



Kephera Diagnostics Laboratory
1 Grant St., Suite 300, Framingham, MA 01702-6767
Tel: 774-777-3558, Fax: 774-777-3559, www.kephera.com
CLIA ID Number: 22D2182419 Email: cia@kepheralab.com;
Andrew E. Levin, Ph.D. Laboratory Director

TEST INSTRUCTIONS

1. Fill out the Test Requisition form:
 - a. Fill out Part 2, PATIENT INFORMATION, on the Test Requisition Form (page 2 of this document).
2. Bring or email your filled Test Requisition to your Healthcare Provider (HCP).
 - a. Your test requisition must be signed by your HCP.
 - b. They can also help you arrange a blood sample collection.
 - c. Print pages 2 and 3 of the Test Requisition Form and bring them with you to the blood sample collection site.
3. After your blood sample (serum or EDTA plasma) is collected and processed, it should be sent to Kephera Diagnostics at the address above, together with a printed copy of your completed and signed Test Requisition. Page 3 of the Test Requisition contains information for blood collection personnel on sample processing and shipping.
4. You will receive your test results within 72 hours of the time that your sample is received by Kephera.
5. Refer to your HCP if you have any questions or concerns associated with your test results.



TEST REQUISITION FORM
SARS-CoV-2 IgG Antibody Quantitative ELISA

1. ORDERING PHYSICIAN INFORMATION (please print)				Provider Facility Name			
Physician Name			NPI		DX Codes		
Provider/Physician Address			City		State	Zip Code	
Phone Number		Fax Number		Email			
Physician Signature					Date (mm/dd/yyyy)		
2. PATIENT INFORMATION (please print)				Employer or Organizational Affiliation			
Last Name		MI	First name		Date of Birth (mm/dd/yyyy)		Sex F M
Mailing Address			City		State	Zip Code	
Phone Number		Email			Guardian Name		
Request Report by				Phone Call or Email			
RACE (Optional)						ETHNICITY (Optional)	
<i>Native American</i>	<i>African American</i>	<i>Asian</i>	<i>Native Hawaiian</i>	<i>White</i>	<i>Other</i>	<i>Hispanic</i>	<i>Non-Hispanic</i>
Date of <u>last</u> COVID-19 Vaccination <i>(mm/dd/yyyy)</i>		Vaccine Dose 1 Dose 2		Vaccine Type Moderna Pfizer J&J Other _____			
<p align="center"><i>By signing this document, I accept financial responsibility and am aware of the testing fees. I understand that I am responsible for payment to Kephera Diagnostics and that I am responsible for submitting my own insurance claim. I understand that my sample will not be processed if the payment is not submitted.</i></p>							
Patient Signature					Date (mm/dd/yyyy)		
3. SAMPLE INFORMATION (FOR THIS TEST, ONLY SERUM OR EDTA PLASMA SAMPLES ACCEPTED)							
Sample Type	<i>Serum</i>	<i>K2 EDTA Plasma</i>	Comments				
Sample Collection Date (mm/dd/yyyy)		Sample Collection Time ____ : ____ AM / PM		Sample Storage Conditions room temp. refrigerated frozen			
Sample Collection Facility			Contact Information (phone number, address)				
<p align="center"><i>PATIENT'S LAST NAME, FIRST NAME, COLLECTION DATE AND DATE OF BIRTH MUST BE ON TUBE LABELS</i></p>							

SEE NEXT PAGE FOR GENERAL SAMPLE HANDLING INSTRUCTIONS



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GENERAL SPECIMEN AND SAMPLE HANDLING INSTRUCTIONS

1. Kephera Diagnostics does not currently collect specimens. Patients for whom a test(s) has been ordered by a healthcare provider should have appropriate specimens collected and sent to Kephera Diagnostics with the test requisition form.
2. All samples to be tested in Kephera Diagnostics' laboratory must be ordered by an authorized provider.
3. Use universal precautions when handling specimens containing blood or other potentially infectious material. Specimens must be handled in a safe manner and according to applicable legal requirements or guidance. Information on safe specimen handling may be obtained from the U.S. Occupational Safety and Health Administration (OSHA) and the Centers for Disease Control and Prevention (CDC).
4. Before sending samples make sure that there is no leakage or visible contamination outside the specimen container and that there are no needles or other sharps in the package that could cause injury or pathogenic exposure to anyone handling or opening the package and inner containers.
5. Sample handling after collection:
 - 5.1. Invert the tube 5-10 times after sample collection.
 - 5.2. For serum collection, allow the blood to clot for sixty minutes and separate by centrifugation (15 minutes at 2200-2500 RPM).
 - 5.3. Separate plasma by centrifugation (15 minutes at 2200-2500 RPM).
 - 5.4. Transfer the serum, EDTA plasma or whole blood to a plastic tube with screw cap and make sure to close the cap tightly. Serum or plasma samples should be clear and free from red cells.
 - 5.5. Acceptable sample volume is:
 - Minimum 0.5 mL of serum or plasma, 1 mL is desirable volume.
 - Minimum 3 mL if whole blood from venipuncture.
 - Minimum 0.35 mL of whole blood from fingerstick.
 - 5.6. Each sample must be labeled with the following:
 - Patient's full name (last and first name)
 - Patient's Date of Birth
 - Date sample was collected.
 - 5.7. Unlabeled tubes will not be accepted.
 - 5.8. Hemolyzed, lipemic, bilirubinemic or cloudy samples will be rejected.
6. Human serum or plasma specimens can be stored at 2 – 8°C for up to 5 days prior to shipping, or frozen at -20°C or below. Serum, plasma, and whole blood samples can be shipped via overnight delivery at ambient temperature.
7. Whole blood samples can be stored at 2 – 8°C for up to 2 days prior to shipping. Never freeze whole blood samples. Whole blood samples can be shipped via overnight delivery at ambient temperature. To minimize the risk of hemolysis, do not place whole blood specimens in direct contact with cool packs.
8. Serum and plasma samples should not go through freeze-thaw cycles. Samples subject to multiple freeze-thaw cycles may yield anomalous results.
9. Ship samples to: ***Kephera Diagnostics, Attn: CLIA Laboratory, 1 Grant St., Suite 300, Framingham, MA 01702-6767.***
10. Samples can be sent by Courier, FedEx, or UPS. Ship samples via overnight delivery to arrive Monday through Thursday.

Contact Kephera Diagnostics Laboratory with questions at 774-777-3558 or email us at clia@kepheralab.com