

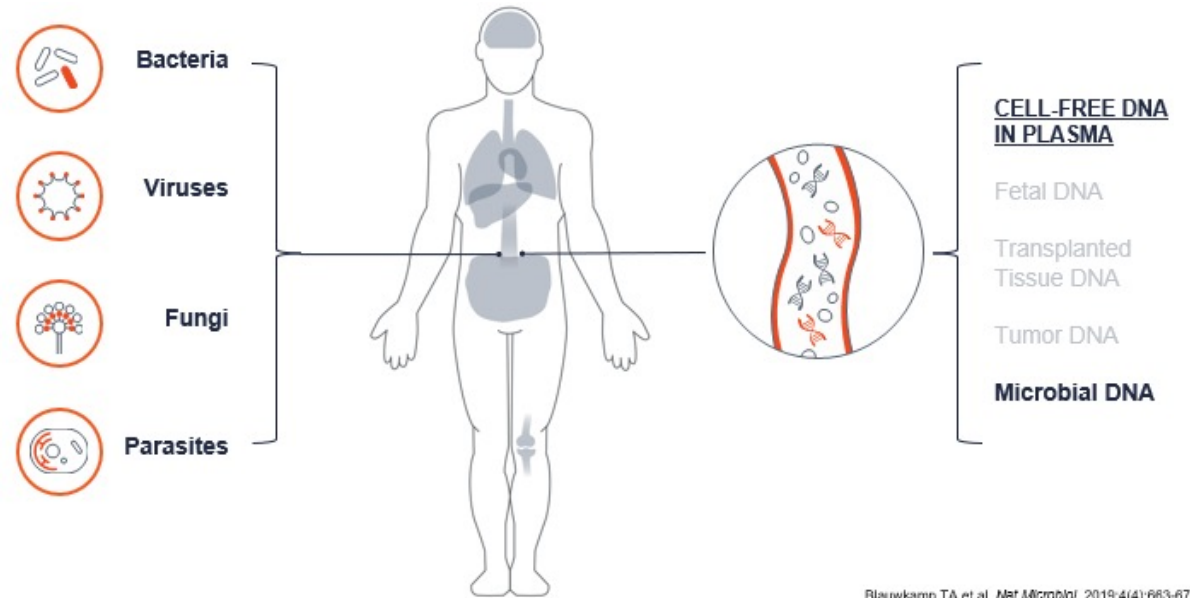
Karius Test[®]

Liquid Biopsy for Infectious Diseases

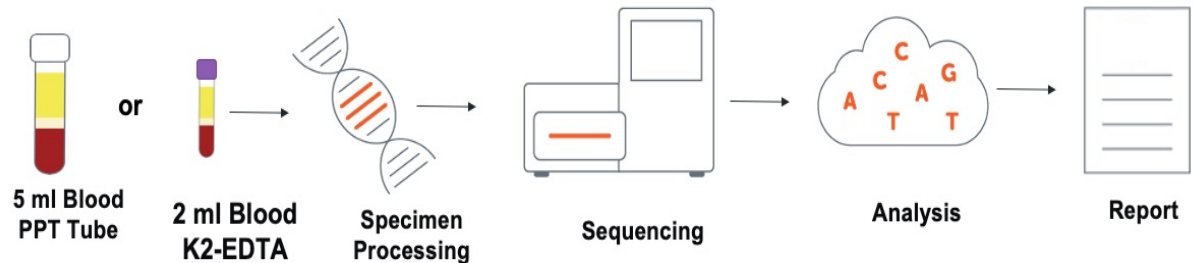
KARIUS
clarity at speed[®]

Plasma-based mcfDNA NGS

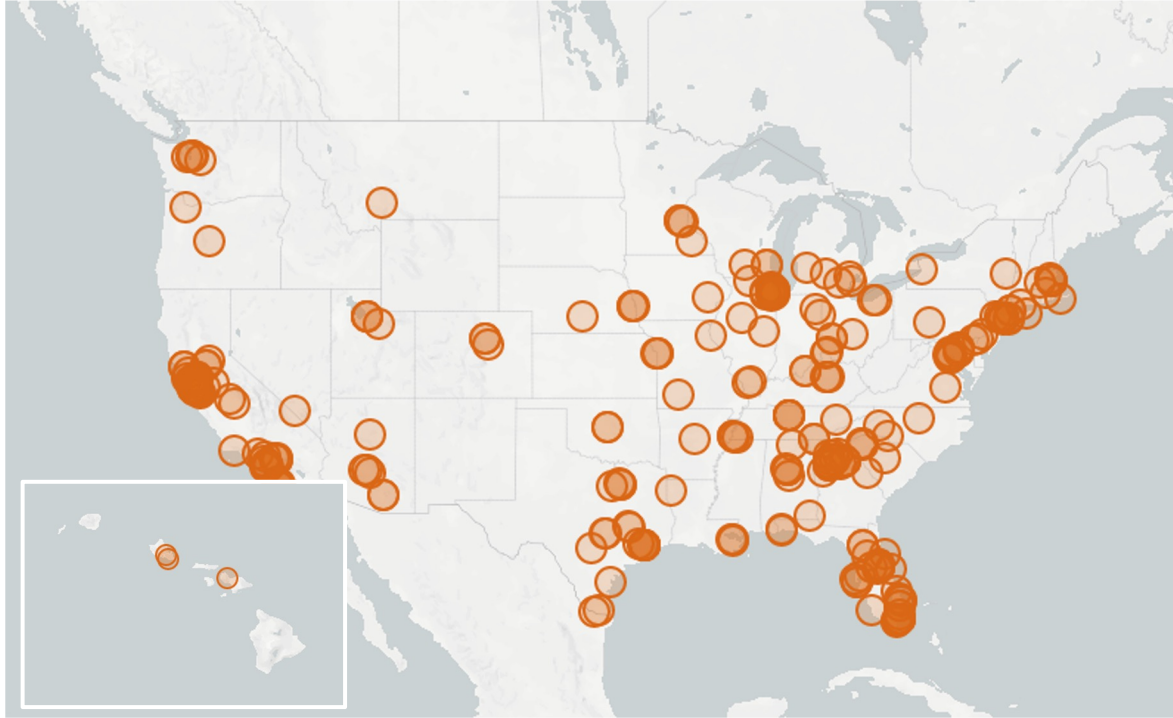
- Blood test based on next-generation sequencing of plasma microbial cell-free (mcf) DNA
- Ability to detect 1000+ microbes
- CAP, CLIA, and New York State



