ALIFAX NEW MICROBIOLOGY

FLEXIBILITY IN BACTERIOLOGY FOR QUICK DIAGNOSTIC RESULTS

APPLICATIONS

- URINE SCREENING
- RAA TEST
- HUMAN BIOLOGICAL LIQUIDS CULTURE
- CENTRAL VENOUS CATHETER TIPS
- STERILITY TEST
- SUSCEPTIBILITY TEST IN URINE
- SUSCEPTIBILITY TEST IN BLOOD CULTURE
- MDRO
  - MRSA
  - ESBL/AmpC
  - CARBAPENEM
- MALDI INTEGRATION
- ENRICHMENT KIT AND NEW SW

lightscattering

URINE CULTURE ANALYSIS

The problem

Urinary Tract infections (UTI's) are considered to be **one of the most common human bacterial infections** second only to respiratory infections.
UTI's are also the most common **nosocomial infections** mostly linked to urethral catheters and invasive diagnostic procedure.

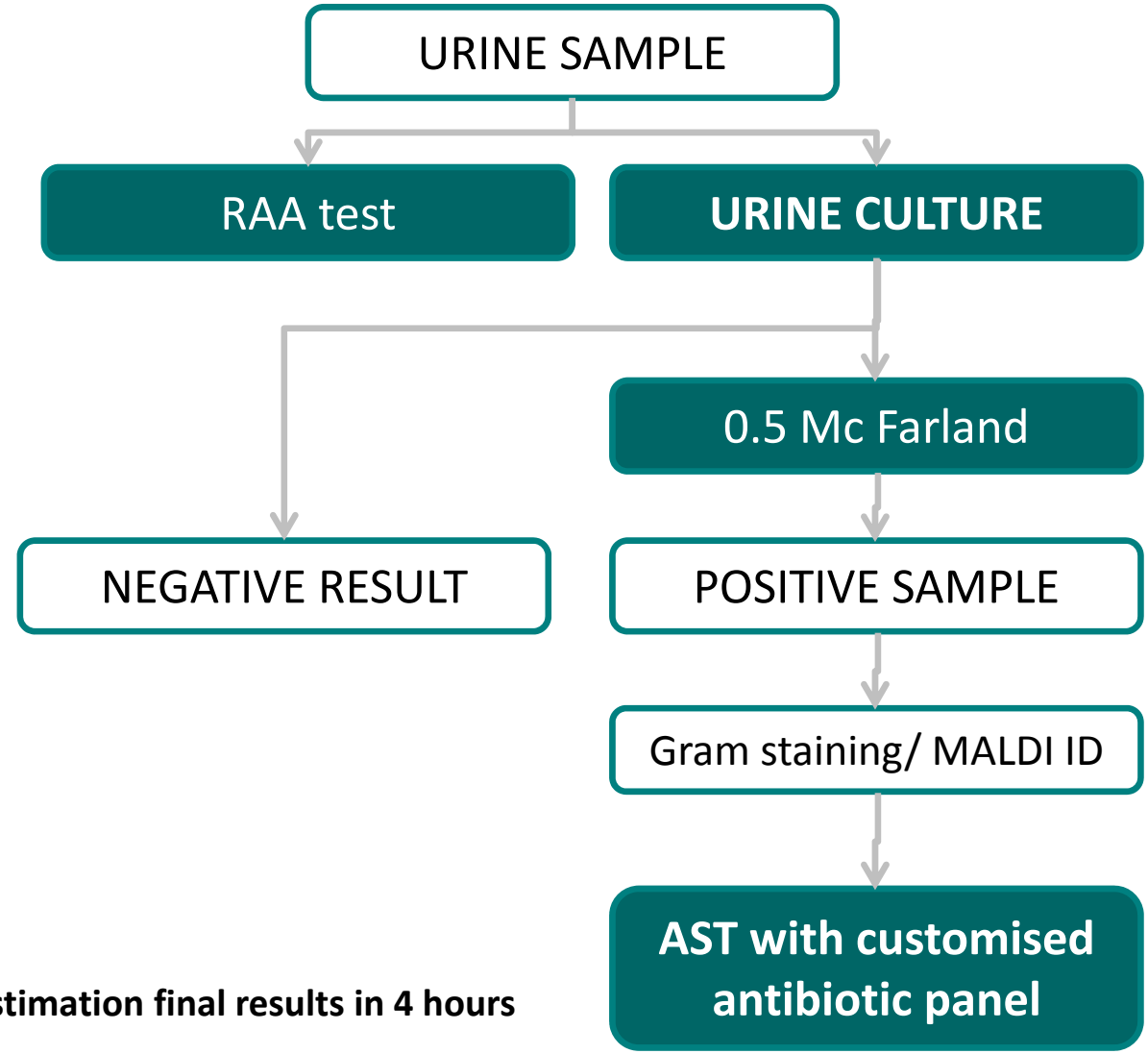
Classical tests

Culture on Petri dish + ID + AST

Tourn Around Time

2-3 days

ALIFAX SOLUTION



Negative are reported after only **3 hours** of incubation

Strong **positive** samples are flagged after only **45 minutes** of incubation with bacteria count in CFU/ml and automated **McFarland**

Estimation final results in 4 hours

AST results are available in **3-5 hours**

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Performances from letterature

Since the year 1993, more than 100 published studies have confirmed the real advantages granted by the system in terms of :

- Method standardization
- Results reproducibility
- Quicker results availability
- Impact on treatment management and patient hospitalization

Author	Year	N° samples	Sensitivity %	Specificity %	PPV %	NPV %
Rif 1	1995	1126	96,3	99,7	99,4	98,1
Rif 2	1997	642	93,24	98,76	98,76	99,11
Rif 3	2008	755	98,5	97,5	97,09	98,78
Rif 4	2013	1500	99,8	90,0	99,9	83,6
Rif 5	2013	886	94,7	97,9	96,7	96,8

1 - Soro O. (Mic Inst Genova Univeristy, Italy) ECCMID 1995
2 - Russo I. (Microbiology Laboratory, Niguarda Hospital, Milan, Italy) ECCMID 1997.
3 - Ricci L. (Laboratory of Microbiology A.O.S.M. Nuova, Reggio Emilia, Italy) SIMPIOS 2008.
4 - Carpi D. et al. (Microbiology Laboratory ASL TO3, Pinerolo TO, Italy) ECCMID 2013
5 – Freiman S. et al, (Hillet Yaffe, Israel) ECCMID 2013

KOL Messages

CARPI D. (Pinerolo Hospital, Italy) ECCMID 2013

On the base of our experience we confirm that the major advantages derived from Alfred60 system are:

1. Workload reduction **thanks to automated report to the LIS of negative samples in 3 hours and to selection of positive samples for sub-culture**
2. **Possibility to re-analyze samples in the same day**
3. **Direct ID and AST for selected samples, reducing TAT time of 24 hours compared to classical method**
4. **Daily negative reports that avoid empiric or improper and costly drug therapies**

FORTINA G. (President Italian Microbiology Assoc.) AMCLI 2014

The **automation of urine culture** can be introduced in a new **laboratory organization to handle the routine** in order to **free up resources to be used on further investigation of the positive or particularly complex samples.**

ADVANTAGES

TECHNICAL

- Fastest Cultural system
- Quantitative results in CFU/ml
- Automated McFarland for AST and ID
- High sensitivity and specificity
- Real time detection of growth curves
- Customizable threshold and incubation time
- Simultaneous multi-testing
- Fully automated
- Full sample traceability
- Connection to LIS
- Easy to use
- CE marked

LAB WORK-FLOW

- Fully automation of Urine culture (majority of the bacteriology tests)
- Negative samples out of the workflow in 3 hours
- Results reported in 1 day
- Rapid bacteria production (pellet) for further investigation (i.e MALDI)
- Reduction of technician handwork
- Method standardization
- Reduction operator exposure risk

PUBLIC HEALTH IMPACT

- Avoid non necessary treatment
- Promptly start the correct pharmacological therapy
- Favor the resolution of the pathology in a short time
- Reduce hospitalization time (Urinary Tract Infections DRG 2.500€)
- Reduce the use of wide spectrum antibiotics
- Reduce the diffusion of resistant bacteria

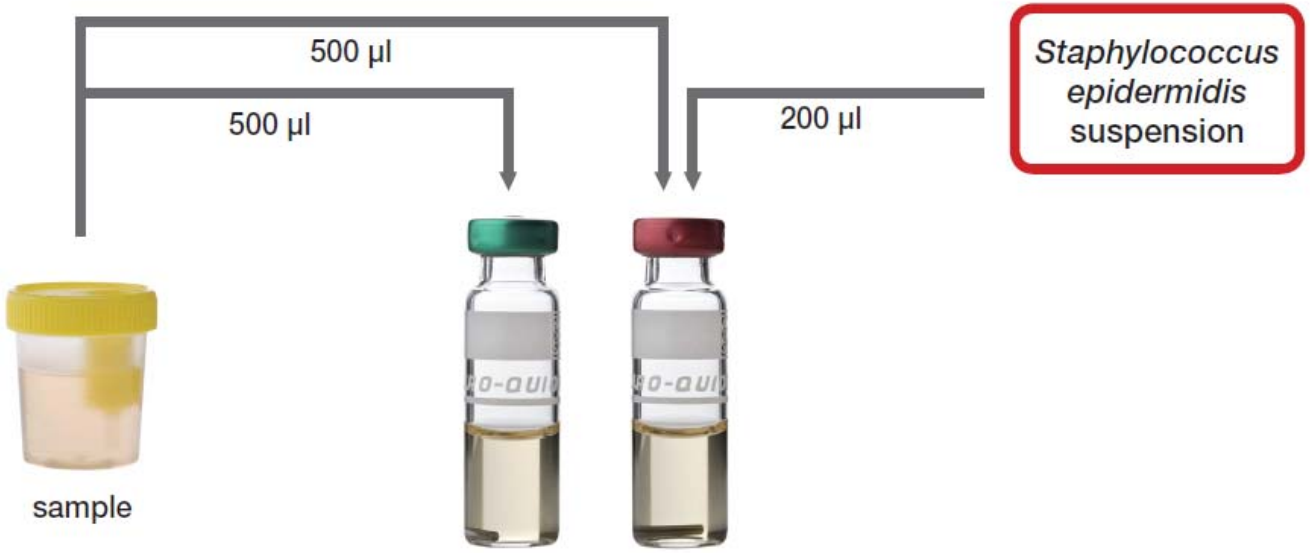
RESIDUAL ANTIMICROBIAL ACTIVITY TEST

The problem

The detection of antimicrobial substances in a sample for bacterial culture is important for correct result interpretation.
In the absence of clinical data the Residual ntimicrobial Activity (RAA) test result is of value to the Microbiologist in the interpretation of the culture test, especially in case of not reported antibiotic therapies, and helps to avoid the reporting of false negative results.

Classical tests

Tourn Around Time



RESULTS INTERPRETATION

RAA-	Culture-	Culture test result is confirmed
RAA-	Culture+	Culture test result is confirmed
RAA+	Culture-	Residual antimicrobial activity detected Further investigations are required
RAA+	Culture+	Residual antimicrobial activity detected Therapy is not working or not reaching the site Further investigations are required

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PAPER

HUMAN BIOLOGICAL LIQUID CULTURE

The problem

The rapid analysis of human biological liquids is decisive to the inpatient for whom the **timely correct diagnosis** and the **beginning of an adequate therapy** in most cases represent the **only way to survive**.
In addition to community acquired infections, hospital acquired infections have a high Public Health impact by increasing **morbidity and mortality rates and costs** through prolonged hospital stays and additional diagnostic and treatment costs.

