



MICRO-Dx™ CE IVD

molzym
reveal DNA

CULTURE-INDEPENDENT MOLECULAR DETECTION OF PATHOGENS

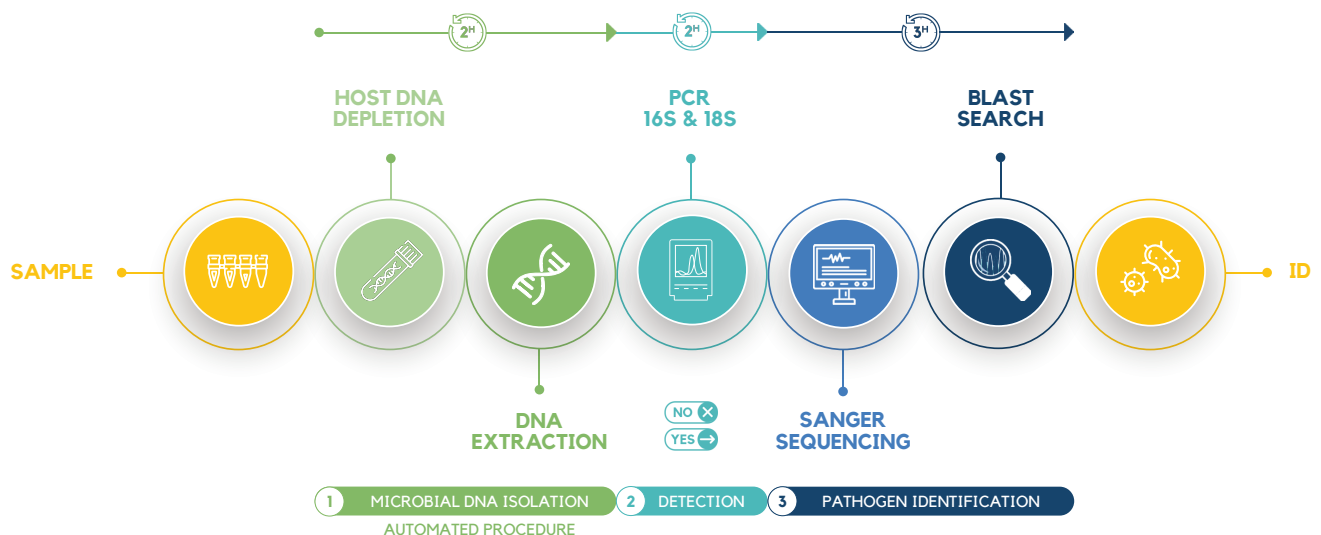
Molecular analysis of microbes directly from samples can be challenging as the contained human DNA compromises the sensitivity of broad-range assays. **Micro-Dx™** addresses this problem and is therefore a unique CE IVD test for culture-free diagnosis of bacterial and fungal targets directly from samples. It includes an automated protocol for depletion of human DNA prior to microbial DNA extraction and purification. For detection of microbial DNA, 16S & 18S rDNA broad-range PCR assays are used, with a first result after only 4 hours. Sanger sequencing and BLAST analysis are applied to identify the pathogens on species or genus level.

PRODUCT FEATURES

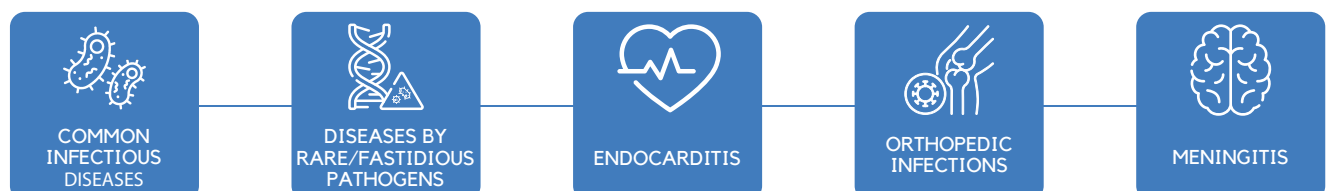
- ✓ Fully automated depletion of human DNA & isolation of bacterial and fungal DNA
- ✓ Broad-range 16S & 18S rDNA PCR detection assays
- ✓ One process for body fluids, swabs & tissues
- ✓ Flexible capacity of 1-12 samples per run
- ✓ All reagents are free of microbial DNA for highest accuracy



