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FDA approves Therascreen EGFR PCR kit as companion test for Gilotrif

Qiagen received FDA approval to market the Therascreen EGFR test as a companion diagnostic to guide the use of Boehringer Ingelheim's new targeted therapy Gilotrif (afatinib) for treatment of metastatic NSCLC in patients whose tumors have certain EGFR gene mutations.

FDA approval of the Therascreen EGFR test follows an FDA priority review of Gilotrif, and the drug's labeling requires the use of an FDA-approved test to select EGFR mutation-positive patients for the therapy. Gilotrif is indicated for non-small cell lung cancer patients with the most common mutations in the EGFR gene, which are EGFR exon 19 deletions and exon 21 L858R substitution mutations.

Analytical performance of the test has been established for 21 EGFR mutations, according to Qiagen, including the most prevalent resistance mutation (T790M).
Gilotrif's approval was supported in part by the LUX-Lung 3 trial. Results showed that within the general study population, in the Gilotrif arm, median progression-free survival was 11.1 months versus 6.9 months for the chemotherapy arm (pemetrexed, cisplatin) ($P<0.001$).

A guide to using the microbiology lab

A new guide developed by the Infectious Diseases Society of America and the American Society for Microbiology will help physicians use laboratory tests appropriately in diagnosing infectious diseases.

Published July 11 in Clinical Infectious Diseases, the recommendations provide guidance on which lab tests are valuable and should be used in specific contexts, which add little or no value, and how to collect and manage specimens.

"Even with the advent of laboratory automation and the integration of genomics and proteomics in microbiology, interpretation of results still depends on the quality of the specimens received for analysis," write the 18 authors.

"Caught in the middle, between the physician and the laboratory," they say, "are those who select and collect the specimen and who may not know or understand what the physician or the laboratory needs to do their work."

The document is organized by body system, and each section has a set of key points. For bone and joint infections there are six, among them the following: "For prosthetic joint infection diagnosis, 3-6 separate tissue samples should be submitted. As an alternative, sonication or bead mill homogenizing of samples from the removed prosthesis are excellent methods to detect pathogens in biofilms."

And this, among others, for lower respiratory tract infections: "The range of pathogens causing exacerbations of lung disease in cystic fibrosis patients has expanded and specimens for mycobacterial and fungal cultures should be collected in some patients."

The guide suggests 10 tenets of specimen management, including the following: "Susceptibility testing should be performed on clinically significant isolates, not on all microorganisms recovered in culture" and "The laboratory should be allowed to set technical policy; this is not the purview of the medical staff. Good communication and mutual respect will lead to collaborative policies."

Bobbi Pritt, MD, MSc, D(TMH), a coauthor of the guide and a member of the CAP Microbiology Resource Committee, says some of the most important aspects of microbiology testing are in the guide's introduction—for example, "that the microbiologist is an essential part of the patient care team," she says, "who must be allowed to make decisions regarding workup of the microbiology specimen." Ultimately, some specimens will not be suitable for testing and the lab must reject them.

“Clinicians can avoid specimen rejection by discussing the case with the microbiologist prior to sample collection, and by adhering to general rules for optimal specimen selection such as submitting tissues, fluids, and aspirate rather than swabs whenever possible, obtaining specimens prior to administration of antibiotics, and taking steps to avoid contaminating a specimen with normal flora,” says Dr. Pritt, director of clinical parasitology, Division of Clinical Microbiology, Mayo Clinic, Rochester, Minn.

Ellen Jo Baren, PhD, of the Department of Pathology at Stanford University School of Medicine and Cepheid R&D, and J. Michael Miller, PhD, of Microbiology Technical Services LLC, Dunwoody, Ga., shepherded the guide to completion after Gary Doern, PhD, editor-in-chief of the Journal of Clinical Microbiology, conceived, organized, and managed the project initially.

The full text is online at http://cid.oxfordjournals.org/content/57/4/485.full.pdf+html.

Leica Biosystems acquires Kreatech

Leica Biosystems has acquired Kreatech Diagnostics, a provider of DNA FISH probes and target labeling reagents for microarrays.

Kreatech will join Leica Biosystems’ Advanced Staining Business Unit based in Newcastle upon Tyne, UK. The combined business will develop targeted biomarker menus for Leica’s instrument platforms. Leica provides the ThermoBrite and Bond systems.

Life Tech to collaborate with Merck Serono

Life Technologies has signed an agreement to collaborate with Merck Serono, a division of Merck KGaA, Darmstadt, Germany, for current and future companion diagnostics projects.

The collaboration will seek to combine the biomarkers identified by Merck’s translational research with Life Technologies’ platform technologies and to develop companion diagnostics concurrently with Merck’s drug development programs. The companies will seek regulatory approval of Merck’s drug and Life’s companion diagnostic.
Ronnie Andrews, Life Tech’s president of genetic and medical sciences, says the agreement highlights Life Tech’s ability “to afford pharmaceutical companies one partner for the design, development, manufacturing, and regulatory clearance of companion diagnostics.”

MDxHealth teams with HistoGeneX

MDxHealth and HistoGeneX are partnering to offer Pharmaco Molecular Diagnostic Services. The collaboration enables MDxHealth to combine its epigenetic technologies with HistoGeneX’s pharmacodiagnostic services. HistoGeneX’s laboratory in Belgium will also perform MGMT service testing on behalf of MDxHealth’s clients.

“This collaboration with MDxHealth allows us to introduce epigenetic testing technologies to our pharmaceutical and oncology clients, further expanding our molecular capabilities and menu,” Mark Kockx, MD, PhD, CEO of HistoGeneX, said in a statement.

In other news, the New York State Department of Health has certified and granted approval for the MDxHealth ConfirmMDx for Prostate Cancer test. This approval completes MDxHealth’s list of state licensures, allowing the company to offer the test in all 50 states. The test is performed on tissue obtained from a previous negative prostate biopsy to help distinguish patients who have a true negative result and may forego an unnecessary repeat biopsy from those at high risk for missed cancer.