Classical tests

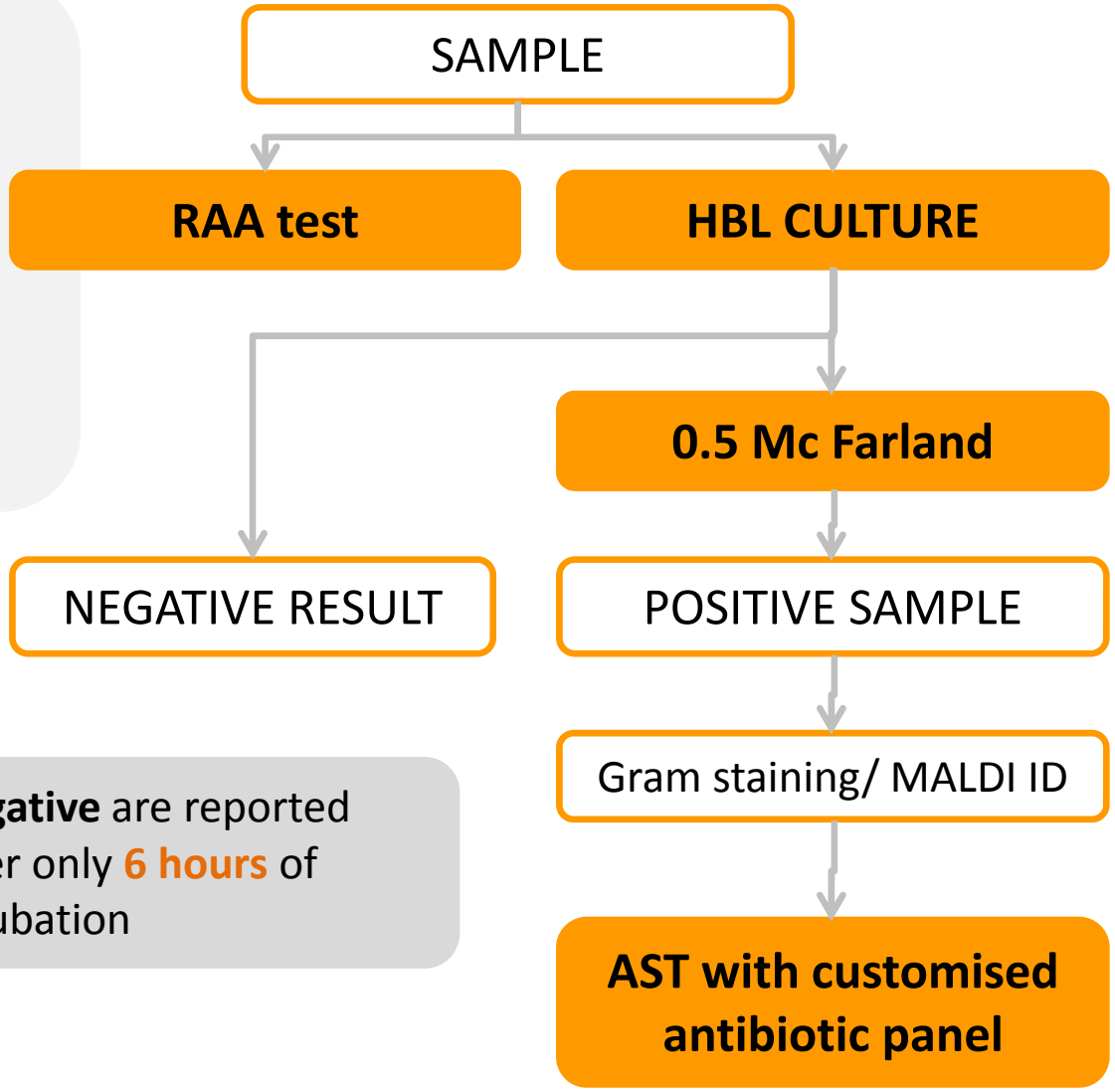
Culture in Hemoculture bottle + colony isolation on Petri dish + ID + AST

Tourn Around Time

3-5 days

ALIFAX SOLUTION

Non sterile
Expectioration
Orotracheal aspiration
Bronchoalveolar lavage
Sterile
Cerebrospinal fluid
Pleural fluid
Synovial fluid
Ascitic fluid
Peritoneal fluid
Central Venous Catheter tips



Strong **positive** samples are flagged after only **45 minutes** of incubation with bacteria count in CFU/ml and automated McFarland

Negative are reported after only **6 hours** of incubation

AST results are available in **3-5 hours**

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Performances from letterature

The results obtained by many studies conducted at in different reference centers demonstrate that Alifax systems offer "**an excellent agreement with the cultural method [Petri dish] and a useful and precise count of the bacteria supplying undoubted advantages especially in those samples for which the bacteria amount represents a validation criteria**"(Fontana 2005).

Author	Year	N° samples	Sensitivity %	Specificity %	PPV %	NPV %	Agreement
Rif 2	2009	546	100	100	100	100	100
Rif 3	2010	322	97,2	100	100	99,9	98
Rif 6	2013	10655	95,5	99,9	96,2	99,8	98

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Fontana C. Med Sci Monit 2009
Tessari A. J Microbiol Methods, 2010
Lanzafame P., Trends in Medicine, 2011

KOL Messages

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FONTANA C. (Tor Vergata University Hospital Roma, Italy) Med Sci Monit, 2009; 15(2)

Considering the rapidity with which the Alifax system achieved the identification of positive specimens, **from 235 min to 6 h**, the approach holds great promise for directly detecting and identifying microbial pathogens and revealing their antimicrobial susceptibilities especially in samples from **sterile body sites** (..)

Taking into account this possibility, **a laboratory could rapidly produce a preliminary report to the physician**. **The timeliness of this information could have great impact on patient treatment and even survival.**

TESSARI, PALU' (Padova University Hospital, PD, Italy) Journal of Microbiological Methods 81 (2010) 235–239

Results of this 12-month study suggest that Alifax system can be considered a powerful system for **respiratory tract infection surveillance in ICUs**: it is able to **speed up the laboratory procedures and grant reliable results for the clinician in very short time**

Last publications

CEREBROSPINAL FLUID CULTURE – Tomei et al. (ASL Aquila) SIPMel 2015

CFS CULTURE ASSOCIATED TO MALDI-TOF IDENTIFICATION: RESULTS IN 8 HOURS AND TAT REDUCTION OF 1 DAY (AT LEAST)

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In the study "***NEW EVIDENCE ON THE APPLICATION OF LIGHT SCATTERING TECHNOLOGY FOR THE CULTURE OF CFS IN SURGICAL PATIENTS. REDUCTION OF TAT***" 84 CSF samples obtained from DVE (derived ventricular external) and DLE (derivation lumbar external) in patients after surgical treatment were tested in duplicate with either Alifax **HB&L CULTURE KIT** and on petri dish with 48 hours incubation.

The use of rapid culture in broth allowed the detection of the majority of positive samples to the presence of pathogens within 8 hours incubation and the confirmation of negativity in 24 hours with a 100% concordance with respect to the reference method in culture plate.

The association with MALDI-TOF for identification of the positive samples directly from the bacterial pellet allowed to reduce the TAT and anticipating at least one day the reporting time if compared to the traditional method.

Last publications

New

BACTERIAL CULTURE OF BRONCHIAL SAMPLES – Barnini et al (Uni Pisa) ECCMID 2016

NEW EXPERIMENTAL PROCEDURE AND BROTH FOR BRONCHIAL SAMPLES: IMPROVED PERFORMANCES

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The poster "**Rapid liquid cultures for respiratory samples**" describes a new experimental procedure, alternative to that validated and reported on Alifax manuals, developed by Dr. Barnini's team from the University of Pisa.

The new method differs from the Alifax method in the **pre-analytical phase** (dilution in physiological solution 1:10.000)

76 respiratory samples were tested with **HB&L CULTURE KIT** and a parallel study was performed analyzing 200 samples with new **SABOURAUD KIT**.

The main advantage of this method is that **significant bacterial pathogen growths (>10^5 CFU/ml) are detected within 7 hours.**

The new **SABOURAUD KIT** kit: preliminary results show a rapid growth of fungi and an **increased sensitivity** compared to the traditional method (**24 samples**, false negative on traditional culture resulted positive on HB&L system).

These two kits, used simultaneously, can provide reliable and more rapid results than the reference method.

ADVANTAGES

TECHNICAL

- Fastest Cultural system
- Quantitative results in CFU/ml
- Automated McFarland for AST and ID
- Real time detection of growth curves
- High sensitivity and specificity
- Customizable threshold and incubation time
- Simultaneous multi-testing
- Fully automated
- Full sample traceability
- Connection to LIS
- Easy to use
- CE marked

LAB WORK-FLOW

- Negative samples out of the workflow in 6 hours
- Results reported in 1 day
- Method Standardization
- Reduction of technician handwork
- Rapid bacteria production (pellet) for further investigation (i.e MALDI)
- Reduction operator exposure risk

PUBLIC HEALTH IMPACT

- Promptly start the pharmacological therapy
- Monitor daily the patient
- Favor the resolution of the pathology in a short time
- Reduce hospitalization time
- Reduce the use of wide spectrum antibiotics
- Reduce the diffusion of resistant bacteria

CENTRAL VENOUS CATHETER TIPS

The problem

Catheter-related bloodstream infections (CRBSIs) are one of the leading causes of healthcare-associated infections and have significant morbidity and mortality rates . CRBSIs are difficult to diagnose because of the lack of observable local symptoms that indicate a catheter infection and the systemic manifestations of the infection are non-specific .
Many catheters are culture-negative upon removal, despite clinical signs of an infection and do not detect all of the microorganisms involved in the infection

Classical tests

Maki's CULTURAL method ON PETRI + ID + AST

Tourn Around Time

2 days

Last publications

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IMPROVED DIAGNOSIS OF CENTRAL VENOUS CATHETER-RELATED BLOODSTREAM INFECTIONS USING THE HB&L UROQUATTRO™ SYSTEM.

Fontana et al (Tor Vergata Uni. Rome) Eur J Clin Microbiol Infect Dis 2012

Results indicate that new culture method allows an improved of catheter-related bloodstream Infections (CRBSI) diagnosis rate.

HB&L System recovered a significant number (18.41 %) of tip cultures resulted negative with the reference method.

The use of the HB&L system significantly reduces diagnosis time: a negative CRBSI diagnosis could be given within 6 hours and a positive diagnosis within 22–28 hours.

This method is used in laboratory routine !

STERILITY TEST

The problem

The sterility testing is an essential procedure to certify microbiological control of transplantation tissue as sclerodermal rims from the donor or pharmaceutical preparations. Nevertheless, as reported in the European Pharmacopoeia, “conventional microbiological methods are slow and results are not available before an incubation period of typically up to 14 days. Thus the results from those methods seldom enable proactive corrective action to be taken”(1).

Classical tests

Pharmacopoeia method: culture in selective media
Alternative method: hemoculture bottle

Tourn Around Time

Pharmacopoeia method: up to 14 days
Alternative method: up to 5 days

1- European Pharmacopoeia, 5.5, 07/2006:50106, 5.1.6. Alternative methods for control of microbiological quality

ALIFAX SOLUTION

- **HB&L CULTURE KIT**
- **HB&L SABOURAUD KIT**
- **HB&L ANAEROBE KIT**

full range CE marked kits

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are specific for the detection of aerobe, **obligate or facultative anaerobic bacteria and fungi** that may be present in products or formulations produced using aseptic procedures as storage liquid media for human cornea.

Thanks to the light scattering technology and the growth curve analysis, is possible to considerably reduce the time required to report a negative result thus assess a microbiologically free sample with high sensitivity and specificity.

HB&L CULTURE KIT Code SI 405.901
HB&L SABOURAUD KIT Code SI 405.910
HB&L ANAEROBE KIT Code SI 405.905

VALIDATION OF ALIFAX BROTHS

HB&L CULTURE KIT

The validation of HB&L Culture kit was performed at Veneto Bank Eye one of the biggest european bank eye.
10,655 samples tested in this study. Results were published Camposampiero et al. in the Journal of Ophthalmology Volume 2013, ***Evaluation of the HB&L System for the Microbiological Screening of Storage Medium for Organ-Cultured Corneas***

FONDAZIONE BANCA DEGLI OCCHI DEL VENETO - ONLUS

Link to the webpage

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HB&L SABOURAUD KIT

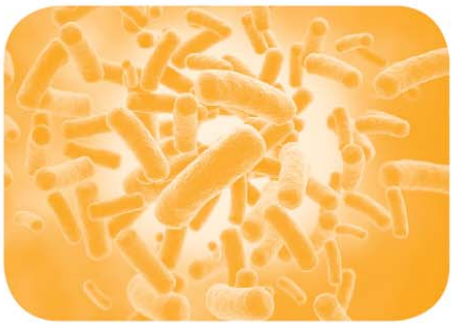
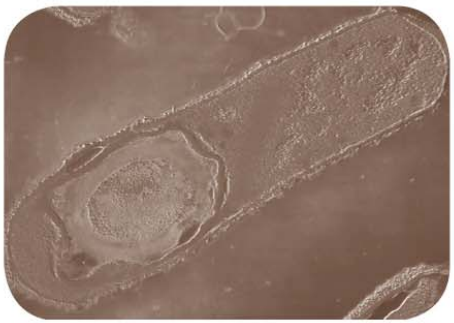
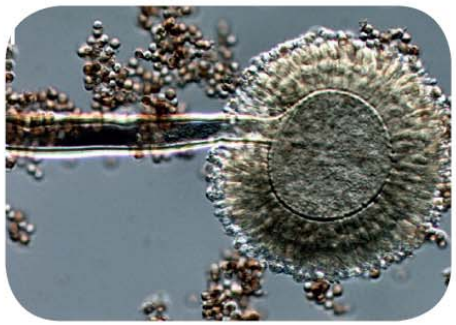
HB&L ANAEROBE KIT

New culture media for anaerobe bacteria and fungi have been done at the eye bank of Monza following the guidelines of Pharmacopoeia reference

Azienda Ospedaliera San Gerardo

STERILITY TEST ADVANTAGES

1. **ALIFAX TIMES ARE SIGNIFICANTLY SHORTER (48 HOURS) THAN THOSE OF BD, bioMérieux**
2. **Alifax allows the culture of aerobic, anaerobic bacteria germs and fungi in agreement with the guidelines of the European Pharmacopoeia**
3. **Volumes required for analysis are much smaller than other instruments**
4. **The culture broths were validated on a matrix (cornea transport media), but the concept is fully extendable to all sterility controls**

Last publications

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RAPID METHOD FOR STERILITY TESTING OF TOTAL PARENTERAL NUTRITION SOLUTION BASED ON THE USE OF HB&L SYSTEM

Athamna et al. – ECCMID 2016

This study was conducted to evaluate the HB&L system performance in detecting the growth of **bacteria and fungi** as compared with the conventional method of direct inoculation into the Fluid Thioglycolate Medium (FTM) of Total Parenteral Nutrition (TPN).

