

Put It on the Board

Therascreen EGFR RGQ PCR kit approved as companion diagnostic for Vizimpro

October 2018—The FDA has approved a PMA supplement expanding the labeling claim of the Qiagen Therascreen EGFR RGQ PCR kit to allow its use as a companion diagnostic with Pfizer's Vizimpro (dacomitinib). Vizimpro is for first-line treatment of patients with non-small cell lung cancer with EGFR exon 19 deletions or an exon 21 L858R mutation.

The Therascreen EGFR RGQ PCR kit is now approved as a companion diagnostic to guide the use of three FDA-approved therapies, including also Gilotrif (afatinib) from Boehringer Ingelheim and Iressa (gefitinib) from AstraZeneca. It is registered in more than 40 countries. This was a project governed under an agreement between Qiagen and Pfizer.

Roche announces liquid biopsy ctDNA test

Roche announced on Sept. 24 the worldwide availability of FoundationOne Liquid, a liquid biopsy test. FoundationOne Liquid can identify circulating tumor DNA and 70 of the most commonly mutated genes in solid tumors, Roche said, including microsatellite instability.

FoundationOne Liquid complements the tissue-based test FoundationOne CDx.

Philips introduces computational pathology software for tumor detection

Royal Philips announced in September the latest release of TissueMark, which the company says now supports region of interest detection for the majority of molecular testing and helps research labs improve the accuracy of tumor estimation.

The new version, showcased Sept. 8–12 at the 30th European Congress of Pathology 2018, uses deep learning artificial intelligence to aid in prostate and ovarian tumor tissue identification.

Innovative computational solutions can help pathologists improve efficiency in the research setting, Philips says, which will ultimately help support precision medicine and enhance the speed and accuracy of diagnosis.

In addition to providing tumor sufficiency guidance for lung histology, lung cytology, and colon and breast tissue samples in 60 seconds, the updated TissueMark software now provides this guidance to whole slide images of adenocarcinoma prostate tissue and high-grade serous carcinoma ovarian tissue.

FDA clearance, CLIA waiver for POC Sofia 2 Lyme FIA

Quidel received 510(k) clearance and CLIA waiver from the FDA to market its Sofia 2 Lyme fluorescent immunoassay. The assay is to be used with the Sofia 2 Fluorescent Immunoassay Analyzer for the rapid differential detection of human IgM and IgG antibodies to *Borrelia burgdorferi* from fingerstick whole blood specimens.

The Sofia 2 Lyme FIA uses a bidirectional test strip format. One side of the test strip detects IgM antibodies to *B. burgdorferi*; the other side of the strip detects IgG antibodies to *B. burgdorferi*.

It is the fourth FDA-cleared, CLIA-waived Sofia test for use on the Sofia 2 system. The others are the Influenza A+B FIA, RSV FIA, and Strep A+ FIA. Quidel also markets the moderately complex Sofia Lyme FIA in the U.S., as well as Sofia Legionella FIA and Sofia *S. pneumoniae* FIA in Europe.

Natera signs agreement with Bristol-Myers Squibb

Natera announced an agreement with Bristol-Myers Squibb for use of Natera's Signatera custom circulating tumor DNA assay in a prospective phase two adjuvant non-small cell lung cancer clinical trial.

The study will use the Signatera ctDNA assay to select patients who have minimal residual disease after surgical resection to receive adjuvant standard of care with or without Opdivo (nivolumab). The first patient is expected to enroll in 2019 once Natera completes validation of its Signatera ctDNA assay.

This study is the first prospective clinical trial using Natera's Signatera ctDNA assay in adjuvant NSCLC, the company said in a statement. Charles Swanton, MD, PhD, senior group leader of the translational cancer therapeutics laboratory, Francis Crick Institute, London, will lead the study.

Draft LCD for Veracyte's Envisia Genomic Classifier

Veracyte received a draft Medicare local coverage determination for its Envisia Genomic Classifier through the MoDx program. WPS Health Solutions posted a draft policy Aug. 30, and the three other MACs (CGS, Noridian Health Solutions, and Palmetto GBA) that participate in the Palmetto GBA-administered MoDx program were expected to issue similar LCDs, according to Veracyte.

The Envisia classifier is the first test to achieve this coverage for use in diagnosing idiopathic pulmonary fibrosis, Veracyte said in a statement.

The draft policy was open to a 45-day comment period.