

SPECIMEN TYPE: PLASMA

SPECIMEN INFORMATION	Collected Jan-08-2018	Received Jan-09-2018	Reported Jan-12-2018	Specimen ID REDACTED
PATIENT INFORMATION	MRN# REDACTED	Last Name REDACTED	First Name REDACTED	Date of Birth REDACTED
INSTITUTION INFORMATION	Ordering Physician REDACTED	Address REDACTED		

TEST RESULTS

MICROORGANISM NAME	DNA MOLECULES PER MICROLITER (MPM)*	REFERENCE RANGE (MPM)**
<i>Klebsiella pneumoniae</i>	55,882	< 10
<i>Staphylococcus epidermidis</i>	38	< 104

* Molecules per microliter = number of DNA fragments present in one microliter of plasma

** Reference range = the 97.5th percentile MPM concentration detected in PPT plasma from a cohort of asymptomatic donors

Karius Medical staff are available to answer any questions about these results: Phone: (866) 452-7487 | Email: medical@kariusdx.com

TEST DESCRIPTION

The Karius Test can identify:

Bacteria: 757 **DNA viruses:** 102 **Archaea:** 1 **Fungi:** 332 **Eukaryotes:** 58

Full list of organisms is found at: www.kariusdx.com/products/Digital-Culture/versions/3.1

The Karius test for infectious disease detects microbial cell free DNA (cfDNA) in plasma from bacteria, DNA viruses, fungi and protozoa using next-generation sequencing (NGS) [1]. The test reports the presence and abundance of microbial cfDNA when statistically significant levels of the associated cfDNA are detected above background.

Microbial cfDNA may be found in plasma when viable microorganisms are not detected in blood by other methods [2]. It can be detected from localized infections [3] or during effective antimicrobial treatment [4]. The reported microorganism(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.

[1] Data on file, Analytical Validation (March 2018)

[2] De Vlaminck, et al. (2013). Cell, 155(5)

[3] The SEP-SEQ Trial: Clinical Validation of the Karius Plasma Next-Generation Sequencing Test for Pathogen Detection in Sepsis (Late-breaking oral session, IDWeek 2017)

[4] Abril, et al. (2016 Jul 12) Open Forum Infect Dis, 12:3(3):ofw144

This test was developed and its performance characteristics determined by Karius. This test has not been cleared or approved by the FDA, nor is it required to be. 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.