HB&L system **is rapid and reliable system allowing the laboratory to shorten the turn-around time for TPN sterility screening with high specificity and sensitivity values**.

It allows hospital pharmacies a **better monitoring of TPN sterility long before the solution expiry date and may enhance patient's safety**.

ANTIBIOTIC SUSCEPTIBILITY TEST

The problem

In cases of serious bacterial infections the timely administration of an effective antibiotic therapy is associated with an increase in disease resolution and subsequent patient survival. For this reason, the microbiology laboratory has to provide **"clinically useful results"** in order to guide the clinician to choose the most appropriate antibiotic therapy as soon as possible. Rapid Antimicrobial Susceptibility Test (AST) results facilitate effective treatment, reduce the number of laboratory tests ordered, days of hospitalization and Public Health costs.

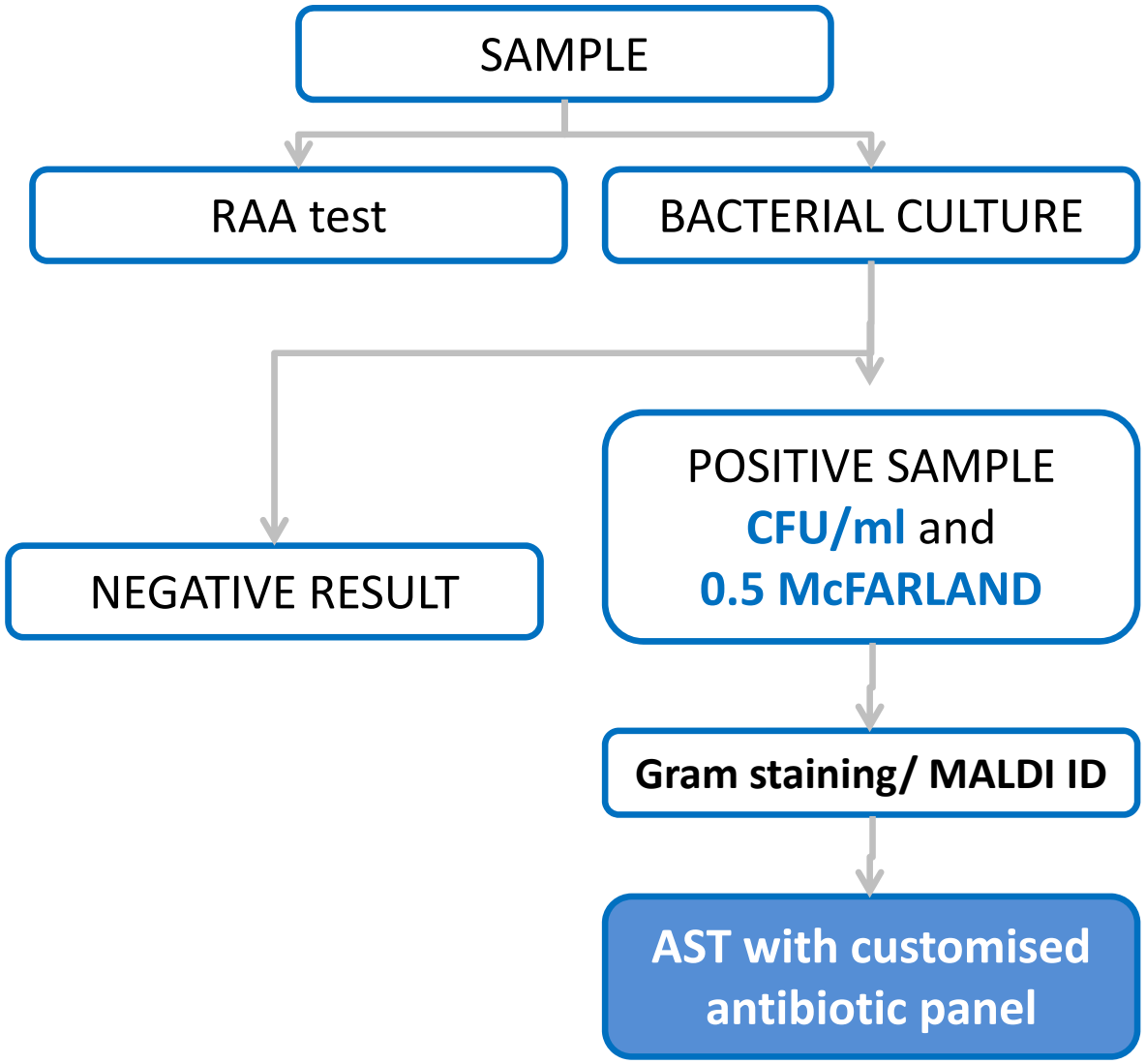
Classical tests

MIC, KB, VITEK2, PHOENIX, MICROSCAN

Tourn Around Time

From 8 to 24 hours

ALIFAX SOLUTION



Strong **positive** samples are flagged after only **45 minutes** of incubation with bacteria count in CFU/ml and automated **McFarland**

AST results are available in **3-5 hours**

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Antimicrobial Susceptibility Test

Alifax patented technology allows to test the sensitivity of pathogen to the antibiotics **starting directly from different materials in 3-5 hours :**

1. **Positive broth cultures (urine, fluids)**
2. **Positive haemoculture without isolation**
3. **Isolated Colonies**

ALIFAX AST

Alifax systems are conceived in order to properly test the positive samples with a **personalized antibiotic panel.**

CLSI and EUCAST molecules available

The results are expressed in **percentage of resistance or sensitivity** to the antibiotic and classified in categories: **Resistant, Intermediate and Sensitive**.

EACH ANTIBIOTIC IS INDIVIDUALLY CE MARKED

	EUCAST LYOPHILISED ANTIBIOTICS	Code
1	AMIKACIN ENTEROBACTERIACEAE	SI 956-AMK
2	AMIKACIN PSEUDOMONAS NN)	SI 978-AMK
3	AMIKACIN STAPHYLOCOCCI	SI 981-AMK
4	AMPICILLIN ENTEROBACTERIACEAE	SI 954-AMP
5	AMPICILLIN ENTEROCOCCI	SI 955-AMP
6	AMPICILLIN-SULBACTAM ENTEROBACTERIACEAE	SI 997-AMS
7	AZTREONAM ENTEROBACTERIACEAE	SI 957-ATM
8	CEFOTAXIME	SI 959-CTX
9	CEFOXITIN CNS	SI 962-FOX
10	CEFOXITIN STAPH. AUREUS	SI 961-FOX
11	CEFTAZIDIME ENTEROBACTERIACEAE	SI 949-CAZ
12	CEFTAZIDIME PSEUDOMONAS	SI 950-CAZ
13	CEFTRIAXONE	SI 951-CRO
14	CEFUROXIME	SI 960-FUR
15	CIPROFLOXACIN	SI 963-CIP
16	CLINDAMYCIN STAPHYLOCOCCI	SI 964-CLI
17	COLISTIN PSEUDOMONAS	SI 983-CST
18	COTRIMOXAZOLE ENTEROBACTERIACEAE	SI 965-SXT
19	COTRIMOXAZOLE STAPHYLOCOCCI	SI 982 - SXT
20	GENTAMICIN	SI 967-GEN
21	GENTAMICIN HLAR	SI 999-GEN
22	GENTAMICIN STAPHYLOCOCCI	SI 968-GEN
23	LEVOFLOXACIN	SI 969-LEV
24	LINEZOLID	SI 970-LZD
25	MEROPENEM ENTEROBACTERIACEAE	SI 971-MEM
26	MEROPENEM PSEUDOMONAS	SI 979-MEM
27	PIPERACILLIN-TAZOBACTAM ENTEROBACTERIACEAE	SI 953-TZP
28	PIPERACILLIN-TAZOBACTAM PSEUDOMONAS	SI 952-TZP
29	RIFAMPICIN	SI 996-RIF
30	TEICOPLANIN CNS	SI 976-TEI
31	TEICOPLANIN S. AUREUS AND ENTEROCOCCI	SI 975-TEI
32	VANCOMYCIN CNS AND ENTEROCOCCI	SI 974-VAN
33	VANCOMYCIN S. AUREUS	SI 973-VAN

SEPSIS

Sepsis kills 1 person every 2 minutes

The problem

Sepsis is a severe infection characterized by a high mortality (estimated 5 times higher than that attributed to stroke and ten times higher than that of infarction) and has become quite common in the world, affecting 26 million people each year. In Europe the incidence is very high: 90 cases per 100 thousand inhabitants, and its frequency is increasing due to the aging of the population is progressive because of the type of patients present in the hospitals Featuring complex diseases and complicated by comorbidity.

Classical tests

Hemoculture + ID + AST

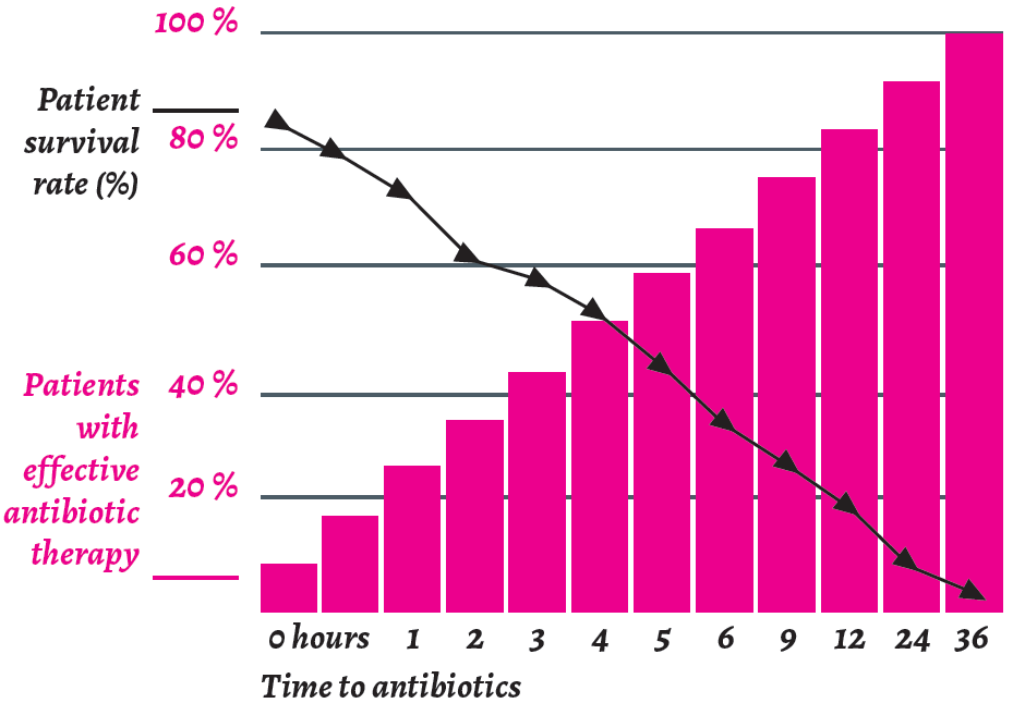
Tourn Around Time

From **24 hours** to **5 days**

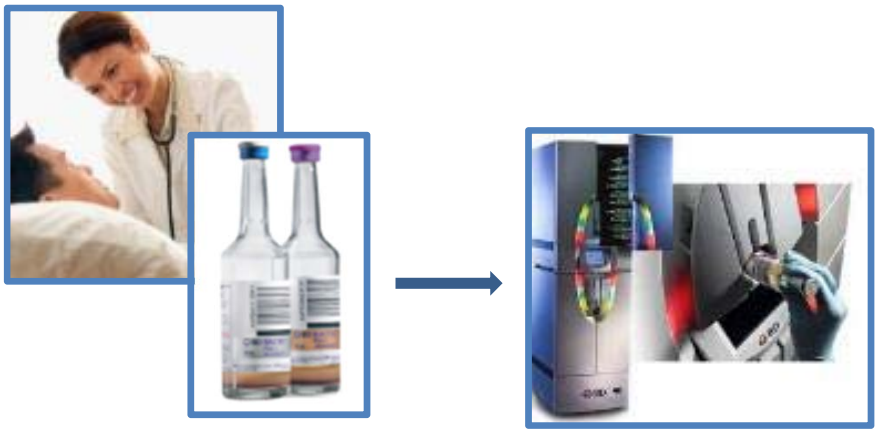
Mortality Risk with Increasing Delays in Initiation of Effective Antimicrobial Therapy

Give the right therapy in a short time could save the life of the critical patient

In the case of systemic bacterial infections, **the time for the diagnosis is a decisive factor for the survival of the patient since the delay of adequate antibiotic therapy increases the likelihood of patient death of 7.5% for each hour of delay and exponentially after 24 hours after the onset of hypotension** (Kumar, Crit Care Med 2006; 34: 1589-96).



