SEPSIS CONTROL

BIOMEDICA

Global Technology.
Local **Solutions.**

2023
09

BIOMEDICA - YOUR PARTNER IN SEPSIS CONTROL

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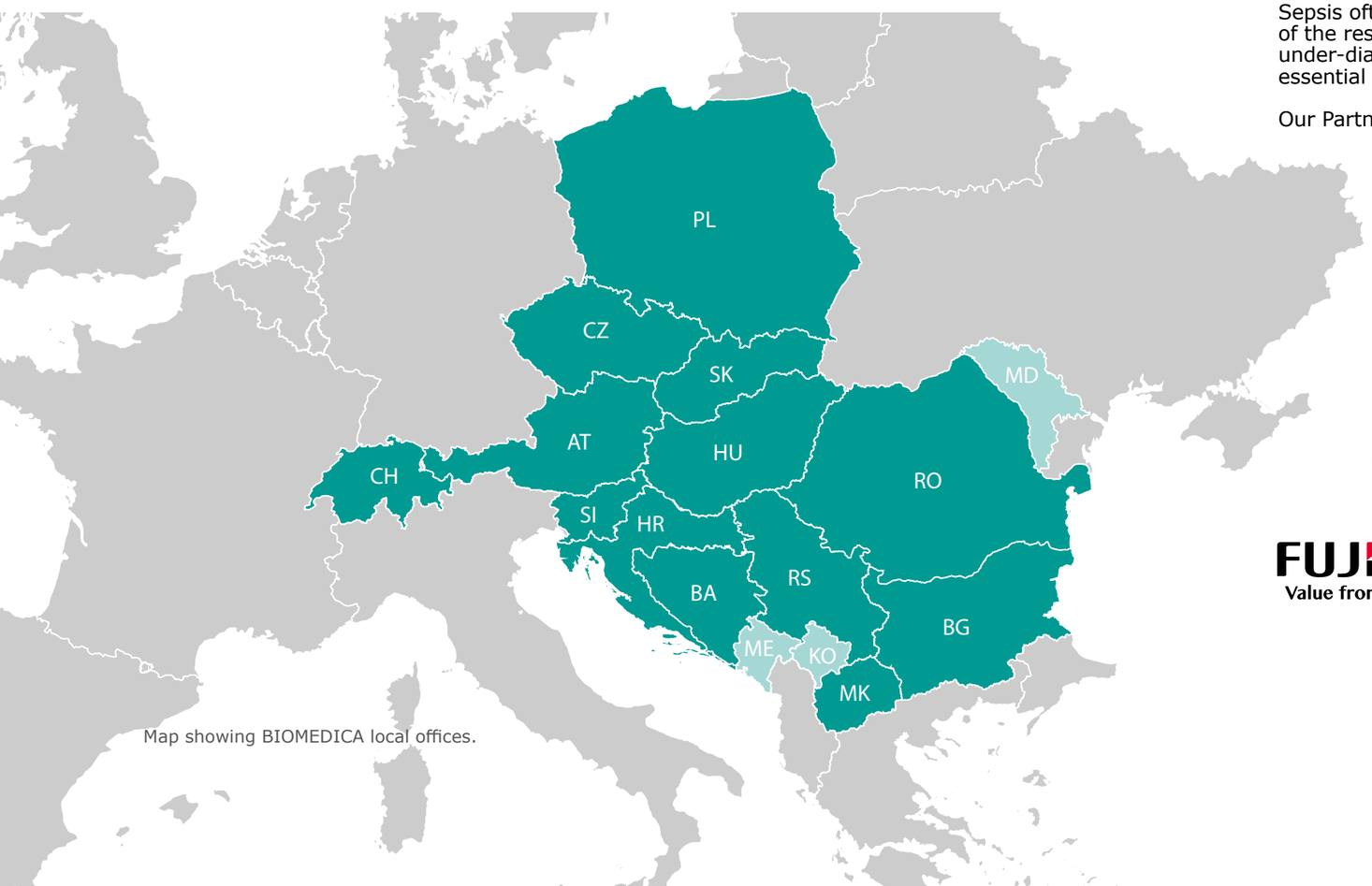
BIOMEDICA has been on the forefront as a distributor of in vitro diagnostics and medical devices for **more than 40 years**.
BIOMEDICA has established **13 local offices**, distributed **across Central Eastern Europe (CEE)**, employing a **team of 280 professionals**. The reliability of BIOMEDICA's business performance and quality of products are evidenced in our daily work and our daily efforts with and for our customers.

