



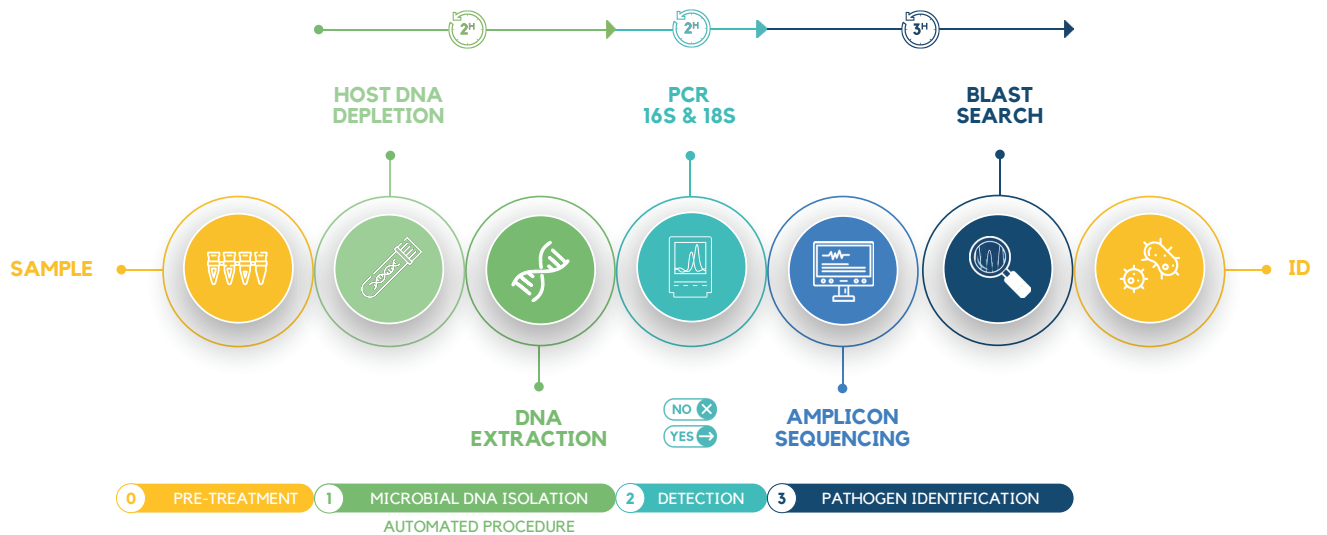
CULTURE-INDEPENDENT MOLECULAR DETECTION OF PATHOGENS

SepsiTest™-UMD is a CE IVD molecular diagnostic test for the *in vitro* diagnosis of pathogens from clinical samples without the need for culture. **SepsiTest™-UMD** is based on a single protocol, including human DNA depletion (MolySis™), microbial DNA enrichment and extraction from intact bacteria & fungi, followed by 16S and 18S rDNA broad-range PCR and sequencing analysis. With this broad approach and the capability to detect even rare, fastidious and non-growing pathogens, it is the perfect solution to complement standard culture methods in routine diagnostic laboratories.

PRODUCT FEATURES

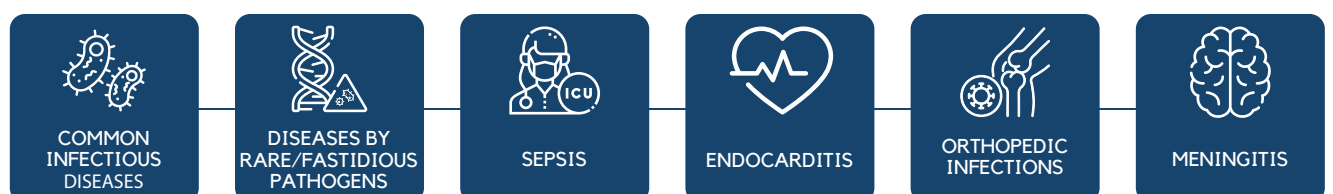
- ✓ Depletion of human DNA ahead of microbial cell lysis for improved sensitivity
- ✓ Efficient lysis of bacteria & fungi
- ✓ Universal 16S & 18S rDNA PCR detection assays
- ✓ Extraction and PCR controls included
- ✓ All reagents are free of microbial DNA for highest accuracy of results
- ✓ Up to 40 PCR cycles without background
- ✓ More than 1 300 bacteria & fungi identified on species & genus level
- ✓ Protocols for body fluids, swabs & tissues

DIAGNOSTIC WORKFLOW*



*Steps 0, 1 and 2 are IVD compliant; Step 3 is the responsibility of the user and not part of the IVD workflow.