CURRENT WORKFLOW FOR BLOODSTREAM INFECTIONS



FROM SAMPLE COLLECTION TO **POSITIVISATION** **8-24 H**

NEGATIVE ARE REPORTED AFTER **5 DAYS** INCUBATION

FROM SAMPLE POSITIVIZATION TO AST:

COLONY ISOLATION **12-24 H**

+

ID/AST

5-8 H (Vitek 2 - Biomerieux)

18-24 H (Phoenix - BD)

ALIFAX SOLUTION:
AST ON POSITIVE HEMOCULTURE

The aim of the Alifax antimicrobial susceptibility testing on positive haemoculture is to

1.Check the efficacy of the first antibiotic treatment administered to the patient

2.Check the efficacy of the second-choice antibiotics

3.Monitor the efficacy of the antibiotic treatment in use

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"Very simple way to safe a life is to know the antibiotic treatment in use by the physician and test its efficiency as soon as possible"

3HOURSRESULT

Positive haemoculture Gram stain

10 ul of blood culture in BHI broth

10 ul

BHI broth

Automated 0.5 Mc Farland

100 ul 100 ul

0.5 McF | Reference vial | Administered antibiotic | Other antibiotics

Automated AST for administered antibiotic in 3 h

KOL Messages

Bruno Viaggi, MD
Intensive Care Unit CTO Careggi (Uni. Florence), Italy

AMCLI congress 2014

" 95% of what I do is "off-label", none of my patients is standard and 1 out of 2 dies therefore I need to interact with the microbiologist to get all the information possible and imaginable to resolve the situation in that moment"

"The microbiologist is the only consultant in intensive care that can address the therapeutic choices and change the outcome of the patient"

"The first experiences of a new method tested in Florence as the clinical **Alifax susceptibility testing provides absolutely important information that can be used in the clinic practice to customize therapy**"

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ITALIAN GUIDELINES FOR BLOODSTREAM INFECTIONS

This document describes the diagnostic procedures and investigations for ***Bloodstream Infections*** caused by bacteria (excluding mycobacteria) and fungi, defining an optimal path that begins with the **formulation of a clinical suspicion**, **define a proper and well-defined laboratory methodological approach** and ends with the of **interpretation of the results**, essential to guide treatment decisions based on the culture results.

DIAGNOSTIC WORKFLOW proposed during the XXXVII Italian National Congress of Clinical Microbiologist Association (AMCLI) - October 2008 Review September 2014

Scientific Board
Carla Fontana,
Fabio Arena,
Marta Argentieri,
Paola Bernaschi,
Giacomo Fortina,
Vesselina Kroumova,
Esther Manso,
Pier Giorgio Montanera,
Pierluigi Nicoletti,
Mario Rassu,
Gian Maria Rossolini

ALIFAX SOLUTION

CLINICAL AST FOR CRITICALLY ILL PATIENT
extract from Italian guidelines 2015

EMOCULTURE (ADULT)

POSITIVE SAMPLE

MICROSCOPIC OBSERVATION after GRAM STAINING

If the culture is monomicrobial it is possible to proceed with

DIRECT OR CLINICAL AST
With customised antibiotic panel testing the therapeutic drugs already administered

ALIFAX SOLUTION

PRELIMINARY REPORT

3-5 h

SUB CULTURE

12- 24 h

DEFINITIVE ID AND AST

5- 24 h

DEFINITIVE REPORT

CLINICAL AST FOR CRITICALLY ILL PATIENT
extract from Italian guidelines 2015

The advantage of the direct AST on blood culture is the **significant reduction of the times of reporting, up to 24 hours, if compared to traditional methods**.

The most critical point is however the standardization of the bacterial inoculum. EUCAST in its document does not encourage the use of direct AST especially on automated systems for which there are no clear indications by the supplier and suggests to perform in any case the susceptibility of traditional isolated.

However, in view of reduce the TAT and provide useful information to the clinician and always in agreement with the physician it is possible to proceed with methods that have the valence of a "clinical susceptibility" giving preliminary information to be added to the traditional one.

CLINICAL AST FOR CRITICALLY ILL PATIENT
extract from Italian guidelines 2015

The direct AST can be performed by agar-diffusion, but also with automated and semi-automated systems. Generally, an aliquot of the broth culture broth is centrifuged and the positive bacterial pellet is used to prepare the standard inoculum.

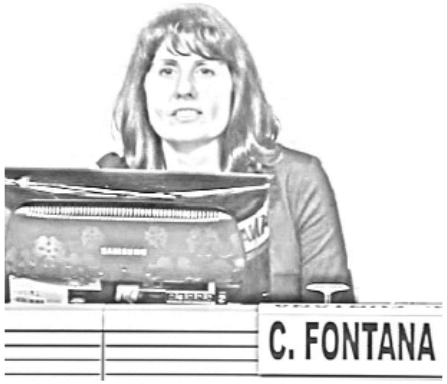
There is also the possibility to perform from the positive bottle a "**clinical AST**" which has the purpose to **"predict" the single combination germ-antibiotic efficacy of the molecules selected for the test such as those used in empirical therapy** (**Kroumova et al., 2010; Rondinelli et al., 2010; Barocci et al., 2010**).

DOWNLOAD

1.Kroumova V, Preliminary indications for antibiotic susceptibility tests in less than six hour in positive blood cultures. Microbiologia Medica, Vol. 25 (1), 2010.
2.Rondinelli V, New method for rapid Susceptibility Testing on blood culture with **HB&L® system**: preliminary data MICROBIOLOGIA MEDICA, Vol. 25 (4): 2010.
3.Barocci S, **HB&L® System**: rapid determination of antibiotic sensitivity of bacteria isolated from blood cultures. MICROBIOLOGIA MEDICA, Vol. 25 (1), 2010.

Last publications – KOL mess

New



Carla Fontana
PhD, Department of Experimental Medicine and Surgery, Tor Vergata Uni. Hospital, Rome, Italy

SUSCEPTIBILITY TESTING FROM POSITIVE HEMOCULTURE – ECCMID 2016

DOWNLOAD

ALIFAX AST IN 3 HOURS VS VITEK2 16 HOURS: BETTER PERFORMANCES AND USEFUL CLINICAL RESULTS FOR CRITICALLY ILL PATIENT

The first poster "**Clinical antimicrobial susceptibility testing as a routine experience**" summarizes, in a very simple and comprehensive way, the results obtained by Dr. Carla Fontana's team (Tor Vergata, Rome) about the comparison of rapid clinical Alifax AST directly from positive blood culture vs Vitek2 AST after colonies isolation. The inconsistent results between the two techniques were confirmed by E-test, micro broth dilution and molecular biology.

The Alifax system demonstrated an excellent concordance with the reference methods resulting in a fast, "**robust and valid system that, introduced in routine for critically ill patients, allowed the clinician to set or even promptly correct the antibiotic therapy, improving the chances of successful treatment impacting also on antimicrobial Stewardship through a calibrated use of antibiotics"**.

Last publications – KOL mess

DOWNLOAD

SUSCEPTIBILITY TESTING FROM POSITIVE HEMOCULTURE

The evaluation of Uro4 HB&L™ for rapid susceptibility testing of Gram-negative bacteria isolated in a blood culture

Zboromyrska et al. Hospital Universitari Clinìc Barcelona **– ECCMID 2016**

Evaluación del sistema Alfred AST® de determinación rápida de la sensibilidad antimicrobiana directamente de hemocultivo positivo

Carrillo et al. Hospital General Universitario Gregorio Marañón. Madrid. España – **SEIMC 2016**

Alfred AST® method can be a very useful method for AST due to its greater speed and its good correlation with the reference method. The opportunity to perform the test directly from positive blood culture reduces the result time.

Further studies will assess the **clinical impact** of the system applied to the diagnosis and treatment of bacteremia.

ADVANTAGES

TECHNICAL

- Fastest AST system : results in 3-5 hours
- High sensitivity and specificity
- Standardization and automation of analyses
- Full sample traceability
- Connection to LIS
- Easy to use
- CE marked

LAB WORK-FLOW

- Every morning the positive blood culture bottles can be tested immediately
- Reduction of hands-on-time by technicians
- Customizable panel of antibiotics

PUBLIC HEALTH IMPACT

- Promptly start the pharmacological therapy
- Monitor daily the patient
- Favor the resolution of the pathology in a short time
- Reduce hospitalization time
- Reduce the use of wide spectrum antibiotics
- Reduce the diffusion of resistant bacteria

Multi Drugs Resistant Microorganisms

MDROs are defined as microorganisms, predominantly bacteria, that are resistant to one or more classes of antimicrobial agents.

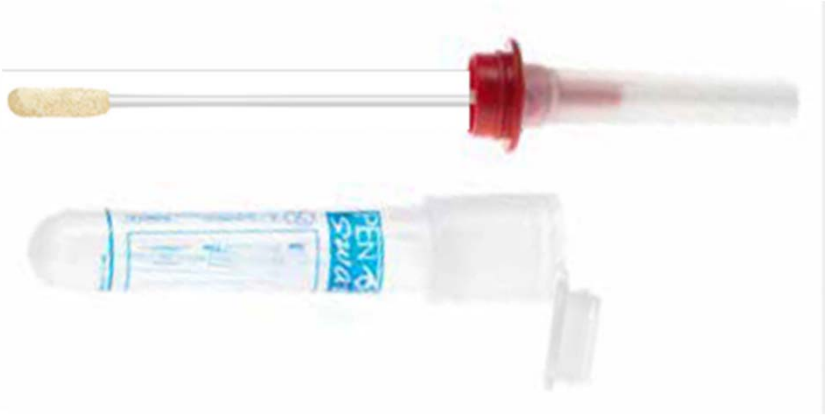
MDRO infections have clinical manifestations that are similar to infections caused by susceptible pathogens. However, options for treating patients with these infections are often extremely limited.

Highly resistant organisms deserve special attention in **healthcare facilities**.

Increased **lengths of stay, costs, and mortality** also have been associated with MDROs.

ALIFAX SOLUTION:
PENOK SWAB and MDRO KITs

First **MDRO screening** based on **phenotype culture method** with dedicated **PENOK SWAB** and **selective media**



HB&L MRSA SCREENING KIT
Methicillin-Resistant *Staphylococcus aureus*

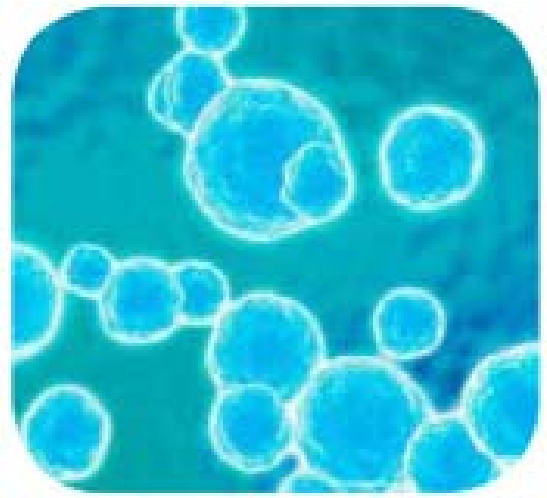
HB&L ESBL/AmpC SCREENING KIT
Extended-Spectrum ß-Lactamase producing bacteria

HB&L CARBAPENEMASE SCREENING KIT
Carbapenem Resistant Enterobacteriaceae

HB&L VRE SCREENING KIT
Vancomycin-Resistant Enterococci (soon available)

Specific broth for multi-drug resistant organisms

MRSA SCREENING



The problem

Some strains called **methicillin-resistant *Staphylococcus aureus* (MRSA)** have developed a resistance to beta-lactam antibiotics which are used in the treatment of numerous infections diseases and therefore difficult to eradicate.
MRSA is troublesome in hospitals where patients with a weakened immune system are more susceptible to infection than the general population.

