Clinical Experience with the Karius Next-Generation Sequencing Test in 1,000+ Patients

The Karius Test

Infectious diseases remain an important and significant cause of morbidity and mortality for patients. Many infections, such as culture-negative and deep-seated infections, can be diagnostically challenging.

The Karius Test can non-invasively identify more than 1,000 pathogens (including bacteria, fungi, DNA viruses, and eukaryotes) using next-generation sequencing of cell-free pathogen DNA in plasma.

The preferred sample type for the Karius Test is 5mL of whole blood collected in a Plasma Preparation Tube (PPT) that is then centrifuged and sent to the Karius CAP-accredited, CLIA-certified laboratory via FedEx overnight service.

SAMPLE PROCESSING METRICS

Of the 1,036 samples tested, 54.7% were from adult patients and 45.3% were from pediatric patients.

The sample acceptance rate in this cohort was 97.6% with a first pass yield of 88.5% and total result yield of 97.7%.

Results were delivered the next day following sample receipt for 82.5% of patients.

CLINICAL APPLICATIONS OF THE KARIUS TEST

The most common clinical scenarios (identified by ICD codes and clinical consultation) for which the samples were submitted included patients who were immunocompromised, complicated pneumonia, infective endocarditis (including *M. chimaera* infections), and sepsis.

Tests for immunocompromised patients were commonly sent in the setting of fever and neutropenia, following stem-cell transplant, or when invasive fungal infection was suspected.

Samples for sepsis patients included culture-negative scenarios where other diagnostics may have had poor sensitivity.

SUMMARY OF THE FIRST 1,000+ KARIUS TESTS

The Karius Test demonstrated clinical utility by identifying challenging infections in the patients tested. There were 261 unique pathogens identified in the 1,036 samples tested. A total of 554 patients had ≥ 1 microbe reported with 69% of these having 1 or 2 microbes reported.

Test results included notable bacteria (such as *Bartonella henselae*, *Legionella pneumonphila*, and *Mycobacterium tuberculosis* complex) and fungi (such as *Histoplasma capsulatum*, *Coccidiodes immitis*, and *Pneumocystis jirovecii*).

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