

# CENTRAL LABORATORY MANUAL

Latin America



## 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:

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**CBP-201-206**

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Accelerating the Development of New Medicines.



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**REGIONAL HOLIDAYS**

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

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

**US Holidays**

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



### Argentina Holidays

| Argentina Holidays             | 2025  |          | 2026  |          |
|--------------------------------|-------|----------|-------|----------|
|                                | Day   | Date     | Day   | Date     |
| <b>New Year's Day</b>          | Wed   | Jan 1    |       | Jan 1    |
| <b>Carnival</b>                | TBC   | TBC      | TBC   | TBC      |
| <b>National Holiday</b>        | Mon   | Mar 24   | Tue   | Mar 24   |
| <b>National Holiday</b>        | Wed   | Apr 2    | Thurs | Apr 2    |
| <b>Holy Friday</b>             | TBC   | TBC      | TBC   | TBC      |
| <b>Labor Day</b>               | Thurs | May 1    | Fri   | May 1    |
| <b>National Holiday</b>        | Sun   | May 25   | Mon   | May 25   |
| <b>National Holiday</b>        | Mon   | Jun 16   | Tue   | Jun 16   |
| <b>National Holiday</b>        | Fri   | Jun 20   | Sat   | Jun 20   |
| <b>Independence Day</b>        | Wed   | Jul 9    | Thurs | Jul 9    |
| <b>National Holiday</b>        | Sun   | Aug 17   | Mon   | Aug 17   |
| <b>National Holiday</b>        | Sun   | Oct 12   | Mon   | Oct 12   |
| <b>National Holiday</b>        | Mon   | Nov 24   | Tue   | Nov 24   |
| <b>Holy Mary Day</b>           | Mon   | Dec 8    | Tue   | Dec 8    |
| <b>Christmas Dec 24th</b>      | Wed   | Dec 24 * | Thurs | Dec 24 * |
| <b>Christmas Day</b>           | Thurs | Dec 25   | Fri   | Dec 25   |
| <b>New Year's Day Dec 31st</b> | Wed   | Dec 31 * | Thurs | Dec 31 * |

**NOTE:** Locally observed holidays may disrupt courier service within your area. Please call your courier in advance for local pickup schedules.

## 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 <sup>1</sup>          | 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 <sup>2</sup>                 | 5.0              | A                     | A <sup>3</sup>           |                              | A           | A           | A               | A           | A                 |
| CK <sup>2</sup>                        | 2.5              | A                     | A <sup>3</sup>           |                              | A           | A           | A               | A           | A                 |
| Hematology <sup>2</sup>                | 3.0              | A                     | A <sup>3</sup>           |                              | A           | A           | A               | A           | A                 |
| Urinalysis <sup>2</sup>                |                  | A                     | A <sup>3</sup>           |                              | A           | A           | A               | A           | A                 |
| Total IgE <sup>4</sup>                 | 2.5              |                       | B                        |                              | B           | B           | B               | B           | B                 |
| CRP <sup>2</sup>                       | 2.5              | A                     | A <sup>3</sup>           |                              | A           | A           | A               | A           | A                 |
| PK <sup>4</sup>                        | 2.0              |                       | C                        | C                            | C           | C           | C               | C           | C                 |
| ADA/nAb <sup>4</sup>                   | 3.0              |                       | D                        |                              |             | D           | D               | D           | D                 |
| Biomarker Sample <sup>4</sup>          | 6.0              |                       | E                        |                              | E           | E           | E               | E           | E                 |
| <b>Total Blood Draw Per Visit (mL)</b> |                  | <b>13.0</b>           | <b>26.5</b>              | <b>2.0</b>                   | <b>23.5</b> | <b>26.5</b> | <b>26.5</b>     | <b>26.5</b> | <b>26.5</b>       |
| <b>On Site Testing</b>                 |                  |                       |                          |                              |             |             |                 |             |                   |
| Urine Pregnancy                        |                  |                       | X <sup>5</sup>           |                              |             | X           | X               |             |                   |

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

Footnotes:

- <sup>1</sup> 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.