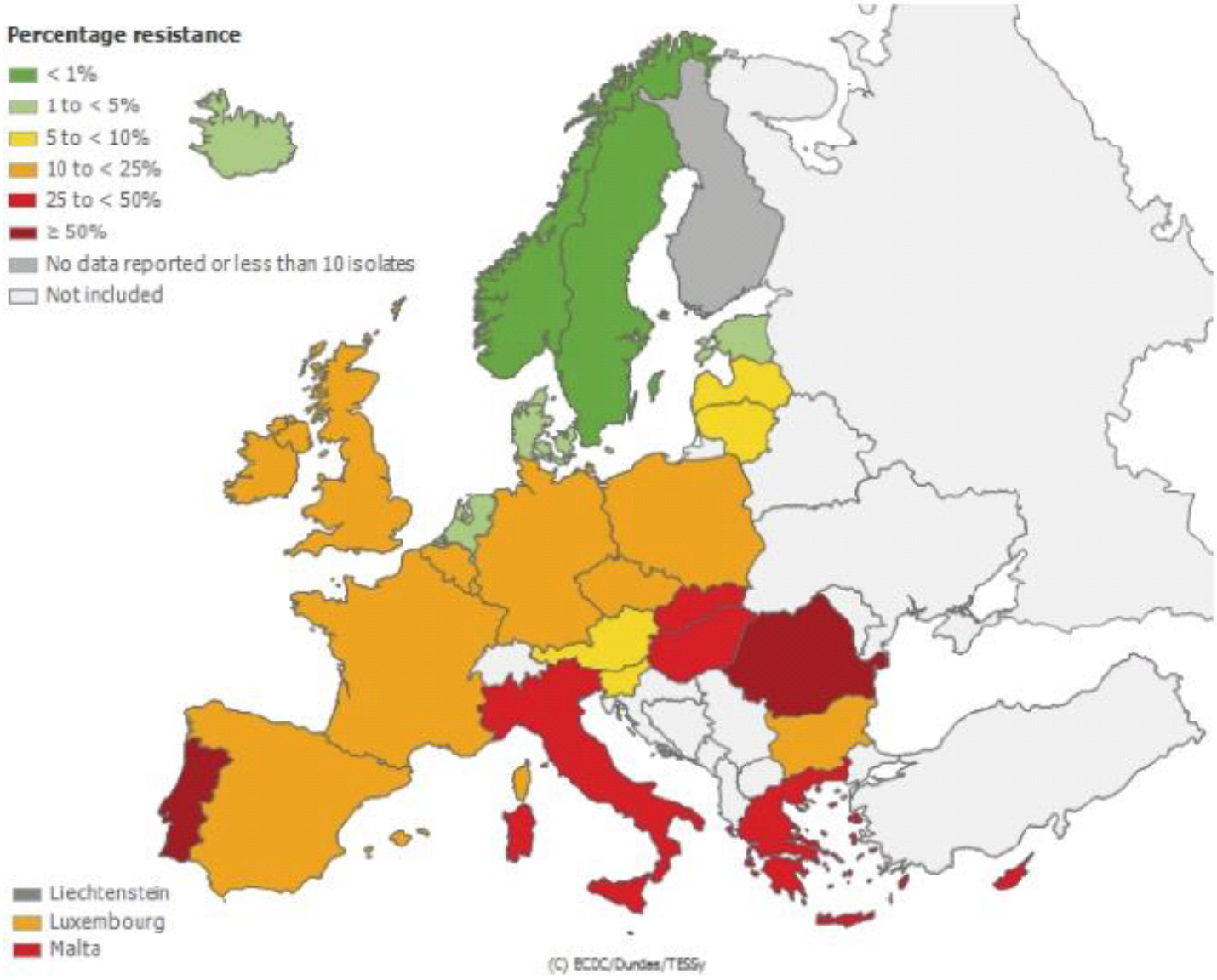
Classical tests

Culture on chromogenic selective media from nasal, throat, inguinal swab (direct or with enrichment) + **Confirmatory test**

Tourn Around Time

24h, 48h, 72h according to the method (direct or with enrichment)

MRSA-Epidemiology Europe 2011



MRSA SCREENING KIT PERFORMANCES

The results obtained in two independent evaluation studies show excellent agreement with conventional standard methods giving:

Specificity:	**100%**
Sensitivity:	**>89%**
Negative Predictive Value:	**100%**
Positive Predictive Value:	**>98%**

In both studies **65% of all positive samples** were detected within only **3 hours** and in **6,5 hours** **also the small count samples were fully detected.**

All the samples evaluated positive with the HB&L system were confirmed by coagulase test and the detection of specific protein PBP2a.

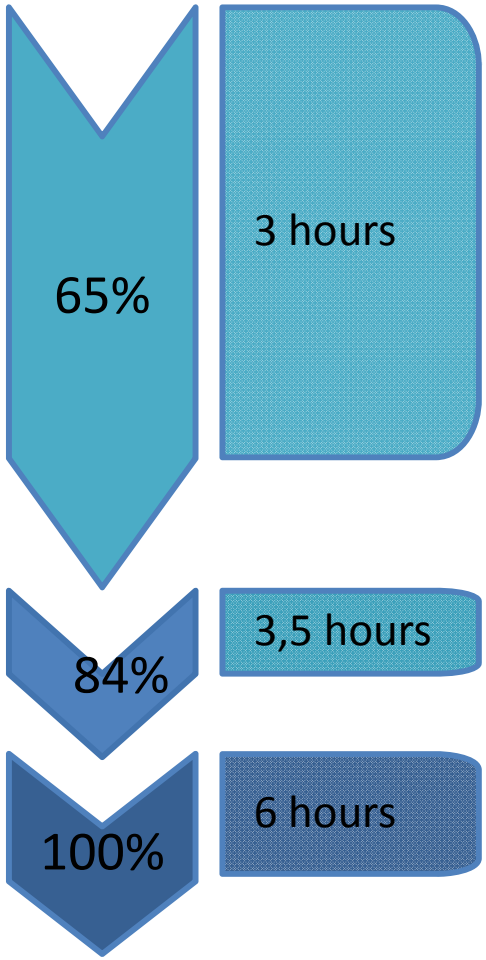
DOWNLOAD

BROCHURE

1- Urlich Weller U. Hämostaseologie Labor Boogen Köln Cologne (Germany) Private communication 2011.
2- Lampert M. MD Hetzelstift Neustadt Hospital laboratories (Germany). Private communication 2013

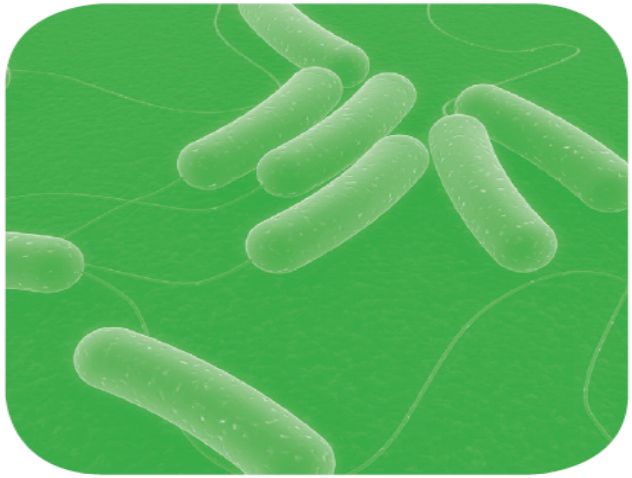
ALIFAX MRSA RESULTS 1 – 6,5 HOURS

Swab type	HB&L Bacteria growth	MALDI Result	Plate count	HB&L Incubation time for positive results
pharyngeal	15.000.000	MRSA +	++	**1h 10**
wound	12.000.000	MRSA +	++	**1h 20**
not specified	10.000.000	MRSA +	++	**1h 25**
wound	10.000.000	MRSA +	++	**1h 25**
wound	4.000.000	MRSA +	++	**1h 35**
pharyngeal	2.000.000	MRSA +	++	**1h 45**
wound	3.000.000	MRSA +	++	**2h 05**
nasal	700.000	MRSA +	enrichment	**2h 10**
wound	300.000	MRSA +	enrichment	**2h 20**
nasal	150.000	MRSA +	++	**2h 45**
wound	150.000	MRSA +	++	**2h 35**
pharyngeal	70.000	MRSA +	++	**2h 50**
nasal	50.000	MRSA +	enrichment	**2h 50**
wound	50.000	MRSA +	+++	**3h 35**
wound	30.000	MRSA +	enrichment	**3h 15**
cutaneous	15.000	MRSA +	+	**3h 10**
n.a.	7.000	MRSA +		**3h 30**
n.a.	1.500	MRSA +	++	**3h 50**
pharyngeal	250	MRSA +	++	**4h 25**
nasal	70	MRSA +	++	**4h 40**
inguinal	70	MRSA +	+	**5h 45**
n.a.	50	MRSA +		**6h 05**



1- Urlich Weller U. Phd and Boogen C. MD, Laboratoriumsmedizin, Hämostaseologie Labor Boogen Köln Cologne (Germany) Study about the performances of a New method: Light scattering rapid kinetic detection for MRSA Screening. Private communication 2011.

ESBL/AmpC SCREENING



The problem

Enterobacteriaceae spp. are one of the most important causes of nosocomial and community-acquired infections. Strong selection pressure exerted by antimicrobial use, especially with newer-generation ß-lactam antibiotics, has led to the proliferation of bacteria carrying enzyme able to hydrolyze and inactivate them.
The two main ß-lactamases present in Enterobacteriaceae spp. are the ESBLs and AmpCs.

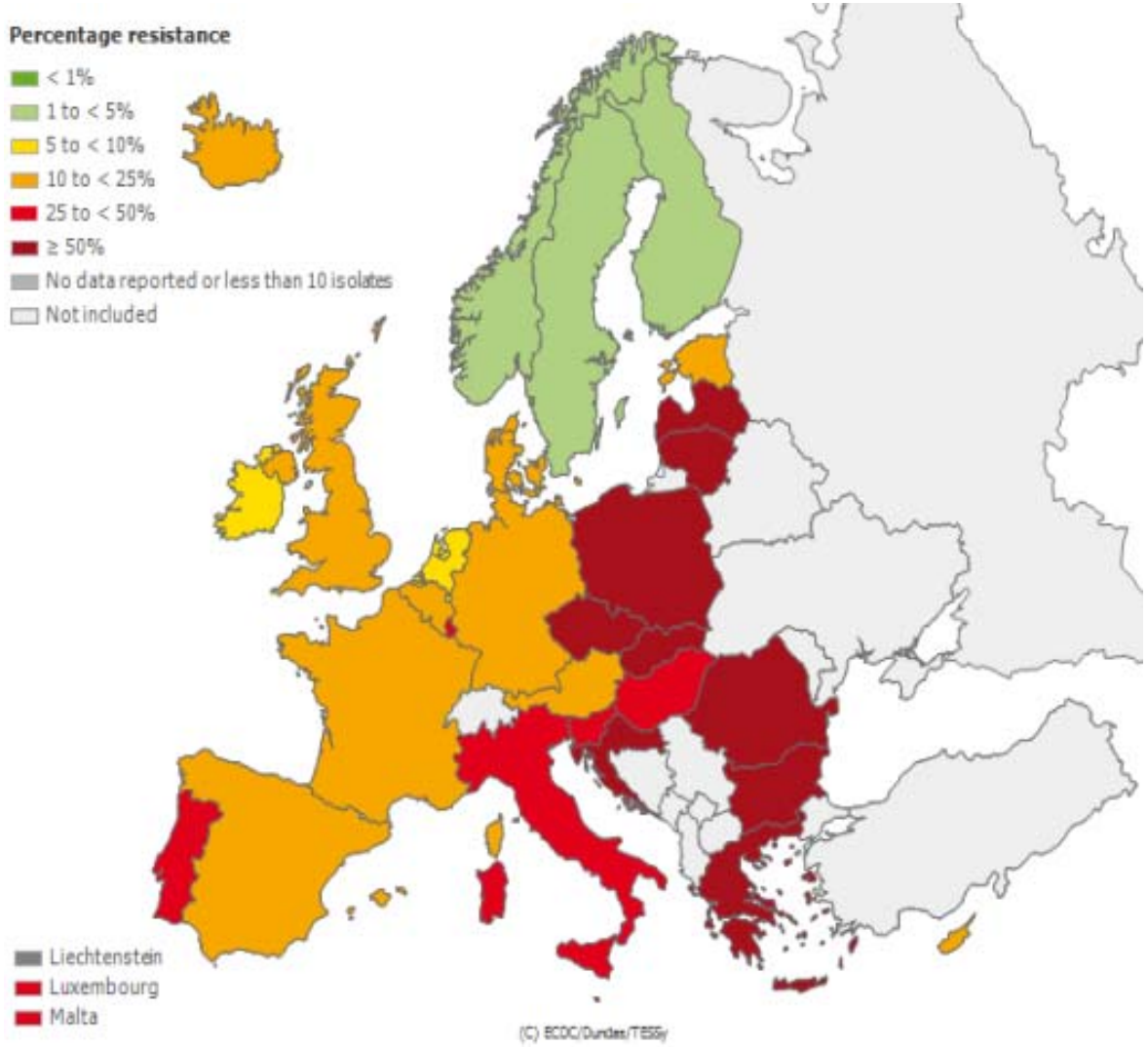
Classical tests

Direct Culture on selective chromogenic media from rectal swab+ **Confirmatory test**

Tourn Around Time

From **24 h to 48 h**

Proportion of 3rd gen. cephalosporins Resistant (R) *Klebsiella pneumoniae* isolates in participating Countries in 2012



ESBL/AmpC SCREENING KIT PERFORMANCES

The performances of HB&L ESBL/AmpC SCREENING KIT were evaluated by a study in a hospital clinical microbiology laboratory in Germany.

399 clinical double headed rectal swab samples, collected by Duo Transtube (MWE, REF MW 164) in the context of screening for ESBL/AmpC-producing *Enterobacteriaceae* spp., were tested.

