## Lab Dept: Molecular Microbiology

## Test Name: KARIUS TEST

### *General Information*

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| **Lab Order Codes:** | KART |
| **Synonyms:** | Karius Digital Culture |
| **CPT Codes:** | 0152U – Infectious disease (bacteria, fungi, parasites, and DNA viruses), DNA, PCR, next-generation sequencing, plasma, detection of >1,000 potential microbial organisms for significant positive pathogens |
| **Test Includes:** | Next-generation sequencing of microbial cell-free DNA. It can identify and quantify over 1,000 clinically relevant pathogens including bacteria, DNA viruses, fungi and parasites. Applications include complicated pneumonia, immunocompromised patients, and endocarditis. |

### *Logistics*

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| **Test Indications:** | •Detecting pathogens in culture-negative infections including sepsis, endocarditis and infections with fastidious organisms, as well as for patients pre-treated with antibiotics<br><br>•Identifying deep-seated infections such as invasive fungal infections that would otherwise require invasive biopsies<br><br>•Enabling targeted antimicrobial therapy and promoting stewardship<br><br>•Monitoring immunocompromised patients susceptible to a broad range of pathogens, including stem-cell transplant recipients and patients with febrile neutropenia |
| **Lab Testing Sections:** | Molecular Microbiology - Sendouts |
| **Phone Numbers:** | MIN Lab: 612-813-6280<br><br>STP Lab: 651-220-6550 |
| **Test Availability:** | Daily, 24 hours |
| **Turnaround Time:** | 2 – 3 days, typically, results will be reported within 24 hours of being received at the Karius lab. |
| **Special Instructions:** | Obtain special Karius PPT collection tube from the Laboratory. Tubes are stocked in the Sendout department. |

## *Specimen*

**Specimen Type:** Blood

**Container:** Karius Test Kit (includes special PPT – plasma preparation tube) preferred

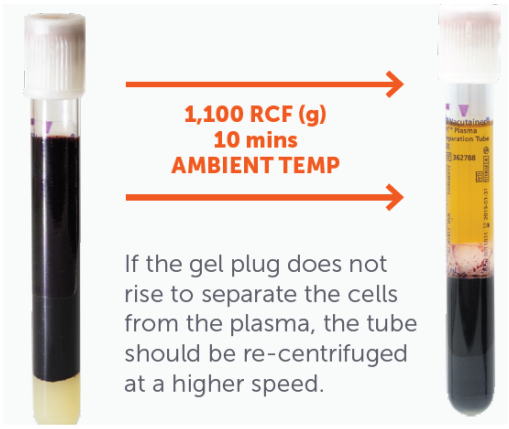
Alternate: Please contact the Lab Sendout department to discuss.

**Draw Volume:** 5 mL whole blood

**Processed Volume:** Same as Draw Volume

**Collection:** Routine venipuncture or line draw, gently invert the tube 8-10 times, label appropriately

**Special Processing:** Lab Staff:
*If collected in the **Karius PPT tube**, centrifuge specimen at 1100 g for 10 minutes at Room Temperature. DO NOT open or transfer the plasma. Specimen must be centrifuged and separated from cells within 6 hours of draw.



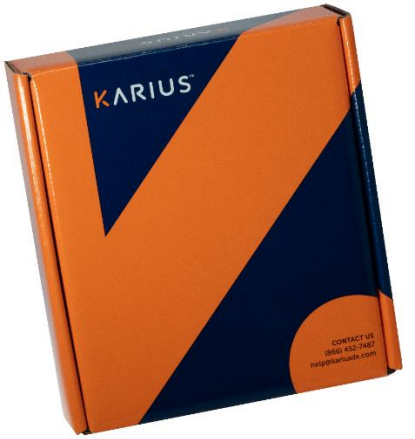

Deliver unopened specimen to Sendouts and store at room temp.

Specimen Stability: 96 hours at room temp, 6 months frozen.

Contact the Lab Sendout Department to discuss alternative specimens and processing.

**Note:** If specimen cannot reach Karius within 96 hours of collection, follow special storage directions found within kit box.

Ship specimens FedEx First overnight to be delivered Monday – Saturday. Use the packaging supplies and instructions enclosed in the kit below to submit the specimen to Karius.




**Sample Rejection:** Plasma separated from whole blood more than 6 hours (PPT) or more than 24 hours (K2-EDTA) after draw; Unfrozen specimen received at Karius more than 96 hours after draw; Specimen with incomplete or improper separations of plasma; Specimen collected in an expired tube; Specimen with few than 2 patient identifiers on the tube; Mislabeled or unlabeled specimens

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***Interpretive***

**Reference Range:** An interpretive report will be provided

**Critical Values:** N/A

**Limitations:** Karius does not provide recommendations on the management or treatment of specific patients. As with any diagnostic test, the Karius test should be interpreted in the context of the patient's clinical picture.

The Karius Medical Affairs team is available for consultation and can provide references to literature that describe the pathogen, its spectrum of disease and treatment options to help guide the care of the patient based on Karius test findings.

If the specimen did not meet minimal acceptance criteria it will be rejected upon receipt, or did not meet the Karius internal quality control standards, a "No result" will be reported.

Karius testing is only validated for blood specimens.

The Karius Test can detect cell-free DNA (cfDNA) from dead and dying pathogens released into the bloodstream. Therefore, the cfDNA signal of a pathogen may still be detected even when a patient has been pre-treated with antibiotics.

Limit of detection is established in terms of microbial cell-free DNA (cfDNA) fragments. The LoD for the Karius Test is approximately 41 molecules of microbial cfDNA per microliter of plasma (MPM). Because this LoD is based on detection of fragments of DNA in cell-free plasma, the value is not comparable to the LoD of other diagnostic assays. There is currently no other validated test that detects pathogen DNA in a small specimen of cell-free plasma like the Karius Test.

There is no established relationship yet between the concentration of cfDNA in plasma and the number of viable microbes in blood. Numerous factors, including, antimicrobial treatment, location of the infection, type of microorganism, can change the relationship between viable microbes and cfDNA from these microbes.

**Methodology:** Next generation sequencing

**References:** Karius website February 2020