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ELITe InGenius™ is an integrated sample to-result solution dedicated to Molecular Diagnostics which automatically performs extraction, amplification and result interpretation with an unprecedented flexibility and assay menu possibility. The system combines a universal extraction process in unitary cartridge with individual and independently controlled RT PCR in cassette based format enabling the laboratories to develop and run custom panels of assays on demand. ELITe InGenius™ is an innovative solution build on our long-lasting expertise to design, optimize and provide PCR solutions for in vitro diagnostic laboratories.

Full AUTOMATION & efficient technologies

ELITe InGenius is a bench-top solution integrating all the steps of molecular diagnostics in a single platform with best-in-class and proven technologies for acid nucleic extraction and RT-PCR amplification (Fig. 1).

The nucleic acid extraction is based on a patented magnetic bead technology combined with sonication and heat treatment to quickly provide a high yield extraction even with low sample volume. The extraction process can be performed from primary tubes directly loaded on the instrument or from secondary tubes. It has been fully validated with a large range of specimens including whole blood, plasma, CSF, urine, nasal swab, throat swab and stool. Regardless of the nucleic acid to extract, genomic DNA, viral and bacterial DNA and RNA, or of the sample matrix, a single type of extraction cartridge is required. For each sample, the extracted nucleic acid is eluted in a dedicated tube and used to perform one or multiple PCR in parallel according to the specific laboratory requirements. At the end of the run, the remaining extracted nucleic acid can be directly stored for additional testing or archiving. The universal ELITe InGenius™ extraction process in a cassette based format enables the laboratory to reduce the hands-on-time to few minutes, optimize the reagent consumption and improve the workflow.

The RT-PCR amplification is performed in independently controlled and unitary thermal cyclers. That means that different thermal profiles even with different types of chemistries can be run simultaneously during the same session simply on demand. In addition, each thermal cycler is equipped with 6 optical channels providing a 6-plex target capability supplemented when appropriate with melt-curve analysis to provide extended multiplexing capability. The optics feature six excitation LEDs equipped with filters & six detection photodiodes, they are compatible with the main commercial dyes and are optimized with ELITechGroup proprietary dyes.

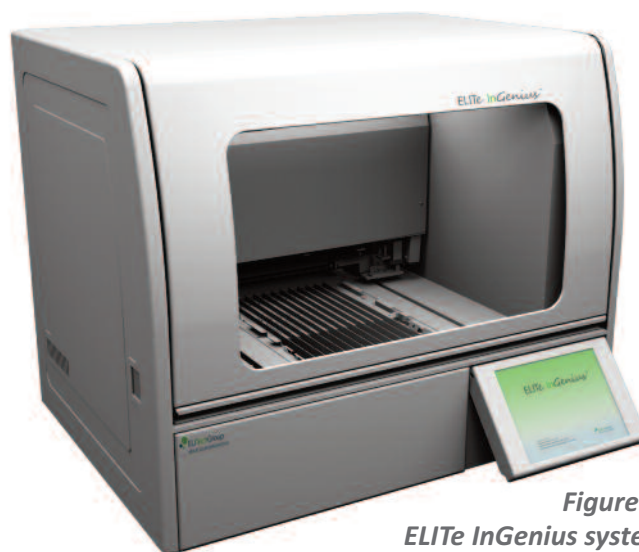


Figure 1:
ELITe InGenius system

A user-friendly touchscreen interface and a bi directional LIS connection provides complete functionality for configuring, operating, result reporting and managing the system. The software seamlessly integrates the following features: user management, assay programming, reagent management, sample and reagent traceability, run set-up and monitoring, assay calibration with the possibility to store the standard curves, assay quality control including Levy Jennings plots, and several kind of detailed or summarized reports which can be customized.

Unrivalled FLEXIBILITY: Unique design & workflow

Within one single session, one to 12 samples can be processed in 12 parallel tracks. Each track combines the functionalities of multiple molecular platforms performing all the steps of MDx from extraction with sonication capability to RT-PCR amplification in a single-use, cassette based format. Also, multiple and independent PCR reactions can be processed in parallel from one extracted sam-

ple thanks to the single nozzle pipettor which dispenses extracted sample and RT PCR reagents according to the specific run set-up. The system supports a large number of RT-PCR reagents including the proprietary CE-IVD ELITE MGB line, MGB® Alert ASRs in the US as well as laboratory developed tests or others of interest which can be stored on board in a separate active cold block.

