“Consolidate complex MDX testing needs in one simple-to-use and flexible solution”
ELITe InGenius™

System Introduction

- ELITe InGenius is a fully automated cassette-based sample-to-result solution featuring a universal extraction with multiple and independent Real-Time PCR enabling to develop and run custom panels with mixed parameters according to the specific lab’s requirements.

- ELITe InGenius is the first fully automated sample-to-result solution offering a comprehensive quantitative menu for transplant monitoring.
Background

- ELITechGroup is a leading innovator in PCR technologies and a global solution provider for MDx.
- Decades of development expertise in chemistries and reagents.
- Proprietary of the Industry leading MGB Technology.
- Broad and growing CE IVD Molecular Diagnostics portfolio for
  - Transplant monitoring, HAI, Infectious diseases, Oncohematology
  - Mastery of Quantitative RT-PCR
  - More than 70 assays for > 40 parameters
- Long-lasting KOL relationships.
- Leader position in Italian market.
- Exclusive partnership with leading global provider of laboratory instruments for nucleic acid extraction.
Benefits

- Full AUTOMATION
- Efficient PERFORMANCE
- Unrivaled FLEXIBILITY
- Unlimited MENU
- Simplified WORKFLOW
Benefits

Full AUTOMATION
- Bench-top solution integrating in a single platform all the steps of molecular diagnostics automated nucleic acid extraction, RT PCR amplification, and result analysis guided step by step by an intuitive touch screen interface
- Primary tube loading capability
- Reduce the hands-on-time to few minutes

Efficient PERFORMANCE

Unrivaled FLEXIBILITY

Unlimited MENU

Simplified WORKFLOW
Benefits

**Unrivaled FLEXIBILITY**

**Efficient PERFORMANCE**
- High yield of extraction even with low sample volume thanks to magnetic beads technology combined with sonication, thermal and chemical sample treatment.
- Best-in class CE-IVD RT PCR menu based on the MGB technology for qualitative and quantitative applications.
- Unitary cassette-based format to guarantee an high result accuracy and control of the reagent consumption.
- Global time to-result from extraction to result analysis, approx. 2h30.

**Unlimited MENU**

**Simplified WORKFLOW**
Benefits

**Unrivaled FLEXIBILITY**
- 1 to 12 samples processed in parallel tracks to mix any kind of samples matrices, to run simultaneously completely different thermal profiles and even different PCR chemistries
- Multiple and independent PCR capability from one extracted sample enabling the laboratory to define customized panel of tests adapted to each patient needs
- Extracted nucleic acid storage for multiple PCR testing, retesting or archiving
- Several operational modes available: extraction only, amplification only, or extraction, amplification and result analysis with a melt curve analysis capability

**Efficient PERFORMANCE**

**Full AUTOMATION**

**Unlimited MENU**

**Simplified WORKFLOW**
Benefits

Full AUTOMATION

Efficient PERFORMANCE

Unrivaled FLEXIBILITY

Unlimited MENU
- First sample-to-result solution with a comprehensive menu dedicated to transplant pathogen monitoring
- Mix and match within the same run CE-IVD assays, laboratory developed assays or any other assays of interest simply on demand
- Personalized menu can be created by saving tests panel

Simplified WORKFLOW
Benefits

- Full AUTOMATION
- Efficient PERFORMANCE
- Unrivaled FLEXIBILITY
- Unlimited MENU

Simplified WORKFLOW

Select
- Pre-programmed assays to be run for each sample
- Multiple PCR from one sample
- Random access test programming

Load
- Mixed various sample matrices
- ELITe InGenius SP 200 & PCR Cassette
- RT-PCR reagents: mixed parameters

Start
- Walk-away
- Flexible mode: extraction and/or amplification & detection with melt-curve capability are automated

Review
- Approve result
- Print report
- Upload data to LIS
1 to 12 samples processed independently in 12 parallel and independent tracks.

Working area organized in 3 main parts:
- Sample loading area
- Sample preparation area
- RT-PCR amplification area

Liquid handling operations performed with:
- Single pipettor arm - PCR reagent and sample liquid handling
- Twelve nozzle head - extraction process & amplification with magnets and lasers
Easy Sample Loading

- 1 to 12 samples processed independently even with different kind of matrices
- Direct sample loading in the secondary tube
- Large validated range of matrices
- Whole blood, plasma, serum, cerebrospinal fluid, nasal swab, throat swab, stool which can be processed during the same run
- Primary tube loading capability

Sample loading in secondary tube with sonication capability – Rack 2

OR

Primary tube loading capability - Rack 1
Universal Sample Preparation

- 12 independent extraction position
- Ready-to-use, prefilled unitary cartridges with all extraction reagents
- Efficient extraction: Magtration® technology (magnetic beads)
- Universal extraction: genomic DNA, viral & bacterial DNA/RNA
- Short turn-around-time: approx. 30 minutes.
- Piercing tip and pipetting tip integrated in a specific cassette
- Remaining extracted NA storage for additional testing or archiving
- ELITe InGenius SP 200 + ELITe InGenius Consumable Set
Universal Sample Preparation

