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CONFERENCE INSIGHT

**How efficient and automated
can be Serology and Stool Testing?**

DiaSorin scientific contribution

Euromedlab Paris, June 23, 2015

Moderator:

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Faculty:

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B. Burde

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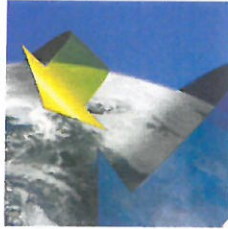
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Quality and Innovation, key factors for laboratory evolution

P. Huynen

To satisfy all the clinical needs efficiently and without any compromise on quality, one solution could be to look towards innovation.

CLIA systems reduce the TAT, with high quality, full traceability and with the advantage of a random access system.

A laboratory has to face several challenges every day: a constant increase in the number of tests to be performed, the need to provide results quickly and the need to achieve a lower turn-around-time (TAT), while maintaining quality assurance and complete traceability of the results. In this context, in order to meet all the clinical needs efficiently without any compromise on quality, one solution could be to look towards innovation and optimize the laboratory with innovative systems (Figure 1).

Automated techniques are currently adopted for the most commonly used serological methods. The first step towards innovation is to move away from the ELISA method to embrace a new technology, chemiluminescence (CLIA), and the new fully automated analysers: LIAISON® and LIAISON® XL. CLIA systems represent a technical improvement over the ELISA automated system. They reduce TAT, while maintaining high quality and full traceability, with the added advantage of a random access system. Ready-to-use reagents on board, a touch-screen monitor, auto-dilution, re-run and reflex testing automatically performed by the system and a STAT position for emergency results are some of the technical characteristics of the new systems. Moreover, with the LIAISON® systems it is possible to test several types of samples (e.g., serum, cerebrospinal fluid and stools) at the same time, in the absence of cross-contamination.

With LIAISON® XL, efficiency can be improved with several advantages: new infectious disease markers (e.g., HIV, hepatitis C); a larger number of reagent integrals on board (from 15 to 25); no more daily maintenance, and disposable tips. Moreover, most of the reagents are the same for the LIAISON® and LIAISON® XL systems, which means easy validation files; the system also provides a backup, if needed. Another challenge in a microbiology laboratory is performance. Implementation of highly automated instrumentation fulfils the needs of the laboratory – i.e., TAT and logistic improvement without any compromise on quality - and enables a good response to clinical needs, including confidence in the results and flexibility (Figure 2).

