

HUMAN BIOLOGICAL LIQUIDS CULTURE

Improving the inpatient diagnostic management to reduce hospitalization time, diagnostic analysis requests and therapeutic treatments



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.

LIGHT SCATTERING TECHNOLOGY APPLIED TO BACTERIAL CULTURE

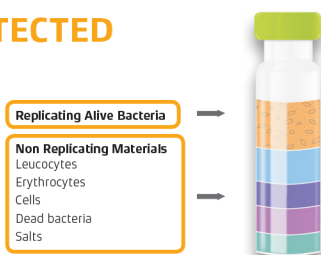
- 1 **Sidecar, Alfred 60/AST** and **HB&L** are the first automated systems for the rapid culture with high **sensitivity** and **specificity**^(2,3).
- 2 Using the patented technology based on **light scattering** they are able to monitor the intense bacteria replication activity from the inoculum step into specific culture broths providing real time growth curves.
- 3 Quantitative **bacterial count results** are reported in **CFU/ml**.
- 4 Due to the optimization of the broth it is possible to perform the bacterial culture in **sterile** and **non sterile** endocavitary samples such as respiratory fluids, cerebrospinal fluid and pleural fluid offering a **sensitivity of 1 CFU/ml in 6 hours**.
- 5 **Enhanced liquid culture media combined with a specific supplement (DEB)** has been developed to detect **aerobic bacteria** and **fastidious micro-organisms** such as *Haemophilus influenzae*, *Neisseria meningitidis* as well as samples characterized by extremely low bacterial counts.
- 6 Broths are in **aseptic vials** with pierceable **screw cap**.
- 7 Samples are incubated at **37°C** and **constantly mixed** avoiding sedimentation, flotation and growth anomalies typical of several micro-organisms.
- 8 **Only live bacteria are detected** while interference from non replicating substances such as erythrocytes, leucocytes, dead cells and salts present in the sample are eliminated during the initial zero reading.



HB&L™ CULTURE KIT Code SI 405.901
HB&L™ DEB KIT Code SI 705.901
HB&L™ ENRICHMENT KIT Code SI 405.915

IVD CE MARKED

ONLY LIVE BACTERIA ARE DETECTED



Applications

Non sterile

Expectoration
Orotracheal aspiration
Bronchoalveolar lavage

Sterile

Cerebrospinal fluid
Pleural fluid
Synovial fluid
Ascitic fluid
Peritoneal fluid
Central Venous Catheter tips
Cornea transport and storage media

Each fluid is individually CE marked

PERFORMANCE IN DIFFERENT PUBLICATIONS

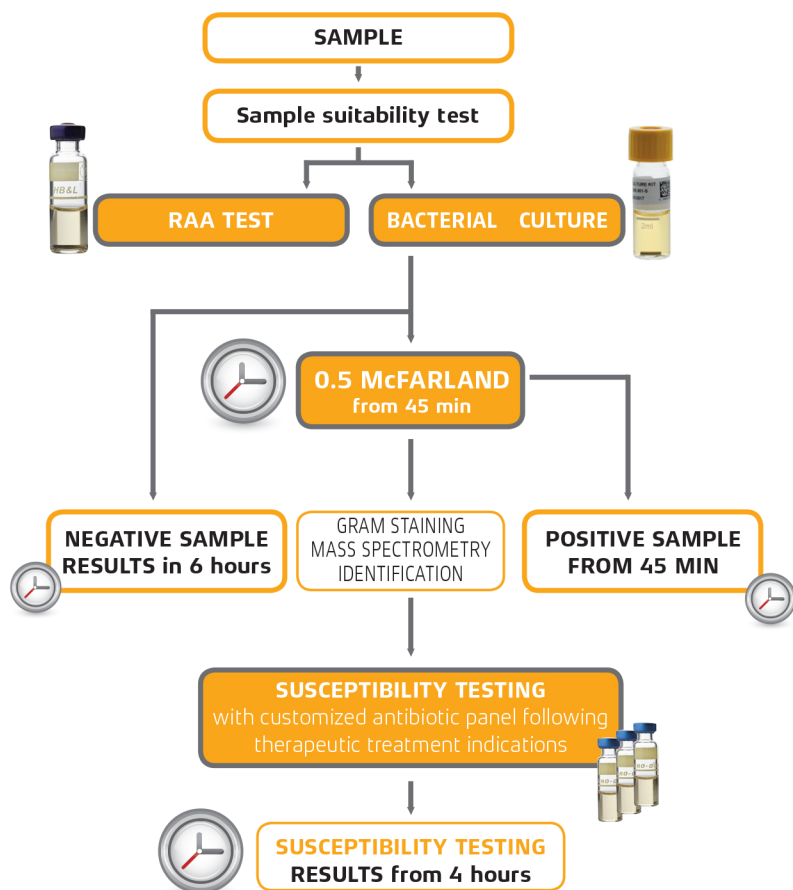
Author	Year	N° samples	Sensitivity %	Specificity %	PPV %	NPV %	Agreement
Rif 2	2009	546	100	100	100	100	100
Rif 3	2010	322	97,2	100	100	99,9	98
Rif 6	2013	10655	95,5	99,9	96,2	99,8	98

The results obtained by many studies conducted at in different reference centres 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”⁽¹⁾**.