We supply customers in the fields of health care and research with **flexible solutions, quality products, technical services and ongoing support.**

The **ISO 9001:2015 certification** throughout the entire group of companies ensures constant improvement in quality of products and services.



Map showing BIOMEDICA local offices.

Sepsis is a potentially life-threatening condition caused by the body's response to an infection.

It's is a global health crisis most common and most dangerous in

- Older adults
- Pregnant women
- Children younger than one year
- People who have chronic conditions, such as diabetes, kidney or lung disease, or cancer
- People who have weakened immune systems

It affects 27 to 30 million people every year, 7 to 9 million die – one death every 3.5 seconds.
Depending on the country, mortality varies between 15 and more than 50 %.
Many surviving patients suffer from the consequences of sepsis for the rest of their lives.

Early treatment of sepsis, usually with antibiotics and large amounts of intravenous fluids, improves chances for survival. However, every hour the treatment is delayed the survival rate drops dramatically.

Sepsis often presents as the clinical deterioration of common and preventable infections such as those of the respiratory, gastrointestinal and urinary tract, or of wounds and skin. Sepsis is frequently under-diagnosed at an early stage - when it still is potentially reversible. Quick and exact diagnostic is essential for the fight against sepsis.

Our Partners:

abionic

asset Design the future

ETHICON Shaping the future of surgery

The Sleep Angel Pillow

T2Biosystems

FUJIFILM Value from Innovation

Wako

suPARnostic by ViroGates

Steripower

ALIFAX

gradientech

CONTENT

JOHNSON & JOHNSON– Biopatch

ETHICON Shaping the future of surgery

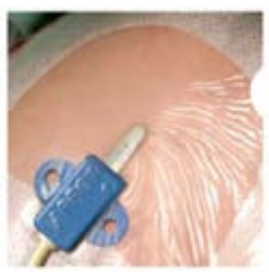
Sponge dressing for catheter related blood stream infections (CRBSI) prevention

Biopatch has been proven to reduce the incidence of CRBSI by 69%, even with an already low infection rate as a baseline. 60% of CRBSI originate from the patient´s own skin. Without continual suppression, bacteria on the skin surface can REPOPULATE and migrate into the bloodstream, elevating the risk of CRBSI.
Biopatch is supported by over a dozen randomized – controlled trials, including all five studies cited in the 2011 CDC (Centre for Disease Control) Guidelines supporting its category 1B.

Biopatch provides proven sustained antimicrobial action over 7 days. Continuous release of Chlorhexidine provides 360° protection around the insertion site for 7 days for ongoing antisepsis between dressing changes.

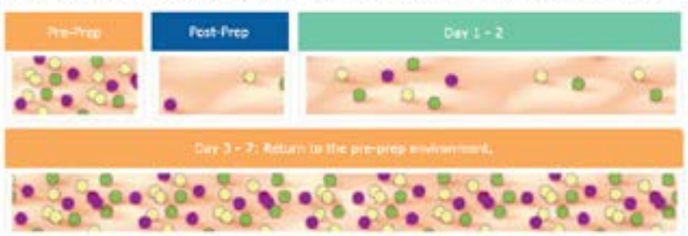
With Biopatch

With BIOPATCH® Protective Disk, post-prep environment extends for up to 7 days*



Without Biopatch

Without BIOPATCH® Protective Disk with CHG, the skin surface returns to the pre-prep environment*