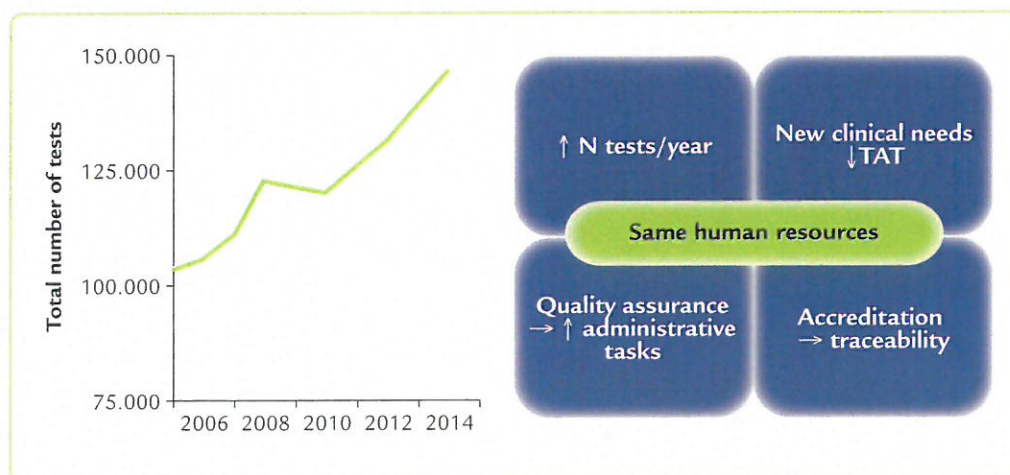


Figure 1. The challenge of our laboratory

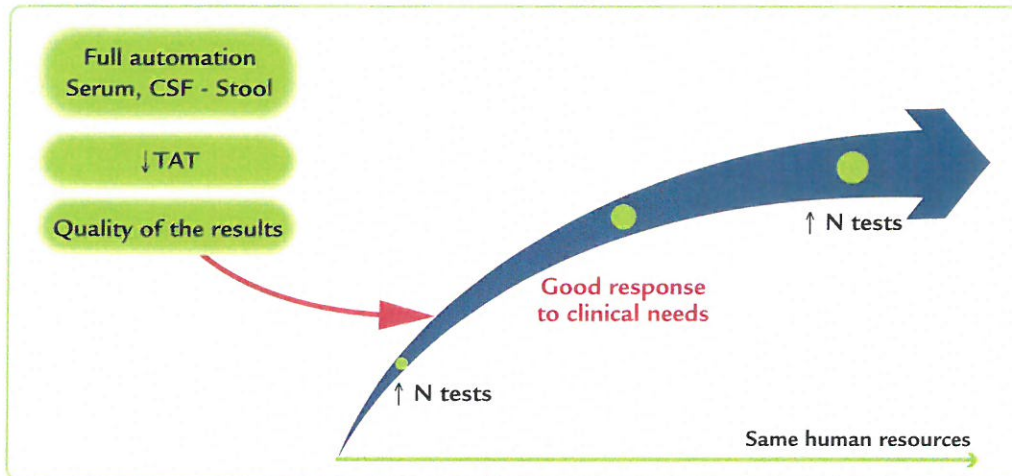


Figure 2. Interaction between laboratory and clinicians

The chronological evolution of the Liège laboratory

The laboratory of Infectious Serology and Antigen Detection is part of the division of Clinical Microbiology of the University Hospital of Liège and performs both infection serology and antigen detection for infectious diseases including *Clostridium difficile*.

The collaboration with DiaSorin started in 2001. Since that time, DiaSorin has been able to support the evolution of the Liège laboratory with an increasing number of infectious disease markers available on the fully-automated analyser and with the ability to consolidate the serology platform.

After that, in addition to the ETI-Max 3000 (ELISA analyzer), between 2003 and 2006 three LIAISON® systems were acquired and an increasing number of infectious disease markers were implemented over the years. In 2011, with the advent of the LIAISON® XL system, the LIAISON® was gradually phased out. Finally, *C. difficile* diagnosis on stool specimens was introduced in 2013, first on the LIAISON® and then on the LIAISON® XL (Figure 3).

Experience with *Clostridium difficile* infection diagnosis

A fully automated solution is necessary for the diagnosis of *C. difficile* infection especially in a laboratory that performs a large number of tests per year.

The advantages of a random access system are flexibility and the ability to provide results quickly and several times a day, as with the rapid tests but with the full traceability of an automated system. Moreover, the LIAISON® can run toxin tests on stools but also on bacterial colonies of *C. difficile*.

The picture shows the workflow in the Liège laboratory. Blood and cerebrospinal fluid samples are aliquoted (if needed) and then tested either manually or by the ELISA automated system or by CLIA. For *C. difficile* diagnosis, after a short extraction step, stools go directly to the LIAISON® system for antigen and toxin detection. At the same time, they are also incubated for 24-48 hours in the bacteriology laboratory, and the colonies obtained after incubation can be tested for toxins on the LIAISON®, if needed (Figure 4).

Future perspectives

A large panel of fully automated parameters has been implemented on the LIAISON® system over the years, and new parameters will be available in the near future, e.g., for Chlamydia, Bordetella pertussis toxins, and, for stool testing, for adenovirus and rotavirus antigens.

Moving from ELISA to CLIA allows us to consolidate our serology platform and to successfully face all our challenges. Quality and innovation are key success factors for the evolution of the laboratory

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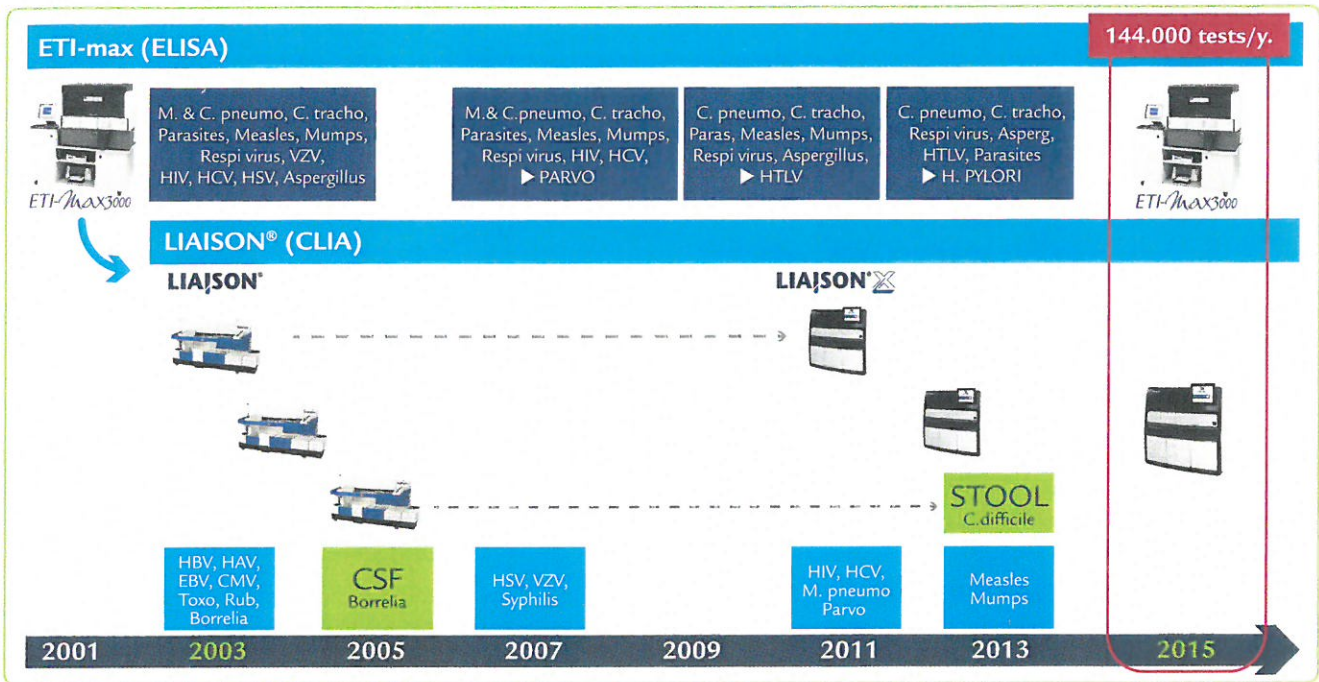