The first swab has been used to inoculate the HB&L ESBL/AmpC SCREENING KIT vial, the second swab has been used to streak ChromID ESBL agar for **24 hours** and re-checked after **48 hours.**

Specificity:	**93.3%**
Sensitivity:	**94.5%**
Negative Predictive Value:	**99.7%**
Agreement:	**93.2 %**

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BROCHURE

Dott. Sabine Bessey Klinikum of Sindelfingen- Boblingen : Zentral Labor Private communication 2014

CARBAPENEM-RESISTANT ENTEROBACTERIACEAE SCREENING

The problem

Carbapenem-resistant Enterobacteriaceae (CRE) have emerged rapidly and extensively worldwide. Invasive infections with CRE strains are associated with high mortality rates (up to 40-50%) thus emphasizing the need for active surveillance programs aimed at preventing the spread especially in the hospital environment. These programs rely on early and accurate detection of aggressive pathogens resistant to the class of carbapenems such as imipenem and meropenem which are in many cases the last line of therapy for Gram negative infections.

Classical tests

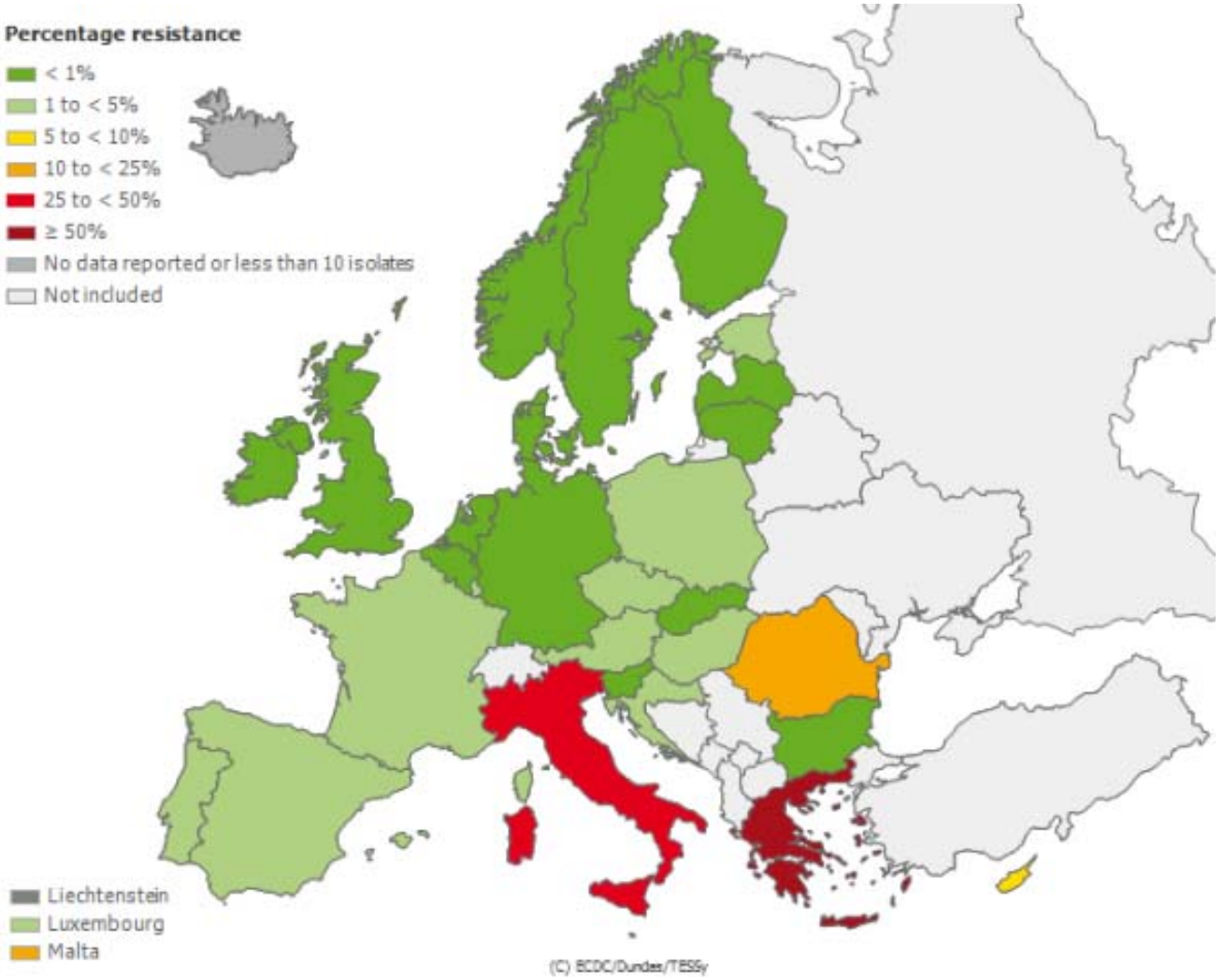
Routine method: Direct Culture on selective chromogenic Petri dish from rectal swab+ confirmatory test

Reference CDC Atlanta test: Enrichment + Culture + confirmatory test

Tourn Around Time

24 h, 48h, 72 h according to the method (direct or with enrichment)

Carbapenem Resistant Klebsiella pneumoniae



Proportion of Carbapenems Resistant (R+I) *Klebsiella pneumoniae* isolates in participating Countries in 2013

ALIFAX CARBAPENEMASE SCREENING KIT

Clinical evaluation of **371 rectal swabs** collected by liquid flocked swabs – Copan Σ swab HB&L Carbapenemase screening kit vs. Direct Culture of Carba /OXA Biomerieux Chromogenic plate (Routine method)

Specificity:	**96,66 %**
Sensitivity:	**98,82 %**
Negative Predictive Value:	**99.70 %**
Positive Predictive Value:	**87,87 %**
Agreement :	**98.65 %**

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BROCHURE

First Validation Study (July - December 2014) : Careggi Hospital , Microbioligy Institute Florence University . Prof. G. Rossolini , Arena , Giani

ALIFAX CARBAPENEMASE SCREENING KIT

Comments :

The 4 samples statistically considered as false positives (HB&L positive / chromogenic plates negative after the direct culture) resulted positive with the **CDC reference method** (culture on chorm-agar plate after 1 night enrichment) should be considered as **false negatives in chromogenic plates culture**

Conclusions :

The data of the study revealed that HB&L Carbapenemase Screening Kit is definitive more sensitive than chromogenic Plates cultures methods performed in routine

THE PERFECT MATCH OF A MODERN METHOD AND A CLASSIC TECHNIQUE FOR A UNIQUE, FAST AND COMPLETE SOLUTION

FEATURES	ADVANTAGES
HB&L CARBAPENEMASE KIT is the only phenotypic test that provides indications regarding CRE presence in a few hours with times comparable to those obtained with molecular techniques and performances superior to direct culture.	• Effective screening of carriers to prevent the microorganism spread • Patient management optimization • Therapy personalization • Patient daily monitoring
The bacterial suspension obtained at the end of the analysis is sufficiently enriched to perform further confirmatory tests through different techniques using the bacterial pellet as starting sample.	• Complete integration of Alifax technology with those already present in the lab to provide clinically useful results in short time and with high reliability
The association with ***Sidecar*** walk-away system allows the streaking of primary sample or enriched culture in total automation.	• Reduced workloads and hands-on time • Optimization of laboratory workflows • Analytical performance implementation through the optimization of the Centers for Disease Control and Prevention (CDC) pre-enrichment reference protocol

KOL Messages

Fabio Arena, PhD
Department of Medical Biotechnologies,
University of Siena,
Siena, Italy

AMCLI congress 2014

"Light scattering technology offers new interesting solutions for the screening of MDRO

In our first experience we evaluate the **Alifax CARBAPENEMASE SCREENING** kit against routine and CDC reberence methods obtaining good performace results.

Within **4 hours** the **61%** of the positive swab samples were correctly detected, without false positive results and with **timing comparable to the molecular method** but with the big advantage of being able to have **bacteria yield for further investigations** and subsequently [**with Sidecar system] isolated colonies on the petri dish**.»

DOWNLOAD

Last publications

CARBAPENEM RESISTANT BACTERIA SCREENING – Crocilla et al (Uni Torino, Italy) SIPMel 2015

DOWNLOAD

ALIFAX CARBAPENEM RESISTANT BACTERIA IN 6 HOURS VS CHROMOGENIC MEDIA 24 HOURS: QUICK RESULTS WITH HIGHER SENSITIVITY

In the study "***Klebsiella pneumoniae resistant to carbapenems: an emerging problem in public health***" **60 samples of rectal swabs** were tested in duplicate with Alifax **HB&L CARBAPENEMASE KIT** and the method of direct culture on chromogenic media with 24 hours incubation.

The HB&L system allows to obtain reliable results more quickly compared to the reference method used in the laboratory. In particular, the **negative samples were available after 6 hours of incubation** while **positive ones, detected after only 4 hours of incubation, were all confirmed positive** after subculture on chromogenic media and AST. **The concordance with the method in use was 100%.** Also one sample, with a low CFU/ml, **negative on plate and positive with HB&L system**, was **confirmed positive** at phenotypic test after subculture of the selective HB&L broth.

.

ADVANTAGES

TECHNICAL

- Fastest Cultural system: 6 h 30min
- Bacterial count of positive in CFU/ml
- High sensitivity and specificity compared to cultural method
- Fully automation analysis
- Real time detection of growth curves
- Connection to LIS
- Easy to use
- CE marked

LAB WORK-FLOW

- Results reported in 1 day
- Low price compared with molecular biology methods
- Bacteria yield from culture broth ready to be loaded on MALDI TOF or other automated systems for ID or antimicrobial susceptibility testing
- Method Standardization

PUBLIC HEALTH IMPACT

- Active surveillance of patients
- Reduce the diffusion of resistant bacteria
- Promptly start the pharmacological therapy
- Monitor daily the patient
- Favor the resolution of the pathology in a short time

INSTRUMENTS

HB&L UROQUATTRO

ALFRED 60

SIDECAR

VIDEO

Features

HB&L UROQUATTRO

- Light Scattering Technology
- Quantitative results expressed in CFU/ml
- Susceptibility testing with customised antibiotic panel
- Real time detection of bacterial growth curves
- Integrated turbidimeter with McFarland Monitor
- Single sample management with customised analysis profile: incubation time, analytical protocol, cut-off
- Continuous loading
- Automatic result reading and reporting
- Integrated thermal printer
- External Barcode-reader
- LIS bidirectional interface
- 37°C incubation
- Dedicated area for lyophilized bacteria reconstitution
- User-friendly software
- Customized reports
- Database for epidemiological studies
- Connection to Alfred 60^{AST} for increased capacity

DOWNLOAD

BROCHURE

HB&L: 120 positions
HB&L Light: 60 positions

Features

ALFRED 60

- Light Scattering Technology
- Quantitative results expressed in CFU/ml
- Automated susceptibility testing with customised antibiotic panels
- Refrigerated area at + 4°C for antibiotics and 0.5 McFarland positive sample storage
- Needle with capacitive sensor
- Check of correct vial loading for autobuffering function in the refrigerated area
- Real time detection of bacterial growth curves
- Integrated turbidimeter with McFarland Monitor
- Single sample management with customised analysis profile: incubation time, analytical protocol, cut-off
- Automatic reagent and sample dispensing
- Sampling with continuous loading of primary closed tubes
- Automatic result reading and reporting
- Built-in barcode reader for sample identification
- LIS bidirectional interface and Query Host application
- 37°C incubation
- User friendly software
- Universal rack that accommodate various tube sizes
- Use of closed tubes (in compliance with the law in force)
- Customised reports
- Database for epidemiological studies
- Connection to HB&L for increased capacity

DOWNLOAD

BROCHURE

New Washing System with Hypochlorite

Alfred Washing Kit (SI 105213)

New Software release

Alfred 60 AST: 60 positions

Connection with HB&L available

SIDECAR

FIRST AUTOMATED STREAKING SYSTEM INTEGRATED WITH THE RAPID BACTERIA CULTURE

The real walk-away system for rapid bacterial culture and plate streaking of liquid samples.
The system is composed of two units:
Alfred 60AST and **Sidecar**.
All the features of Alfred60AST are integrated in **Sidecar**, an automated **streaking system able to store 240 Petri dishes and up to 12 different media**.
The **streaked dishes are incubated on board at 37°C for the requested analysis time.**
In the main operating setting **only the positive samples are plated automatically.**

DOWNLOAD

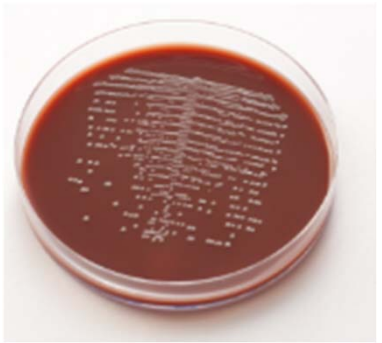
BROCHURE

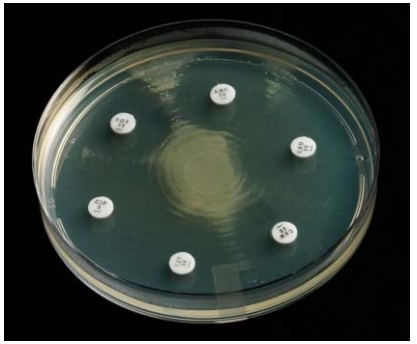
Sidecar: 60 positions
Connection with HB&L available