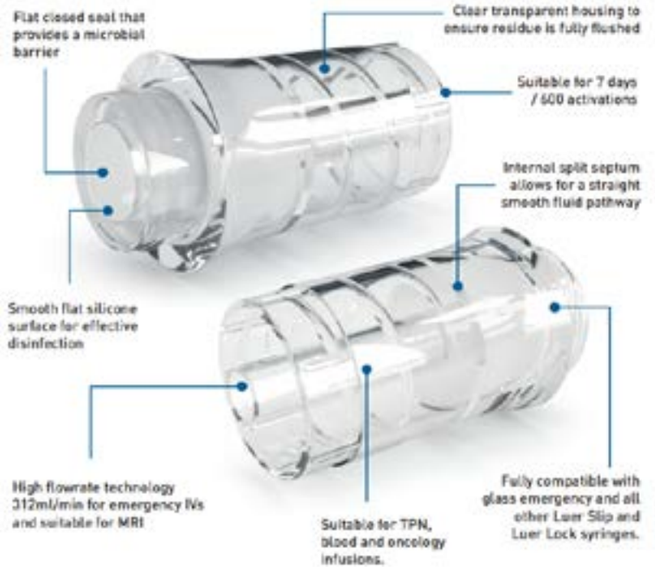


ASSET MEDICAL – FlowArt®

Sterile Infusion Therapy Devices-needle free valves

FlowArt® is a needle-free valve that has a fully transparent clear housing with an integrated flat silicone seal and internal fluid pathway, that protects the patient and nursing staff from exposures.

- Meeting the latest international IV recommendations
- Fully transparent and clear housing with an integrated flat silicone seal and split septum
- Straight internal transparent fluid pathway(easy flushable and no dead space)
- Protects healthcare professionals from needle stick injuries
- Entirely closed system helps infection control-BSI (Bloodstream infections)
- Reduces blood contact risk
- CDC (Central for Disease Control) recommends split septum valves in order to minimize infection risks in intra venous therapy.



FlowArt® Needle-free Valves

PREVENTION

ASSET MEDICAL – SwabArt®

Disinfecting Caps for Swabable needle free valves

SwabArt® is a single-use disinfection product with a high liquid absorbent sponge saturated in Alcohol.

- SwabArt® Disinfecting Cap for swabable needle-free valves is a single-use disinfecting product that protects patients from infection.
- Provides active disinfection for up to 7 days if not removed
- SwabArt® Disinfecting Caps are impregnated with a high liquid absorbent sponge saturated with 70% Isopropyl Alcohol (IPA).
- Swab Art® Disinfecting Caps not only disinfect the needle-free valve port but also protect disinfected surface by acting as a physical barrier to contamination for up to 7 days.

SwabArt® Disinfecting Cap for Swabable Needle-free Valves

SLEEPANGEL® -Infection Control Bedding

Reduce Infections Risks, Improve Patient Care, Save Your Hospital Money.

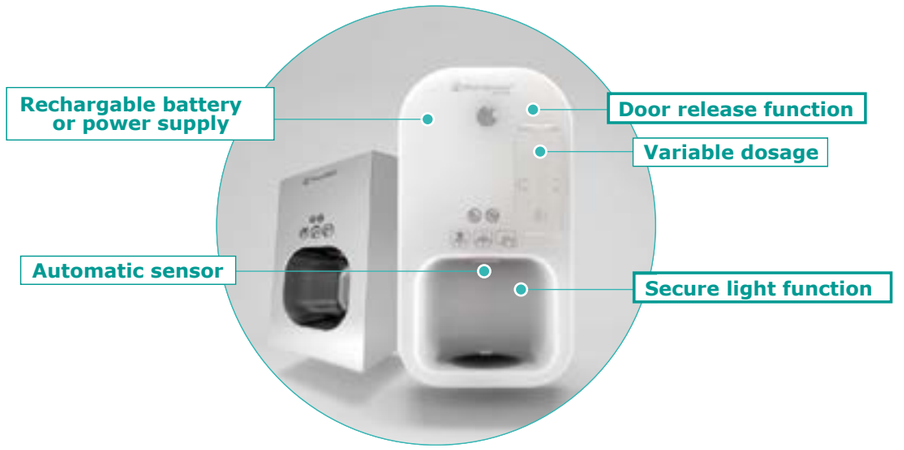
SleepAngel® bedding provides a clinically proven barrier to product contamination and features the patented Pneuma-Pure™ Filter Technology which enables the product to ventilate but prevents the passage of liquid and air borne pathogens that colonise the interior of standard bedding products.

