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SilverSky Insights:

ECCMID 2018
Impressions

28th **ECCMID**

Madrid, Spain
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Building Trust. Building Business.



SilverSky Insights: ECCMID 2018 Impressions

Author: SilverSky Unternehmensberatung GmbH

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Overall Impression

The 28th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Madrid was visited by roughly 12,000 microbiologists and clinicians. The attached exhibit, with about 180 presenting companies, was well organized and attended, however with less pharma industry presence (related to number of companies and sizes of booths) compared to previous years. In contrast, all big players in the diagnostics space were present accompanied by many small start-ups.

General SilverSky conclusion: the ID testing market has become highly competitive with almost all large IVD players offering PoC- and high-through-put pathogen identification (Roche, QIAGEN, bioMérieux and others) as well through smaller companies with promising new break-through technologies. Besides smaller, cheaper and faster PoC pathogen ID, companies focusing on rapid phenotypic antibiotic resistance profiling.

Relevant Highlights

PoC ID Testing: Two Significant New Market Entries

Two large players introduced their universal PoC systems at ECCMID 2018:

1) *QIAGEN with Stat Dx*

Earlier this year QIAGEN acquired STAT-Dx, a Spanish privately-held company. At this ECCMID, QIAGEN displayed this fully integrated multiplex platform for syndromic disease testing at their booth. They claim easy-to-use assays, suitable for any clinical sample type with qualitative as well as quantitative results for 48-plex real-time PCR testing in about one hour. Based on the proprietary DiagCORE technology, the system also allows immunoassay-based testing for proteins.

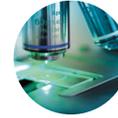


2) *BOSCH HEALTH SOLUTIONS / in-house development*

Bosch launched its platform Vivalytic with a big bang – one of the largest booth with spectacular, modern marketing material. Bosch is partnering with other firms for applying assays to their platform, as well for distribution (currently two companies: Randox Laboratories and R-Biopharm).



The all-in-one open platform Vivalytic with small footprint combines a broad range of test options in its test cartridge. The device supports end-point PCR, quantitative real-time PCR, melting curve analysis and microarray technology. Using ultrasound, sample materials such as fluids, tissue samples or sputum can be processed. Programmable microfluidics allow viruses, bacteria and fungi to be analyzed in two parallel processes independently of one another. Depending upon the test application, Vivalytic delivers results in 30 minutes. It does not require any peripheral devices and supports common standards such as HL7, GDT and POCT1-A. The first tests available on the Vivalytic are Randox's panels for respiratory and sexually transmitted infections. The URT simultaneously detects 22 viral and bacterial pathogens, while the STI test enables the detection of 10 viral, bacterial and protozoan STIs from swab samples. R-Biopharm will offer a new product line specially developed for the Vivalytic platform, providing multiplex and economical low- and single-plex infection panels.



PoC ID Testing: Other Established Competition

Results of Market consolidation and new products launched by established players:



ABBOTT was well present. After last year's acquisition turmoil between ABBOTT and ALERE, ABBOTT now clearly has integrated the ALERE POC portfolio. The brand name ALERE was still visible although all was clearly under the ABBOTT umbrella. Apparently ABBOTT was also demonstrating a new technology, only accessible to invitees. The ALERE portfolio (ELISA-based) is positioned as a cost effective first line diagnosis tool for instance for *C. diff*. In case a positive result for *C. diff* the diagnosis may be extended by a molecular test for ToxA/ToxB genes. This approach is already established in many hospitals.



GENMARK was present at the ECCMID as well. Their product offering is not really POC but comes close. Genmark offers panel testing including respiratory and sepsis. The e-PLEX system is state of the art technology. Genmark offers sample to result technology, meaning that additional sample prep is not required. GENMARK's (q)PCR is done with capillary systems allowing for fast amplification and requires less sample volume. Detection is done with CMOS technology, for which fluorescence probes are no longer required thus expensive optic systems are no longer required. Although the system may very well be set-up as a POC system, GENMARK focuses on higher throughput markets. The system can run in 8 -24 samples simultaneously. Yet, GENMARK's business is not doing well. Main reason may be found in the very high pricing per test (around 250€ per test!) and still missing reimbursement for multiplexed testing. Pricing is often based on the US market where CLIA labs claim that the COG for multiplex testes is around 250 US\$.



