

unyvero

a product by curetis

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.

Distributed by: A.Menarini Diagnostics S.r.l.

Legal Site: Via Sette Santi, 3 - 50131 Florence, Italy - Operative Site: Via Lungo L'Enza, 7 - 50012 Bagno a Ripoli (FI), Italy - Website: www.menarini.com

BENELUX - MENARINI BENELUX N.V./S.A: Division Diagnostics De Kleetlaan 3/1831 Machelen/Belgium
Tel. 0032-2-721 49 30 - Fax 0032-2-721 50 49

FRANCE - A. MENARINI DIAGNOSTICS FRANCE S.A.S.U.: 3 - 5, rue du Jura BP 70511 F-94633 Rungis Cédex
Tel. 0033-1-56 34 69 10 - Fax 0033-1-56 34 69 11

GERMANY - A. MENARINI DIAGNOSTICS DEUTSCHLAND: Division der BERLIN-CHEMIE AG Glienicke Weg 125 D-12489 Berlin
Tel. 0049-30-6707 3000 Fax 0049-30-6707 3020

GREECE - MENARINI DIAGNOSTICS S.A.: 575, Vouliagmenis Ave. GR-164 51 Argiroupolis - Athens
Tel. 0030-210-99 44 952 - Fax 0030-210-99 45 029

ITALY - A. MENARINI DIAGNOSTICS S.r.l.: Via Lungo l'Enza, 7 50012 Bagno a Ripoli (Firenze)
Tel. 0039-055-5680-422/394 - Fax 0039-055-5680-905

PORTUGAL - MENARINI DIAGNOSTICOS LDA: Quinta da Fonte Edifício D. Manuel I, 2º B 2770-203 Paço de Arcos - Lisbon
Tel. 00351-210-930 000 - Fax 00351-210-930 001

SPAIN - MENARINI DIAGNOSTICOS S.A.: Avenida del Maresme, 120 08918 Badalona (Barcelona)
Tel. 0034-93-50 71 000 - Fax 0034-93-27 80 215

UK - A. MENARINI DIAGNOSTICS LTD: 405 Wharfedale Road Wetherers, Wokingham Berkshire RG41 5RA
Tel. 0044-118 944 4100 - Fax 0044-118 944 4111

Caution – Investigational Device. Limited by Federal US Law to investigational Use. Not available for Sale in the United States.