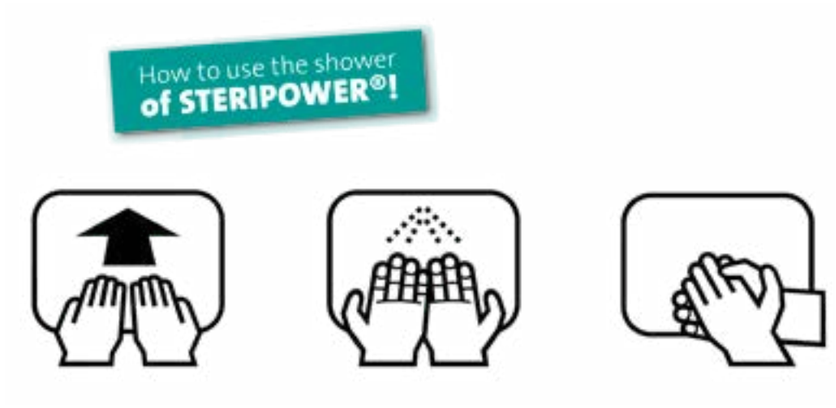
- Durable, soft touch and high performance textile that blocks out contaminants. Vapour permeable and waterproof
- Heat sealed seams provide complete barrier – no stitching holes.
- Breathable mechanical filter that allows clean air flow into the pillow but blocks out pathogens and allergens.
- Certified Class I Medical Device.
- PneumaPure Filter Technology
- Effective barrier also against the Coronavirus
- Awarded several times

STERIPOWER®

The simple and touchless disinfection solution

- It´s a simple solution of portable device providing touchless hand disinfection
- Can be provided in many different forms and so oblige the diversity of market
- The automatic pump is very reliable and can be used even when canister (disinfectant bottle) is secured below the pump itself
- Comes with the possibility of application´s counter and variable settings (1 application of disinfectant can be set up between 0,5-5 ml)





VIROGATES - suPARnostic®

suPAR (soluble urokinase plasminogen activator receptor) is a prognostic biomarker useful for risk stratification of acute medical patients across diseases.

The plasma level of suPAR reflects immune activation and is increased in several infectious diseases, such as SARS-CoV-2 infection, HIV-1-infection, malaria, tuberculosis, Streptococcus pneumonia bacteraemia, sepsis, pneumococcal pneumonia as well as bacterial and viral CNS infection. Furthermore, high suPAR levels are associated with increased inflammation, disease progression and risk of mortality. Measuring suPAR levels can thus serve as a marker to determine chances for survival upon hospital admission as well as for monitoring for prevention of disease progression and earlier intervention time point.

In critically ill patients, the suPAR level is significantly increased. suPAR is an independent prognostic marker, and the change over time correlates with organ dysfunction.
suPAR is elevated and has a prognostic value in patients with:

- SIRS (systemic inflammatory response syndrome)
- Sepsis/septic shock
- Burn injuries
- Traumatic brain injuries

The suPAR level reflects the body's immune response to infections, and the level increases with the severity of the infection. In patients with organ dysfunction, the suPAR value is often a two-digit value. In particular hepatic and renal dysfunction affects the suPAR level.
suPAR has been studied in patients with SIRS who were acutely admitted to the emergency department (n=902). The studies showed that suPAR is a stronger marker of 2-day, 30-day, and 90-day mortality than age, CRP, IL-6, creatinine, and procalcitonin. However, for diagnostic purposes, IL-6 and CRP are superior to suPAR in predicting a positive blood culture.

A Greek multicenter study including 1914 patients with sepsis showed that suPAR is a strong predictor of mortality, and that a suPAR level above 12 ng/mL is linked to a >80% sensitivity for mortality and a negative predictive value of 94.5%.
In addition, the prognostic value of suPAR in patients with sepsis is independent of relevant covariates like APACHE score, CRP, etc..

In patients with burn injuries and inhalation trauma requiring mechanical ventilation, the plasma suPAR level and BAL fluid level correlate to IL-6 and coagulation factors. An elevated plasma suPAR level is associated with prolonged ICU stay and the duration of mechanical ventilation.

The suPAR level is elevated in patients with traumatic brain injury. In trauma patients who suffered a brain injury within 12 hours prior to blood sampling, the mean suPAR level is 14.9 ng/mL ± 6.9 vs. 2.8 ng/mL ± 0.7 in control subjects. In these patients suPAR is associated with severity of the brain injury and with mortality.

suPARnostic® is the only CE-IVD certified product range applied for clinical determination of suPAR (soluble urokinase Plasminogen Activator Receptor) in human plasma and serum.

