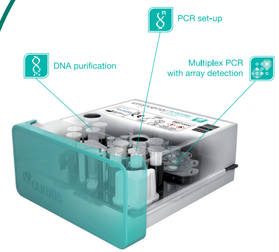
unyvero

Unyvero’s sample-to-answer platform provides rapid results for severe infectious diseases in hospitalized patients

Powerful multiplex PCR technology combined with the broadest range of microorganism and resistance targets sets the Unyvero System apart.

The Unyvero System consists of:

- Lysator to lyse and process a variety of native samples
- Cockpit to manage testing process, display, store, and transmit results
- Analyzer to perform DNA testing with random-access, multiplex PCR



A single test handles one patient sample, analyzes over 100 DNA analytes and delivers reliable results within just 4-5 hours

Unyvero L4 Lysator

Unyvero C8 Cockpit

Unyvero A50 Analyzer

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Unyvero is designed to expand with your growing needs

Applications for severe infections:

- Blood Culture – BCU
- Hospitalized Pneumonia – HPN
- Intra-Abdominal Infection – IAI
- Implant & Tissue Infection – ITI
- Urinary Tract Infection – UTI

The Unyvero System is distributed on an exclusive basis by A.Menarini Diagnostics in the following countries: Benelux, France, Germany, Greece, Italy, Portugal, Spain, United Kingdom.

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Intra-Abdominal Infection

Fast & Simple Syndromic Testing for Severe Infections - Improving Patient Outcomes

A.MENARINI diagnostics

Intra-abdominal infections (IAI) are often associated with poor prognosis, particularly in high-risk patients

- Early clinical diagnosis and appropriate antimicrobial therapy are essential in the management of intra-abdominal infections.[1]
- Conventional microbiology methods can take 1-4 days and diagnosis of anaerobic bacteria up to 14 days.
- Delayed or inadequate antimicrobial therapy is associated with poorer outcomes and increased death.[2]

IAI is the second most commonly identified cause of sepsis in the intensive care unit.[3,4]

- Global antibiotic resistance continues to rise steadily and can make therapy selection difficult.[5]
- Cost of antifungal treatment is very high.[6]

1 Sartelli M et al., Management of intra-abdominal infections: recommendations by the WSES 2016 consensus conference. World J Emerg Surg. 2017; 12:22.
2 Solomkin JS et al., Diagnosis and management of complicated intra-abdominal infection in adults and children: guidelines by the Surgical Infection Society and the Infectious Diseases Society of America. Clin Infect Dis. 2010;50(2):133-64.
3 Lopez N et al., A Comprehensive review of abdominal infections. World J Emerg Surg. 2011; 6:7.
4 Sartelli Met al., Current concept of abdominal sepsis: WSES position paper. World J Emerg Surg. 2014; 9:22.
5 WHO Antibiotic Resistance Fact Sheet. November 2017.
6 Pagès A et al., Cost Effectiveness of Candida Polymerase Chain Reaction Detection and Empirical Antifungal Treatment among Patients with Suspected Fungal Peritonitis in the Intensive Care Unit. Value Health. 2017;20(10):1319-1328.

Sample Types

Ascites and peritoneal fluid, pancreatic juice, bile, tissue, puncture fluid, swabs, catheter/drainage tips, and samples from positive blood culture bottles that have been inoculated with ascites/puncture fluid.

Easy Workflow

Multiple Sample Types

24/7 Results

Faster detection enables earlier optimization of therapy

The Unyvero IAI Application simultaneously detects a large panel of bacteria, fungi, toxins and antibiotic resistance markers directly from IAI samples.