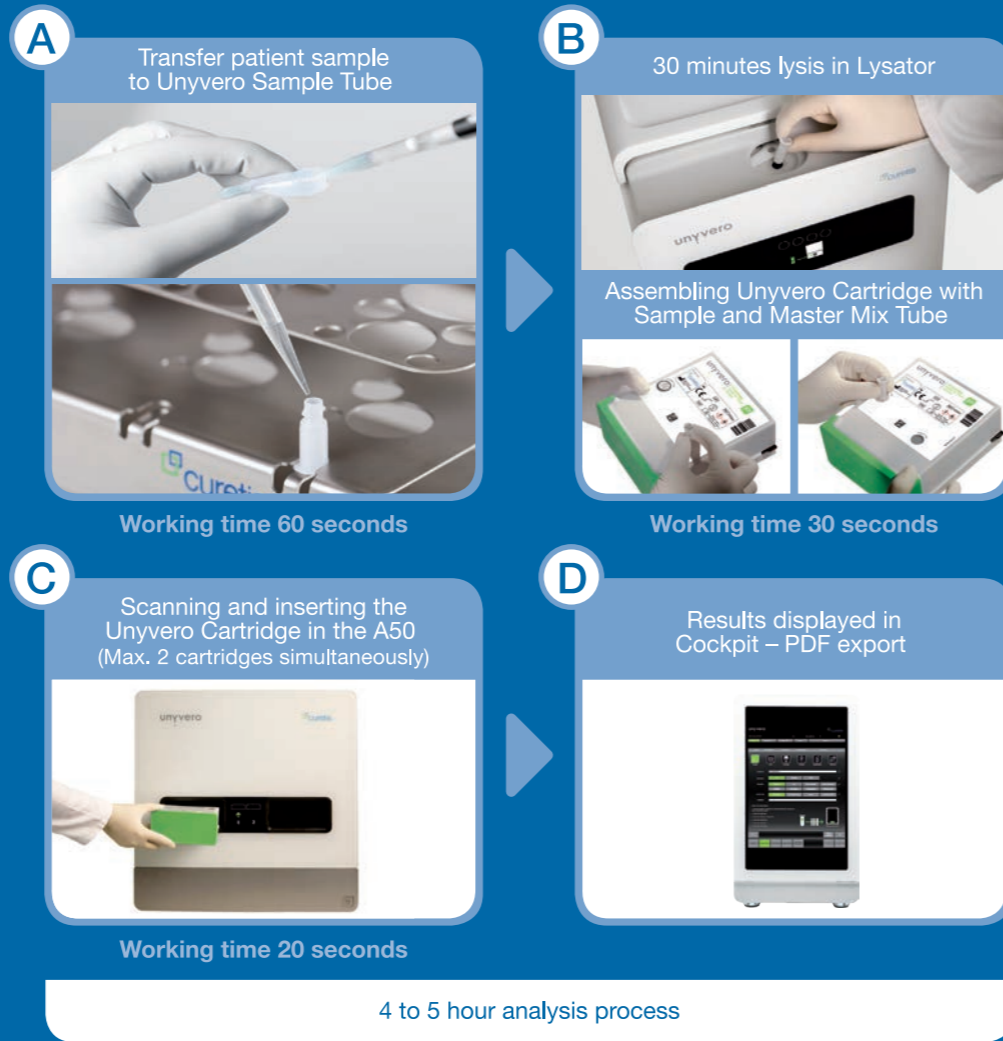
unyvero

System Workflow



Unyvero L4 Lysator Unyvero C8 Cockpit Unyvero A50 Analyzer

FOR PROFESSIONAL USE ONLY Cod. 51261



unyvero



Urinary Tract Infection (UTI) Cartridge

Gram-positive bacteria	Universal bacteria	Resistance	Gene
<i>Staphylococcus aureus</i> <i>Coagulase negative staphylococci</i> <i>Staphylococcus saprophyticus</i> <i>Streptococcus agalactiae</i> <i>Enterococcus</i> spp. <i>Enterococcus faecalis</i> <i>Enterococcus faecium</i> <i>Corynebacterium urealyticum</i>	Detection of prokaryotic genetic sequence	Oxacillin	<i>mecA</i>
		Glycopeptides	<i>vanA</i> <i>vanB</i>
	Non-fermenting bacteria	3rd generation Cephalosporins	<i>ctx-M</i>
	<i>Acinetobacter baumannii</i> complex <i>Pseudomonas aeruginosa</i>	Carbapenem	<i>kpc</i> <i>imp</i> <i>ndm</i> <i>oxa-23</i> <i>oxa-24/40</i> <i>oxa-48</i> <i>vim</i>
Enterobacteriaceae	Anaerobic bacteria	Polypeptides/ polymyxins	<i>mcr-1</i>
<i>Enterobacteriaceae</i> <i>Citrobacter freundii</i> / <i>koseri</i> <i>Klebsiella aerogenes</i> (<i>E. aerogenes</i>) <i>Enterobacter cloacae</i> complex <i>Escherichia coli</i> <i>Klebsiella oxytoca</i> <i>Klebsiella pneumoniae</i> <i>Klebsiella variicola</i> <i>Proteus</i> spp. <i>Providencia</i> spp.	<i>Bacteroides</i> spp. / <i>Prevotella</i> spp.	Fluoroquinolone	<i>qnrB</i> <i>qnrS</i>
	Fungi	Sulfonamide	<i>sul1</i>

103*

Sample Types
Urine (mid-stream, suprapubic, fresh catheter) and tissue.

