

KRAS mutation test receives CE-IVD marking, 10/15

Biocartis launched its CE-IVD Idylla KRAS Mutation Test, a sample-to-result test for the fast, accurate, and reproducible detection of 21 relevant mutations in the KRAS oncogene. The fully automated test, for routine use, detects all clinically relevant driver mutations of the KRAS oncogene in tissue of colorectal cancers at a sensitivity of five percent. The test detects all relevant mutations in exon 2 (codons 12 and 13), exon 3 (codons 59 and 61), and exon 4 (codons 117 and 146) of the KRAS gene.

Validation studies and premarket trials on more than 500 mCRC patient samples have demonstrated the accuracy of the test. During the validation study, the Idylla KRAS Mutation Test detected eight percent more mutations than the reference test. Between-lab reproducibility studies showed a 100 percent agreement between all participating sites, demonstrating that the test is easy to implement and highly standardized.

The test runs on the Idylla platform and provides results in approximately two hours. Hands-on time is less than two minutes as the formalin-fixed, paraffin-embedded tissue is directly inserted into the Idylla cartridge without prior deparaffinization or other preprocessing steps.

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