RISK ASSESSMENT / PROGNOSIS

The suPARnostic® brand consists of the following 3 products:

suPARnostic® TurbiLatex Reagents, 100 tests
The **suPARnostic® TurbiLatex** test is a **turbidimetric immunoassay** that quantitatively determines suPAR in human plasma/serum samples.
The suPARnostic® TurbiLatex product is CE-IVD approved and validated on the Roche Diagnostics Cobas c 501/2 and c 701/2 systems, the Siemens Atellica, and ADVIA Chemistry XPT, and the Abbott Architect c and Alinity ci systems. Validation on other turbidimetric platforms will follow.

suPARnostic® Quick Triage kit, 25 tests
The **Quantitative suPARnostic® Quick Triage test** is based on the Lateral Flow principle and consists of a nitro cellulose membrane with two immobilized antibody zones and a running buffer with gold particles.
The quantitative results are read by the suPARnostic® Quick Test Reader with a detection interval of 2-16 ng/mL suPAR.

suPARnostic® AUTO Flex ELISA kit, 96 tests
Enzyme immunoassay for **quantitative determination of soluble urokinase plasminogen activator receptor** in human plasma and serum.
Developed for clinical application in central labs

- For clinical routine - automated and manual procedures
- Modular and flexible – 12x8 strips and up to 91 single tests
- Fully quantitative results in less than 1½ hours
- Choice of 3- to 5-point standard curve for high accuracy
- Ready-to-use reagents & software tool for easy results

suPAR level and mortality risk

Patients below the age of 70:

suPAR (ng/mL)	30 days	90 days
All (n=5925)	1.4%	2.5%
0-3 (n=3852)	0.2%	0.5%
3-6 (n=1661)	1.7%	3.4%
6-9 (n=287)	7.3%	11.1%
>9 (n=169)	16.6%	23.1%

Patients above the age of 70:

suPAR (ng/mL)	30 days	90 days
All (n=3666)	8.8%	15.3%
0-3 (n=750)	2.3%	3.5%
3-6 (n=1970)	5.3%	10.9%
6-9 (n=567)	16.6%	28.1%
>9 (n=379)	27.7%	43.0%

Source: The emergency departments at Hvidovre Hospital and Hillerød Hospital, Denmark. n=9591.

ABIONIC - abioSCOPE® PSP

Pancreatic Stone Protein (PSP) on the abioSCOPE® is the Earliest Marker of Sepsis

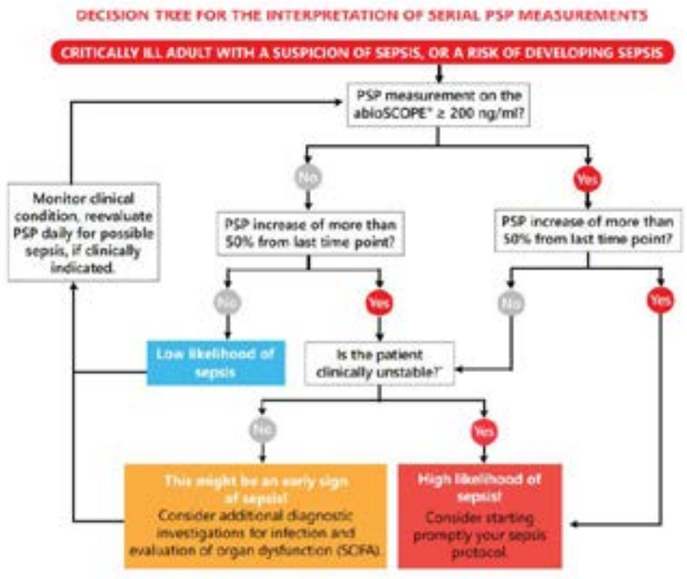
The IVD CAPSULE PSP is a rapid, single-use in vitro diagnostic test for the quantitative measurement of pancreatic stone protein (PSP) in blood. The test is intended to be used in conjunction with other clinical assessments and laboratory findings to aid in the early detection of nosocomial sepsis in adults.

