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Liquid Biopsy performance comparison of Sysmex Inostics OncoBEAM RAS CRC and BioCartis Idylla ctKRAS testing published in Scientific Reports (Nature Journal)

Germany (ots) -

Sysmex Inostics, a global leader in blood based circulating tumor DNA (ctDNA) analysis and molecular diagnostics for oncology, today announces publication of a study comparing the performance of plasma RAS mutation detection by two commercial liquid biopsy testing platforms, the OncoBEAM(TM) RAS CRC and the Idylla ctKRAS Mutation Test from the BioCartis Group NV. Preliminary results were previously presented at the American Society of Clinical Oncology's Gastrointestinal Cancer Symposium ASCO GI in 2018.

This study was conducted by a group of four leading Spanish hospitals that perform liquid biopsy testing in routine colorectal cancer (CRC) clinical practice. They found significant differences in clinical sensitivity for KRAS mutation detection between enhanced digital PCR-based OncoBEAM and real-time PCR Idylla technology. The investigators identified a "gray zone" below 1% Mutant Allele Fraction (MAF) where OncoBEAM reliably detected KRAS mutations across 116 patient plasma samples, but Idylla did not.

Notably of the 63 samples where the measured MAF was above 0.1% but below 1.0%, OncoBEAM detected 63/63 (100.0% sensitivity) whereas Idylla detected 41/63 (65.1%), with a significant p-value of <0.0001. In the 16 samples where the measured MAF was below 0.1%, OncoBEAM detected 16/16 (100% sensitivity) whereas Idylla detected 7/16 (43.8%), with a significant p-value of 0.0077. The OncoBEAM RAS CRC test has an analytical sensitivity down to 0.03% MAF. Of the 116 clinical samples tested by both platforms, a majority of them (79/116 or 68.1%) had minor allele frequencies of less than 1%.

"These results show an important 'gray area' where real-time PCR based assays like Idylla show reduced KRAS mutation detection accuracy in plasma as compared to tissue testing and digital PCR testing with OncoBEAM", commented Dr. Ana Vivancos, Principal Investigator, Cancer Genomics Group at Vall d'Hebron Institute of Oncology (VHIO, Barcelona Spain). "Precise and sensitive tests for targeted therapy are crucial, in particular for liquid biopsy, and this should serve as a reminder that not all assays are equivalent. Clinicians and translational scientists need to be aware that assays lacking appropriate sensitivity may result in diminished detection of certain mutations and, hence, impact the treatment decision."

The publication, titled "Comparison of the Clinical Sensitivity of the Idylla Platform and the OncoBEAM RAS CRC Assay for KRAS Mutation Detection in Liquid Biopsy Samples", was published in Scientific Reports (a Nature Journal publication) June 20, 2019 by Ana Vivancos and Eduardo Diaz-Rubio et al. PMID: 31222012 (<https://www.ncbi.nlm.nih.gov/pubmed/31222012>) DOI:10.1038/s41598-019-45616-y (<https://doi.org/10.1038/s41598-019-45616-y>)

About Sysmex Inostics

Sysmex Inostics, a subsidiary of Sysmex Corporation, is a molecular diagnostic company that is a pioneer in blood-based cell-free tumor DNA (ctDNA) mutation detection in oncology utilizing highly sensitive technologies such as OncoBEAM(TM) (digital PCR) and SafeSEQ (NGS). These technologies were initially developed by experts at the Johns Hopkins School of Medicine over a decade ago and this deep expertise in ctDNA analysis extends to the core of Sysmex Inostics' capabilities for technology development and implementation.

With more than 10 years' of experience in liquid biopsy Sysmex Inostics is a trusted partner to leading pharmaceutical companies, advancing their efforts to bring the most effective personalized cancer therapies to global markets, from discovery through companion diagnostics.

Sysmex Inostics' OncoBEAM(TM) and SafeSEQ services are readily available to support clinical trials and research in oncology. In addition, OncoBEAM(TM) tests are available through a CLIA-certified laboratory for routine clinical analysis as well as distributed kit products in the EU.

Sysmex Inostics' headquarters and GCP Service Laboratory are located in Hamburg Germany; Sysmex Inostics' CLIA-certified and GCP Clinical Laboratory is located in Baltimore, Maryland. For more information refer to www.sysmex-inostics.com or email info@sysmex-inostics.com.

Contact:

Sysmex Inostics
Press Release
Phone: +49-(0)-40-3259070
Mail: info@sysmex-inostics.com

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