ELITe InGenius SP 200
wells 1 to 8 for extraction + 2 wells for sample heating

1: Lysis buffer, 2: Proteinase K, 3: Carrier, 4: Magnetic beads, 5: Binding buffer, 6-7: Wash buffers 1 & 2, 8: Elution buffer

- Ready-to-use, prefilled unitary cartridges with all extraction reagents including the magnetic beads + 2 empty positions for thermal treatment combined to Magtration® technology (magnetic beads) & sonication for a quick and efficient sample preparation
- Positive cartridge identification: 2D barcode & integrated reader
- No reagent preparation
- Fixed input volume: 200 µl
- 3 elution volumes possible: 50 µl, 100 µl, 200 µl
- ELITe MGB RT-PCR line CE-IVD validated with 100 µl
- Same volume of elution set for all the samples during one session
**ELITE InGenius™**

Real-Time PCR Amplification

- 12 discrete and independently controlled RT PCR thermal cyclers to run simultaneously various PCR assays
- **Multiplexing capability with 6-optical channels per thermal cyclers** enhanced by melt curve analysis
- **Multiple PCR tests in parallel from one extracted sample.**
  - From one extracted sample stored in the extracted NA storage tube, several PCR can be done.
  - Considering 100µl of elution, 4 ELITE MGB tests can be done in parallel.
- Random access test programming & sample batch processing

**ELITE InGenius PCR Cassette**: universal PCR vessel with auto-capping function

**Reagent manager area** for storage of RT-PCR reagents in monoreagent format & Internal Control
**Real-Time PCR Amplification**

- **Inventory Reagent manager area** for storage of RT-PCR reagents in monoreagent format & Internal Control
- **ELITe InGenius PCR Cassette**: universal PCR vessel with auto-capping function

- Open capability compatible with several chemistries including ELITe MGB®, Taqman, Scorpion, Sybergreen
- Custom menu capability including CE-IVD, laboratory developed tests or any other tests of interest
- Amplification turn-around-time: approx. 75 min with ELITe MGB® reagents, depending on the thermal profile
- Total RT-PCR reaction volume: 20µL to 50µL
- Different volume of sample and different volume of RT PCR reagent can be used independently in each reaction
- RT PCR monoreagent format is mandatory.
- ELITe MGB RT PCR reagents are directly loaded in the Inventory reagent manager area
Real Time PCR Assays

- Comprehensive menu based on the proprietary industry leading **MGB technology**
- Validation of microbiology and virology parameters for **transplant monitoring & Healthcare Associated Infections**
- Qualitative and quantitative results correlated to the **W.H.O International Units**
- Unique MRSA/SA assay targeting exclusively conserved sequences and first to detect the newly identified **mecC strain**
- **ELITe MGB® line parameters**: CMV, EBV, HSV1, HSV2, BKV, HSV6, VZV, HHV7, HHV8, JCV, Parvovirus B19, Adenovirus, Aspergillus, MTB complex, Toxoplasma gondii, MRSA/SA (with mecC detection), **C. difficile** – Validated on Whole Blood, Plasma, Urine, CSF, Stool, Swab as appropriate.
ELITe InGenius™

ELITe MGB Comprehensive Quantitative Menu

**Transplant Monitoring**
- CMV, EBV, VZV, HSV1, HSV2, ParvoB19, Adenovirus
  - Whole Blood
- BKV - Urine
- VZV, HSV1, HSV2, Enterovirus - Plasma

**Meningitis**
- VZV, HSV1, HSV2, Enterovirus - CSF
- MRSA/SA - Nasal swab
- C. Difficile - Stool

**HAI**
- ELITe MGB assays: HHV6, HHV8, JCV, HHV7, Aspergillus, MTB, T.gondii, West Nile Virus

**Open Capability**
- Laboratory Developed Tests
- New matrices
- Other assays of interest

CE-IVD validation and/or feasibility with ELITe MGB assays in combination with ELITe InGenius
2 patients with suspicion of viral meningitis – CSF sample tested with EN, HSV1, HSV2, VZV ELITe MGB assays
1 patient tested for respiratory infection – BAL sample tested a triplex assay – LDTests
1 patient followed after transplant tested for CMV, EBV (whole blood) & BKV (urine) - ELITe MGB assay
Case Study 1

- 2 patients with suspicion of viral meningitis – CSF sample tested with EN, HSV1, HSV2, VZV ELITe MGB assays
- 1 patient tested for respiratory infection – BAL sample tested a triplex assay – LDTests
- 1 patient followed after transplant tested for CMV, EBV (whole blood) & BKV (urine) - ELITe MGB assay