Pancreatic stone protein (PSP) is a biomarker involved in the immune response to pathogens

- PSP is mostly secreted by the acinar cells of the pancreas but also by the intestine and the stomach
- It is an early sensor of sepsis and multiple organ dysfunction
- It acts as an "alert signal" to help clinicians to provide adequate infection control strategy and organ support to restore homeostasis
- PSP is a stable biomarker which detects potential sepsis 24 hours before first symptoms
- PSP has high specificity to an infection-caused organ dysfunction (sepsis), compared to a systemic inflammatory response caused by metabolic stress of non-infectious origin.
- The PSP level in sepsis correlates with illness severity

The IVD CAPSULE PSP on the abioSCOPE® device in the early detection of sepsis in ICU patients at high risk of developing sepsis

- 7,5 minutes total turn around time
- High prognostic value.
- Near patient testing (on ICU)
- Samples capillary blood and venous blood



RISK ASSESSMENT / PROGNOSIS

The abioSCOPE®: True Game Changer for the Future of Diagnostics

Rapid results
5-minute measuring time to get accurate actionable results

Easy to use
4 simple steps with 50 µl of blood from a fingerstick or venous blood

No maintenance
Contamination-free device, no washing step required

Laboratory quality results
Performances equivalent to those obtained in a laboratory

Connectivity options
Input: Barcode scanner, remote software upgrade
Output: HL7, ethernet to HIS/LIS, QR code

Complementary menu in development
Available tests: cSOFA test, a severity score for COVID-19 patients
Coming soon: CRP, D-Dimer

TRUE ENABLER OF EARLY SEPSIS DETECTION

SEE EARLIER - ACT FASTER

T2 Biosystems - Pathogen Panels

Sepsis Pathogen detection directly from whole blood.

Run on the fully automated T2Dx Instrument, the T2Dx panels identify the most deadly and prevalent species that are often not covered by broad-spectrum therapy directly from whole blood. This enables physicians to initiate appropriate therapy within hours of the blood draw. This is especially important given that research has shown that the mortality rate for sepsis rises 8% every hour treatment is delayed. Today, most tests for fast species identification rely on blood culture, which is hampered by a sensitivity of 50% and a lag time of up to 2 to 6 days for species identification or negative result. When up to half of infections are missed, even the most accurate blood-culture-reliant diagnostic cannot detect what blood culture missed.

- The **T2Dx Instrument** is an easy to use, fully-automated, random access benchtop diagnostic system that enhances sepsis management with rapid, actionable species identification.
  - Direct from whole blood
  - Results in 3-5 hours
  - LoD as low as 1 CFU/mL
  - Easy to operate
  - Cartridge based

- **T2Candida Panel** detects the following Candida species directly from whole blood: C. albicans, C. tropicalis, C. parapsilosis, C. krusei and C. glabrata
  - 91,1% sensitivity & 99,4% specificity

- **T2Bacteria Panel** detects the following bacteria directly from whole blood: Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa and Escherichia coli
  - 95,8% sensitivity & 98,1% specificity

Detection within 6 hours of blood sample receipt helps physicians to:
- Get species ID faster than ever before
- Get patients on the right therapy faster
- Improve morbidity and mortality outcomes
- Improve antimicrobial stewardship
- Consider de-escalation of antimicrobials before blood-culture results are available
- Reduce the costs of sepsis management

SEPSIS PATHOGEN DETECTION

T2 Biosystems - Resistance Panel

The first direct-from-blood detection of resistance markers

The T2Resistance® Panel is designed for the direct-from-blood detection of antibiotic resistance genes associated with sepsis-causing pathogens. The panel is currently available as a CE/IVD-marked product and is designed to detect many of the resistance mechanisms described in the 2019 CDC Urgent Threat list.

