



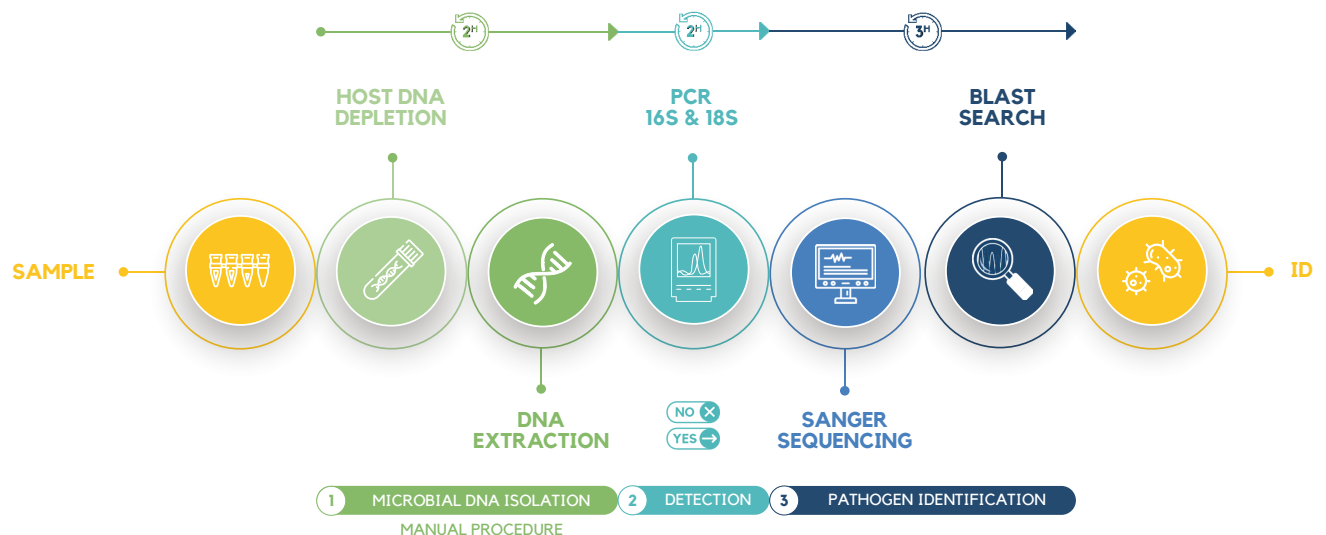
CULTURE-INDEPENDENT MOLECULAR DETECTION OF PATHOGENS

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.

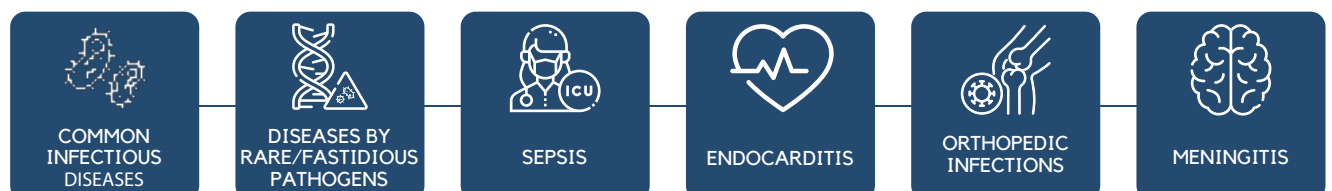
PRODUCT FEATURES

- ✓ 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

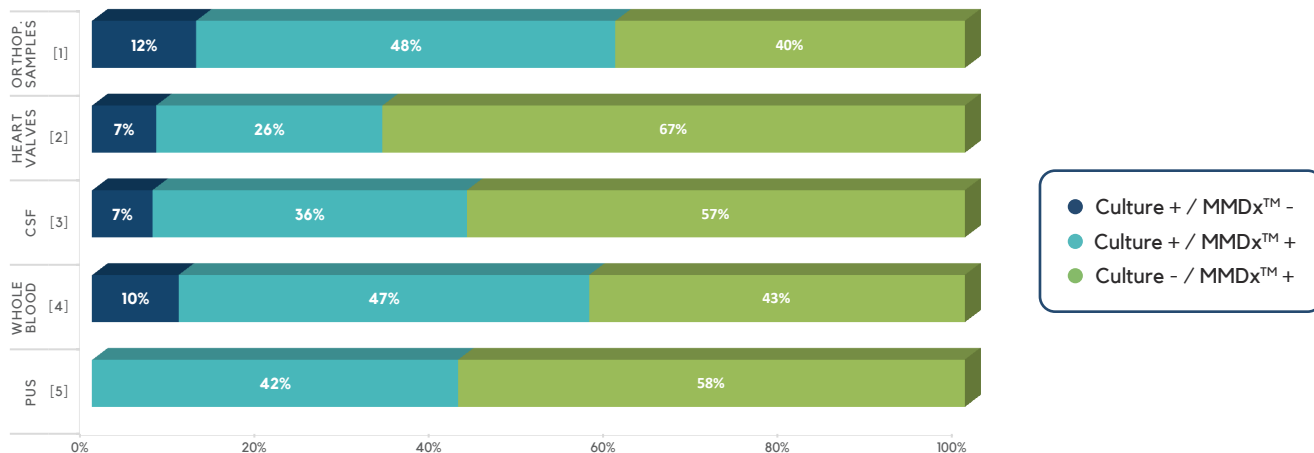


APPLICATIONS OVERVIEW



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
Add-On 10 CE IVD Add on to be used with SepsiTest™-UMD for volumes of up to 10 ml fluid samples	24 reactions	U-120-024
	48 reactions	U-120-048
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

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.

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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.