GALAXY™
ADVANCED MICROBIAL DIAGNOSTICS

How to Order Testing (International)

Updated 10-11-2024

Step 1: Discuss Testing with a Provider/Patient

Galaxy Diagnostics will accept specimens from all over the world. While we are unable to supply specimen collection kits to physicians and patients outside of the United States, we are happy to perform testing on samples received from other countries if the following criteria are met:

1. **A healthcare provider with a certification/license number creates an account with Galaxy.**
2. **Samples are sent following the packing and shipping directions provided in the packet.**

Importantly, international test orders come with additional expenses for the patient, including the cost of international priority shipping, specimen collection materials, and packing/shipping supplies.

How to Create an Account

1. The **provider or clinic must register on our website** at *www.galaxydx.com/create-an-account/*
2. Add your certification/licensing number in the place of the NPI number.
3. Begin assembling the materials needed for sample collection. In the meantime, Galaxy will send the required test forms and permits to the ordering provider, as well as a log-in to our results portal.

Step 2: Fill out the Test Request form

Clinical laboratory regulations in the United States require that the sample(s) be sent with a completed test request form that includes patient details (name, DOB, gender) and sample information (draw date). Full data is required before processing test orders. Our forms can be downloaded off of our website. The required forms are also included in this attached International Order Packet.

Forms are on our website!

Step 3: Collect the Sample(s) in Standard Serum Separator Tubes (SST), and/or EDTA tubes, and/or a Sterile Urine Collection Cup

Blood/Serum samples must be collected aseptically by a trained nurse or phlebotomist. Clinical laboratory regulations require that specimen tubes be labeled properly with at least two identifiers (first/last name, DOB). **Urine samples** must be collected within 24 hours in a sterile container, and sealed before immediate shipment.

Please see our Specimen Collection Instructions for details including how to centrifuge serum samples. If your healthcare provider does not perform blood draws, you will need to go elsewhere for a blood draw. A local medical facility or laboratory may perform the draw(s) with a physician's order.

Step 4: Pack and Ship the Sample(s)

Pack the specimen(s) along with the required forms following the enclosed instructions for clinical specimens. Following IATA (International Air Transport Association) shipping regulations, samples should be triple packed and then shipped by international priority overnight with a FROZEN icepack using FedEx or UPS. Samples must be protected from high heat to ensure viability for testing.

- **Include the CDC (Center for Disease Control) import permit (Galaxy will supply this)**
- **Include commercial invoice/proforma**
  (a sample commercial invoice is included in the attached packet)

Step 5: Receive Results

The turnaround time for our testing is 2-3 weeks and varies by test type. Providers can access results as soon as they are available using our online provider portal. Results can also be sent to physicians via fax upon request. Patients may submit a Results Request Form with the test order to receive a copy of the results by fax or mail. HIPAA data privacy regulations do not allow us to send results via e-mail.

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Laboratory-use Only:
Logged in by _____ Date received _____
Account #_____
Order # _____ Date entered _____

Test Request Form

Form HH100; Revised 10-1-2024

Highlighted fields required | Ship samples Mon-Thurs with FROZEN cold pack | ALL SST (yellow-top) tubes must be centrifuged

Patient Information			Provider Information		
First Name	Last Name		Provider Name		
Date of Birth (MM/DD/YYYY)	○ Male ○ Female	○ Nonbinary	Provider Clinic		
Address			Clinic Address		
City	State/Country	Zip Code	City	State/Country	Zip Code
Phone	Email		Phone	Fax	
ICD-10 Codes (required for superbill)			License Number		
Sample Information			Sample Information		
Collection Date (MM/DD/YY)			☐ Whole Blood ☐ Serum ☐ Urine		

Pre-payment is required for all orders. Galaxy Diagnostics does not accept insurance.

