to LC Cleveland	641018	
2ml Cryobox w/ 9x9 Grid	221001		Refrigerated Shipper w/ UPS return AWB to LC Cleveland	641017	
23G Butterfly Needle (1 pack, 50 butterfly needles)	441030				

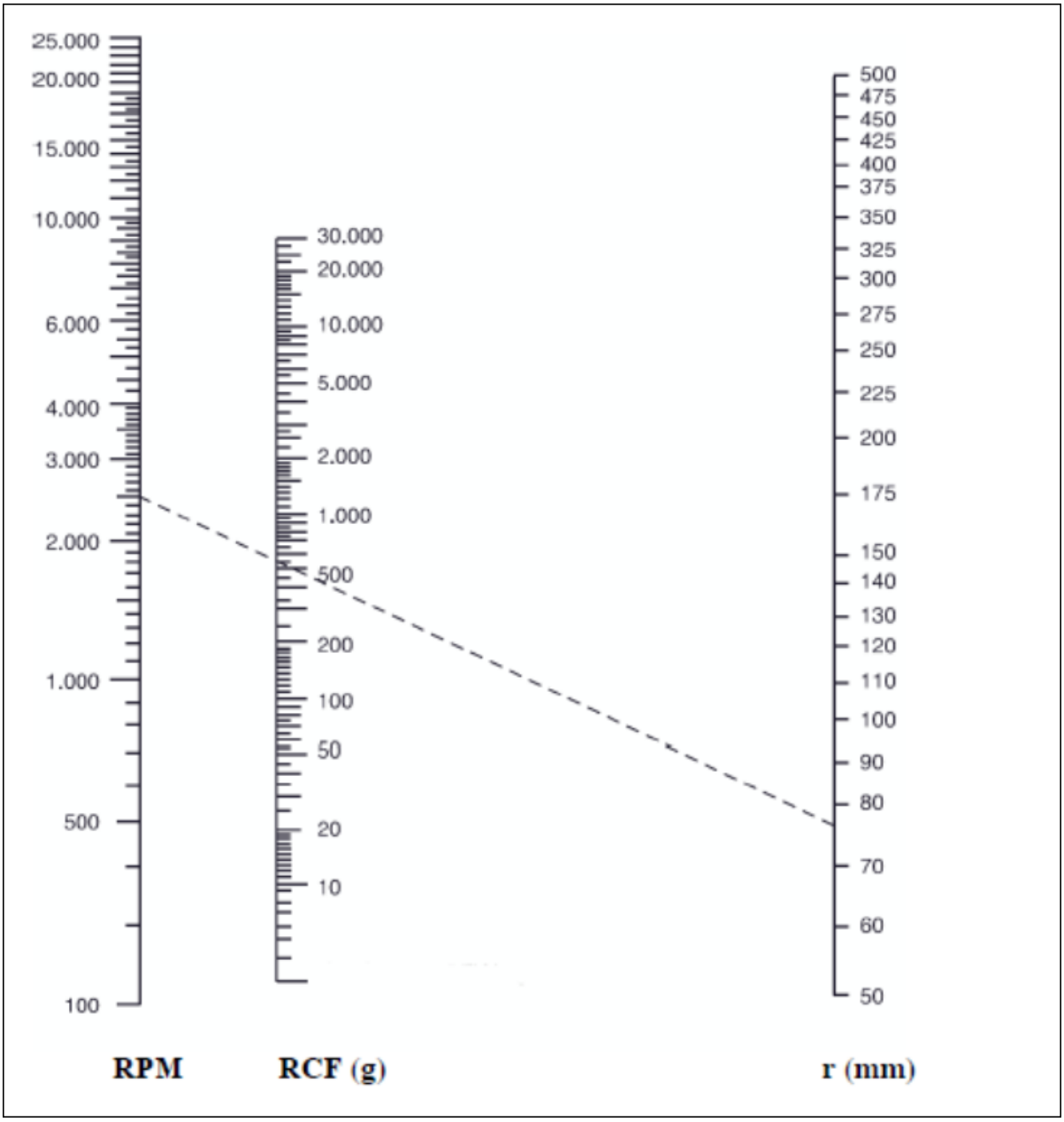
LabConnect US DOES NOT process orders between December 18th and December 31st each year. To have orders fulfilled in December orders must be received by December 9th (if December 9th falls on a weekend, orders must be received the Friday prior).

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.

Sure-Vue® Orina hCG — Ficha Técnica

Prueba rápida para la detección cualitativa de gonadotropina coriónica humana (hCG) en orina.