- <sup>2</sup> Hematology, clinical chemistry, and urinalysis parameters are provided in Appendix C of the protocol.
- <sup>3</sup> 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.
- <sup>4</sup> 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.
- <sup>5</sup> 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(LA)           |
| B          | IgE(LA)              |
| C          | PK(LA)               |
| D          | ADA/nAb(LA)          |
| E          | Biomarker Sample(LA) |

**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 (courier 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(LA)           | LabConnect Miami-Refrigerated   | LabConnect Miami-Frozen        | Investigator |
| B: IgE(LA)              | LabConnect Miami-Refrigerated   | Investigator                   | Investigator |
| C: PK(LA)               | LabConnect Miami-Primary Sample | LabConnect Miami-Backup Sample | Investigator |
| D: ADA/nAb(LA)          | LabConnect Miami-Primary Sample | LabConnect Miami-Backup Sample | Investigator |
| E: Biomarker Sample(LA) | LabConnect Miami-Primary Sample | LabConnect Miami-Backup Sample | Investigator |

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

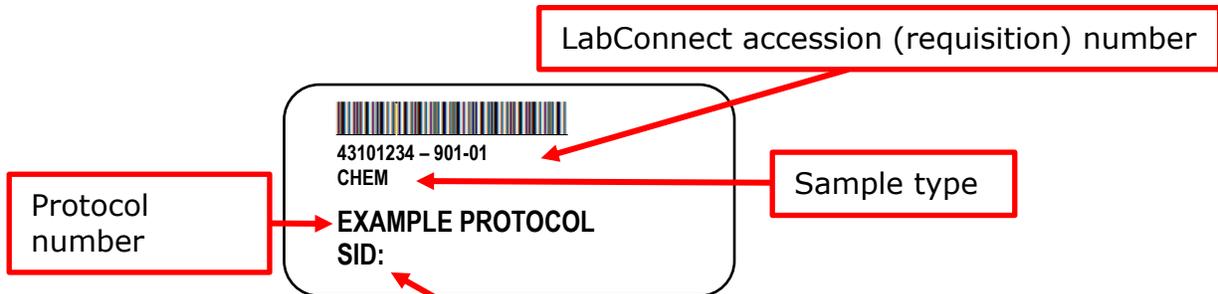




### Completing Labels

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.*



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](mailto: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).



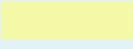
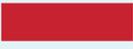
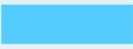
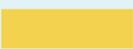
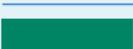
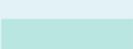
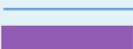
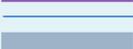
## General Collection and Processing Guidance

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

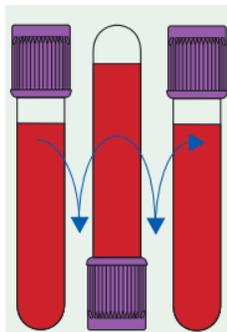
Published order of draw provided for reference: 1. No additive tube or blood culture, 2. Citrate blood, 3. Blood for serum, 4. Heparin blood for plasma, 5. EDTA blood, 6. Other tubes.

