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2014**

BIOFOOD

THE INTERNATIONAL NEWSLETTER FOR BIOMERIEUX **FOOD DIAGNOSTIC** PARTNERS



**BIOMÉRIEUX
RISES TO THE CHALLENGE**

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BIOMÉRIEUX
INDUSTRY

PIONEERING DIAGNOSTICS



Nicolas Cartier

Corporate Vice-President,
Industrial Microbiology

Dear bioFood Readers,

With the internationalization of trade, the increased need of food production, modification of eating habits, a regulatory environment that is increasingly becoming more stringent and geographically diverse, the emergence of new pathogens, ...: The world of the food industry is changing totally. Moreover, the level of knowledge and especially, the legitimate requirements of consumers make food safety a top priority in many countries. Recent political guidelines emerging from major nations such as the United States (Food Safety modernization Act – FSMA 2011) and China (new Food Law – draft 2014) on food safety are the best examples.

Aware of these deep changes and of new needs linked to them, our challenge is to support you in your objectives aimed at ensuring the perfect quality of your analyses and products, and to also become your partner for the improvement of efficiency of your laboratory, as well as your plants.

Editorial

BIOMERIEUX RISES TO THE CHALLENGE

FOR 50 YEARS, BIOMERIEUX HAS BEEN ACQUIRING HIGH-PERFORMING BIO-INDUSTRIAL ASSETS AT THE CUTTING-EDGE OF INNOVATION

Today, bioMérieux includes 19 industrial sites in nine countries and, in this issue, we propose you a visit of the manufacturing plant located in Marcy l’Etoile (France), mostly dedicated to the reagents used by the automated VIDAS® system.



This network allows bioMérieux to provide products that comply with the most stringent international regulations and meet the highest quality standards, to customers throughout the world

Launched in 1991, *Vidas* rapidly became a great success. With approximately 31,000 instruments used by clinical and industrial professionals, VIDAS® accounts for the largest installed base of immunoassay systems in the world and is a global reference for industrial diagnostics.



A proven solution for more than 20 years to serve the food safety.

FOCUS on Marcy L’Etoile

Occupying a site of over 11 hectares, bioMérieux started its headquarters in 1963 where 1,300 employees currently work. In addition to the global and support functions and the Research and Development laboratories, **it is here that the VIDAS® reagents (spr, strips and vials) used on the VIDAS® automated immunoassay systems are manufactured.**

Our presence in over 150 countries, our daily contacts with professionals in all sectors, our involvement in professional associations and authorities with international dimension (IAFP, GFSI, ISO, ...) helps us to get a better understanding of the worldwide issues in food quality and safety.

With of over 50 years of experience in microbiology and in synergy with the know-how of the AES CHEMUNEX employees recently integrated into our group, bioMérieux offers proven analytical and innovative solutions "from sample to result, for a decision with confidence".

It is a great pleasure to send you the 8th issue of our bioFood newsletter.

Herein, we wish to inform you of news of our Group, with a special focus on the manufacturing of VIDAS[®] reagents. The VIDAS[®] analyzer, is an internationally recognized platform and we have just celebrated the 20th anniversary for the "detection of food pathogens" applications.

We would like to thank you again for your confidence in bioMérieux.

Please enjoy reading!

ANALYTIC PERFORMANCE IS BIOMERIEUX'S CORE OBJECTIVE

QUALITY ASSURANCE

The site at Marcy l'Etoile employs over 20 people dedicated to the implementation, management and development of the Quality management system. It is certified ISO 9001:2008, quality management and customer satisfaction; ISO 13485:2012, specific to medical devices and 21 CFR part 820, standard from the Food and Drug Administration (FDA) that complies with the best practices for manufacturing medical devices.

This manufacturing facility hosts visits from certification and regulation bodies and indeed our clients multiple times per year.

VIDAS[®] reagents, dedicated to food testing and veterinary products, are produced under the same stringent quality and control rules as the In Vitro Diagnostic (IVD) products within the same bio-industrial center of expertise.

THE QUALITY CONTROL LABORATORY

To insure that the lots are in conformity with the specifications, the production steps are validated and each lot is tested by the teams from the Quality Control (QC) laboratory divided into three separate laboratories:



The site received in 2013 its "Letter of Conformity"

In 2013, the site successfully received its "Letter of Conformity" which attests that it conforms to Sedex Members Ethical Trade Audit (4-pillar SMETA), the reference standard for ethical trade. The 4-pillars are essentially based on four key areas: Labour standards, Health and Safety, Environment and Business ethics.