Blauwkamp TA et al. *Nat Microbiol*. 2019;4(4):663-674



The Karius Test has been adopted by leading hospitals and transplant centers throughout the US



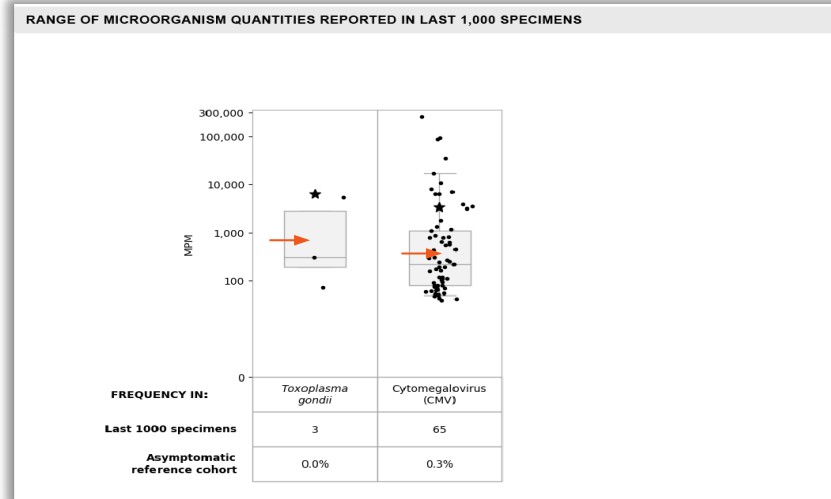
300+ hospitals have used the Karius Test to date

- 90+ Transplant Centers
- 40+ Children's Hospitals

Test Report Interpretation

- **Relevance:** mcfDNA present in statistically significant amounts are reported
- **Quantification:** Concentration of microbial cell-free DNA is expressed as MPM (molecules per microliter) to quantify/monitor pathogens
- **Reference range:** Reference interval determined from 684 asymptomatic adult donors
- **Reports:** Fax to the hospital, online portal and mobile application
- Interpretation available with infectious disease physicians

SPECIMEN TYPE: PLASMA				
SPECIMEN INFORMATION	Collected	Received	Reported	Specimen ID
PATIENT INFORMATION	MRN#	Last Name	First Name	Date of Birth
INSTITUTION INFORMATION	Ordering Physician		Address	
TEST RESULTS				
MICROORGANISM DETECTED		DNA MOLECULES PER MICROLITER (MPM)*		REFERENCE INTERVAL (MPM)**
Toxoplasma gondii		6,321		< 10
Cytomegalovirus (CMV)		3,985		< 10



Test Report Interpretation

RESULT	SUBSET	INTERPRETATION
Positive	Quantitative	Demonstrates the amount of mcfDNA in MPMs
	Qualitative	Demonstrates the presence of an organism but the specimen did not meet the minimum sequencing coverage metric required by our quality controls, therefore the reported organism was not quantified and potential co-infections may not be detected
Negative		No statistically significant microbes were detected and controls passed
Requeue		The specimen did not pass a control and is being re-evaluated
No result		No statistically significant microbes were detected and controls did not pass on 2 separate evaluations

Example of Detections in Pediatrics/Adults

LUNG

Coccidioides immitis
Pneumocystis jirovecii
Legionella pneumophila
Chlamydia psittaci
Rhizopus microsporus



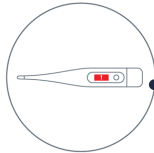
LIVER & SPLEEN

Fusobacterium nucleatum
Echinococcus multilocularis
Helicobacter cinaedi
Bartonella henselae
Tropheryma whippelii