**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 show 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.



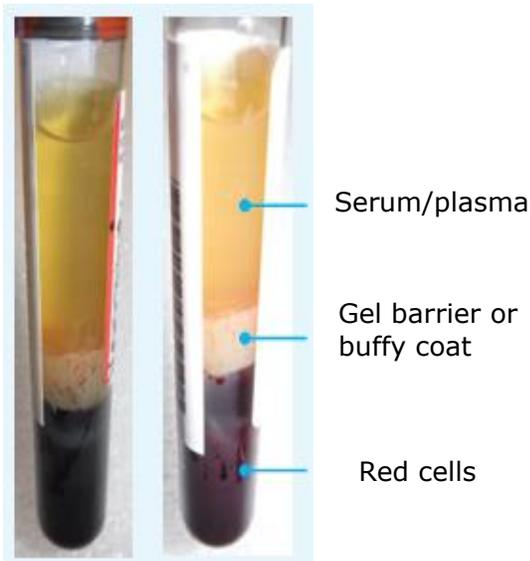
**Centrifugation Guidelines**

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.*

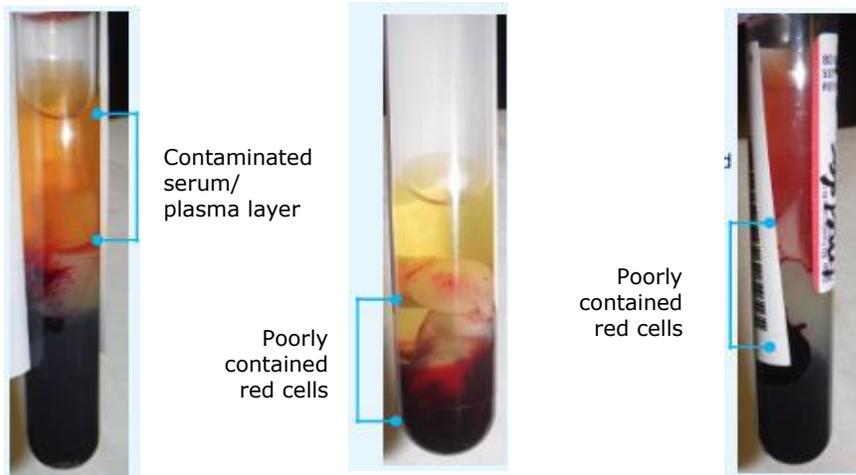
Properly separated blood will show clear separation of serum/plasma, buffy coat, gel barrier (if applicable), and red blood cells.

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

The 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. The result turnaround time listed below is in business days from receipt at testing laboratories.

| Test            | Collection Device  | Preparation Instructions  | Transport Container   | Temperature  | Stability  | TAT               |
|-----------------|--|---|---|--------------|------------|-------------------|
| Chemistry Panel | 1 x 5 mL Red SST<br><br><b>CHEM 1</b>       | <ol style="list-style-type: none"> <li>Invert 5 times to mix</li> <li>Wait at least 20 minutes for blood coagulation.</li> <li>Centrifuge at 1800-2200 g for 10-15 minutes</li> <li>Transfer all serum, minimum of <b>2 mL</b></li> <li>Refrigerate until ready for shipment.</li> </ol>  | 1 x 4 mL Transport Tubes<br><br><b>CHEM</b>  | Refrigerated | 3 days     | 1 business day    |
| Total IgE       | 1 x 2.5 mL Red SST<br><br><b>Immuno</b>     | <ol style="list-style-type: none"> <li>Invert 5 times to mix.</li> <li>Clot.</li> <li>Centrifuge at 1800-2200 g for 10-15 minutes.</li> <li>Transfer a minimum of <b>0.50mL</b> of serum and refrigerate until ready for shipment.</li> </ol>   | 1 x 4 mL Transport Tube<br><br><b>IgE</b>  | Refrigerated | 30 days    | 1-3 business days |
| CK              | 1 x 2.5 mL Red SST<br><br><b>CK 1</b>       | <ol style="list-style-type: none"> <li>Invert 5 times to mix. Wait at least 20 minutes for blood coagulation.</li> <li>Centrifuge at 1800-2200 g for 10-15 minutes.</li> <li>Transfer all serum, minimum of 0.50mL</li> <li>Refrigerate until ready for shipment.</li> </ol>  | 1 x 4 mL Transport Tube<br><br><b>CK</b>   | Frozen       | 1 month    | 1 business day    |
| CRP             | 1 x 2.5 mL Red SST<br><br><b>CRP 1</b>    | <ol style="list-style-type: none"> <li>Invert 5 times to mix.</li> <li>Clot.</li> <li>Centrifuge at 1800-2200 g for 10-15 minutes.</li> <li>Transfer a minimum of <b>1mL</b> of serum and refrigerate until ready for shipment.</li> </ol>  | 1 x 4 mL Transport Tube<br><br><b>CRP</b>  | Refrigerated | 3 weeks    | 1 business day    |
| ADA/nAb         | 1 x 3 mL Red No Gel<br><br><b>ADA/nAb</b> | <p><i>Note: Sponsor-provided instructions</i></p> <ol style="list-style-type: none"> <li>Invert 5 times to mix.</li> <li>Clot for at least 30 min.</li> <li>Centrifuge at 1300 ±20g for 10 minutes at Room Temperature, within 120 min after collection.</li> <li>Transfer a minimum of <b>0.50 mL</b> of serum to each cryovial and freeze immediately until ready for shipment (-70°C or -80°C preferred, -20°C acceptable).</li> </ol> | 2 x 2mL Cryovials<br><br><b>ADA/nAb 1</b><br><br><b>ADA/nAb 2</b> | Frozen       | Indefinite | N/A               |