Visa / Mastercard / Amex / Discover Exp __ __/__ __ (mm/yy) CSV __ __ __ Billing zip code _____

Name on card _____ Card # __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __

Signature _____

DUAL DETECT (Lyme + *Bartonella*)

1 ☐ **Lyme *Borrelia* Nanotrap® + *Bartonella* 4-Species IFA Serology, IgG** (urine + serum)
CPT (PLA): 0316U | 86317-59 x4

BORRELIOSIS (Lyme disease)

2 ☐ **Lyme *Borrelia* Nanotrap®** (urine)
CPT (PLA): 0316U

BARTONELLOSIS (Cat scratch disease)

3 ☐ **4-Species IFA Serology, IgG** (serum)
B. henselae, B. quintana, B. vinsonii berkhoffii, B. koehlerae.
CPT: 86317-59 x4

Digital ePCR™

4 ☐ **Digital ePCR™ 1 Day Draw** (whole blood)
CPT (PLA): 0302U

5 ☐ **Digital ePCR™ 3 Day Draw** (whole blood **X 3**)
CPT (PLA): 0302U x3

Digital ePCR™ + IFA Serology

6 ☐ **Digital ePCR™ 1 Day Draw + 4-Species IFA Serology, IgG** (whole blood + serum)
CPT (PLA): 0302U | 86317-59 x4

7 ☐ **Digital ePCR™ 3 Day Draw + 4-Species IFA Serology, IgG** (whole blood **X 3** + serum)
CPT (PLA): 0302U x3 | 86317-59 x4

Patient Name_____ **Date**_____ **LAB USE ONLY: Accession #**_____

Galaxy Diagnostics, Inc.

INFORMED CONSENT FORM FOR RESEARCH

Revised 10-01-2024

INFORMATION

You are going to have blood drawn or other clinical samples obtained for the medical tests your provider ordered. S/he will give you the results of these tests and use them to plan your care. Even though the amount of sample(s) obtained will only be what is needed for your care, there may still be some left over after all the tests are done. We would like to store the remaining sample(s) in our biobank at Galaxy Diagnostics for new test development or for use in current or future research.

The purpose of creating a biobank to store human clinical samples (including sample and health information) is so that our Galaxy research team and our collaborators can use the stored materials in current or future studies. Through such studies, we hope to find new ways to detect, treat, and prevent health problems associated with vector-borne diseases. Some of the studies may lead to new products, such as better tests for vector-borne diseases.

Permission is required for all research-use only (RUO) testing.

COLLECTION OF INFORMATION

We will collect and store research data from studies done using your sample and information.

DURATION OF STORAGE

There is no limit on the length of time we will store your sample and information. We may keep using them for research unless you decide to stop taking part or we close our biobank, at which point all samples will be destroyed.

BENEFITS

You should not expect to see direct health benefits from this research. The main reason you may take part is to help researchers find new ways to detect, treat, and prevent health problems in the future.

CONFIDENTIALITY

No reference will be made in scientific presentations or publications that could link you to the study. The information in the study records will be kept strictly confidential, and at no time will your personal information be released. Your samples will be stored and studied using a unique identifying number. Paper data will remain in a locked location at Galaxy Diagnostics. Electronic data will be stored securely using a password-protected database in compliance with HIPAA data security standards.

GALAXY DIAGNOSTICS CONTACT

If you have questions at any time about the study or the procedures, you or your physician may contact the laboratory at 919-313-9672 or by email at contact@galaxydx.com.

CONSENT

❑ I am the patient, signing for myself.

❑ I am the parent/guardian/patient representative, signing for the patient. _____

Relationship to patient

Please **INITIAL** your choice below:

_____ I give permission to use my clinical sample(s) for new test development or for use in current or future research. I understand that my sample will not be linked to my identity in any way.

_____ I decline use of my samples for any current or future research projects.

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Sample Collection Instructions

Form HH133; Revised 10-1-2024

Required collection materials vary depending on the test type. If multiple tests are ordered, then you may need multiple sample types.

See chart for specific draw instructions.

CHECK EXPIRATION DATE OF SPECIMEN TUBES PRIOR TO DRAW.

Collection Type		Tests	Amount	Draw Instructions
	Lavender EDTA tube (purple-top)	**How many tubes?** Digital ePCR™ 1 Day Draw **(1)** Digital ePCR™ 3 Day Draw **(3)**	3-5 mL blood	Write **patient's name, date of birth**, and **collection date** on the tube. Collect 3-5 mL of blood into the EDTA tube(s). Invert the EDTA tube(s) a minimum of 8-10 times to mix.
	Gold SST tube (yellow-top)	**How many tubes?** 4-Species IFA Serology **(1)**	3-5 mL serum	Write **patient's name, date of birth, and collection date** on the tube. Collect 3-5 mL of blood into the SST tube(s). Invert the tube 5 times and allow it to rest for 30 minutes. **Centrifuge** the SST for 10-15 minutes at 3000 RPM. Do not transfer into another tube.
	Urine cup	**How many samples?** Lyme *Borrelia* Nanotrap® **(1)** ***Must be received within 48 hours after collection unless frozen.**	50 mL urine	Write **patient's name, date of birth, and collection date** on the container. Collect *at least 40 cc (mL)* of urine. Secure the lid. Urine can be collected all at once or in multiple instances within a 24-hour period.

