



Molzym

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Press Release

Molzym Automated Pathogen Enrichment and PCR Test, Micro-Dx™, Gets CE Mark for In Vitro Diagnostics

Bremen, 9th November 2017

Molzym announces CE IVD marking of their robotic microbial DNA isolation and direct PCR test, Micro-Dx™, for routine pathogen diagnosis.

With Micro-Dx™ Molzym introduces its latest development of products in line with SepsiTest™-UMD which was released in 2008. Micro-Dx™ is based on walk-away automated human DNA removal and pathogen DNA enrichment from samples combined with the amplification and sequencing of parts of the 16S and 18S rRNA genes for the direct diagnosis of bacterial and fungal pathogens, respectively. The isolation of microbial DNA is operated on the SelectNA™ *plus* robotic platform. A broad range of routine clinical samples can be analysed by Micro-Dx™, including fluid and tissue biopsies.

More than 1,300 strains have been identified in clinical and other evaluations using Molzym's 16S/18S rDNA test portfolio so far. PCR results of the presence or absence of bacterial and fungal DNA are obtained within 4 hours. Pathogens are identified by Sanger sequencing of amplicons within another 3 hours.

“By Molzym's proprietary robotic DNA isolation, Micro-Dx™ is further adapted to the needs of routine diagnosis in hospitals and private laboratories for low hands-on solutions. The test is a means of rapid, non-targeted and precise identification of microbial species without the need for cultivation which guides early therapy also in case of rare and antibiotic inhibited pathogens” states CEO Michael Lorenz. Micro-Dx™ was launched early 2016 as research use only product and is launched CE IVD marked on 15th November 2017.