Solo para uso profesional de diagnóstico in vitro.

USO INDICADO

La Prueba Sure-Vue® Orina hCG es un inmunoensayo cromatográfico rápido para la detección cualitativa de la Gonadotropina Coriónica humana en orina, para la detección precoz del embarazo.

RESUMEN

La Gonadotropina Coriónica humana (hCG) es una hormona glucoproteica producida por la placenta en desarrollo poco después de la fertilización. En el embarazo humano, la hCG puede detectarse tanto en orina como en suero ya a los 7-10 días de la concepción.[1-4] Los niveles de hCG continúan aumentando muy rápidamente, superando las 100mUI/ml tras la primera falta[2-4] y alcanzando el máximo en torno a 100.000-200.000mUI/ml a las 10-12 semanas de embarazo. La aparición de hCG en orina y suero poco después de la concepción y su posterior aumento rápido durante el principio de la gestación convierten a esta hormona en un excelente marcador para la detección precoz del embarazo.

La Prueba Sure-Vue® Orina hCG es una prueba rápida que detecta cualitativamente la presencia de hCG en una muestra de orina con una sensibilidad de 25mUI/ml. La prueba utiliza una combinación de anticuerpos monoclonales y policlonales para detectar selectivamente los niveles elevados de hCG en orina. Con el nivel de sensibilidad mencionado, la Prueba Sure-Vue® Orina hCG no muestra interferencias cruzadas con otras hormonas glucoproteicas estructuralmente relacionadas, FSH, LH y TSH, en niveles fisiológicos altos.

PRINCIPIO

La Prueba Sure-Vue® Orina hCG es un inmunoensayo cromatográfico rápido para la detección cualitativa de la Gonadotropina Coriónica humana en orina, para el diagnóstico precoz del embarazo. La prueba utiliza dos líneas para indicar el resultado. La línea de la prueba utiliza una combinación de anticuerpos que incluyen un anticuerpo monoclonal hCG para detectar selectivamente niveles elevados de hCG. La línea de control está compuesta por anticuerpos policlonales de cabra y partículas coloidales de oro. El ensayo se realiza añadiendo la muestra de orina al pocillo de la placa y observando la formación de líneas de color. La muestra migra por acción capilar por la membrana para reaccionar con el conjugado de color.

Las muestras positivas reaccionan con el conjugado de color del anticuerpo específico anti-hCG para formar una línea de color en la región de la línea de la prueba de la membrana. La ausencia de esta línea de color sugiere un resultado negativo. Para servir como control del procedimiento, siempre aparecerá una línea de color en la región de la línea de control, si la prueba se ha realizado correctamente.

REACTIVOS

La placa contiene partículas anti-hCG y anti-hCG que recubren la membrana.

PRECAUCIÓN

- Solo para uso diagnóstico profesional *in vitro*. No utilizar después de la fecha de caducidad.
- La placa deberá mantenerse en la bolsa sellada hasta el momento de su utilización.
- Todas las muestras deberían considerarse potencialmente peligrosas y manipularse como si se tratara de un medio infeccioso.
- La prueba, una vez utilizado, debe desecharse de acuerdo con las regulaciones locales.

ALMACENAMIENTO Y ESTABILIDAD

Almacenar tal como está empaquetado en la bolsa sellada a temperatura ambiente o refrigerado (2-30˚C). La placa se mantendrá en la bolsa sellada hasta su uso. **NO CONGELAR.** No utilizar después de la fecha de caducidad.

OBTENCIÓN Y PREPARACIÓN DE LA MUESTRA

Valoración en Orina

Se debe tomar una muestra de orina en un envase limpio y seco. Se prefiere la primera muestra de orina de la mañana, ya que contiene generalmente la concentración más alta de hCG; sin embargo, se pueden usar muestras de orina recogidas en cualquier momento del día. Las muestras de orina que presenten precipitados visibles se deberán centrifugar, filtrar o dejar posar para obtener una muestra transparente para la realización de la prueba.

Almacenamiento de las Muestras

Las muestras de orina pueden almacenarse a 2-8˚C hasta un periodo de 48 horas previo a su valoración. Para un almacenamiento más prolongado, las muestras se deben congelar y almacenar a menos de -20˚C. Las muestras que hayan sido congeladas, deben descongelarse y proceder a su agitación para lograr una buena mezcla antes de su utilización.