➢ 3-Day Draw test

DO NOT COLLECT ALL EDTA TUBES ON THE SAME DAY.

3 Day Draw tests require 3 separate EDTA tubes of whole blood to be collected on **three different days within a 5-8 day period.** After each draw, **refrigerate the samples and hold them until the final collection day**.

Day 1 Day 2 Day 3

➢ Serum

ALL SERUM MUST BE SPUN BEFORE SHIPMENT.

Testing is not validated on UNSPUN, hemolyzed, icteric, or lipemic serum samples.

➢ Antimicrobial Treatments

In the absence of scientific data, we are unable to provide guidance on how treatments may affect test methods. Unless specifically directed by your practitioner, do not change your treatment regimen before testing.

Sample Storage Requirements

- **Blood & Serum** must be tested within two weeks of collection if kept at 2-8 °C or minus 20 °C.
- **Urine** must be tested within three days of collection if stored at 2-8 °C; or within four weeks of collection if frozen at minus 20 °C .

- Blood must be collected in an **EDTA tube**
- Serum must be collected in an **SST tube AND SPUN**
- Urine must be collected in a **sterile container**

Samples may be rejected for the following reasons: Improper labeling of name or date of birth on specimen container; SST (yellow-top) tube is unspun; cold pack missing; improperly stored; gross contamination; insufficient sample quantity, sample damaged/leaking; serum is hemolyzed, icteric, or lipemic; laboratory accident; missing information; courier delays; or sample received over holidays/weekends.

ALL samples must be LABELED, shipped OVERNIGHT Mon-Thurs with a FROZEN cold pack, and include COMPLETED test forms.

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Shipping Instructions

Form HH136; *Revised 10-01-2024*

All specimen's must be triple packed according to UN 3733 Category B shipping instructions.

See details on the next page.

Before Packing

- ☐ Freeze cold pack (minimum freeze time 24 hours).
- ☐ Confirm the specimen tubes/container have not expired.
  - Under CLIA regulatory guidelines, *we cannot process specimens collected in **expired tubes***.
- ☐ Patient **NAME, DOB, and DRAW DATE** are labeled clearly on tubes/container. Must match test request form.
  - CLIA regulations restrict us from processing samples without *patient name and DOB* on each specimen collection tube.
- ☐ Complete the Test Request form fully with all required patient, physician, and billing information.

Packing

See **Shipping Instructions for Clinical Specimens (UN 3733 Cat B)** within this packet.

- ☐ Ensure the specimens are securely sealed in properly labeled tubes/or sterile container.
- ☐ Ensure that the tubes/container are lying side-to-side and secure in an absorbent material for spills. (e.g. biohazard bag, plastic screw top container)
- ☐ Place **FROZEN** cold pack on top of samples inside shipping cooler (e.g. Styrofoam cooler)
- ☐ Place completed test forms away from the specimen (in a sealed bag if possible)
- ☐ Place all in the secondary outer box and secure. Refer to triple packing instructions for additional guidance.

Shipping

- ☐ See **Shipping Instructions for Clinical Specimens (UN 3733 Cat B)** within this packet.
- ☐ Please work with your local courier to pack things correctly. We recommend FedEx or UPS. Do not use USPS.
- ☐ Ship priority overnight with a frozen cold pack to our physical street address. →

Galaxy Diagnostics
6 Davis Drive
Suite 201
RTP, NC, 27709
United States

DO NOT SHIP FRIDAY OR PRIOR TO HOLIDAYS

International Orders

Galaxy Diagnostics does not supply specimen collection kits to physicians and patients outside of the U.S.

However, we are happy to perform testing on samples received from other countries. International test orders come with additional expenses for the patient, including the cost of international priority shipping, specimen collection materials, and packing/shipping supplies. Following IATA shipping regulations, samples should be triple packed and then shipped by **international priority overnight** with a FROZEN icepack using **FedEx or UPS.**

Shipping Instructions for Clinical Specimens (UN 3733 Cat B) are on the next page.