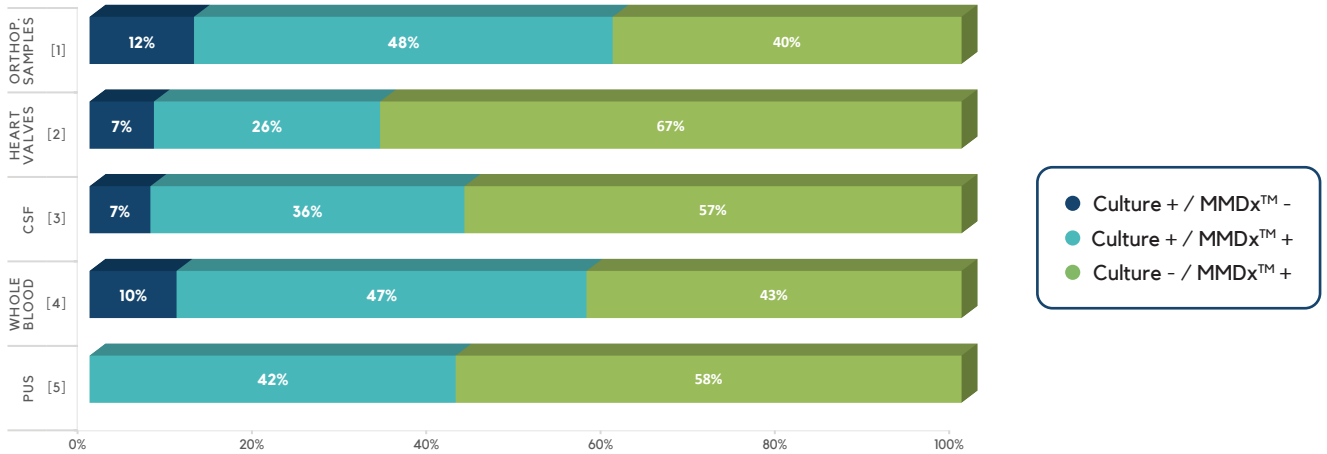
APPLICATIONS OVERVIEW





DIAGNOSTIC ADDED VALUE

Since its release, **SepsiTest™-UMD** has proven to be an accurate and rapid tool for the identification of pathogens - growing or static - directly from samples. The clinical utility was evaluated by analyzing its diagnostic added value especially in culture-negative cases.



Ratio of positive results by culture, MMDx™ or both methods obtained from orthopedic samples, heart valves, CSF, whole blood and pus

A large number of independent studies show that **SepsiTest™-UMD**, as part of Molzym's Molecular Diagnostic Solutions (MMDx™), provides reliable clinical results for better and faster patient management, including therapeutic decisions.

- ↑ MMDx™ increases the rate of diagnosis of true infections by the identification of pathogens in culture-negative samples
- ↓ Reduced time-to-result: MMDx™ identifies pathogens 12 hours^[2] to 8 days^[6] earlier than culture
- ⊕ Diagnosis of true infections in patients who have already started antibiotic therapy
- ⊖ MMDx™ outcomes support clinicians in decisions on antibiotic therapy: initiation, adjustment or de-escalation

ORDER INFORMATION


SepsiTest™-UMD CE IVD Manual pathogen DNA extraction and broad-range PCR analysis directly from body fluids, swabs and tissues	24 reactions	U-010-024
	48 reactions	U-010-048
UMD Tubes RUO Prefilled vials containing cryo-protectant for storage of 0,4 - 2 ml fluid samples at -70 to -80 °C	20 tubes	Z-801-020

Automation: The process of human DNA depletion and microbial DNA isolation from body fluids, swabs and tissue samples is also available fully automated on the **SelectNA™plus** instrument.

References:

^[1] Grif et al., J. Clin. Microbiol. 2012, 50: 2250; ^[2] Kühn et al., J. Clin. Microbiol. 2011, 49: 2919; ^[3] Meyer et al., J. Clin. Microbiol. 2014, 52: 1751; ^[4] Wellinghausen et al. 2009, J. Clin. Microbiol 47: 2759; ^[5] Gabas et al., J. Infect.. 2019, 79: 462-470; ^[6] Marsch et al., Interact. Cardia Vas. Thorac Surg. 2015,20: 589-509.

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



SepsiTest™-UMD and Add-On 10 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.

Request a quote at info@molzym.com