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Merck unveils first all-in-one genetic stability assay to accelerate biosafety testing

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Proprietary Aptegra platform reduces five assays to one

MilliporeSigma, the US and Canada Life Science business of Merck KGaA, Darmstadt, Germany, has launched the first all-in-one, validated genetic stability assay of its kind. The Aptegra CHO genetic stability assay leverages whole genome sequencing and bioinformatics to significantly accelerate biosafety testing for clients and therefore, their move into commercial production.

Currently, FDA guidance requires biotech companies to use multiple assays to address genetic stability requirements. This traditional package of assays is costly, time-consuming, and often results in data that need additional interpretation and support. The Aptegra platform addresses these pain points by replacing five different assays and four different technologies with one assay utilising the next-generation sequencing technology platform. This approach reduces testing time by 66 percent and reduces costs by 43 percent compared to traditional methods. The platform meets all regulatory requirements for genetic stability assurance, including copy number assessment.

The company has made significant investments over the last five years to expand its biosafety testing capabilities for clients across the globe. Its global biosafety testing network includes sites in Shanghai, China; Singapore; Stirling and Glasgow, UK; and Rockville, MD, USA.

The Aptegra digital platform adds to a transformative portfolio of digital technologies developed by MilliporeSigma. In December, it launched AIDDISON, an artificial intelligence (AI)-powered platform that integrates generative design with predictive synthesis planning, allowing rapid identification of promising candidates and reducing risk of late-stage failures. Additionally, the company offers a first of its kind Bio4C Software Suite, which combines data analytics and visualisation, automation, and control software for GMP manufacturing.