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

| Test                        | Collection Device  | Preparation Instructions                                   | Transport Container   | Temperature  | Stability | TAT            |
|-----------------------------|--|--|---|--------------|-----------|----------------|
| Urinalysis with Microscopic | Fresh Random Urine<br>  | 1. Transfer urine.<br>2. Invert 8-10 times.                | 1 x 8 mL Yellow top (with preservative)<br><br><b>UAWMIC</b> | Refrigerated | 72 hours  | 1 business day |
| <b>On-Site Testing</b>      |  |  |   |              |           |                |
| Urine Pregnancy             | Fresh Random Urine<br> | 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(LA)            | Refrigerated     | Day of Collection   | LabConnect Miami |
| A: Safety(LA)- <b>CK</b> | Frozen           | Day of Collection   | LabConnect Miami |
| B: IgE(LA)               | Refrigerated     | Day of Collection   | LabConnect Miami |
| C: PK(LA)                | Frozen           | Primary:<br>Next-planned frozen shipment.<br>(PK 1)<br><br>Back-up: Back-up:<br>Next-planned frozen shipment after primary shipment<br>(PK 2)           | LabConnect Miami |
| D: ADA/nAb(LA)           | Frozen           | Primary:<br>Next-planned frozen shipment.<br>(ADA/nAb 1)<br><br>Back-up: Back-up:<br>Next-planned frozen shipment after primary shipment<br>(ADA/nAb 2) | LabConnect Miami |
| E: Biomarker Sample(LA)  | Frozen           | Primary:<br>Next-planned frozen shipment.<br>(BS 1-2)<br><br>Back-up: Back-up:<br>Next-planned frozen shipment after primary shipment<br>(BS 3-4)       | LabConnect Miami |

**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. If you need additional pre-printed air waybills, please contact our customer service team to place an order via telephone or email [csbio@ocasa.com](mailto:csbio@ocasa.com)



**FILLING OUT AN OCASA AWB:**

The image shows a detailed OCASA AWB form with various sections and callouts. The callouts are as follows:

- Enter Date Ingrese Fecha:** Points to the 'DATE / FECHA' field in the 'LABORATORY OF DESTINATION INFO' section.
- Enter total Weight Ingrese el peso total:** Points to the 'WEIGHT / PESO' field in the 'LABORATORY OF DESTINATION INFO' section.
- Enter Description of contents Ingrese descripcion de contenido:** Points to the 'DESCRIPTION OF CONTENTS / DESCRIPCION DE CONTENIDO' field in the 'LABORATORY OF DESTINATION INFO' section.
- Shipper's Signature Firma de remitente:** Points to the 'SHIPPER'S SIGNATURE / FIRMA SOLICITANTE' field in the 'SHIPPER INFORMATION' section.
- Shipper's Name Nombre de remitente:** Points to the 'SHIPPER'S NAME / NOMBRE SOLICITANTE' field in the 'SHIPPER INFORMATION' section.
- Date / Fecha:** Points to the 'DATE / FECHA' field in the 'SHIPPER INFORMATION' section.
- Time / Hora:** Points to the 'TIME / HORA' field in the 'SHIPPER INFORMATION' section.
- Enter Amount of pieces Ingrese la cantidad de piezas:** Points to the 'QUANTITY / CANTIDAD' field in the 'SHIPPER INFORMATION' section.

**Commercial Invoice**

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

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

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

**Non-Infectious Certification Statement**

Electronic copies of Non-Infectious Certification Statements are provided by your LabConnect Project Manager.



## **Shipment Booking**

**OCASA- This can also be found in the starter pack provided to the site:**

To ship samples, please follow the instructions listed in your site-specific starter pack.

1. Please book the pick-up by contacting the courier (see contact details listed in your starter pack) at least 24 hours before the planned pick-up and take note of your booking reference number, the courier representative will provide.
2. Please confirm the exact location (including floor and room number) of the pick-up and the name and phone number of the person preparing the shipment is listed accurately on your starter pack.
3. Note the delivery address where samples will be shipped
4. Each shipment must be accompanied by:
  - Courier air waybill
  - Commercial/Proforma invoices
    - i. Ensure a copy is placed inside the courier shipper
    - ii. Ensure a copy is provided to the courier pickup contact
    - iii. Ensure a copy is kept for site records
    - iv. Ensure a copy is attached to the outside of the package in the provided pouch

When inquiring about your shipment, please reference the air waybill number.