REAL WALK-AWAY SYSTEM

Features

- Light Scattering Technology
- Quantitative results expressed in CFU/ml
- Automated susceptibility testing with customised antibiotic panels
- Real time detection of bacterial growth curves
- Automatic reagent and sample dispensing
- Continuous loading of primary closed tubes
- Automatic results reading and reporting
- Built-in barcode reader for automatic sample identification
- LIS bidirectional interface and Query Host application
- Connection to HB&L for increased capacity
- Refrigerated area at + 4°C for the storage of primary samples, antibiotics and 0.5 McFarland positive samples
- Storage area for 240 petri dishes
- Up to 12 different culture media
- Incubator at 37°C for 240 petri dishes
- Automated labelling system for single plate
- Calibrated Loop automated sterilisation with heat before and after each streaking procedure
- Different streaking procedures
- Single sample management with customised analysis profile: incubation time, analytical protocol, cut-off and solid media selection
- Batch and expiry date management software
- User friendly software with touch screen
- HEPA filter



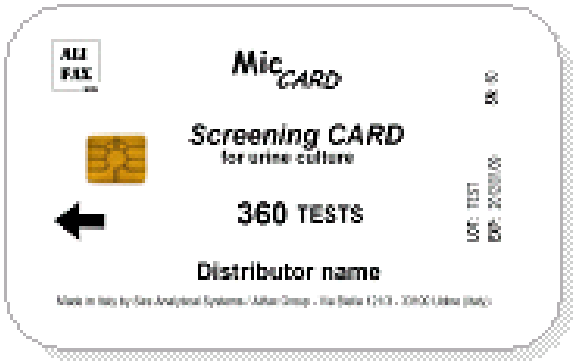

New Washing System with Hypochlorite
New Software release

CONNECTION WITH EXTERNAL HB&L TO IMPROVE THE THROUGHTPUT

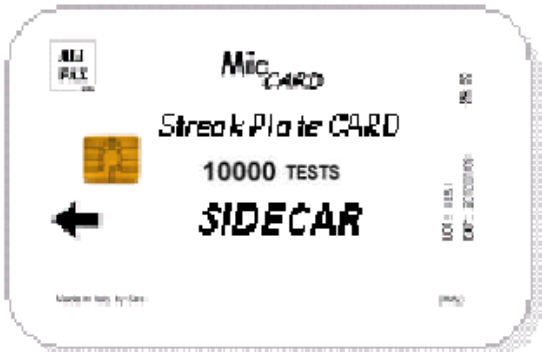
60 samples

Mic Card

- **NEW SMART CARD** for test loading to be used on ALFRED 60, HB&L and HB&L Light.
- The cards are customized with the name of one single owner.
- The new smart card application is available for HB&L and Alfred 60 instruments working with the Windows OS and requires the software release vs. 1.3.0 or above.

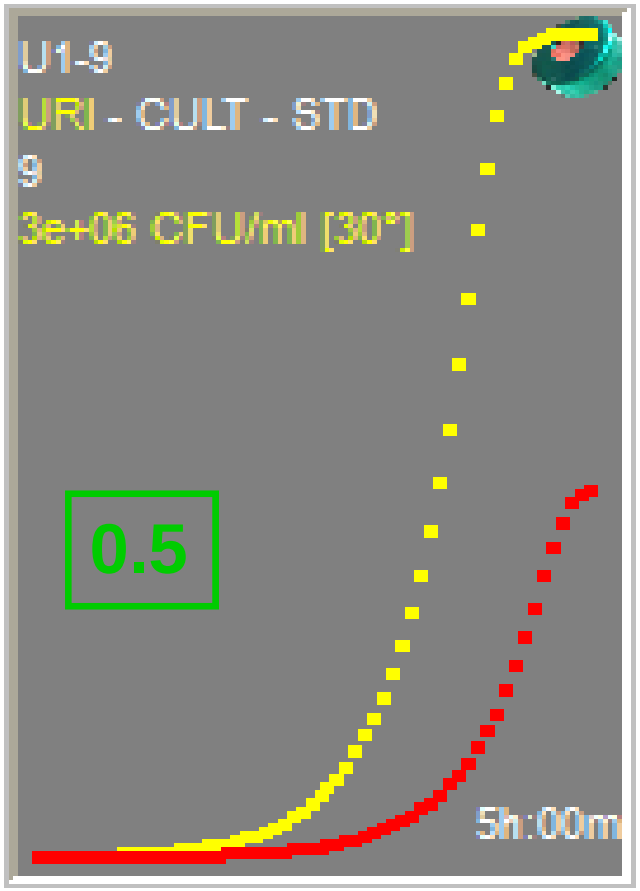


- **NEW STREAK PLATE CARD** for test loading on SIDECAR.
- The cards are customized with the name of one single owner.



lightscattering

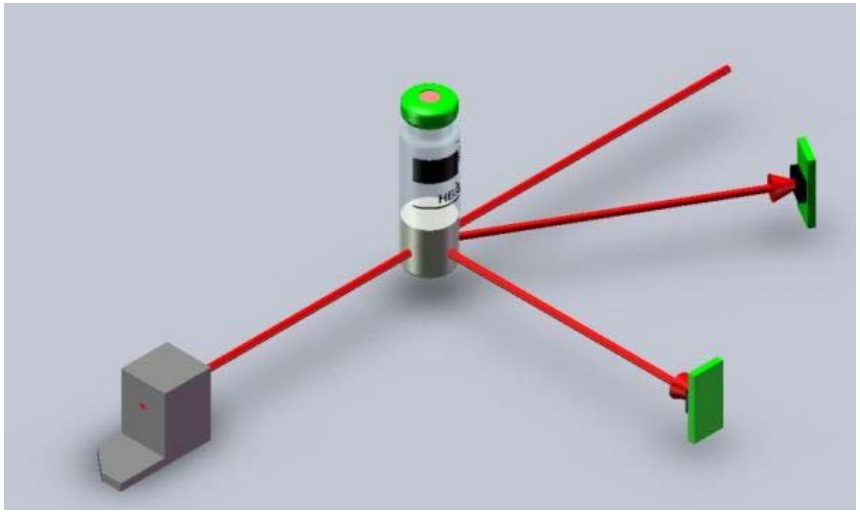
The patented light scattering based technology allows to follow the **growing bacteria** from the inoculum step in specific culture broths and to display the **kinetic growth curves** showing the bacterial count expressed in **CFU/ml**.

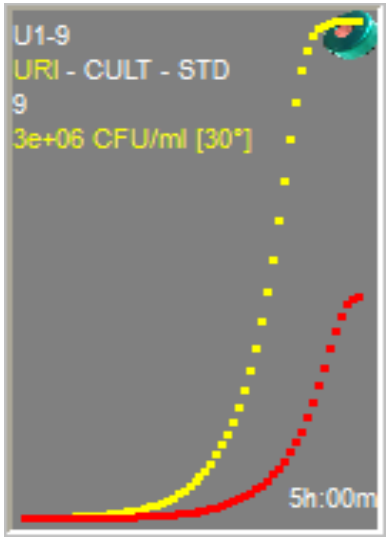


Patented Technology

The scattering signals are analysed, elaborated and converted into growing curves plotted in **real time**.

The mathematical elaboration gives not only a **qualitative evaluation of the micro-organism presence/absence** but also a **quantitative evaluation of initial bacteria amount expressed in CFU/ml**





kinetics growth curves of viable bacteria

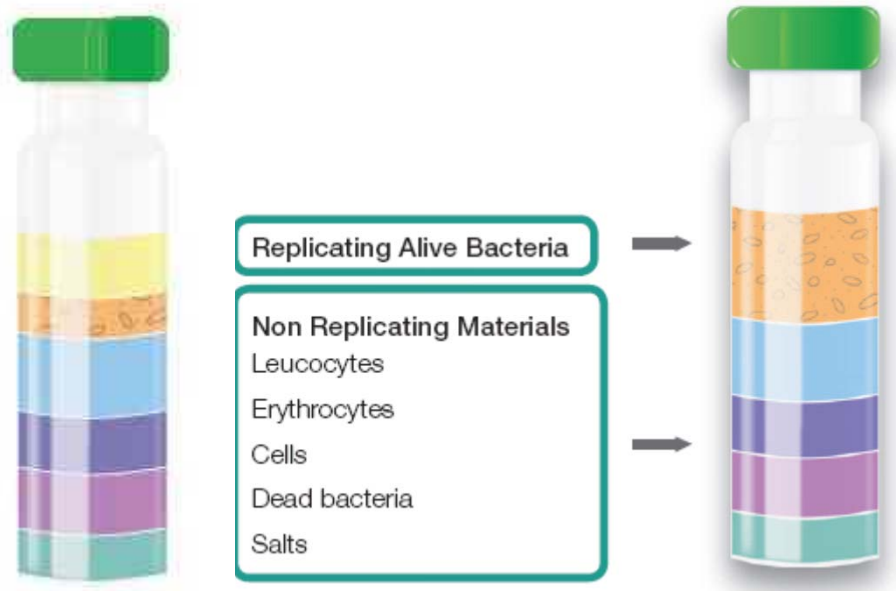
Culture Media: Alifax broths

- The **broth guarantees optimal conditions for the bacteria growth and nutrients availability**.
- specific broths were developed for all the **aerobic, anaerobic bacteria** and fungi in liquid samples.
- Broths are in **sterile vials with** pierceable cap**, thus** considerably reducing contaminations.

Only alive bacteria are detected

Samples are incubated at **37°C** and **constantly mixed** avoiding sedimentation, flotation and growth anomalies typical of several micro-organisms.

Only alive bacteria are detected while salts, erythrocytes, leucocytes, epithelia cells or dead bacteria signals are eliminated by the initial blank value reading.



The Fastest Cultural System

ADVANTAGES

- The strongly positive samples are flagged after only **45 minutes** from the analysis start.
- The **sensitivity threshold** can be customized according to the laboratory needs and type of sample.

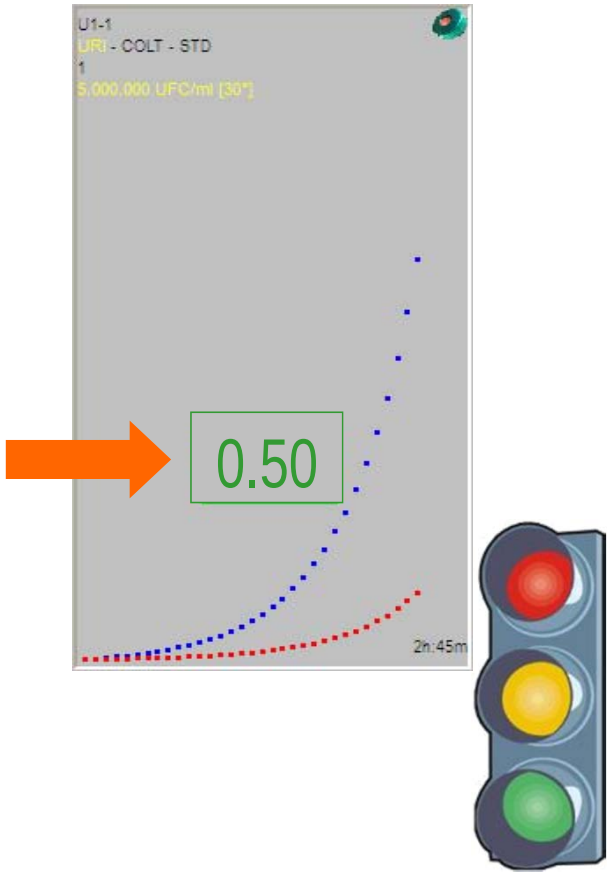
  for example:

  - 3 hours for 30.000 CFU/ml (i.e. external patient sample)
  - 4 hour for 1.000 CFU/ml (i.e. paediatric sample)
- Results are displayed in **real time**.

McFarland 0.5

The McFarland Monitor is an application that allows to monitor in real time the culture turbidity value during bacteria growing.