MATERIALES

Materiales Suministrado

- Placas
- Cuentagotas
- Ficha técnica

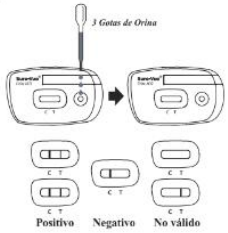
Materiales Requerido no Suministrado

- Ficha técnica
- Cronómetro

INSTRUCCIONES DE USO

Deje que la placa, la muestra de orina y/ó los controles alcancen la temperatura ambiente (15-30˚C) antes de realizar la prueba.

1. Dejar estabilizar la bolsa sellada a temperatura ambiente antes de abrirla. Extraiga la placa de la bolsa sellada y utilícela en cuanto sea posible.
2. Coloque la placa en una superficie limpia y nivelada. Mantenga el cuentagotas en posición vertical y deposite 3 gotas de orina (aproximadamente 100µl) en el pocillo de la placa y ponga en marcha el cronómetro. Evite que queden retenidas burbujas de aire en el pocillo de la placa. Véase la siguiente ilustración.
3. Espere hasta que aparezcan una o dos líneas coloreadas. Los resultados deberán leerse a los 3 minutos.



NOTA: Una concentración baja de hCG podría dar lugar, después de un periodo de tiempo prolongado, a la aparición de una débil línea en la región de la prueba (T); por tanto, no interprete el resultado después de 10 minutos.

INTERPRETACIÓN DE RESULTADOS

(Consultar la figura anterior)

POSITIVO:* Aparecen dos líneas coloreadas distintas. Una línea quedará en la región de control (C) y otra línea quedará en la región de la prueba (T).

***NOTA:** La intensidad del color de la línea de la región de la prueba (T) puede variar dependiendo de la concentración de hCG presente en la muestra. Por lo tanto, cualquier coloración, por muy débil que este la línea en la región de prueba (T) debe considerarse como resultado positivo.

NEGATIVO: Una línea coloreada aparece en la región de control (C). No aparece ninguna línea coloreada en la región de la prueba (T).

NO VÁLIDO: No aparece la línea de Control. Un volumen de la muestra insuficiente o una técnica incorrecta son las razones más frecuentes del fallo de la línea de control. Revise el procedimiento y repita la prueba con una nueva placa. Si el problema persiste, deje de utilizar ese kit inmediatamente y llamada 1-800-637-3717 para Asistencia Técnica.

CONTROL DE CALIDAD

Se incluye un control interno del procedimiento en la prueba. La línea coloreada que aparece en la región de control (C) actúa como control interno del procedimiento. Confirma que hay suficiente volumen de muestra y que la técnica empleada es la correcta. Un fondo claro es un control interno negativo del procedimiento. Si aparece un fondo de color en la ventana de resultados que interfiere con la posibilidad de leer los resultados de la prueba, estos pueden ser no válidos.

Se recomienda evaluar un control positivo de hCG (que contenga 25-250mUI/ml de hCG) y un control negativo (con "0"mUI/ml de hCG) para verificar el comportamiento adecuado de la prueba cada vez que se reciba un nuevo envío de kits.

LIMITACIONES

1. Las muestras muy diluidas, que vienen indicadas por una densidad específica baja, pueden no contener niveles representativos de hCG. Si se sigue sospechando un embarazo, se recogerá la primera orina de la mañana 48 horas después, y se repetirá la prueba.
2. Esta prueba puede producir resultados falsos negativos cuando los niveles de hCG se encuentren por debajo del nivel de sensibilidad de la prueba. Si se sigue sospechando un embarazo, se recogerá la primera orina de la mañana 48 horas después, y se repetirá la prueba. En caso de sospecha de embarazo y continuos resultados negativos, el medico confirmará el diagnóstico con resultados clínicos y analíticos.
3. Poco tiempo después de la implantación hay niveles muy bajos de hCG (menos de 50mUI/ml) en las muestras de orina. Sin embargo, como un número importante de embarazos terminan en el primer trimestre por causas naturales,[5] una prueba con resultado positivo débil se confirmará volviendo a estudiar otra muestra con la primera orina de la mañana obtenida 48 horas después.
4. Esta prueba puede producir resultados falsos positivos. Hay varias situaciones, además del embarazo, que dan lugar a niveles altos de hCG,[6,7] como son la enfermedad trofoblástica y ciertas neoplasias no trofoblásticas, como tumores testiculares, cáncer de próstata, cáncer de mama y cáncer de pulmón. Por lo tanto, la presencia de hCG en una muestra de orina no se usará para diagnosticar un embarazo a menos que se hayan descartado estas afecciones.
5. Esta prueba proporciona un diagnóstico de presunción del embarazo. El médico sólo establecerá un diagnóstico confirmado del embarazo después de evaluar todos los resultados clínicos y analíticos.