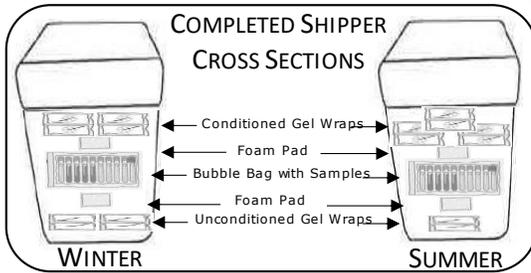
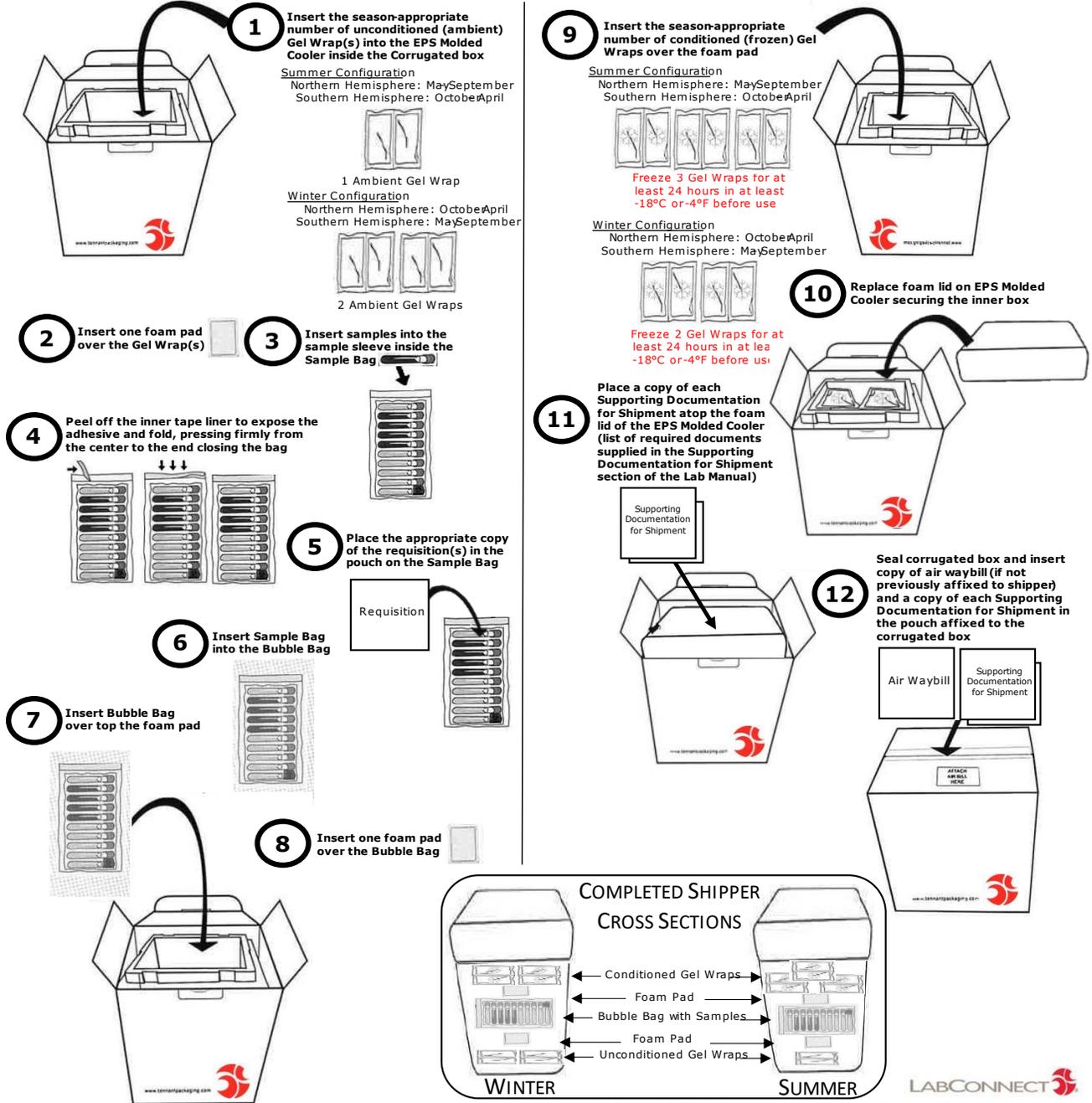
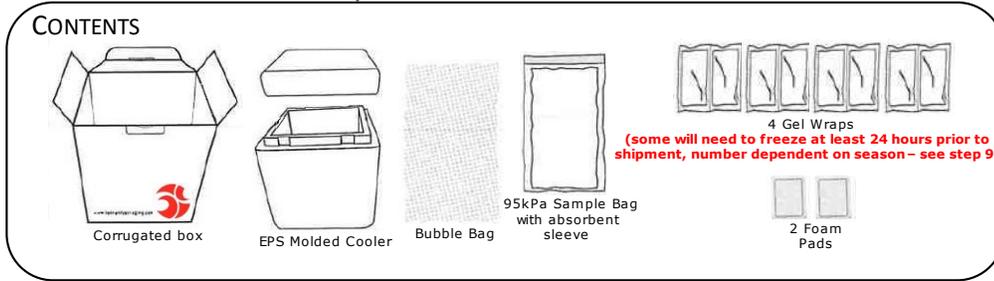
For **Dry Ice** shipments please call the OCASA customer service team a day in advance of the pickup date **(or as instructed in site specific Starter Pack)** to make the necessary arrangements in case dry ice is needed for the shipment(s). Dry ice is provided upon request. For Dry ice requests, please call our customer service team a day in advance **(or as instructed in site specific Starter Pack)** to the pickup date to coordinate the delivery of the dry ice. The site personnel will be responsible for packing, marking, and labeling the shipments. Once ready, please provide the shipment(s) to our messenger.