This certification is part of bioMérieux's effort towards societal and environmental responsibility.



The Q.C.

- > 8 teams with 5 dedicated for VIDAS[®] instrumentation and one P2 laboratory
- > + 75 dedicated personnel
- > + 600 control processes
- > 450,000 tests per year on the VIDAS[®] analyzer

- ➡ Preparation of the biological tools used for controlling the reagents (standard solutions, preparation of strains, sera, ...)
- ➡ Control of raw materials, individual control of the spr, strips, vials in term of homogeneity and stability, define standard and control thresholds and manufacture the Master Lot Entry data (MLE)
- ➡ Release of the finished products and support to clients



EVERYONE IS COMMITTED TO CONTINUOUS IMPROVEMENT

Continuous improvement of our performance is achieved through the implementation of corrective and preventive actions and also by the daily commitment of our employees whose expertise and trend analysis capabilities provide solutions to optimize their work. As evidence of their involvement, 1,405 ideas were received in 2013 from which 1,048 were selected and 84% of these were implemented.

A CONSTANTLY EVOLVING MANUFACTURING FACILITY

The innovation process does not stop once a product has been launched. It is also present at each production step and in each profession. bioMérieux's production experts are always looking for technical optimizations to constantly manufacture the highest quality product, with a quick release while ensuring a reduction of its environmental footprint.

The VIDAS® range shows a dynamic growth with even more innovative products. That is the reason why **Marcy l'Etoile's site is continually adapting.**

Sign of success for the VIDAS® range was **an extension of the VIDAS® production building** completed at the end of 2013 (more than 600 m²) to increase the capacity by 50% while optimizing the ergonomics of some workstations.

Machines are regularly renewed to improve productivity, reliability and flexibility, to increase employees safety and also to adapt to the technological evolution brought by the new parameters developed.

For example, freeze-dryers, used to manufacture control vials and calibrators as well as culture media supplements, were replaced to better control and increase the robustness of the freeze-dryer cycles.



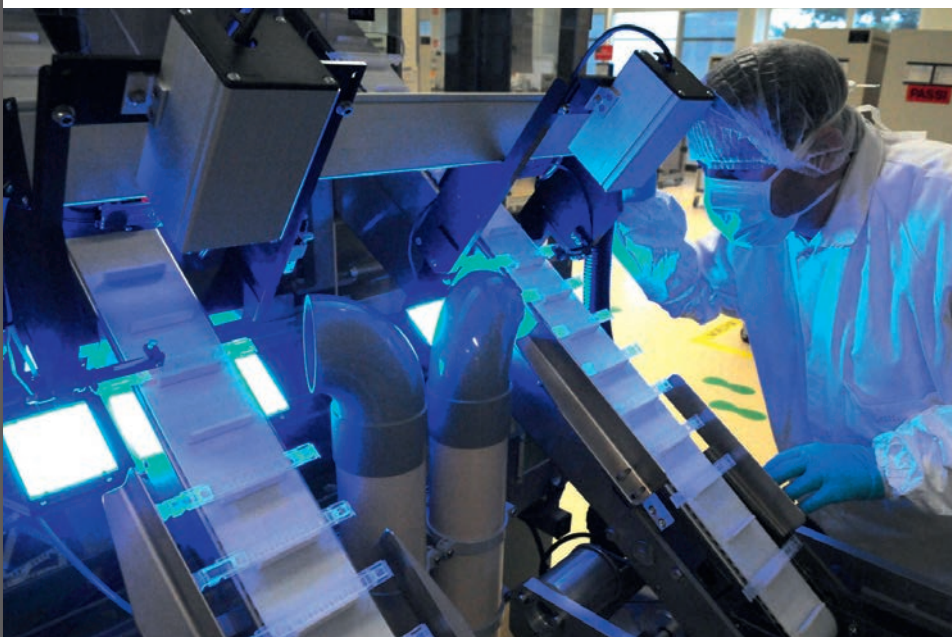
Thus, equipped with the most advanced systems, the site is significantly reducing its energy and water consumption. These developments to reduce the environmental impact are included in the **"bioMérieux goes green"** environmental program, initiated by bioMérieux in 2008.



