INNOVATIVE, RAPID AND EASY TO USE DIAGNOSTIC MULTIPLEX PLATFORMS THAT ENABLE INDIVIDUALIZED CARE

I. Vandenbroucke¹, P. van den Bogaard², B. Claes¹, K. Van Acker¹, E. Sablon¹, G. Maertens¹
¹Biocartis NV, Mechelen, Belgium
²Biocartis SA, Lausanne, Switzerland

Individualized approaches to the treatment of cancer require easy-to-use, rapid diagnostics platforms that can operate at the point-of-need. Biocartis has developed 2 platforms that are expected to meet such requirements. Biocartis’ high multiplex platform leverages advanced semi-conductor technologies and micro-fluidics to provide fast, flexible and multiplexed detection and quantification of nucleic acid and proteins. The platform can measure over 200 analytes simultaneously over a wide range of concentrations.

The second, molecular diagnostics (MDx) platform is a sample-in, result-out system that enables the detection of up to 30 reportable nucleic acid (DNA, RNA, meDNA, miRNA) biomarkers in a single disposable cartridge with minimal user intervention. A wide range of solid and liquid sample types, including formalin-fixed, paraffin-embedded (FFPE) tissue can be used. A single FFPE shaving is directly placed in the cartridge. The complete process for sample preparation, PCR and reporting is less than 90 min, with <2 minutes hands-on time. A prototype BRAF V600 Mutation assay has been shown to have superior analytical sensitivity (detection of <1% of mutant in wt background), ease of use, turnaround time, and detects a broader range of mutations (V600E, E2, D, K, R, and M) compared to existing diagnostic tests and Sanger sequencing, as shown in a series of >65 FFPE samples. Concordance with deep sequencing was 100%.