KARIUS FOCUS | BAL

TEST REPORT
KA-123456

SPECIMEN: BAL FLUID

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

PATIENT

Last name	KBAL
First name	SAMPLEREPORT
Date of birth	Jan 1, 2000
MRN	X100514769

ORDERED BY

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

TEST RESULTS

MICROBIAL CELL-FREE DNA DETECTED
SORTED ALPHABETICALLY WITHIN EACH GROUP

ANNOTATIONS

Obligate & Opportunistic Pathogens[1] May cause lung infection

Fungi	***Aspergillus fumigatus*** Alert result

Microbes with Pathogenic Potential & DNA Viruses[1] May cause lung infection or represent commensals

Viruses	**Cytomegalovirus (CMV)**

Upper Respiratory Tract Flora[1] More commonly commensals than the cause of lung infection

Bacteria	***Actinomyces oris***
	Rothia mucilaginosa

[1] Based on a review of Carroll KC, Pfaller MA. 2019. Manual of Clinical Microbiology, 12th Edition. ASM Press, Washington, DC and Bennett JE, Dolin R, Blaser MJ. 2019. Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases, 9th Edition. Elsevier, Philadelphia, PA, and PubMed references.

Karius staff are available to answer questions about these results at (866) 452-7487 or help@kariusdx.com

Karius Focus | BAL test can detect

Full list of microbes: kariusdx.com/our-solution/pathogens?product=bal

Parasites | Fungi | Bacteria | DNA viruses

Test description

The Karius Focus | BAL test is a BAL fluid based microbial cell-free DNA (mcfDNA) metagenomic sequencing diagnostic test for agnostic detection, identification, and quantification of mcfDNA from human lung pathogens, including parasites, fungi, bacteria, and DNA viruses. The results obtained from this assay should always be used in combination with patient medical history, clinical examination, and other findings.

Assay limitations

- This test has been validated only for human BAL fluid. Other lung specimens including sputum, mini-BAL fluid, bronchial washes, endotracheal aspirates and pleural fluid are unacceptable.
- This test is intended solely for use in the diagnosis and management of lung infections.
- Reliable results are dependent on adequate specimen collection, processing, transport, and storage procedures.
- 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.
- Microbes within a taxonomic family are not reported when detected at less than 25% of the most abundant microbes within the family.
- 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 mcfDNA in the patient BAL fluid. It may or may not be the cause of a lung infection.
- The results obtained from this assay should always be used in combination with clinical examination, patient medical history, and other findings.

Analytical performance and clinical validation

The Karius Focus | BAL 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 Focus | BAL 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-focus-bal

Reference interval

The reference interval is derived from a study of 118 adult immunocompromised patients with pneumonia [1][2]. For each microbe within the clinical reportable range (CRR) of the Karius Focus | BAL test, the reference interval is defined as the 97.5th percentile of reported microbes observed among the samples in this cohort when not adjudicated as the cause of pneumonia. Overall, 32% of the cohort samples had no microbes reported.

The following microbes were reported in more than 2.5% of all patients when not adjudicated as the cause of pneumonia:

Actinomyces graevenitzii 9.40%
Actinomyces israelii 2.54%
Actinomyces odontolyticus 15.65%
Actinomyces oris 25.86%
Alloscardovia omnicolens 4.24%
Campylobacter gracilis 3.39%
Candida glabrata 4.24%
Capnocytophaga gingivalis 2.54%
Capnocytophaga granulosa 2.54%
Capnocytophaga ochracea 2.59%
Capnocytophaga sputigena 2.54%
Enterococcus faecalis 10.26%
Enterococcus faecium 3.42%
Epstein-Barr virus (EBV) 2.54%
Fusobacterium nucleatum 18.10%
Granulicatella adiacens 7.83%
Haemophilus parainfluenzae 6.90%
Prevotella melaninogenica 20.00%
Rothia mucilaginosa 34.21%
Slackia exigua 4.31%
Staphylococcus aureus 3.54%

References

[1] Bergin S, et al. Clin Infect Dis 2024;78(3):775-784.

[2] Cheng G, et al. Ann Am Thorac Soc 2023;20(3):341-353.