In the same way, to optimize their consumption of energy, the Industrial Cleaning department invested in a new, high performance, high capacity washing-machine, reducing very significantly the number and duration of cycles. The result was an annual saving in the consumption of water (-76%), detergents (-62%) and neutralizers (-68%). With its motorized loading carriage, an

operator's work is greatly facilitated. The installation of this new equipment totally complies with our environmental policy's specifications.

Technology, robotics and automation are present at every stage of our production lines but it is men and women at bioMérieux who make and will always continue to make the difference. Through their knowledge and their expertise, at every step of manufacturing, they invent and improve their tools, day after day, to deliver quality reagents that contribute to food safety all over the world.



AN EXAMPLE OF PARTNERSHIP: THE CHINA MENGNIU DAIRY COMPANY

One of the world's leading dairy product manufacturers in China chose Chemunex® for the fast release of its UHT milk.

With demand for high quality dairy products rising, the Group has expanded its production capacity and implemented BactiFlow® ALS rapid microbiological analyzers to meet the requirements of the market.

INTERVIEW WITH MRS LI, QUALITY DIRECTOR FOR MENGNIU DAIRY GROUP

Q: what were the reasons for Mengniu Company to integrate a rapid microbiology system for its quality control process?

A: Partly because of the new regulation implementation and partly because of our wish to reduce the release time from the current 7-10 days down to 3 days. In addition, we wanted to improve the lab efficiency and testing accuracy by using automated analysis instruments.

Q: Why did you decide to introduce bioMérieux's BactiFlow® ALS systems?

A: We wanted the rapid method to meet the following requirements:

- A rapid Time to Result
- Accuracy > 99.5% compared with GB4789 (China traditional culture media plate method)
- False negative at 0%
- Reproducibility > 99.5%
- High throughput
- Compatible with different products: UHT white milk, flavored milk, milk beverage, yoghurt, process water, etc.

A comparison of seven different methods available on the market showed that BactiFlow® ALS automat was the best choice for us.

Q: Which aspects were considered during the decision-making process? In which step of the production sections does BactiFlow® ALS analyzer have the greatest advantage?

A: We have now installed 23 BactiFlow® ALS units in our group. The most important thing for us is the regular supply of reagents and the quality of after-sale service. Now we are using the BactiFlow® ALS analyzer to test UHT milk and release the finished product according to the test results. So the testing itself, actually, is part of our production process.

In the future, we will also start to investigate the opportunity of using BactiFlow® ALS analyzer to test Yoghurt products.

Q: How does this method influence the product release?

A: Previously, we used traditional plate methods, we needed 5 days pre-incubation and 2 further days for the plate method. By using BactiFlow® ALS system, we only need 3 days, thus it saves at least 4 days for us to release our products from the warehouse into the market for sale. This means our company can significantly increase its cash flow, after all, we have many sites and the total volume of UHT milk in our company is the largest.



Q: Was a classical culture media method also applied in parallel?

A: During our evaluation we used different strains to compare BactiFlow® ALS analyzer and the culture media plate, and we did not see any significant difference.

During the installation in the sites, in the first weeks, we still carried out tests in parallel but after continuous proven equivalence between the two methods we now just rely on BactiFlow® ALS analyzer without the culture media plate method.

Q: Do you see advantages of this new method only for Quality Control or are there other advantages for your group?

A: As we can now reduce the inventory, increase the cash flow and prolong the time of products on the shelf, BactiFlow® ALS analyzer has strengthened our company's competitiveness in the market.

As I said, thanks to the Chemunex® technology, it is not only a testing method but a part of our production cycle and supply chain.



THE VIDAS® ANALYZER IN BRAZIL



Organizing and hosting a mass event such as the Football World Cup or the Olympic Games is not just building stadiums, remodeling airports, improving transportation and safety, it is also to ensure the security of all participants.

Food safety is a part of it which involves the producers, consumers and health authorities

Brazil, having hosting the 2014 Football World Cup, considered it as a major priority. It was estimated that approximately 600,000 international tourists would have visited the country during this period, and that 3 million Brazilians would have circulated between the different centers. Added to these figures, the volunteers, police, and all others that were in the backstage involved in the organization, it was a huge number of vulnerable souls. Health authorities in Brazil tried to organize everything to mitigate health problems linked to food-borne diseases (FBD). They inspected restaurants, trained food handlers, intensified inspections and prepared the official labs by buying equipment and updating workers in new technologies. A number of them chose the VIDAS® solution to prevent and control the FBD.