MICRONICS: PanNAT® Molecular Diagnostic System is a POC-instrument capable of processing distinct cartridges, each designed to perform a single and /or multiplexed nucleic acid amplification assay. Each assay is fully integrated into the disposable cartridge that includes all necessary reagents. Only a small volume of biological sample is required for assay performance. The PanNAT System provides a sample on – result off answer in approximately one hour, with no sample preparation required. The platform is uniquely configured for use in decentralized environments and offers full connectivity. Micronics is advancing the PanNAT System with a focus on point of care infectious disease diagnostics.

Companies with Recent or Shortly Upcoming Launches of Interesting Products

More competition on the horizon:

- SPINDIAG's centrifugal-microfluidic test system with PCR directly from swab samples in under 30 min, now focuses on resistance testing of 25 most prevalent drugs, but is still quite away from launch.
- MOBIDIAG launched the CE-marked Novodiag platform with a *C. diff* application to be followed by GTI. Their disposable, a sealed cartridge with multiplexed R-PCR/array delivers results in about one hour with random access operation including LIMS connectivity. It is a benchtop, small-sized instrument with four independent slots per instrument.



- CURETIS – Unyvero LRT test and platform is now FDA approved, the US panel is not as comprehensive as its EU version. Smaller low-to-mid-plex system in R&D, expected for commercialization in 2019; new Unyvero CE-IVDD cartridge for urinary tract infection.
- ATLAS GENETICS - Their system promoted since years, consists of a small, easy-to-use instrument (io instrument) and test-specific, disposable cartridges (io cartridge), providing test results in 30 minutes; first application STD. Technology is based on electrochemical detection and does not need any laser/optics.
- OPTOLANE. A Korean company focusing on multiplexing and POC presented, the “MENDEL” using multiplex PCR for the detection of viruses and bacteria. The run time for such assay varies from 25 – 30 minutes. The detection platform is using “microarray” technology in combination with CMOS. Therefore, multiplexing may vary from 9 to 22k samples. Since the system uses CMOS technology combined with microarray, the readout can be done by any USB compatible device like smart phones. The MENDEL system is about 20x10x10 cm, therefore small and compact. Currently OPTOLANE still requires additional sample preparation, however R&D is working on a sample in result out technology. The panels they will have are respiratory, Sepsis, Tuberculosis, STD. The MENDEL system will be launched in 2019.

Other noteworthy Trends / Observations

Whole Blood Testing – Diagnosing Sepsis – the Holy Grail:

DNAe’s LiDia

The company DNAe presented its’ LiDia platform, based on semiconductor genomic analysis technology (next generation sequencing (NGS)). LiDia will be launched in one year from now. The cartridge based test handles whole blood samples for sepsis testing in three hours and claims sensitivity of one CFU/ml. LiDia can perform highly parallel individual assays and NGS on the same type of chip and there is no need to measure optical signals or use lasers and microscopes. They claim long read lengths, at the low cost per base, and high output per run, filling the gap of NGS to be applied in the clinical environment.



Q-LINEA ATriD

The ASTriD platform, currently under development, will identify pathogen directly from venous blood and deliver an antibiotic susceptibility profile in ten hours. The pathogen ID panel will cover 33 pathogens and 10 pathogen groups, as well as 11 resistance markers. The panel of antibiotic substances will contain up to 48 antibiotics and bacterial growth or inhibition reported as MIC values. Q-linea’s technology for pathogen detection is based on highly specific padlock probes and circle-to-circle isothermal nucleic acid amplification technology (C2CA). This technology allows substantially higher degree of multiplexing capability, compared to PCR-based techniques.



Low Cost Mid-/Low-Plex Pathogen ID – Many Kids on the Block

A couple of smaller, some newly established companies were showing impressive low-costs cartridge systems for low-plexing, like Abacus Diagnostics – a 1 x 2 x 0,4 cm consumable part at just a few cents only.

HTS and ID Testing – Becomes Competitive

A couple of vendors showed high-throughput pathogen ID using automated stations (e.g. MobiDiag based on a Qiagen platform).