Audio and visual signals advise the reaching of the suitable bacteria concentration at **0.5 McFarland** to perform the **direct Antimicrobial Susceptibility Testing (AST).**



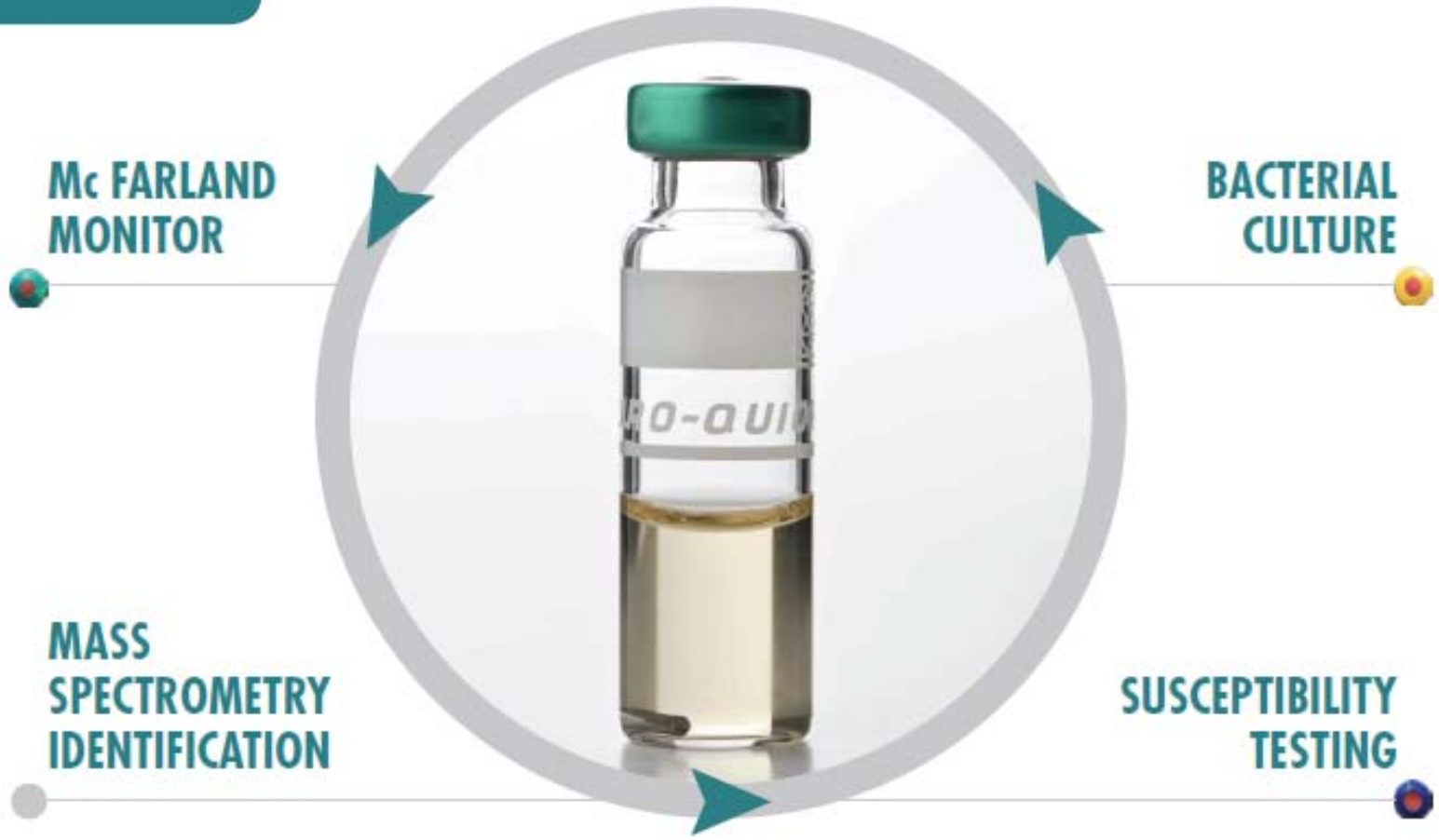
ADVANTAGES

1 test 2 results: **Urine culture result + 0.5 McFarland sample**

The positive sample can be immediately tested with a customized antibiotic panel following therapeutic treatment indications without waiting the analysis end and further dilution steps.

FULLY INTEGRATED TECHNOLOGIES

1 DAY RESULT



Technology integration

Biochemical test:
- **Coagulase test**
- **Oxidase test**
- **Catalase test**
- **Indol test**

MALDI ID

Other technoclogies?

DOWNLOAD

Doc 20

ENRICHMENT KIT - SI 405.915

New vial with **3,5 ml of culture media (BHI)** for the enrichment step developed in order to obtain enough volume of bacterial suspension from 1 drop of **positive blood culture** for further tests starting from **different McFarland values** (no CFU/ml will be displayed):

- Sidecar streaking on Petri dish
- Auto-buffering for Susceptibility test
- Bacterial suspension for MALDI ID

DOWNLOAD

BROCHURE

NEW SOFTWARE RELEASE FOR ALFRED60/AST AND SIDECAR

1- EXTENDED ENRICHMENT

"Extended Enrichment" is a procedure to monitor the growth of a bacterial suspension in vial according to its turbidity (McFarland levels) with the possibility to set different threshold in order to buffer and store different aliquots of the suspension to perform different tests

- 0.2 McFarland Sidecar streaking on Petri dish
- 0.5 McFarland: suspension for AST
- 1.0 McFarland: suspension for MALDI-ID

NEW SOFTWARE RELEASE FOR ALFRED60/AST AND SIDECAR

2- NIGHT SHIFT

"**Night Shift**" profile allows to perform the **enrichment** and the **susceptibility test** in automatic mode on biological samples.

It provides the automatic execution of the following operations:

- **Assignment of an antibiotic panel for Susceptibility Tests** (with the possibility to assign the profile also "on the run", this is even during enrichment phase) according with the Gram staining performed on the positive blood culture bottle
- **Enrichment** of the sample
- **Buffering of the enriched sample** into the Alfred's fridge zone (it requires fridge in hybrid configuration, or fridge in configuration for susceptibility test in case of Alfred stand alone)
- **Automatic execution of the susceptibility test depending from the antibiotic panel previously selected**.

Integration with MALDI-TOF references

DOWNLOAD

Blood culture

1. Kroumowa_MassSpec 2010
2. Cellinini ECCMID 2015
3. Fontana _AMCLI 2015

Human Biological Liquids

5. Tomei _SipMel 2015
6. Lilo ECCMID 2014

Urine samples

7. Weller ECCMID 2010
8. Weller ASM 2010
9. McConnell_poster_ICAAC 2014

QUICKEST AND EASIEST URINE COLLECTION DEVICE FOR TRANSPORTATION AND DIRECT USE ON ALIFAX AUTOMATED INSTRUMENTS

PENOK™

Urine Penok is the new CE marked device conceived to simplify the urine collection that can be performed directly by the patient.

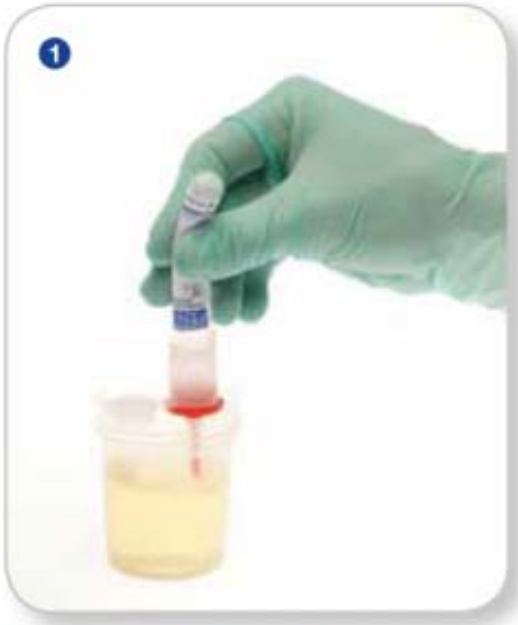
A simple press on the tube allows the sample aspiration and after the removal of the needle the so filled tube is ready to be sent to the laboratory and loaded onto Alifax instruments.

DOWNLOAD

BROCHURE

VIDEO

PENOK™



1. Squeeze PENOK and dip the top into the sample. Gently release the tube

2. Uncap lightly pressing the red beak

3. Close PENOK with the white cap

PENOK can be loaded directly into **Alfred 60^{AST}** or Sidecar sample rack for a fully automated analysis

Optional use of **PENOK** for rapid chemical analysis with urine strip

ADVANTAGES

TECHNICAL

- Economic
- Easy to use
- Easy to carry
- Patented
- CE marked
- Full sample traceability by unique and unrepeatable barcode
- Compatible with urine dipstick for chemistry analysis

LAB WORK-FLOW

- Direct loading into Alfred60AST and Sidecar with no need to open the tube
- Reduction of contaminations
- Reduction of technician handwork and exposition
- Petri dish streaking

PUBLIC HEALTH IMPACT

- The sample collection can be performed directly by the patient
- One single tube for multiple tests

Unique Swab CollectionDevice

PENOK SWAB is the new patent-pending device for the collection of samples with new **Σ-SWAB®***, an open-celled foam-tipped swab.

It's been designed for the **multi drug resistant microorganisms screening on the Alifax automated systems**

PENOK SWAB can be also used as a classical dry swab for conventional routine bacteriological investigation as Gram staining, culture and molecular test.

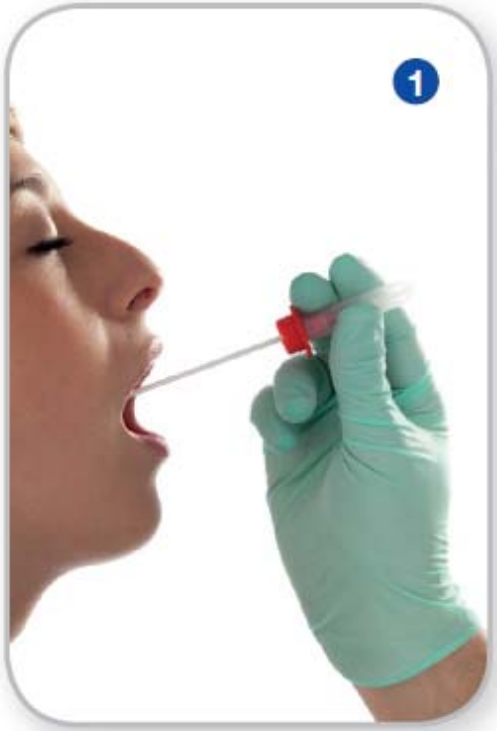
DOWNLOAD

BROCHURE

VIDEO

* Σ-SWAB® is a registered trade mark of Medical Wire – Corsham, UK

1 - SAMPLING



1. Use the PENOK SWAB for the sample collection

2. Insert the PENOK SWAB in the tube

Under Validation Process

2A – USE IN COMBINATION WITH ALIFAX MDRO SCREENING KIT

3. Aspirate the selective broth media

4. The media passes through the SWAB to enhance the release of bacteria into the broth

5. Close the tube with the cap

PENOK SWAB can be loaded directly into **Alfred60^{AST}** or **Sidecar** sample rack for a fully automated analysis of up to **60 samples**

Specific broth for multi-drug resistant organisms

HB&L MRSA SCREENING KIT Methicillin-Resistant *Staphylococcus aureus*
HB&L ESBL/AmpC SCREENING KIT Extended-Spectrum ß-Lactamase producing bacteria
HB&L CARBAPENEMASE SCREENING KIT Carbapenem Resistant Enterobacteriaceae
HB&L VRE SCREENING KIT Vancomycin-Resistant Enterococci (soon available)

2B – CLASSICAL DRY SWAB USE

PENOK SWAB
can be used as a classical dry swab for Gram staining, Petri dish streaking culture and molecular test

ADVANTAGES

TECHNICAL

- 24-48 hrs viability at room temperature for many microorganisms and 24 hrs at 4°C for fastidious bacteria without media
- High absorbency
- Open cell for complete flow through medium and reagents
- Maximum release of microorganism (>81% release)
- Easy to use
- Easy to carry
- Patented
- CE marked
- Full sample traceability

LAB WORK-FLOW

- Direct loading into Alfred60AST and Sidecar with no need to open the tube
- Reduction of contaminations
- Reduction of technician handwork and exposition
- Petri dish streaking

PUBLIC HEALTH IMPACT

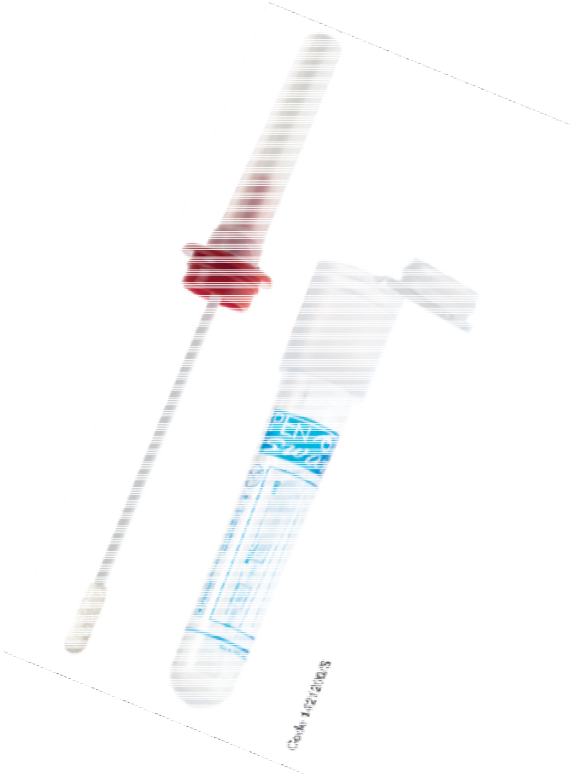
- Easy sample collection

VIDEO

SIDECAR

PENOK™

PENOK SWAB



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