# Shipment Materials and Packaging Instructions

## Refrigerated Shipper Instructions

### REFRIGERATED SHIPPER WITH TUBE/VIAL SPECIMEN TYPES





## 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](mailto: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:  
+1 844-202-1548**

**[MIAQueryResolutions@labconnect.com](mailto:MIAQueryResolutions@labconnect.com)**

### **Non-Digital Query Process**

1. Customer Service will send an email to the site coordinator (1<sup>st</sup> attempt)
2. If a response is not received, Customer Service will send a follow-up email the next morning (2<sup>nd</sup> attempt) and again the next morning if there is still no response (3<sup>rd</sup> 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](mailto: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](mailto:PC@labconnect.com)



### Laboratory Report Access Form Example



**Complete all fields on the form, sign, and return completed form to [PC@labconnect.com](mailto: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](mailto: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](mailto: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 via the selected delivery method.

**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 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:** \_\_\_\_\_

**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.

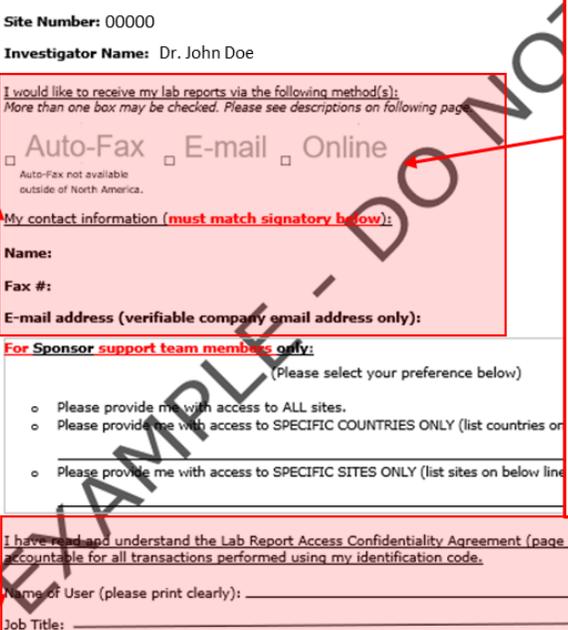
LabConnect sends the LabConnect Lab Report Access Form to the designated person at the Investigator site via E-mail during the study set-up process. The site confirms the E-mail address and signs the agreement giving LabConnect permission to send lab reports via E-mail.

**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.

Complete applicable fields





**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: -----<br>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   | (0.2 - 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 if 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](mailto: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 test cancellation, please contact Customer Service:  
+1 (800) 501-7947 ext. 3  
[Customerservice@labconnect.com](mailto:Customerservice@labconnect.com)**



**APPENDIX A: LABCONNECT SUPPLY REORDER FORM**

**Complete Form and email to: [workorders@labconnect.com](mailto: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. Allow up to 6 days of transit time for kits and shippers from LabConnect US, which may be extended by Customs clearance.

|                                   |                                |                       |
|-----------------------------------|--------------------------------|-----------------------|
| <b>Sponsor:</b> Connect Biopharma | <b>Protocol:</b> CBP-201-206   | <b>LC #:</b> CONN1206 |
| <b>Site Number:</b> _____         | <b>Date Ordered:</b> _____     |                       |
| <b>Investigator's Name:</b> _____ | <b>Date Needed:</b> _____      |                       |
| <b>Requested By:</b> _____        | <b>Telephone Number:</b> _____ |                       |

