MAYO CLINIC LABORATORIES

Test Definition: KDBAL

Karius Focus, Direct Ship, Bronchoalveolar Lavage

Overview

Useful For

Detection of microbial cell-free DNA from over 500 bacteria, fungi, parasites, and DNA viruses known to cause lung infections in bronchoalveolar lavage fluid

Testing Algorithm

For information regarding when to order the Karius Spectrum test or diagnostic algorithms, see Considerations for the Implementation of the Karius Spectrum and Karius Focus BAL Tests.

Highlights

The Karius Focus: BAL test employs pathogen-agnostic metagenomic microbial cell-free DNA (mcfDNA) sequencing of bronchoalveolar lavage fluid for the unbiased detection, identification and classification of over 500 human pathogens that cause lung infections.

This test is designed to quickly identify the etiology of lung infections and improve diagnostic yield over standard of care testing.

For more information see Karius Focus: BAL A new diagnostic tool for patients with suspected lung infection.

Method Name

Metagenomic Sequencing

NY State Available

Yes

Specimen

Specimen Type

Bronchoalveolar Lavage

Ordering Guidance

Order this test when shipping specimens directly to Karius.
If this is your first time ordering this test, contact Customer Service (800-533-1710) to ensure your account is set up and you have the appropriate supplies for directly shipping to Karius labs.

Shipping Instructions

1. Place the specimen in the biohazard bag with an absorbent pad.
2. Wrap the ambient gel pack around the specimen bag.
3. Place the wrapped specimen bag in the foil bubble mailer and then in the test kit cardboard box.

4. Include the batch sheet from MayoACCESS or MayoLINK in the test kit cardboard box.
5. Ship ambient to Karius Labs.

Specimen Required

Supplies: Karius KDBAL Kit (T1015)
Container/Tube: Streck CP tube
Specimen Volume: 1 mL
Collection Instructions:
1. Collect bronchoalveolar lavage fluid (BALF) specimen according to your institutional guidelines.
2. Within 12 hours of specimen collection, transfer at least 1 mL of BALF specimen to the Streck CP tube using disposable sterile pipette, taking care to avoid spilling storage reagent in Streck CP tube.
3. Screw the cap tightly and gently invert the tube 8 to 10 times.
4. **Do not freeze the Streck CP tube.**
5. See Shipping Instructions for how to package and ship the specimen to Karius Labs.
Additional Information:
1. **Specimen cannot be shared with other tests**.
2. **Specimen trap collection containers (with suction catheters attached) will be rejected** due to the high risk of leakage and contamination upon opening. Avoid use of these for BALF specimens.

Alternate Collection Instructions for when storage is needed before shipment
1. Collect BALF specimen according to your institutional guidelines.
2. Freeze BALF in the sterile collection tube. **Do not use the Streck CP tube**, as it must not be frozen.
3. When ready to prepare for shipment, thaw the frozen BALF specimen.
4. Label the Streck CP tube with the patient's first and last name, a unique patient identifier (eg, date of birth or medical record number), the collection date and time, **and the thawing date**.
5. Use a disposable pipette to carefully transfer 1 mL of BALF into the labeled Streck CP tube containing storage reagent. Avoid spilling the reagent.
6. Securely tighten the cap and gently invert the tube 8 to 10 times to mix.
7. **Do not freeze the Streck CP tube**.
8. See Shipping Instructions for how to package and ship the specimen to Karius Labs.

Specimen Minimum Volume

See Specimen Required

Reject Due To

All specimens will be evaluated by the processing and performing laboratory for test suitability.

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Bronchoalveolar Lavage	Ambient	7 days	

Clinical & Interpretive

Clinical Information

The Karius Focus BAL test is a bronchoalveolar lavage fluid-based microbial cell-free DNA (mcfDNA) metagenomic sequencing diagnostic test for agnostic detection, identification, and quantification of mcfDNA from human lung pathogens, including bacteria, fungi, parasites, and DNA viruses. Patients who may be appropriate for testing include individuals with suspected pneumonia or other pulmonary infections who are undergoing bronchoscopy to identify an infectious cause as well as those with imaging concerning opportunistic, atypical, or fungal pneumonia or not responding to empiric therapy and in need of rapid diagnostic testing.

Reference Values

An interpretive report will be provided.

Interpretation

A positive result indicates that microbial cell-free DNA (mcfDNA) of one or more potentially pathogenic microorganisms was detected.

A negative result indicates absence of detectable mcfDNA from potentially pathogenic bacteria, fungi, parasites, or DNA viruses. A negative result does not rule out the presence of a pathogen due to lack of a reference sequence in the database used or the presence of mcfDNA in quantities lower than the assay's limit of detection. Results should be interpreted in the clinical context of the patient.

For more information see Understanding the Karius Focus: BAL Test Report.

Cautions

The Karis Focus Test does not detect RNA viruses. The test has been validated only for bronchoalveolar lavage fluid specimens.