VALORES ESPERADOS

Se esperan valores negativos en mujeres sanas no gestantes y en varones sanos. Las mujeres sanas gestantes presentan hCG en sus muestras de orina y suero. La cantidad de hCG variará mucho con el tiempo de gestación y entre distintas mujeres.

La Prueba Sure-Vue® Orina hCG tiene una sensibilidad de 25mUI/ml, y puede detectar un embarazo ya en el primer día de la falta.

CARACTERÍSTICAS TÉCNICAS

Exactitud

Se realizo una evaluación en numerosos centros en la que se compararon los resultados obtenidos con la Prueba Sure-Vue® Orina hCG y otra prueba comercial de membrana para la determinación de hCG orina. El estudio incluyó 159 muestras de orina y ambos métodos de análisis identificaron 88 resultados negativos y 71 positivos. Los resultados demostraron una exactitud > del 99% para la Prueba Sure-Vue® Orina hCG cuando se comparó con la otra prueba en membrana de hCG.

Método de Referencia hCG

		Positivo	Negativo
Prueba Sure-Vue® Orina hCG	Positivo	71	0
	Negativo	0	88

Sensibilidad y Especificidad

La Prueba Sure-Vue® Orina hCG detecta hCG en concentraciones de 25mUI/ml o mayores. La prueba ha sido estandarizada de acuerdo con las normas de W.H.O. International Standard. La adición de LH (300mUI/ml), FSH (1.000mUI/ml), y TSH (1.000µUI/ml) a muestras negativas (0mUI/ml hCG) y positivas (25mUI/ml hCG) no mostró una reactividad cruzada.

Interferencias con otras Sustancias

Se añadieron las siguientes sustancias que podrían provocar interferencias en muestras negativas y positivas de hCG.

Acetaminofenona	20mg/ml	Cafeína	20mg/ml
Ácido Acetilsalicílico	20mg/ml	Ácido Gentísico	20mg/ml
Ácido Ascórbico	20mg/ml	Glucosa	2g/dl
Atropina	20mg/ml	Hemoglobina	1mg/dl
Bilirrubina	2mg/dl		

Ninguna de las sustancias anteriores en las concentraciones indicadas provocaron interferencias en el análisis.

BIBLIOGRAFIA

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2. Catt KJ, MI. Dufau, JI. Vaitukaitis "Appearance of hCG in pregnancy plasma following the initiation of implantation of the blastocyte", *J. Clin. Endocrinol. Metab.* 1975; 40(3): 537-540
3. Braunstein GD, J Rasor, H. Danzer, D Adler, ME Wade "Serum human chorionic gonadotropin levels throughout normal pregnancy", *Am. J. Obstet. Gynecol.* 1976; 126(6): 678-681
4. Lenton EA, LM Neal, R Sulaiman "Plasma concentration of human chorionic gonadotropin from the time of implantation until the second week of pregnancy", *Fertil. Steril.* 1982; 37(6): 773-778
5. Steier JA, P Bergsjo, OL Myking "Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion and removed ectopic pregnancy", *Obstet. Gynecol.* 1984; 64(3): 391-394
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7. Braunstein GD, JL Vaitukaitis, PP Carbone, GT Ross "Ectopic production of human chorionic gonadotropin by neoplasms", *Ann. Intern Med.* 1973; 78(1): 39-45

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Número: 1155811101
Fecha efectiva: 2006-12-26

LABCONNECT

Sure-Vue® Urine hCG — Package Insert

A rapid, one step test for the qualitative detection of human chorionic gonadotropin (hCG) in urine.
For professional in vitro diagnostic use only.