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

| Collection Kit          | Shipper Type | Qty |
|-------------------------|--------------|-----|
| A: Safety(LA)           | Refrigerated |     |
|                         | Frozen       |     |
| B: IgE(LA)              | Refrigerated |     |
| C: PK(LA)               | Frozen       |     |
| D: ADA/nAb(LA)          | Frozen       |     |
| E: Biomarker Sample(LA) | Frozen       |     |

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

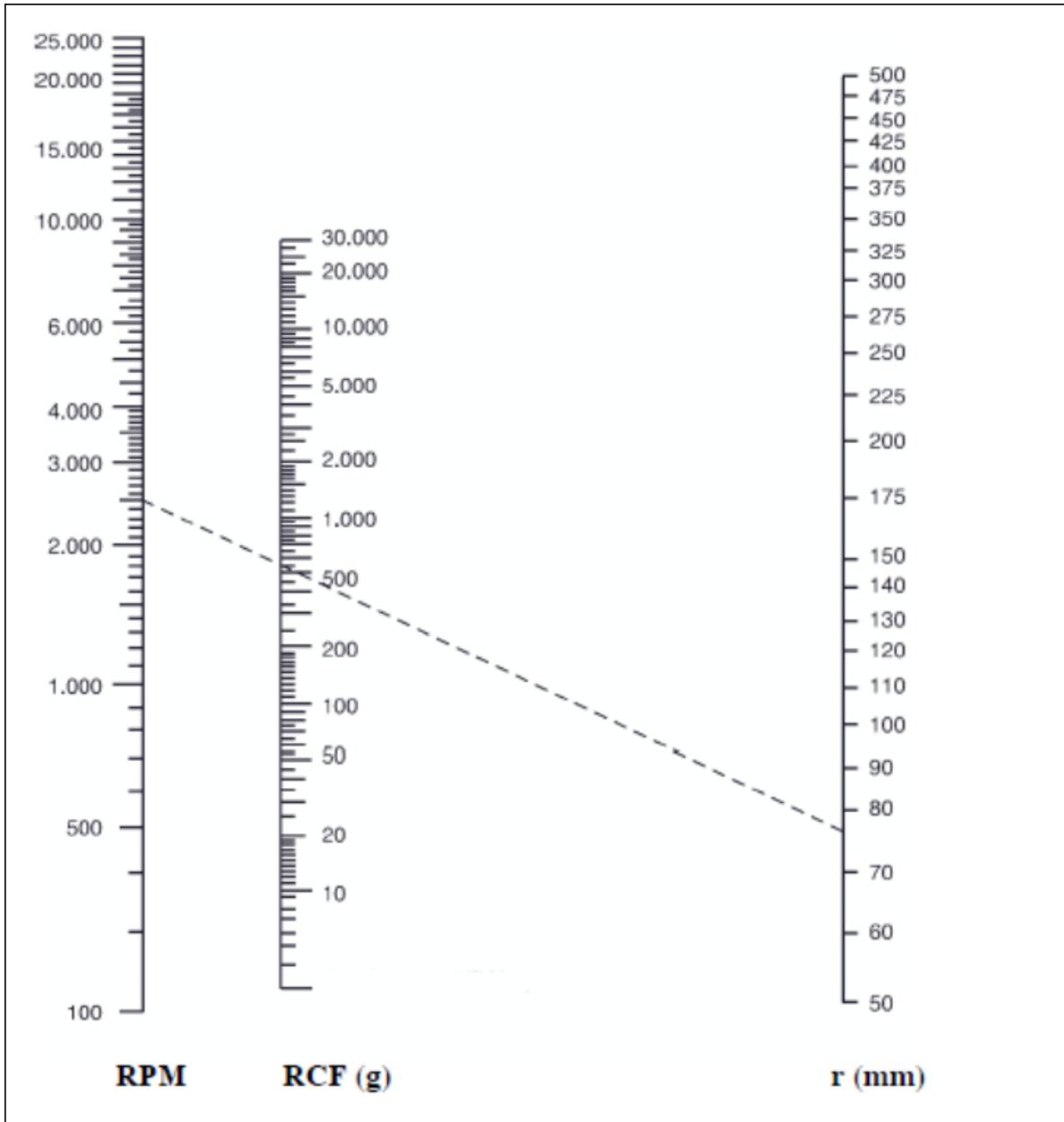
| Additional Supplies                       | Part Number | Qty | Shippers                                      | Part Number | Qty |
|---|-------------|-----|---|-------------|-----|
| PREGNANCY KIT (IVD) (CE)                  | 731008      |     | SHPR: 72HR REFRIG KIT W/ LC LOGO BOX (NO AWB) | 641017      |     |
| Urine Collection Cup with Lid             | 411071      |     |   |             |     |
| 2ml Cryobox                               | 221001      |     |   |             |     |
| 23G butterfly needle (1 pack, 50 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**

|                                   |                    |
|-----------------------------------|--------------------|
| <b>Date Order Received:</b> _____ | <b>SO #:</b> _____ |
| <b>Date Order Shipped</b> _____   | <b>ID:</b> _____   |

**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  $\geq 6$  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](mailto:PC@labconnect.com).