The Unyvero IAI Cartridge can be used for the diagnosis of:

- Acute abdomen
- Ascites
- Cholecystitis
- Diverticulitis
- Peritonitis
- Surgical site infections

Unyvero Intra-Abdominal Infection (IAI) Cartridge

Gram-positive bacteria	*Enterobacteriaceae*	Anaerobic/facultative anaerobic bacteria	Non-fermenting bacteria
Coagulase negative staphylococci	*Escherichia coli*	*Aeromonas* spp.	*Acinetobacter baumannii* complex
Enterococcus faecalis	*Klebsiella aerogenes (E. aerogenes)*	*Bacteroides fragilis group*	*Pseudomonas aeruginosa*
Enterococcus spp.	*Enterobacter cloacae* complex	*Bacteroides* spp. / *Prevotella* spp.	
Streptococcus spp.	*Klebsiella pneumoniae*	*Clostridium difficile*	
Staphylococcus aureus	*Klebsiella oxytoca*	*Clostridium perfringens*	
	Klebsiella variicola	*Finegoldia magna*	
	Proteus spp.	*Cutibacterium acnes (P. acnes)*	

Universal bacteria
Detection of prokaryotic genetic sequence

Toxin	Marker
Toxin B	*tcd*B
Shiga Toxin	*stx*1/2

Fungi
Candida spp.
Candida albicans
Candida glabrata
Candida tropicalis
Issatchenkia orientalis (Candida krusei)

Resistance	Gene
Oxacillin	*mecA* *mecC*
Vancomycin	*vanA* *vanB*
Aminoglycoside	*aac* A4
3rd generation Cephalosporins	*ctx*-M
Fosfomycin	*fosA3*
Polypeptides/ polymyxins	*mcr*-1
Nitroimidazole	*nimA* *nimB*
Fluoroquinolone	*qnrA* *qnrB* *qnrS*
Tetracycline	*tetA*
Carbapenem	*kpc* *imp* *ndm* *oxa-23* *oxa-24/40* *oxa-48* *oxa-58* *vim*

Clinical evidence demonstrates the benefits provided by the Unyvero solution

Study 1

CE Performance evaluation study.

Number of samples
332 culture positive samples.

Sample types
Ascites, bile, drainage fluid, pancreatic juice, peritoneal fluid, pus, swabs, tissue; positive blood cultures inoculated with ascites.

89.2% Sensitivity

Additional identification

- Additional potential pathogens were detected in 308 cases.
- >292 were confirmed as true positives (PCR and sequencing).

99.5% Specificity

Unyvero turnaround time 4-5 hours

Analytical performance

- All analytes included in the panel achieved a sensitivity of at least 75% while 13/27 targets achieved a sensitivity of 100%.
- Specificity ranged from 98.5% to 100% over all panel targets.

Study 2

Multicentre Clinical Evaluation. Barts Health NHS Trust, The Great Romagna Hub, CHU Amiens and CHU Toulouse.

Number of samples
300 samples (mainly peritoneal fluids, ascites, pus and bile).

Eligibility
Samples from patients with suspicion of intra-abdominal infection.

91.2% Sensitivity

99.5% Specificity

Improved microorganism detection

- Additional microorganisms identified, in particular anaerobes, with most detections (91.4%) confirmed by sequencing.
- Microbiology reported results negative for 86 samples:

Of these, 62 samples (72%) also negative with Unyvero IAI while pathogens were detected in the remaining 24.

In 16/24 samples, pathogens detected by Unyvero IAI were confirmed by sequencing.

Time saving

- Using Unyvero, the average time to results was reduced by 17h compared to identification results.

17 hours saved (ID)

(39:06 ± 16:09h for microbiology vs 22:02 ± 4:12h Unyvero IAI).

- Using Unyvero, the average time to results was reduced by 41h compared to full AST results.

41 hours saved (AST)

(64:19 ± 12:10h for microbiology vs. 23:44 ± 3:58h Unyvero IAI).

Ciesielczuk et al., Multicenter performance evaluation of the Unyvero IAI cartridge for detection of intra-abdominal infections. Eur J Clin Microbiol Infect Dis. 2018; 37(11):2107-2115