The unique ELITE InGenius design confers an unrivaled flexibility in comparison to other sample-to-result solutions enabling the laboratory to define and customize panels of tests including multiple PCR from one extracted sample simply on demand. Several operational modes are also available: extraction only or amplification only or the full sample processing including extraction, amplification and result analysis with a melt curve analysis possibility.

Virtually Unlimited MENU

ELITE InGenius is the first sample-to-result solution offering at launch a CE-IVD core menu for transplant pathogen monitoring based on the validated and proprietary ELITE MGB® line. This range of quantitative RT-PCR assays is absolutely unique by its breadth and its technical features. More than 15 assays validated on a large range of sample matrices like whole blood, plasma, CSF or BAL are currently available. The main viral and bacterial pathogens, responsible for opportunistic infections in immunosuppressed patients after solid organ or stem cells transplant, are targeted along with the full herpes virus family from HSV1 to HSV8, CMV, EBV as well as HHV7 and other less frequent pathogens like *Toxoplasma gondii* or West Nile Virus.

All ELITE MGB assays and MGB® Alert ASRs are based on the proprietary Minor Groove Binder (MGB) technology and incorporate a suite of technical innovations developed by ELITEchGroup Molecular Diagnostics R&D department which is recognized for its expertise in the development of RT-PCR solutions. Conjugated to the probe, the MGB molecule interacts with the minor groove of the DNA to increase the stability of the hybridization between probes and target DNA. In practice, the MGB improves the performance of RT-PCR assays enabling the use of shorter probes targeting more highly conserved and more specific sequences in comparison to other PCR technology. ELITE MGB assays and MGB® Alert ASRs also incorporate engineered nucleotides. These so called Superbases™ are used in the primer and probe design to improve stability of A-T bonds and reduce secondary structure in G rich sequences. Their selective use during the assay design optimizes RT-PCR assay performance. A specific quencher developed to minimize signal background, the Eclipse® dark quencher, is also used in all ELITE MGB assays and MGB® Alert ASRs to improve the Real-Time PCR assay sensitivity.

These technical features, totally transparent to the end user, serve one single objective: to provide robust, specific

and sensitive assays for an accurate diagnosis and a reliable patient follow-up.

In August 2015, the ELITE InGenius was CE-IVD marked for IVD applications in Europe. Three ELITE MGB assays are already CE-IVD marked in combination with ELITE InGenius: VZV ELITE MGB, HSV1 ELITE MGB and BKV ELITE MGB assays for the detection and the quantification of DNA extracted and amplified from whole blood, plasma and urine. The validation plan for each parameter was performed in parallel on several instruments and executed on several steps. First, the analytical studies including efficiency, linearity, accuracy, repeatability and reproducibility testing enabled to verify the PCR performance. Then a sensitivity study was performed along with a complete system performance verification using certified reference material. Finally, a clinical study was performed with a significant number of samples to assess the clinical sensitivity and the clinical specificity of each assay. The analytical sensitivity was verified at 10 copies per reaction for each one and the clinical sensitivities were: 98% for VZV and 96.7% for HSV1 respectively with whole blood samples, and 100% for BKV with urine and plasma samples after discrepant resolution. 100% specificity was obtained for the three assays regardless the matrix. Given the excellent results obtained, several validations are underway to rapidly extend the transplant menu.

ELITE InGenius is also available in the US as Laboratory Use Equipment, and several laboratories are working to establish their performance with MGB® Alert ASRs in terms of linearity, reproducibility, sensitivity and clinical performance.

The transplant core menu will be rapidly expanded with multiplex healthcare-associated-infections assays, then adding complementary clinical applications like respiratory assays to offer a complete solution for infectious disease diagnostics.

Besides, the ELITE InGenius flexibility enables the user to combine within the same run CE-IVD assays, laboratory developed assays or other assays of interest simply on demand providing a virtually unlimited menu. Personalized menu can be created by saved test combination to perfectly fit with the lab routine.

Conclusion

ELITE InGenius is a breakthrough for molecular diagnostics which combines technical features not available on other sample-to-result systems and a unique menu. Its capability to consolidate complex molecular testing operations in one simple-to-use and flexible solution will reduce hands on time to a minimum and contribute to significant improvements in laboratory workflow.

For further information about ELITE InGenius™ and ELITEchGroup please visit our website www.elitechgroup.com or directly email your questions to info@elitechgroup.com.