DIAGNOSTIC WORKFLOW

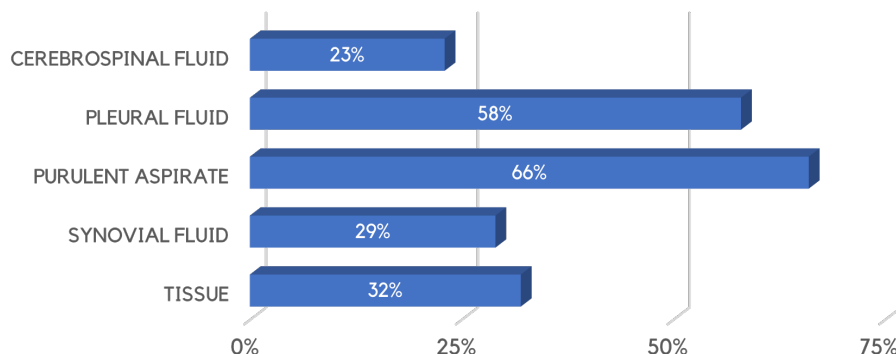


APPLICATIONS OVERVIEW



DIAGNOSTIC ADDED VALUE

Micro-Dx™ as part of Molzym's Molecular Diagnostic Solutions (MMDx™) is a valuable method for the diagnosis of infectious agents, having the advantage of being culture-independent and therefore being able to even detect rare, challenging and non-growing pathogens.



Positive results [%] with Micro-Dx™ in culture-negative samples^[1]

The depletion of human DNA in combination with the ultra-pure reagents enables highly sensitive detection of pathogens and allow treatment decisions to be made based on these results^[1], thus improving patient care.



MMDx™ identifies relevant pathogens in culture-negative samples and in samples from patients treated with antibiotics



Shorter time-to-result compared to culture: MMDx™-based diagnosis can be made within 7 hours



Improved pathogen identification: 64% higher positivity rate compared to in-house 16S assays^[2]



Added value in culture-negative infections: Change of antimicrobial treatment in 38% of PCR-positive and 7% of PCR-negative cases^[1]

ORDER INFORMATION

Micro-Dx™ CE IVD <i>Automated pathogen DNA extraction and broad-range PCR analysis directly from body fluids, swabs and tissues</i>	24 reactions	U-200-024
	48 reactions	U-200-048
Pipette Tips <i>DNA-free pipette tips for use with SelectNA™plus instrument</i>	2x [2x 96] tips	D-925-024
	4x [2x 96] tips	D-925-048
	8x [2x 96] tips	D-925-096
Waste bags <i>For SelectNA™plus instrument</i>	500 pieces	D-928-500
SelectNA™plus CE IVD <i>Bench-top instrument for host DNA depletion and pathogen DNA extraction</i>	1 unit	D-400-001
UMD Tubes RUO <i>Prefilled vials containing cryo-protectant for storage of 0,4 - 2 ml fluid samples at -70 to -80 °C</i>	20 tubes	Z-801-020

References:

^[1] Marbjerg et al., *Diagn Microbiol Infect Dis.* 2020, 22: 115028; ^[2] Schubert, *ECCMID 2017*, oral presentation OS0779

Molzym GmbH & Co. KG
 Mary-Astell-Str. 10
 D-28359 Bremen, Germany
 +49 (0) 421 69 61 62 0
www.molzym.com



Micro-Dx™ and SelectNA™plus are CE IVD-marked in EU and not for diagnostic use in the USA. UMD Tubes are for Research Use Only [RUO] and not for use in diagnostic procedures.