Shipping Instructions for Clinical Specimens (UN 3373 Cat B)

All clinical specimens possibly infected with Bartonella spp bacteria are considered UN 3373 **Biological Substances Category B**. The UN 3373 Category B designation is regulated under the US Department of Transportation (DOT) Transportation of Hazardous Materials Regulations (HMR) for domestic shipments and under the International Air Transport Association (IATA) Dangerous Goods Regulations (DGR) for international shipments worldwide.

Samples should be packed according to UN 3373 Category B packaging, labeling, and shipping requirements. Basic instructions for the required **TRIPLE PACKAGING** method are provided below with links to more information.

TRIPLE PACKAGING REQUIREMENTS

1. Primary containers that meet KPA 85 standards (e.g., vacuum tubes with space left for expansion)
2. Wrap primary containers separately in absorbent material for spills and packed securely against impact in leak-proof secondary container (e.g., biohazard bag, plastic screw top container)
3. Secondary container should be securely packed in rigid outer box with required test form(s)
4. Temperature control devices, e.g., gel packs or ice packs (NO LOOSE ICE!) may be packed in secondary container or in outer box. *
5. All shipping docs should be placed in unsealed pouch with shipping label.

**Please note that shipping on dry ice is possible, but more complicated. Dry ice is regulated as hazmat under UN 1845 and special training is required for handling and packaging in foam and rigid outer box. Importantly, some couriers (like FedEx) do not like shipping outer foam boxes, even in rigid cardboard outer box, and will charge an extra pickup fee.*

HELPFUL LINKS FOR UN 3373 CATEGORY B SHIPPING:

http://www.cdc.gov/nceh/vsp/cruiselines/OPRP/docs_word/diagnostic_specimen_shipping_detailed.doc
http://images.fedex.com/downloads/shared/packagingtips/pointers.pdf
http://www.ups.com/content/us/en/resources/ship/hazardous/responsible/diagnostic.html
http://www.dhl-usa.com/custserv/serviceupdates/Bulletin7.asp?nav=FindServInfo/ServiceUpdates

DOMESTIC SHIPPING DOCUMENTATION

- Test Request Form(s) – 1 per patient in the box
- Domestic airbill – ground shipping less expensive

INTERNATIONAL DOCUMENTATION

- Test Request Form(s) – in the box
- International airbill – 2-3 day
- 3 copies Proforma/Commercial Invoice (See example on the next page)
- Copy of required import/export permits for possibly or known infectious material **

**** Please contact Galaxy directly to request copy of US import permit.**
Shipper addresses must be reported to the CDC for first time shipments. **

Sample Commercial Invoice

Please note that individual couriers provide fillable commercial invoice forms. Basic information is reflected in this example.

COMMERCIAL INVOICE	
Date: February 5, 2024	Carrier:
Reference #:	Airbill #:
SHIP FROM	SHIP TO
Name:	Name: Galaxy Diagnostics, Inc.
Street Address:	Street Address: 6 Davis Drive, Suite 201
City, State, Postal Code:	City, State, Zip: Research Triangle Park, NC 27709
Country:	Country: USA
Phone:	Phone: +1.919.313.9672

PACKAGE INFORMATION					
Qty	Pkg	Volume	Description	Weight	Value
2	tubes	8 ml	Diagnostic Specimens: tissue or bodily fluid, possibly infected with Bartonella, Borrelia, Ehrlichia, Rickettsia, Ehrlichia, or Anaplasma spp	< 1 lb	$10
Total Packages		2	Total	<1lb	$10

I declare all the information contained in this invoice to be true and correct.

_____ _____

Shipper's signature Date

IMPORTATION OR TRANSFER AUTHORIZED BY

PHS Permit No._____

Expiration Date _____

TO:

DO NOT OPEN INTRANSIT

BIOMEDICAL MATERIALS
ETIOLOGICAL AGENTS OR VECTORS

NOTICE TO CARRIER: If inspection on arrival in U.S. reveals evidence of damage, leakage, or suspected contamination involving an infectious substance, immediately notify: DOT National Response Center 1-800-424-8802.

CDC 0.1007 3/2008

IMPORTATION OR TRANSFER AUTHORIZED BY

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