Karius Test® Improves the Diagnosis and Management of Pneumonia in Patients Undergoing Treatment for Blood Cancer

Multi-center study shows a 40% (20/52) relative increase in diagnostic yield when the Karius Test, a liquid biopsy for infectious diseases, was added to usual care testing

REDWOOD CITY, CA – October 10, 2023 - A pivotal multi-center study published in Clinical Infectious Diseases demonstrates the effectiveness of the Karius Test®, a blood test based on metagenomics next generation sequencing of microbial cell-free DNA, by increasing the identification of pathogens causing pneumonia in immunocompromised patients by 40% (20/52) when combined with usual care diagnostic testing[1]. This first-of-its-kind PICKUP Study–a collaborative effort among ten leading medical institutions including Duke University Health System, University of Pittsburgh Medical Center, Fred Hutchinson Cancer Research Center, MD Anderson Cancer Center, City of Hope, Tulane Medical Center, University of California, San Francisco Medical Center, University of Colorado Denver, Weill Cornell Medicine, and Memorial Sloan Kettering Cancer Center–demonstrated the additive diagnostic value of the Karius Test in managing pneumonia patients with blood cancers.

“Pneumonia commonly complicates hematopoietic cell transplantation and treatment of hematologic malignancies, yet current diagnostic standards identify a causative pathogen in less than half of our patients undergoing bronchoscopy and extensive noninvasive testing,” said Dr. Stephen Bergin, Duke Clinical Research Institute faculty and Principal Investigator for the PICKUP Study. “Often clinicians must weigh the risks of invasive procedures in medically fragile patients with an anticipated low diagnostic yield. The PICKUP Study significantly advances our understanding of how noninvasive plasma microbial cell-free DNA (mcfDNA) sequencing can enhance management of pneumonia.” Pneumonia is a leading cause of death among patients currently undergoing treatment for blood cancer, as they are often at elevated risk of infection throughout their treatment[2,3].

Identifying the specific cause of pneumonia in patients with blood cancers who are often severely immunocompromised is difficult and critically important to successful treatment. “This well-designed clinical trial conducted at leading academic centers shows that the Karius Test is highly valuable in immunocompromised patients with suspected infection,” said Dr. Ned Sharpless, former Director, National Cancer Institute, and newest Karius board member. “The ability to identify the causal pathogen with true urgency is critical in this patient population, and more rapid diagnosis through use of the Karius Test will reduce suffering and death in these vulnerable patients.”

The Study, “Pneumonia in the ImmunoCompromised – Use of Karius Test for the Detection of Undiagnosed Pathogens (PICKUP),” enrolled 257 hospitalized adults with pneumonia and active hematologic malignancies, had recently undergone a hematopoietic cell transplant, or were receiving immunosuppressive therapy for active graft versus host disease.

“Adding this novel platform to current standards of care significantly improved causative pathogen identification. Future PICKUP Study publications will evaluate the impact of plasma microbial cell-free DNA sequencing on time to diagnosis, detection of co-infections, and potential avoidance of invasive procedures,” said Dr. Stephen Bergin. This primary study endpoint measured the additive diagnostic value of the Karius Test, defined as the percent of patients where the Karius Test identified the cause of pneumonia for whom all usual care testing was negative within 7 days of admission through adjudication. Results showed that the Karius Test identified the probable cause of pneumonia in 12% (21/173) of patients (P<0.001, 95% confidence interval 7.7 yo 18%), when all usual care testing, including bronchoscopy failed to identify a probable cause of pneumonia. The study also evaluated and found that antimicrobial therapy could have been optimized among 81% (17/21) of patients in whom the Karius Test exclusively identified a probable cause of pneumonia[1]. In several instances, the Karius Test also identified probable causes of pneumonia when all usual care testing failed to find hard-to-identify pathogens such as *Rhizomucor pusillus, Nocardia cyriacigeorgica, Legionella species*, and *Aspergillus fumigatus*. Editors of Clinical Infectious Diseases, a journal published by the Infectious Diseases Society of America (IDSA) concluded, "mcfDNA sequencing is likely to bring added diagnostic value for some heme/STC [hematologic malignancy/stem cell transplant] patients with pneumonia."

“These patients have much to gain through an improved etiologic diagnosis, and the better and more directed treatment of these infections that make this possible,” said Brad Perkins, Chief Medical Officer at Karius. “This is not only beneficial in the avoidance of the direct morbidity and mortality associated with these infections (26.6% of our enrolled patients died during this study) but in also gaining earlier and uninterrupted access to in-many-cases increasingly life-saving treatments for their underlying disease, in this case hematologic malignancies.”

References:

1. Bergin SP, et al. Clinical Infectious Diseases. October 2023
2. Schuster MG, et al. Open Forum Infect Dis. 2017;4(2):ofx050
3. Lucena CM, Torres A, Rovira M, et al. Bone Marrow Transplant. 2014;49(10):1293-9.

About Karius

Karius Inc., a global leader in liquid biopsy for infectious diseases, harnesses metagenomics, next-generation sequencing, and artificial intelligence (AI) to help enhance the precision and speed of pathogen diagnosis. The Karius Test®, used in over 300 healthcare institutions–including 90+ transplant centers and 40+ children’s hospitals across the United States–identifies more than 1,000 pathogens, including

viruses, bacteria, fungi, and parasites from a single blood draw typically within a day of sample receipt. A landmark study in the Journal of Clinical Microbiology found that the Karius Test detected 701 unique microbial taxa across a cohort of 15,000 patients, making it the largest study of its kind, demonstrating the capability of the Karius Test in pathogen identification. The Karius Test also has been incorporated into the diagnostics recommendations in the 2023 Duke-ISCVID Criteria for Infective Endocarditis.

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