Supportive Data

A robust analytical validation strategy characterized Karius Focus: BAL test performance in light of metagenomic-specific challenges using 11 diverse pathogens that span the extremes of over 500 pathogens characteristics. Clinical performance of microbial cell-free DNA (mcfDNA) sequencing of bronchoalveolar lavage fluid (BALF) was compared to standard of care (SOC) testing results in a prospective observational study conducted at 10 tertiary care centers, including 118 patients with a hematologic malignancy undergoing bronchoscopy for suspected pneumonia.(1) mcfDNA sequencing was performed using the Karius Focus BAL test to detect and quantify mcfDNA from over 500 organisms in BALF. Results of mcfDNA sequencing and all BALF-based SOC testing were adjudicated by a panel of experts for identification of probable causes of pneumonia.

Microbial cell-free DNA sequencing of BAL identified an adjudicated probable cause of pneumonia in 40/118 participants (33.9%, 95% CI 25.1-42.7), compared to SOC which identified an adjudicated probable cause of pneumonia in 29/118 (24.6%, 95% CI 16.5-32.6). mcfDNA sequencing of BALF exclusively identified a probable cause of pneumonia in 15/118 participants (12.7%, 95% CI 6.4-19.1), resulting in a relative diagnostic yield increase of 15/29 (51.7%, 95%CI 33.0-70.4). In addition, mcfDNA sequencing of BALF identified additional or alternative adjudicated causes of pneumonia in 7/29 (24.1%, 95% CI 7.9-40.4) specimens with a SOC-adjudicated cause of pneumonia and provided speciation for genus-level SOC causes of pneumonia in all 5 cases where SOC identified the cause at the genus level. Based on the composite results of all diagnostics tests, mcfDNA sequencing of BAL demonstrated 90.9% +/-9.1% positive percent agreement (PPA), compared to PPA of 65.9% +/-14.5% for all SOC-BAL testing combined.

For more information see Analytical and Clinical Validation of Microbial Cell-free DNA Sequencing of Bronchoalveolar Lavage Fluid.

Clinical Reference

1. Bergin SP, Chemaly RF, Dadwal SS, et al. Plasma microbial cell-free DNA sequencing in immunocompromised patients with pneumonia: A prospective observational study. Clin Infect Dis. 2024;78(3):775-784
2. Blauwkamp TA, Brick K, Jarman K, et al. Analytical and Clinical Validation of Microbial Cell-free DNA Sequencing of Bronchoalveolar Lavage Fluid Test. ASM Microbe 2025 Poster CIV-P-403
3. Cheng GS, Crothers K, Aliberti S, et al. Immunocompromised host pneumonia: Definitions and diagnostic criteria: An official American Thoracic Society Workshop report. Ann Am Thorac Soc. 2023;20(3):341-353. doi:10.1513/AnnalsATS.202212-1019ST

Performance

Method Description

One mL of bronchoalveolar lavage fluid (BALF) is treated with proteinase K to break down proteins, spiked with internal controls, and prepared for sequencing with an in-matrix library preparation method. Pooled libraries were sequenced on Illumina NextSeq500/550 or NovaSeq6000 platforms, yielding approximately 24M reads per sample. The test employs multiple quality control strategies designed to control common sources of error in metagenomic tests including contamination, carry-over cross contamination, pathogen cross reactivity, and impaired limits of detection. The target agnostic chemistry process generates a data file containing all detected sequencing reads. The sequencing reads from each sample are aligned against a highly curated reference genome database containing thousands of microbial species and a high-quality human reference. Potentially pathogenic species with statistically significant numbers of aligned reads that also pass our analytical and clinical thresholds are reported. The list of reportable pathogens includes over 500 bacteria, DNA viruses, fungi, and parasites known to cause lung infections.

For reporting purposes, microbes are functionally categorized as:
1. Obligate pathogen, likely to cause lung infection at any concentration
2. Opportunistic pathogens, may cause disease, especially in immunocompromised hosts
3. Microbes with pathogenic potential and DNA viruses, which may either cause lung infection or represent commensal organisms
4. Upper respiratory tract flora, which are more commonly commensal organisms than the cause of lung infections

For a listing of pathogens, see https://kariusdx.com/our-solution/pathogens?product=bal

PDF Report

Referral

Day(s) Performed

Monday through Saturday

Report Available

3 to 5 days

Specimen Retention Time
90 days

Performing Laboratory Location
KARIUS LABORATORY DIRECT SHIP

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
The Karius Focus: BAL test was developed and its performance characteristics 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 laboratory testing. This test has not been reviewed or cleared by the US Food and Drug Administration.

CPT Code Information
87999

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
KDBAL	Karius Focus Direct, BAL	Not Provided

Result ID	Test Result Name	Result LOINC® Value
KDBAL	Karius Focus Direct, BAL	Not Provided