New Functional Competition – Not just PCR

Many companies still focusing on traditional PCR technologies, however interesting functional competition arises, as rapid phenotype-based AST or reagent-free culturing, e.g.:

- Competitive to ACCELERATE, AFFINITY BIOSENSORS' LifeScale AST provides a rapid phenotype-based antibiotic susceptibility test instrument utilizing advanced micro-electro-mechanical systems (MEMS) fabrication methods analyzing and quantifying living microbes. It can access up to 26 antibiotics at various concentrations and delivers results in three hours.
- METASYSTEMS HARD & SOFTWARE GMBH: Similar to Accelerate, the German diagnostics company MetaSystems Hard & Software GmbH has succeeded in augmenting traditional FISH technology. At ECCMID the company presented the Metafer® system that enables multiplex pathogen identification from blood cultures and directly from respiratory samples within minutes. In addition, the company offers solutions for automated Gram stain and TB stain imaging.
- POCARD Diagnostics promotes direct specimen, fully automated, reagent-free microorganism detection, identification and enumeration in minutes based on physical properties of intrinsic fluorescence using their platforms P-1000 and PS. The technology captures the emitted light from the interaction between photons and molecules to detect the pathogens' unique optical properties and subsequently an algorithm determines results.
- BIOSPARQ showed their new platform (under development) based on single Cell MALDI-ToF. Using this technology allows direct detection of pathogens from the crude sample, thus avoiding costly and time-consuming sample prep. Up to present, MALDI-ToF may only be used after sample enrichment like culturing. MALDI-ToF is a very fast and very cost-effective identification method. It usually takes less than a minute and costs are extremely low (Cents). The earning model is in providing access to a MALDI-ToF spectrum library containing all spectra of known pathogens, however the system is not able to identify any pathogen not present in the library. The system is built for detection of bacteria, Fungi and other pathogens and currently does not handle viruses although development is in process.

Increasing Interest of Pharma in Fast Pathogen ID for Streamlining Clinical Trials

MDx as novel tool for pharma to facilitate patient enrollment:

After the successful implementation of rapid pathogen identification in antimicrobials clinical trials (e.g. for Cempra's phase III trial for its oral drug for community-acquired bacterial pneumonia) other pharmaceutical companies become interested in using this approach, e.g. Astellas, MDS, Achaogen, Eumedica, MSD and Nabriva.

Summary:

This year the focus of many (M)Dx companies is on PoC. PoC requires a fully integrated system, reagent and sample processing and result evaluation in one and the same component. This will for sure have an impact on reagent suppliers. In addition, Time to Result is getting shorter, meaning less than one hour (Sample in Result out). Also CMOS is getting more popular. Since the CMOS is based on voltage/current measurement, the need for fluorescence and optics is no longer necessary. Therefore such systems may become very small. In short, PoC is one step closer to real breakthrough: Fast Time to Result, Sample in Result out and miniaturization.



About SilverSky and our Diagnostics Practice

More than 100 years expertise in diagnostics:

SilverSky is a small and highly specialized consultancy focused on diagnostics, medtech and biotech. It purposefully restricts its services to corporate financing, business building and innovation funding. Founder Dr. Mirko Stange has put together an energetic, experienced, international and interdisciplinary team to efficiently cover a wide range of skills decisive in the successful founding, expansion and motivation of life science organizations.



Dr. Ron Opstelten, Ph.D.

Our trained Ph.D. with his in-depth experience in global sales, marketing and business development will support you on business aspects such as developing and executing business plans, setting up sales strategies and organizing sales channels, and launching and managing your innovative product. He will use his experience of 30 years in exploiting new market opportunities, as well as the challenging phases of startups, to surpass the “Valley of Death” phenomenon. Ron’s support is not restricted to developing plans; plan execution is also well within his offering.



Dr. med. Anne Thews, M.D.

Our trained medical doctor will use her significant experience in international marketing and global medical affairs to assist you with launching and managing your challenging product. She will use her deep understanding, gained from over two decades building new international business units and startups, to fine-tune your go-to-market strategy and, if needed, could support you hands-on with implementation.



Dr. Mirko Stange, Ph.D.

Dr. Stange is founder and CEO of the SilverSky Group. His expertise in corporate finance is derived from his longstanding position as a consultant at Mc Kinsey and Droege Comp. As interim managing director of numerous medtech and diagnostics companies, he also has proven track record in successfully securing risk capital and business building. He gained a PhD in Biochemistry and Biophysics with a focus on cardiovascular diseases from the University of North Carolina at Chapel Hill and a diploma in chemistry from the Heinrich Heine University Duesseldorf.

E-Mail: info@silversky-lifesciences.com

Phone: +49 211 302708-12

Web: www.silversky-lifesciences.com



SilverSky
Unternehmensberatung GmbH

Brunnenstraße 23
40223 Düsseldorf
Deutschland

Phone: +49 211 302708-12
E-Mail: info@silversky-lifesciences.com
Web: www.silversky-lifesciences.com