INTENDED USE

The Sure-Vue® Urine hCG is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

SUMMARY

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in both urine and serum as early as 7 to 10 days after conception [1-4]. hCG levels continue to rise very rapidly, frequently exceeding 100mIU/mL by the first missed menstrual period [1-4], and peaking in the 100,000-200,000mIU/mL range about 10-12 weeks into pregnancy. The appearance of hCG in both the urine and serum soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy.
The Sure-Vue® Urine hCG is a rapid test that qualitatively detects the presence of hCG in urine specimen at the sensitivity of 25mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, the Sure-Vue® Urine hCG shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

PRINCIPLE

The Sure-Vue® Urine hCG is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The test utilizes a combination of antibodies including mouse monoclonal anti-hCG antibodies and goat polyclonal anti-hCG antibodies to selectively detect elevated levels of hCG. The assay is conducted by adding a urine specimen to the specimen well of the test device and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.
Positive specimens react with the specific colored antibody conjugates and form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

REAGENTS

The test device contains anti-hCG particles and anti-hCG coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test device should be discarded in a proper biohazard container after testing.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

A urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided

- Test devices
- Package insert
- Disposable specimen droppers

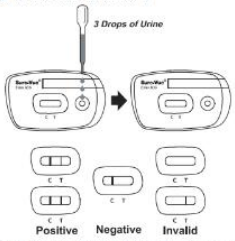
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow the test device, urine specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100µL) to the specimen well of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well. See the illustration below.
3. Wait for the red line(s) to appear. The result should be read at 3 minutes. It is important that the background is clear before the result is read.



Note: A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:* Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).
***NOTE:** The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG present in the specimen. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.
NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and call 1-800-637-3717 for Technical Assistance.

QUALITY CONTROL

Internal procedural controls are included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.
It is recommended that a positive hCG control (containing 25-250mIU/mL hCG) and a negative hCG control (containing "0"mIU/mL hCG) be evaluated to verify proper test performance. It is recommended that federal, state, and local guidelines be followed.

LIMITATIONS

1. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
2. False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
3. Very low levels of hCG (less than 50mIU/mL) are present in urine specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons [5], a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.
4. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG [6-7]. Therefore, the presence of hCG in urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine and serum specimens. The amount of hCG will vary greatly with gestational age and between individuals.
The Sure-Vue® Urine hCG has a sensitivity of 25mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

PERFORMANCE CHARACTERISTICS

Accuracy

A multi-center clinical evaluation was conducted comparing the results obtained using the Sure-Vue® Urine hCG to another commercially available urine membrane hCG test. The study included 159 urine specimens: both assays identified 88 negative and 71 positive results. The results demonstrated a 100% overall agreement (for an accuracy of ≥ 99%) of the Sure-Vue® Urine hCG when compared to the other urine membrane hCG test.

Reference hCG Method

		Positive	Negative
Sure-Vue® Urine hCG	Positive	71	0
	Negative	0	88

Sensitivity and Specificity

The Sure-Vue® Urine hCG detects hCG at a concentration of 25mIU/mL or greater. The test has been standardized to the W.H.O. Third International Standard. The addition of LH (300mIU/mL), FSH (1,000mIU/mL), and TSH (1,000µIU/mL) to negative (0mIU/mL hCG) and positive (25mIU/mL hCG) specimens showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to hCG negative and positive specimens.

Acetaminophen	20mg/mL	Caffeine	20mg/mL
Acetylsalicylic Acid	20mg/mL	Gentisic Acid	20mg/mL
Ascorbic Acid	20mg/mL	Glucose	2g/dL
Atropine	20mg/mL	Hemoglobin	1mg/dL
Bilirubin (urine)	2mg/dL		

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

BIBLIOGRAPHY

1. Batzer FR. "Hormonal evaluation of early pregnancy", *Fertil. Steril.* 1980; 34(1): 1-13
2. Catt KJ, ML Dufau, JL Vaitukaitis "Appearance of hCG in pregnancy plasma following the initiation of implantation of the blastocyte", *J. Clin. Endocrinol. Metab.* 1975; 40(3): 537-540
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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 29-Jul-2025 | 9:36:00 AM PDT

Revision History

Version	Date	Details

Final V2.0	29-Jul-2025	• *Specimen Collection Table*
		  ○ *Updated ADA, Biomarker, and PK processing instructions*
		• *Specimen Shipment Guide*
		  ○ *C: PK(AM): updated shipping frequency for PK 1 sample to Next planned frozen shipment from within 7 days*
		  ○ *D: ADA/nAb(AM): updated shipping frequency for ADA/nAb 1 sample to Next planned frozen shipment from within 7 days*
		  ○ *E: Biomarker Sample(AM): updated shipping frequency for BS 1-2 sample to Next planned frozen shipment from within 7 days*
		• *Shipment Booking*
		  ○ *Added FedEx Same Day Booking Instructions for Sunday shipments*

Final V1.0	28-Mar-2025	Initial Version

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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:	• Allow per session cookies

	• Users accessing the internet behind a Proxy Server must enable HTTP 1.1 settings via proxy connection

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