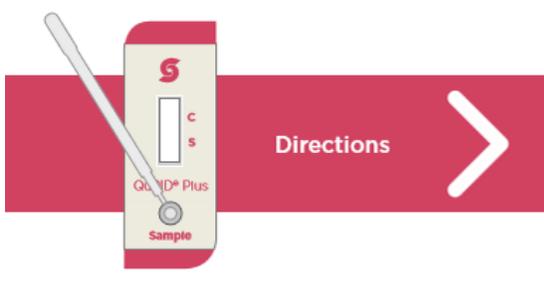
**APPENDIX E: ON-SITE TESTING INSTRUCTIONS**

**Urine Pregnancy Instructions:**

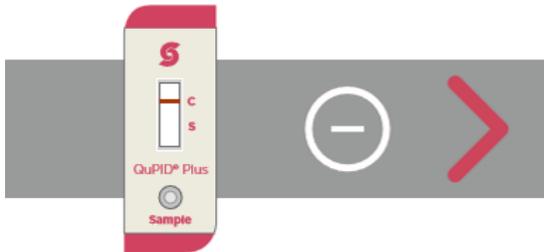
**Stanbio Laboratory**

**QuPID® PLUS** reference chart



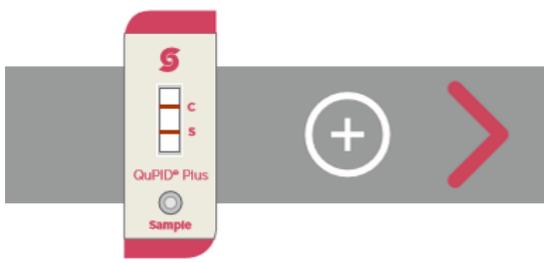


1. Bring specimen to room temperature before use. Remove QuPID® test device from foil pouch and identify as patient or control.
  2. Holding the dropper vertically, add 2 drops of sample to round sample well.
  3. Read at 3 MINUTES for urine and 5 MINUTES for serum.
- IMPORTANT!** Do not interpret result after indicated read time.



**NEGATIVE RESULT**

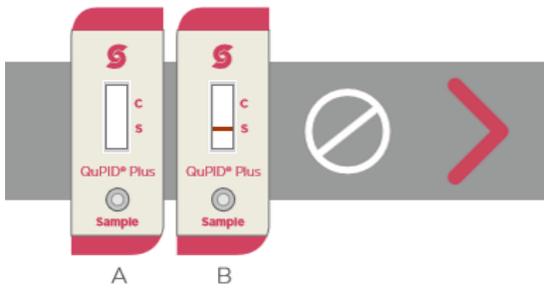
The test is negative if only a line appears at the Control Zone (C) in the result area.



**POSITIVE RESULT**

The test is positive if two (2) colored lines appear. One (1) colored line will appear at the Specimen Zone (S) and one (1) at the Control Zone (C).

The appearance of any pink to red colored line in the Specimen Zone (S) along with a line in the Control Zone (C) should be considered positive. Intensity of colored lines is not an indication of the concentration of hCG in the sample.



**INVALID RESULT**

A) No lines appear  
 B) Only specimen line appears. (No control line appears)

> **Repeat the test.**

REF0003.00 Eff.Date 12/13/14 DAR# 14.1578  
 Product Ref.# 1230-025 & 1230-050

For questions call Stanbio's Technical Service Department: 1-800-531-5535



**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 Sabina Mathur

Title Clinical Trials Senior Manager

Signed by:  
*Sabina Mathur*  
FF7E4CD95DA64AC...

Signature \_\_\_\_\_  
Date 28-Aug-2025 | 3:26:20 PM PDT



## **Revision History**

| <b>Version</b> | <b>Date</b> | <b>Details</b> |
|----------------|-------------|----------------|
| Final V1.0     | 26-AUG-2025 | Final Version  |
|                |             |                |