*88 Pathogens, 15 Resistance Genes



unyvero

a product by curetis

Panel Overview





unyvero



Blood Culture (BCU) Cartridge

Gram-positive bacteria	Universal bacteria	Fungi	103*	
<i>Staphylococcus aureus</i> Coagulase negative staphylococci <i>Streptococcus</i> spp. <i>Streptococcus agalactiae</i> <i>Streptococcus pneumoniae</i> <i>Streptococcus pyogenes</i> / <i>dysgalactiae</i> <i>Enterococcus</i> spp. <i>Enterococcus faecalis</i> <i>Listeria monocytogenes</i>	Detection of prokaryotic genetic sequence	<i>Aspergillus</i> spp. <i>Candida</i> spp. <i>Candida albicans</i> <i>Candida dubliniensis</i> <i>Candida glabrata</i> <i>I. orientalis</i> (C. krusei) <i>Candida parapsilosis</i> <i>Candida tropicalis</i>		
Enterobacteriaceae	Non-fermenting bacteria			
<i>Citrobacter freundii</i> / <i>koseri</i> <i>Escherichia coli</i> <i>Enterobacter cloacae</i> complex <i>Klebsiella aerogenes</i> (E. aerogenes) <i>Klebsiella oxytoca</i> <i>Klebsiella pneumoniae</i> <i>Klebsiella variicola</i> <i>Proteus</i> spp. <i>Serratia marcescens</i>	<i>Acinetobacter baumannii</i> complex <i>Pseudomonas aeruginosa</i> <i>Stenotrophomonas maltophilia</i>			
Corynebacteriaceae	Anaerobic bacteria	Resistance Gene		
<i>Corynebacterium</i> spp.	<i>Cutibacterium acnes</i> (P. acnes)	Aminoglycoside aac(6'')/aph(2'') aacA4		
	Other Gram-negative bacteria	Macrolide/Lincosamide ermA		
	<i>Haemophilus influenzae</i> <i>Neisseria meningitidis</i>	Oxacillin mecA mecC		
		Glycopeptides vanA vanB		
		3rd generation Cephalosporins ctx-M		
		Carbapenem kpc imp ndm oxa-23 oxa-24/40 oxa-48 oxa-58 vim		

Sample Types

Positively flagged blood cultures.

*86 Pathogens, 17 Resistance Genes



unyvero



Hospitalized Pneumonia (HPN) Cartridge

Gram-positive bacteria	Non-fermenting bacteria	Resistance	Gene	48*	
<i>Staphylococcus aureus</i> <i>Streptococcus pneumoniae</i>	<i>Moraxella catarrhalis</i> <i>Pseudomonas aeruginosa</i> <i>Acinetobacter baumannii</i> complex <i>Stenotrophomonas maltophilia</i> <i>Legionella pneumophila</i>	Macrolide/Lincosamide	ermB		
Enterobacteriaceae		Oxacillin	mecA mecC		
<i>Citrobacter freundii</i> <i>Escherichia coli</i> <i>Enterobacter cloacae</i> complex <i>Klebsiella aerogenes</i> (E. aerogenes) <i>Proteus</i> spp. <i>Klebsiella pneumoniae</i> <i>Klebsiella oxytoca</i> <i>Klebsiella variicola</i> <i>Serratia marcescens</i> <i>Morganella morganii</i>		Penicillin	tem shv		
	Others / Fungi	3rd generation Cephalosporins	ctx-M		
	<i>Pneumocystis jirovecii</i> <i>Haemophilus influenzae</i> <i>Mycoplasma pneumoniae</i> <i>Chlamydomphila pneumoniae</i>	Carbapenem	kpc imp ndm oxa-23 oxa-24/40 oxa-48 oxa-58 vim		
		Sulfonamide	sul1		
		Fluoroquinolone	gyrA83 gyrA87		

Sample Types

Sputum, bronchoalveolar lavage, tracheal aspirates.