The T2Resistance® Panel can detect 13 resistance genes from both gram-positive and gram-negative pathogens direct-from-blood. There is broad inclusivity of resistance variants and ≤10 CFU/mL detection demonstrated for all targets. Developmental studies have shown no cross-reactivity or inhibition by common interfering substances. Studies have also shown a dramatic decrease in time to resistance gene identification.[1]

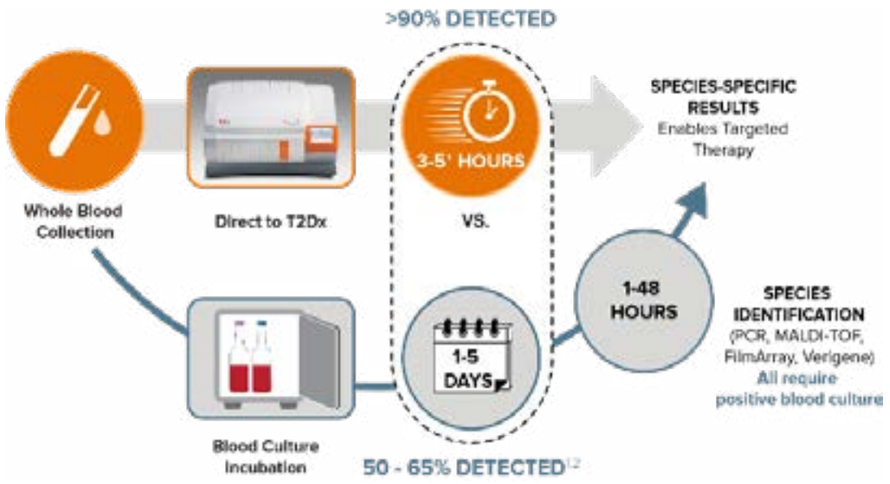
T2Resistance panel
- Sensitivity ≥ 91% and specificity ≥ 98%

Gram-negative marker
- KPC
- OXA-48
- NDM/VIM/IMP
- CTX-M 14/15 AmpC(CMY/DHA)

Gram-positive marker
- vanA/B
- mecA/C

Potential patient populations that may benefit from the T2Resistance Panel:

- Patients with a history of infection or colonization with antimicrobial resistant organisms
- Patients not responding to broad-spectrum antibiotic therapy
- Patients with risk factors for antimicrobial resistance
- Patients with positive T2Bacteria result or positive blood culture



1. De Angelis G, editor. Clinical experience with a bacteria panel and resistance markers direct from whole blood. ECCMID; 2019.

MOLECULAR MOUSE

REAL TIME PCR SYSTEM & SEPSIS PANEL - READY TO USE LAB-ON-CHIP CARTRIDGE

The Lab-on-Chip is an electrically active microsystem that precisely controls the reaction temperature. It is a disposable device based on a silicon chip manufactured using innovative semiconductor technology. The widest panel for the critically ill patient management and Rational use of antibiotics.

Up to 6 instruments can be managed independently with one software session!
5 different cartridges for rapid detection of microorganisms of major clinical relevance and their antibiotic resistance genes, starting from positive blood cultures. Up to 18 targets detected simultaneously. Positive and negative controls included.

MicroWell
All necessary reagents are lyophilized in each 5 uL microwell for multiplex reactions

RFID tag
stores product and test information used by the software to perform the analysis

- **64 different targets**: 44 microorganisms and 20 resistance genes
- Detection of the main antibiotic resistances for **ß-lactams and carbapenems**
- Ability to analyse **polymicrobial samples**
- Rapid results in about **1 HOUR**
- **NO extraction** is needed*
- Easy pre-analytical step in **only 5 minutes***
- **User-Friendly**
- **Reduced** reagents use and waste production

*except for yeast and fungi cartridges

SEPSIS PATHOGEN DETECTION

POSITIVE BLOOD CULTURE

GRAM-STAINING

GRAM NEGATIVE AND RESISTANCES

MM GRAM NEG ID
code SI 1701.0102/L

Acinetobacter baumannii
Enterobacteriaceae
Klebsiella aerogenes
Enterobacter cloacae
Escherichia coli/Shigella spp
Haemophilus influenzae
Klebsiella oxytoca
Klebsiella pneumoniae
Neisseria meningitidis
Proteus spp
Proteus mirabilis
Pseudomonas aeruginosa
Salmonella typhi
Serratia marcescens
Stenotrophomonas maltophilia

MM GRAM NEG RES
code SI 1701.0101/L

KPC	*Carba resistance*
VIM	
NDM	
IMP	
OXA-23-like	
OXA-48-like	
SHV	*ß-lactams resistance*
SHV ESBL	*ESBL*
CTX-M-1/9 groups	
CTX-M-2/8 groups	
CMY-2	*AmpC resistance*
mcr-1	*Colistin resistance*
mcr-2	

