

Biocartis Idylla platform, 10/17

October 2017—Biocartis Group announced the availability of its Idylla platform in the United States. The Idylla is a fully automated, walkaway, real-time PCR system with a hands-on time of less than two minutes. Its access on-demand design and assay turnaround time of between 90 and 150 minutes allow pathologists to analyze samples at any time, without the need for batching or for trained operators, in virtually any laboratory. The Idylla console and instrument are class II exempt.

Idylla assays, for research use only, are available for KRAS, NRAS, BRAF, and EGFR. The Idylla RAS/BRAF panel consists of the KRAS assay and the NRAS/BRAF assay, with each test requiring only one slice of FFPE tissue. It is also available for liquid biopsies, requiring only 1 mL of plasma per cartridge. The panel detects 44 mutations in KRAS, NRAS, and BRAF.

The Idylla EGFR Mutation assay allows simultaneous detection of 52 EGFR mutations directly from one slice of FFPE tissue. A liquid biopsy version of this assay, the Idylla ctEGFR assay, is in development.

The Idylla BRAF assays detect seven different mutations within the *BRAF* gene, directly from one slice of FFPE tissue or 1 mL of plasma.

The FDA granted 510(k) clearance in September for the Idylla Respiratory (IFV-RSV) panel, a fully automated molecular diagnostic test developed by Janssen Diagnostics.

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