Figure 3. Innovation in our laboratory

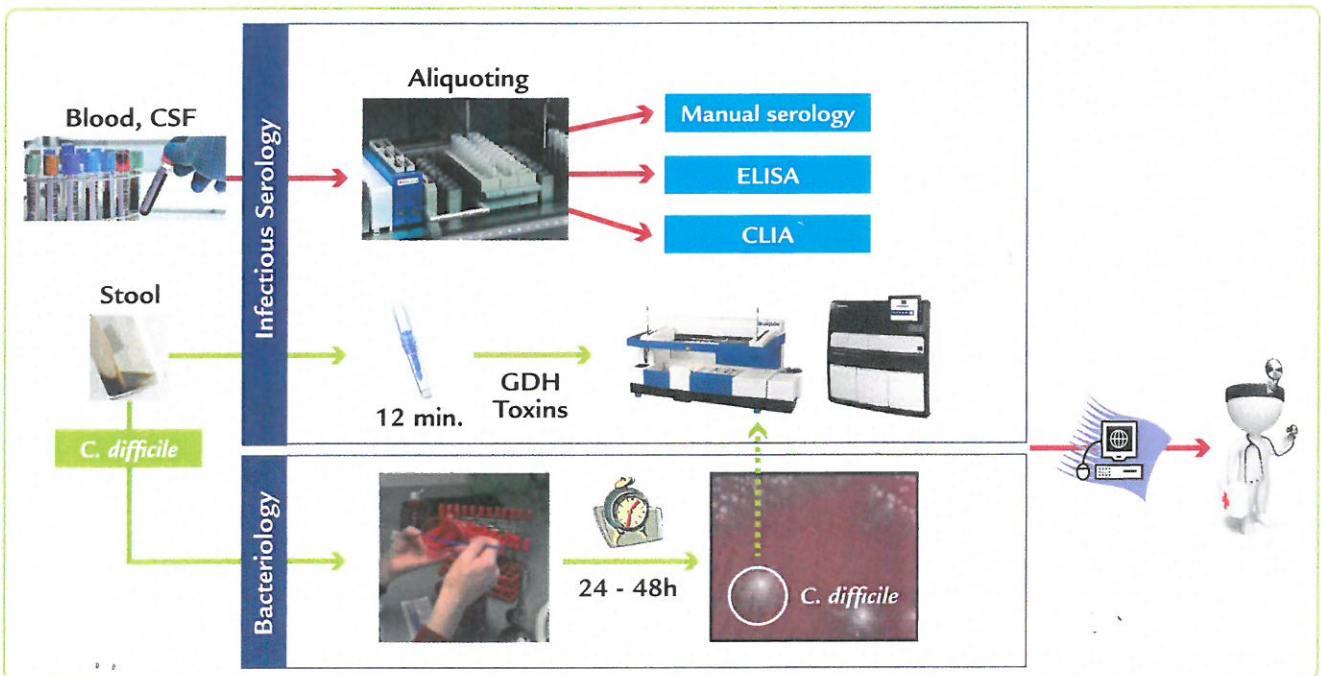


Figure 4. From sample to results

To conclude, clinical needs have to be met efficiently and without any compromise on quality. Moving from ELISA to CLIA allows us to consolidate a serology platform and successfully tackle all the challenges faced by laboratories. Indeed quality and innovation are key success factors for the evolution of the laboratory and contribute to improving performance with a good response to clinical needs.