GRAM POSITIVE AND RESISTANCES

MM GRAM POS NO STAPH
code SI 1701.0104/L

Bacillus subtilis
Enterococcus spp
Enterococcus faecalis
Enterococcus faecium
Listeria monocytogenes
Streptococcus spp
Streptococcus agalactiae
Streptococcus anginosus
Streptococcus pneumoniae
Streptococcus pyogenes

vanA	*Vancomycin resistance*
vanB	
vanC1	
vanC2/3	

MM GRAM POS STAPH
code SI 1701.0103/L

Staphylococcus spp
S. aureus
S. epidermidis
S. haemolyticus
S. lugdunensis
S. sciuri
S. hominis
S. simulans
S. saprophyticus
S. xylosus

mecA	*Methicillin resistance*
mecC	
SSCmec-orfX	*MRSA*
vanA e vanB	*Vancomycin resistance*

YEAST

MM YEAST BLOOD
code SI 1701.0105

Candida albicans
Candida glabrata
Candida krusei
Candida parapsilosis
Candida tropicalis
Candida auris
Candida lusitaniae
Candida dubliniensis
Candida guilliermondii

Each kit code is composed by 20 cartridges.

MOLECULAR MOUSE SYSTEM
(code SI 1701.100/I - included: PC, software, Molecular Mouse instrument with power supply, USB cable, 1 cartridge holder and 2 self check cartridges)

Gradientech

QuickMIC® is an ultra-rapid system for phenotypic antibiotic susceptibility testing.
Product is designed to offer personalized treatment options for sepsis patients, thereby contributing to increased survival, reduced healthcare costs and lower antibiotic resistance.

- Reports precise MIC values in 2-4 hours
- Directly from positive blood cultures
- Antibiotic panels for G- bacteria
- Shorter initial empirical therapy. Minimise the use of high-dose,broad-spectrum antibiotics.
- Confirm optimal antibiotic treatment
- Simultaneous MIC and ID. Get your MIC results at the same time as you get your bacterial ID.
- Personalised treatment: Optimise dose and minimise adverse effects
- Modular system for small and larger hospital laboratories

SEPSIS PATHOGEN DETECTION

FUJIFILM
(1—›3)-ß-D-glucan Monotest

The β-Glucan Test is an in vitro diagnostic test for the quantitative determination of (1→3)-β-D-glucan in serum or plasma and helps to detect many invasive fungal infections. The assay is performed on the LIMUSAVE MT-7500 device.
In most pathogenic fungi, (1->3)-ß-D-glucan is an integral component of the cell wall. Small quantities are released into the blood during infection.
The Limulus reagent (LAL: Limulus amebocyte lysate), made from the extract of blood cells of horseshoe crabs, has drawn attention as an in vitro diagnostic reagent for mycosis.
It reacts with (1->3)-ß-D-glucan as well as with endotoxin. The ß-Glucan Test exclusively measures the (1->3)-ß-D-glucan concentration through a kinetic turbidimetric assay in a sample pretreated with a solution which inactivates endotoxin by the use of a non-ionic detergent and polymyxin B.

- FJ-997-04101 ß-Glucan Test (50 tests)

Additional reagents and consumables needed:
- FJ-993-04201 ß-Glucan Sample Pretreatment Solution (50 0,9 ml)
- FJ-999-04301 ß-Glucan Sample Dilution Buffer (10 x 0,9 ml)
- FJ-995-04901 Aluminium Caps, sterile (10 x 10 caps)
- FJ-995-04401 LAL Control Wako (10 x 0,5 ml)
- FJ-995-05001 BC Tip Wako EXT (100 pcs)
- FJ-991-05101 BC Tip Wako 1000-R (100 pcs)

Key features:
- Monotest reagents
- Calibration by QR Code Scan
- Quality control available
- Simple procedure
- Ready to use reagents
- Intuitive Software
- Quantitative ß-D-glucan measurement
- Measurement range: 6 to 600 pg/mL
- Cut-off value: 7 pg/mL
- High precision and no significant interference observed due to bilirubin, hemolysis or antifungal drugs

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