BIOMERIEUX RISES TO THE CHALLENGE: AES Blue Line™ LAUNCH

COMBINED EXPERTISE OF AES AND BIOMÉRIEUX COMPANIES IS AVAILABLE WORLDWIDE

AES Chemunex and bioMérieux Laboratories merged on the 31st December 2013 in order to provide a global and consistent worldwide offer from sample to decision. The "historical" range from AES, commonly called the "Blue Line" is now marketed under the name "AES Blue Line™" in all countries where bioMérieux is present, currently 150 countries including 41 subsidiaries.

LAUNCH OF A NEW TRADEMARK: AES Blue Line™

The new trademark, AES Blue Line™, includes instruments such as Dilumat™, Smasher™, Masterclave® and APS One. This AES range is fully integrated into bioMérieux's global offer.

Performance, flexibility and ease of use are now accessible to all food professionals and contract labs.

The combination of AES and bioMérieux's expertise in microbiology provides a high level of advice and services helping laboratories to optimize their organization to improve their effectiveness (Workflow audit -LEAN management).

Today, bioMérieux does not only market products and services but provides a real partnership with its customers all the way through to the results and productivity performance.



Automated Solutions
from Sample
to Decision

FOOD SAFETY
DECIDE WITH CONFIDENCE

ISO AND CEN STANDARDIZATION COMMITTEES - FOOD MICROBIOLOGY - HIGHLIGHTS*

The 2 structures (the European Committee for Standardization (CEN) & the International Organization of Standardization (ISO)) in charge of standardization in the Microbiology of the Food Chain, at international and European levels, ISO/TC 34/SC9¹ and CEN/TC 275/WG6² have had their annual meetings from 23rd to 27th June 2014, in Washington DC, hosted by USDA (U.S. Department of Agriculture), invited by the US mirror committee.

About 50 participants coming from 9 different European countries, as well as Australia, Canada, Egypt, Korea, Japan, Tanzania, and an enlarged participation from US (more than 10 delegates), which agreed to take the lead of 3 new working groups, were present, as well as different organizations: AOAC International, 8 European reference laboratories, the Nordic Committee on Food Analysis (NMKL), and the WHO Collaborating Centre for *Listeria*.

In the area of Microbiology of the Food Chain, the 2 committees work **very closely**, in the frame of a CEN/ISO cooperation agreement, to **develop common CEN/ISO Standards**, each under ISO or CEN lead.

For many years, bioMérieux experts provide scientific input in the development of ISO and CEN standards. **Isabelle Desforges**, Marketing Scientific Manager - Food (bioMérieux Industry) and expert in various working groups, was again this year a representative of the French commission (AFNOR V08B) in Washington.

Here are some main aspects of the meeting of the ISO committee, chaired by Bertrand LOMBARD, ANSES (Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du Travail, France) and managed by Gwénola HARDOUIN, AFNOR (French standardization organization):

- Enquiry to non-European members on the degree of adoption of ISO Standards as national Standards/reference methods (for European countries, common CEN/ISO Standards are mandatorily taken over as national standards and referenced in regulation EC 2073/2005 modified)
- In the Standard detection methods for different bacterial targets, to indicate the maximum test portion size for which the method has been validated, based on its level of detection (LOD)
- Finalization of the revision of EN ISO 6887 series on preparation of test samples, initial and decimal dilutions
- Initial phase for the revision of EN ISO 7218 on rules and guidelines for analysis in food microbiological labs
- Finalization of the 2 first parts of EN ISO 16140 on method validation: vocabulary and validation of alternative/proprietary methods in comparison with a reference method
- Additional parts of EN ISO 16140 under preparation
- Finalization of the 2 first standards on Parasites *Trichinella* and *Cryptosporidium* & *Giardia*
- Initial works on immunological detection of *C. botulinum* toxins

Regarding the CEN committee, convened by **Alexandre LECLERCQ** (Institut Pasteur, France) and managed by **Gwénola HARDOUIN**, AFNOR:

- In Standard methods, a direct reference to proprietary products shall be avoided, unless there is no other option. Instead, performance characteristics that have to be met for the method should be specified
- The use of technical specification instead of full EN ISO standard and their recognition by accreditation bodies should be further investigated
- The approach to "modular" Standard methods, comprising "open" steps (without any detailed procedure), should be further investigated, in particular in relation to lab accreditation (examples EN ISO/TS 13136 and EN ISO/TS 15216)
- Presentation of the results of inter-laboratory studies, for the full validation of the **15 main reference Standard methods** (new or under revision) for the detection and/or quantification of the pathogenic microorganisms, funded in the frame of the Mandate M381 given to CEN by the European Commission
- Initial phase for the development of two Standard PCR-based methods for (i) identification of monophasic *Salmonella* Typhimurium, (ii) confirmation and species identification for *Campylobacter*
- Investigation to the use of identification of bacteria and yeasts by Maldi-Tof in the framework of revision of EN ISO 7218 standard
- Agreement to launch a standardization work on use of genomics (WGS), with ISO lead and to have an harmonized approach between food and clinical microbiology

Invited by the Dutch committee for Microbiology of the Food Chain, the next ISO/TC 34/SC 9 and CEN/TC275/WG 6 annual meeting will be held in the Netherlands from the 22nd to 26th June 2015.



G. Hardouin (AFNOR) - A. Leclercq (Institut Pasteur) - B. Lombard (ANSES) - I. Desforges (bioMérieux)

* Complete article in the next "Microbiology Standard monitoring Newsletter" (November 2014)

¹ Sub-committee 9 « Microbiology » of ISO Technical Committee 34 « Food products »

² Working Group 6 « Microbiology of the food chain » of CEN Technical Committee 275 "Analysis of food products – Horizontal methods"

GFSI 2014 ANAHEIM

The Global Food Safety Initiative (GFSI), founded in 2000, is a business-driven initiative for the continuous improvement of food safety management systems to ensure confidence in the delivery of safe food to consumers worldwide.

The GFSI 2014 Consumer Goods Forum was held in Anaheim, California, February 26 – 28. The theme of the conference was "One World, One Safe Food Supply". Over 1,000 attendees from all over the world attended the meeting. GFSI provides a platform for collaboration between some of the world's leading food safety experts from retailer, manufacturer and food service companies, service providers associated with the food supply chain, international organizations, academia and governmental bodies.

bioMérieux, the Premium sponsor of the Consumer Goods Forum and partner for the worldwide food companies, has committed to supporting next year's meeting which will take place in Kuala Lumpur, Malaysia from 4th - 6th March 2015.



IAFP

With record attendance from around the world, the International Association for Food Protection 2014 (IAFP) was held in Indianapolis (Indiana – US) from the 3rd to 6th August, and was another successful gathering of the global food safety community. The bioMérieux exhibit was praised for a new look and welcoming atmosphere. Visitors to the bioMérieux booth were given guided tours of the FOOD Microbiology Pathway, bioMérieux Performance Solutions, and Services. Lastly, bioMérieux hosted over 450 attendees at the 13th annual bioMérieux Symposium, which featured Dr. Randy Rasmussen (BioFire), Dr. Paula Cray (NC State Univ), and Dr. Eric Brown (FDA). The theme of the symposium explored cutting-edge diagnostic tools for the food microbiology community. Attendees to the IAFP signature event really enjoyed the symposium format and continued the evening with good food and networking.

We are looking forward to welcoming you in Portland (Oregon) from the 25th to the 28th July 2015.

BIOMÉRIEUX UPS ITS SAILS FOR THE ROUTE DU RHUM

The 10th Route du Rhum, is a well-known legendary transatlantic solo race held every four years. It will commence from the old corsair city of Saint Malo on the 2nd November 2014. Navigators will sail to the Pointe-à-Pître in Guadeloupe, travelling around 6,500 km.

This year, the skipper Gilles Lamiré, will sail under the colors of bioMérieux. Our group decided to sponsor his adventure on the open sea. He participated in many transatlantic voyages across the ocean and thanks to his passion achieved numerous prizes: 3rd place in the Transat Jacques Vabre; 2nd place in the Transact Quebec-St Malo; 2nd place in the Grand Prix Guyader on 5th May; and finally, 6th place in the last Route du Rhum in "ultime" category.

After participating in the Route du Rhum three times, the skipper, from Cancale, will sail this year on the famous 50-foot trimaran, currently called « Rennes Métropole – Saint-Malo Agglomération », which also won the competition in 2010 under the name of "Prince de Bretagne".

Above all, this event embodies the common values of both bioMérieux and Gilles Lamiré: commitment, determination, team spirit, boldness, ambition and self-improvement!

**LET'S EMBARK ON THIS ADVENTURE AND SUPPORT GILLES LAMIRÉ.
LET'S WISH HIM, FAIR WIND!**



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