KARIUS SPECTRUM

TEST REPORT
KA-123456

SPECIMEN: PLASMA

Collected Nov 18, 2025
Received Nov 20, 2025
Reported Nov 21, 2025

PATIENT

Last name KPLA
First name SAMPLEREPORT
Date of birth Jan 1, 2000
MRN X100514774

ORDERED BY

Doctor Client
Mayo Clinic Laboratories
3050 Superior Drive NW
Rochester, MN 55905

TEST RESULTS

No microbes were detected at significant levels.

Karius staff are available to answer questions about these results:

Phone (866) 452-7487
Email help@kariusdx.com

The Karius Spectrum test can detect

Full list of microbes: kariusdx.com/our-solution/pathogens

763	209	77	68
Bacteria	Fungi	DNA viruses	Parasites

Test description

The Karius Spectrum test for infectious disease detects microbial cell-free DNA in plasma from bacteria, fungi, DNA viruses, and parasites using next-generation sequencing (NGS) [1]. The test reports the presence and abundance of microbial cell-free DNA when significant levels are detected.The test also detects the following antimicrobial resistance (AMR) markers: SCC*mec*, *mecA*, *mecC*, *vanA*, *vanB*, CTX-M, or KPC in relevant microbes (see kariusdx.com/our-solution/karius-spectrum/amr).

Microbial cell-free DNA may be found in plasma when viable microbes are not detected in blood by other methods [2]. It can be detected from localized infections or during effective antimicrobial treatment [1, 3, 4]. The reported microbe(s) may or may not be the cause of patient infection. Results should be interpreted within the context of clinical data, including medical history, physical findings, epidemiological factors, and other laboratory data.

Assay limitations

- This test has been validated only for human plasma collected in EDTA anticoagulant.
- Reliable results are dependent on adequate specimen collection, processing, transport, and storage procedures.
- This test will report uncertain or unresolved species within the corresponding genus, e.g., Aspergillus flavus/oryzae or Neisseria species.
- This test detects antimicrobial resistance conferred by the following markers: SCC*mec*, *mecA*, *mecC*, *vanA*, *vanB*, CTX-M, or KPC. Evaluation for these markers will be performed when a microbe known to utilize the antimicrobial resistance mechanism is reported.
  - The antimicrobial resistance marker may not always be linked with the microbe indicated.
  - Presence or absence of an antimicrobial resistance marker does not always correlate to the expected phenotype.
- The assay analytical sensitivity is influenced by the depth of sequencing achieved. A minimum sequencing depth is required to pass quality control. Many batches achieve greater than this minimum sequencing depth resulting in enhanced sensitivity.
- Concentration values for different microbes may not be comparable to each other.
- To increase the clarity of the report as it relates to infections, microbes detected as frequently co-occurring are not reported when found together in one specimen. This may reduce the sensitivity to detect polymicrobial events such as mucosal membrane barrier disruptions, skin disruptions, gut injuries or aspiration pneumonia.
- Microbes within a taxonomic family may not be reported when detected at less than 25% of the most abundant microbe within the corresponding taxonomic family.
- Microbes within a taxonomic superkingdom are not reported when detected at less than 3% of the most abundant microbe within the superkingdom.
- False positive or false negative results may occur for reasons including but not limited to sporadic contamination from specimen collection, reagent, and materials or hospital and laboratory environments, technical and biological factors.
- The report of a microbe signifies the presence of its cell-free DNA in the patient plasma specimen. It may or may not be the cause of an infection.
- Recent treatment with defibrotide sodium, an oligonucleotide drug derived from porcine tissue, may result in detectable microbial cell-free DNA from porcine-associated microbes and should be considered when interpreting results.

Analytical performance and clinical validation

The Karius Spectrum test was developed and its performance characteristics were determined by Karius. The Karius laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) and is accredited by the College of American Pathologists (CAP) to perform high-complexity clinical laboratory testing. The Karius Spectrum test has not been reviewed or cleared by the FDA.

For a summary of the analytical performance and clinical validation see kariusdx.com/our-solution/karius-spectrum

Concentration interpretation

Positive results will display the concentration of microbial cell-free DNA detected in units of molecules of unique, cell-free DNA fragments of a given microbe per 100 nanoliters of plasma. Several variables impact the concentration, including the location of infection, prior or ongoing antimicrobial treatment, and genome size of the microbe. In cases where multiple microbes are reported, comparison of concentrations across microbes in the context of etiology should be done with caution.

Antimicrobial Resistance (AMR) testing criteria

AMR testing will be included if the following conditions are met:

- Specimen volume is sufficient for testing
- Microbes associated with the following AMR markers: SCC*mec*, *mecA*, *mecC*, *vanA*, *vanB*, CTX-M, or KPC are detected. See the AMR microbe list at: kariusdx.com/our-solution/karius-spectrum/amr
- Additional analytical conditions are met

Reference interval

The reference interval is derived from a study of 458 asymptomatic adults. For each microbe within the clinical reportable range (CRR) of the Karius Spectrum test, the reference interval is defined as the 97.5th percentile of values observed among the samples in this asymptomatic cohort. Overall, 90.4% of the cohort samples had no microbes reported. No microbe in the CRR was reported in more than 0.9% of the cohort samples.

References

[1] Blauwkamp T, et al. Nat Microbiol 2019;4(4):663-674.

[2] De Vlaminck I, et al. Cell 2013;155(5):1178-1187.

[3] Farnaes L, et al. Diagn Microbiol Infect Dis 2019;94(2):188-191.

[4] Rossoff J, et al. Open Forum Infect Dis 2019;6(8).