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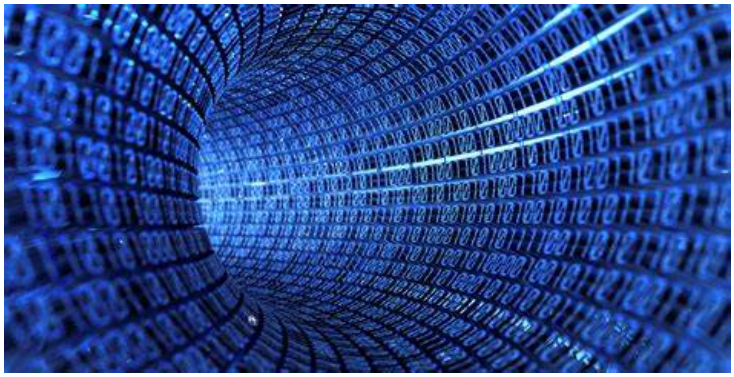
Qiagen announces new data of the QIAstat-Dx Meningitis/Encephalitis panel

12 April 2019 | News

New data presented at ECCMID 2019 ahead of planned H2 2019 CE-IVD launch of panel, addition to current respiratory and gastrointestinal panels for use on syndromic testing platform



QIAGEN has announced new data of the QIAstat-Dx Meningitis / Encephalitis panel. The panel is in late-stage development and being prepared for CE-IVD commercialization in the second half of 2019 for use on the QIAstat-Dx multiplex syndromic testing system. The preliminary data demonstrates effective detection of the most prevalent central nervous system pathogens with high analytical sensitivity and specificity levels, including the discrimination of clinically relevant strains and subtypes.

This new test will expand the QIAGEN menu of diagnostic panels for syndromic testing, adding to CE-IVD marked DiagCORE tests for respiratory and gastrointestinal infections that were launched in 2018. The U.S. regulatory clearance of QIAstat-Dx is expected in mid-2019, and a deep menu of additional tests covering infectious diseases and other therapeutic areas is in development.

The planned QIAstat-Dx Meningitis / Encephalitis panel in Europe is designed to enable one-step, fully integrated molecular diagnosis of meningitis (inflammation of the membrane surrounding the brain and spinal cord) or encephalitis (inflammation of the brain itself) conditions. The QIAstat-Dx panel will provide actionable insights in about one hour, analyzing more than 20 pathogens that cause meningitis / encephalitis syndromes, including bacteria, viruses and yeast and provides information on Ct values as well as amplification curves – some of the many features QIAstat-Dx boasts that no other syndromic system can offer.

“Our new QIAstat-Dx panel meets an urgent need for rapid and reliable diagnosis of meningitis and encephalitis infections, and will enable clinicians to select appropriate therapies in a timely manner. The panel delivers valuable insights with high sensitivity and specificity to identify these life-threatening syndromes,” said Thierry Bernard, Senior Vice President and Head of QIAGEN’s Molecular Diagnostics Business Area. “Laboratories in Europe are embracing the new platform and the power of syndromic testing based on proven PCR technologies to identify syndromic conditions with the simplicity of a true Sample to Insight solution. Demand for syndromic testing is growing rapidly, and we are developing a deep menu of assays to significantly increase the utility of QIAstat-Dx for an increasing range of applications.”

The data presented at the 29th European Congress of Clinical Microbiology & Infectious Diseases (ECCMID 2019), taking place April 13-16 in Amsterdam, Netherlands, showed the QIAstat-Dx Meningitis / Encephalitis panel offered combined

automated sample preparation, amplification, detection and analysis in one step for molecular analysis of more than 20 pathogens. These included targets for *Neisseria meningitidis* (meningococcal strains including serotypes A, B, C, D, W, X, Y), *Streptococcus pneumoniae*, *Streptococcus agalactiae* (Group B *Streptococcus*), *Listeria monocytogenes* and all relevant *Haemophilus influenzae* subtypes.

An estimated 2.8 million cases of meningitis occurred globally in 2016, the most recent year for which data are available, according to a World Health Organization (WHO) report in February 2019. While deaths due to meningitis have declined in recent years, the disease still took an estimated 290,000 lives in 2015. Among survivors, meningitis can lead to brain damage, hearing loss or other permanent disabilities.

The QIAstat-Dx system's key advantages include:

- **Powerful technology capabilities:** Using QIAGEN sample and assay technologies, the system can deliver true Sample to Insight processing of even the most challenging samples, opening up opportunities in a broad range of application areas not possible with currently available systems. Samples include tissue samples in pathology, liquid or difficult-to-handle sputum samples in infectious disease, with direct onboard swab processing.
- **Multi-analyte capabilities:** The system is the only multiplex syndromic testing system based on real-time PCR (polymerase chain reaction) technology that can process up to 48 targets, and is designed with the additional capability to process immuno-assays. These features create unmatched target and application versatility, as well as disease management options.
- **Integration of real-time PCR technology:** This system enables customers to precisely quantify biological targets, which is specifically important in oncology or transplantation patients and leads to improved treatment decisions. The use of real-time PCR also allows a vast portfolio of current real-time PCR tests to be portable onto the system. The value of Ct values is currently in validation.
- **Flexible approach to results:** The proprietary workflow design with an attractive cost of ownership has the potential to enable laboratories to take a tailored approach to the selective analysis and reporting of tested molecular targets. The flexible approach will represent a significant improvement over currently available systems that offer rigid panel designs, and therefore require co-processing of molecular targets found to be irrelevant in the patient sample, which may complicate reimbursement.