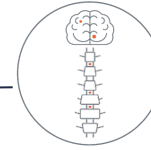
SYSTEMIC & FUO

Francisella tularensis
Rickettsia typhi
Trypanosoma cruzi
Leptospira interrogans
Streptobacillus moniliformis
Brucella melitensis



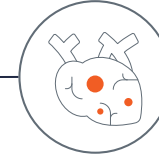
BRAIN/CNS

Balamuthia mandrillaris
Angiostrongylus cantonensis
Capnocytophaga canimorsus
Naegleria fowleri
Cladophialophora bantiana
Aspergillus fumigatus
Cunninghamella



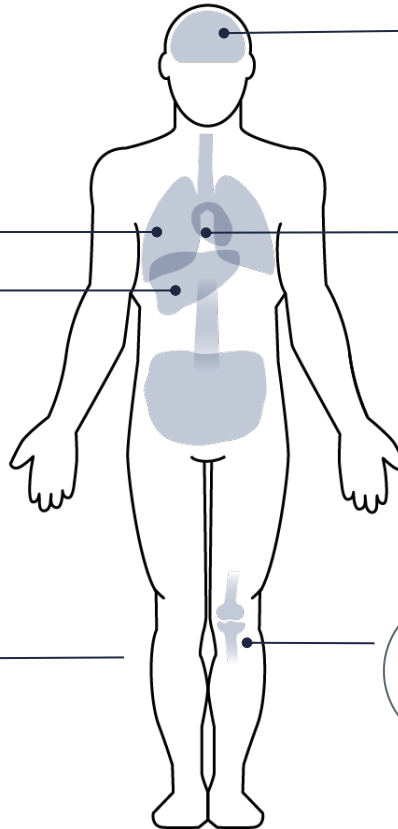
HEART

Bartonella vinsonii, *B. henselae*
Coxiella burnetii
Coccidioides posadasii
Cardiobacterium hominis
Haemophilus parainfluenzae



BONE/JOINT

Mycobacterium tuberculosis
Ureaplasma parvum
Salmonella enterica
Neisseria gonorrhoeae
Kingella kingae
Staphylococcus aureus



Karius identification of Nationally Notifiable Conditions (pathogens)

- Karius technology technically does not fulfill surveillance case definitions, although a few may be loosely interpreted (e.g., culture independent diagnostic test)
- Concern, however, regarding ensuring notifiable pathogens are brought to public health attention

KARIUS TEST REPORT

Karius ID: [REDACTED]

SPECIMEN TYPE: PLASMA

SPECIMEN INFORMATION	Collected [REDACTED]	Received [REDACTED]	Reported [REDACTED]	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 DETECTED	DNA MOLECULES PER MICROLITER (MPM)*	REFERENCE INTERVAL (MPM)**
<i>Salmonella enterica</i> ⚠	251	< 10
This organism is on the Centers for Disease Control and Prevention's list of Nationally Notifiable Conditions. You may need to notify the appropriate local or state health department about this result.		

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

** Reference Interval = the 97.5th percentile MPM concentration detected in PPT plasma from a cohort of 684 asymptomatic donors

Results can also be accessed via our online secure portal

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

Karius is a covered entity under HIPAA

TEST DESCRIPTION

The Karius Test can detect:

Bacteria: 982 **DNA viruses:** 106 **Archaea:** 1 **Fungi:** 403 **Eukaryotes:** 68

Full list of organisms is found at: <https://www.kariusdx.com/pathogenlist/>

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 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 or during effective antimicrobial treatment [1, 3, 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] Blauwkamp T, et al. *Nat Microbiol.* 2019;4(4):663-674.

[2] De Vlaminc 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).

Karius identification of Nationally Notifiable Conditions (pathogens)

- Reports sent to relevant health departments in states requiring additional laboratory licensures (e.g., CA, NY, MD, FL, PA, RI, and MN)
- Other states/jurisdictions reaching out to Karius regarding reporting as they learn of testing

Attn: [REDACTED]

[REDACTED] Health Department

Fax: [REDACTED]

Confidential Health Information Enclosed.

Health care information is personal and sensitive. It is being faxed to you after appropriate authorization or under circumstances that do not require patient authorization. You, the recipient, are obligated to maintain this information in a safe, secure and confidential manner. Re-disclosure without additional consent or authorization of the patient or as permitted by law, or failure to maintain the confidentiality of this information, could subject you to penalties under Federal and/or State law. Please notify the sender immediately if you have received this communication in error to arrange the return or destruction.

Re: Lab Reportable Condition

The attached laboratory test result was sent by Karius to [REDACTED] in [REDACTED] on [REDACTED] 2021. It includes *Legionella longbeachae* which is included on the list of reportable conditions for the state of [REDACTED] patients.

Karius provides an infectious disease diagnostic test out of its laboratory located in Redwood City, CA. As a testing laboratory, we do not have the patient's address, however, patient name and DOB as well as ordering physician's information are included in the report.

Please let us know if you need additional information from us.

Best,

[REDACTED]
Customer Success
Karius Inc

More Information about KARIUS

Information about the Karius Test

www.kariusdx.com

Contact Information

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