*29 Pathogens, 19 Resistance Genes



unyvero



Implant & Tissue Infection (ITI) Cartridge

Gram-positive bacteria	Universal bacteria	Fungi	102*	
<i>Staphylococcus aureus</i> Coagulase negative staphylococci <i>Streptococcus</i> spp. <i>Streptococcus agalactiae</i> <i>Streptococcus pneumoniae</i> <i>Streptococcus pyogenes</i> / <i>dysgalactiae</i> <i>Granulicatella adiacens</i> <i>Abiotrophia defectiva</i> <i>Enterococcus</i> spp. <i>Enterococcus faecalis</i>	Detection of prokaryotic genetic sequence	<i>Candida</i> spp. <i>Candida albicans</i> <i>Candida glabrata</i> <i>I. orientalis</i> (C. krusei) <i>Candida tropicalis</i>		
Enterobacteriaceae	Non-fermenting bacteria			
<i>Citrobacter freundii</i> / <i>koseri</i> <i>Escherichia coli</i> <i>Enterobacter cloacae</i> complex <i>Klebsiella aerogenes</i> (E. aerogenes) <i>Klebsiella pneumoniae</i> <i>Klebsiella oxytoca</i> <i>Proteus</i> spp.	<i>Acinetobacter baumannii</i> complex <i>Pseudomonas aeruginosa</i>	Resistance Gene		
		Macrolide/Lincosamide ermA ermC		
	Anaerobic bacteria	Aminoglycoside aac(6'')/aph(2'') aacA4		
	<i>Cutibacterium acnes</i> (P. acnes) <i>Finogoldia magna</i> <i>Bacteroides fragilis</i> group	Oxacillin mecA mecC		
		Glycopeptides vanA vanB		
		3rd generation Cephalosporins ctx-M		
	Corynebacteriaceae	Carbapenem kpc imp ndm oxa-23 oxa-24/40 oxa-48 oxa-58 vim		
	<i>Corynebacterium</i> spp.			

Sample Types

Sonication fluids, swabs, tissue, pus, aspirate/exudate, bone fragments, etc.

*85 Pathogens, 17 Resistance Genes



unyvero



Intra-Abdominal Infection (IAI) Cartridge

Gram-positive bacteria	Anaerobic/facultative anaerobic bacteria	Toxin	Marker	130*	
Coagulase negative staphylococci <i>Enterococcus faecalis</i> <i>Enterococcus</i> spp. <i>Streptococcus</i> spp. <i>Staphylococcus aureus</i>	<i>Aeromonas</i> spp. <i>Bacteroides fragilis</i> group <i>Bacteroides</i> spp. / <i>Prevotella</i> spp. <i>Clostridium difficile</i> <i>Clostridium perfringens</i> <i>Finogoldia magna</i> <i>Cutibacterium acnes</i> (P. acnes)	Toxin B tcdB	Shiga Toxin stx1/2		
Enterobacteriaceae		Resistance Gene			
<i>Escherichia coli</i> <i>Klebsiella aerogenes</i> (E. aerogenes) <i>Enterobacter cloacae</i> complex <i>Klebsiella pneumoniae</i> <i>Klebsiella oxytoca</i> <i>Klebsiella variicola</i> <i>Proteus</i> spp.	<i>Acinetobacter baumannii</i> complex <i>Pseudomonas aeruginosa</i>	Oxacillin mecA mecC			
	Non-fermenting bacteria	Glycopeptides vanA vanB			
		Aminoglycoside aacA4			
		3rd generation Cephalosporins ctx-M			
		Fosfomycin fosA3			
		Polypeptides/polymyxins mcr-1			
		Nitroimidazole nimA nimB			
	Fungi	Fluoroquinolone qnrA qnrB qnrS			
	<i>Candida</i> spp. <i>Candida albicans</i> <i>Candida glabrata</i> <i>Candida tropicalis</i> <i>Issatchenkia orientalis</i> (Candida krusei)	Tetracycline tetA			
Universal bacteria		Carbapenem kpc imp ndm oxa-23 oxa-24/40 oxa-48 oxa-58 vim			
Detection of prokaryotic genetic sequence					

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.

*105 Pathogens, 3 Toxins, 22 Resistance Genes