Not for sale in U.S.

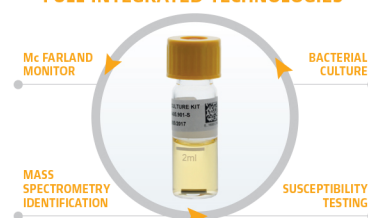
Due to regulatory requirements, the products listed herein are available for sale in any relevant Country territory provided that they have been registered according to the applicable domestic law. The products listed herein may have incurred changes with respect to the last available edition.

HUMAN BIOLOGICAL LIQUIDS CULTURE



1DAYRESULT

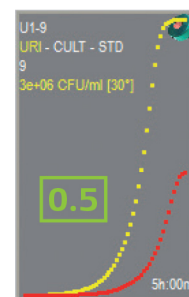
FULL INTEGRATED TECHNOLOGIES



McFARLAND MONITOR

The McFarland Monitor is a new instrument application that monitors the turbidity levels of positive samples during the bacterial culture test.

A visual and audible alert advises the Operator when the sample reaches the suitable bacteria concentration at 0.5 McFarland to perform the direct susceptibility testing.



Advantages

1 test 2 results:

Bacterial culture result + 0.5McFarland 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.
- The use of a bacterial culture in a logarithmic phase reduces the stress conditions and the mutations that could occur when bacteria reach the stationary phase.



HB&L™ CULTURE KIT Code SI 405.901

60 Disposable yellow screw cap glass vials with broth culture and D2 barcode
1 Mic CARD

SHELF LIFE

From production: 14 months

STORAGE CONDITIONS

Room temperature (+4÷30°C)



HB&L™ DEB KIT Code SI 705.901

Culture supplement for human biological liquids

8 Vials Reagent A b-NAD
1 Vial Reagent B
8 Disposable droppers for reconstituted reagent A
20 Blotting paper strips
45 Disposable tips

SHELF LIFE

From production: 8 months +2÷8 °C
From reconstitution: 1 months at +2÷8 °C

STORAGE CONDITIONS

Refrigerated temperature (+2÷8 °C)



HB&L™ ENRICHMENT KIT Code SI405.915

60 Disposable orange screw cap glass vials with 3,5 ml broth culture.
1 Mic CARD

The high volume of culture broth allows the collection of different bacterial suspension aliquots to perform further tests and subcultures

SHELF LIFE

From production: 14 months

STORAGE CONDITIONS

Room temperature (+4÷30°C)

NEW APPLICATIONS

FOR HB&L™ CULTURE KIT SI 405.901 has been validated also to test microbiological suitability of substances, preparations or formulations produced using aseptic procedures.

Related Kit

HB&L™ R.A.A. kit- Code SI 605.901

Bibliography

- Fontana C. et al. "Coltura ed arricchimento dei campioni biologici liquidi: utilizzo routinario dell'Uro-Quick (Alifax)", SIM National Congress, Milan, 26-30 October 2004.
- Fontana C. et al. "A novel culturing system for fluid samples" Med Sci Monit, 2009 15(2): BR55-60
- Tessari A. et al. "Evaluation of the Uro4 HB&L system for the rapid diagnosis of lower respiratory tract infections in intensive care units" J Microbiol Methods. 2010 Jun;81(3):235-9
- Fontana C. et al., "Improved diagnosis of central venous catheter-related bloodstream infections using the HB&L UROQUATTRO™ system" Eur J Clin Microbiol Infect Dis. 2012 Jun 27
- Ronca A. et al. "Evaluation of HB&L system for the culture of prosthetic and osteoarticular origin samples" Microbiologia Medica, Anno 2010, Vol. 25, N° 2, 108-109
- Lanzafame P. et al. "Assessment of a light-scattering system in the culture screening of biological fluid samples" Trends in Medicine, July 2011 Vol. 11, N° 3 125-129
- Camposampiero D. et al. Evaluation of the HB&L System for the Microbiological Screening of Storage Medium for Organ-Cultured Corneas, Journal of Ophthalmology Volume 2013