One single run

1 secondary tube – CSF
1 universal extraction
Case Study 1

- 2 patients with suspicion of viral meningitis – CSF sample tested with EN, HSV1, HSV2, VZV ELITe MGB assays
- 1 patient tested for respiratory infection – BAL sample tested a triplex assay – LDTests
- 1 patient followed after transplant tested for CMV, EBV (whole blood) & BKV (urine) - ELITe MGB assay

One single run

1 secondary tube – CSF

1 universal extraction

4 multiple PCR: EN, HSV1, HSV2, VZV
Case Study 1

- 2 patients with suspicion of viral meningitis – CSF sample tested with EN, HSV1, HSV2, VZV ELITe MGB assays
- 1 patient tested for respiratory infection – BAL sample tested a triplex assay – LDTests
- 1 patient followed after transplant tested for CMV, EBV (whole blood) & BKV (urine) - ELITe MGB assay

One single run

2 secondary tubes – CSF

2 universal extraction

2x4 multiple PCR: EN, HSV1, HSV2, VZV
Case Study 1

- 2 patients with suspicion of viral meningitis – CSF sample tested with EN, HSV1, HSV2, VZV ELITe MGB assays
- 1 patient tested for respiratory infection – BAL sample tested a triplex assay – LDTests
- 1 patient followed after transplant tested for CMV, EBV (whole blood) & BKV (urine) - ELITe MGB assay

One single run

2 secondary tubes – CSF
1 secondary tube - BAL
3 universal extraction
2x4 multiple PCR: EN, HSV1, HSV2, VZV
1 PCR in multiplexing: FluA, FluB, RSV
Case Study 1

- 2 patients with suspicion of viral meningitis – CSF sample tested with EN, HSV1, HSV2, VZV ELITe MGB assays
- 1 patient tested for respiratory infection – BAL sample tested a triplex assay – LDTests
- 1 patient followed after transplant tested for CMV, EBV (whole blood) & BKV (urine) - ELITe MGB assay

One single run

2 secondary tubes – CSF
1 secondary tube - BAL
1 secondary tube - WB

4 universal extraction

2x4 **multiple** PCR: EN, HSV1, HSV2, VZV
1 PCR in **multiplexing**: FluA/B, RSV
1 multiple PCR: EBV, CMV
Case Study 1

- 2 patients with suspicion of viral meningitis – CSF sample tested with EN, HSV1, HSV2, VZV ELITe MGB assays
- 1 patient tested for respiratory infection – BAL sample tested a triplex assay – LDTests
- 1 patient followed after transplant tested for CMV, EBV (whole blood) & BKV (urine) - ELITe MGB assay

- 2 secondary tubes – CSF
- 1 secondary tube - BAL
- 1 secondary tube - WB
- 1 secondary tube - urine

5 universal extraction

2x4 multiple PCR: EN, HSV1, HSV2, VZV
1 PCR in multiplexing: FluA/B, RSV
1 multiple PCR: EBV, CMV
1 PCR: BKV
Case Study 1

- 2 patients with suspicion of viral meningitis – CSF sample tested with EN, HSV1, HSV2, VZV ELiTe MGB assays
- 1 patient tested for respiratory infection – BAL sample tested a triplex assay – LDTests
- 1 patient followed after transplant tested for CMV, EBV (whole blood) & BKV (urine) - ELiTe MGB assay

- 2 secondary tubes – CSF
- 1 secondary tube - BAL
- 1 secondary tube - WB
- 1 secondary tube - Urine

- 5 universal extraction

- 2x4 multiple PCR: EN, HSV1, HSV2, VZV + IC
- 1 PCR in multiplexing: FluA/B, RSV
- 1 multiple PCR: EBV, CMV + IC
- 1 PCR: BKV + IC

Time-to-results approx. 2h30

Hands-on-time reduced to few minutes per sample

12 RT PCR reactions including single and multiplex assays, 10 different parameters, 4 different matrices tested in one unique workflow
12 patients followed after transplant kidney - Plasma samples – to be tested for CMV, EBV and BKV

36 assays to perform

36 reactions assays, first patient samples in approx. 2h30
Time-to-first-result oriented workflow
Case Study 2

- 12 patients followed after transplant kidney - Plasma samples – to be tested for CMV, EBV and BKV
- 36 assays to perform

**Complete Workflow**
- Run 1: 150 min
  - 4 Patients - Plasma
  - 4 Extractions
  - 4 PCR CMV, EBV, BK
- Run 2: 150 min
  - 4 Patients
  - 4 Extractions
  - 4 PCR CMV, EBV, BK
- Run 3: 150 min
  - 4 Patients
  - 4 Extractions
  - 4 PCR CMV, EBV, BK

**36 reactions assays in approx. 8h, first patient samples in approx. 2h30**
**Time-to-first-result oriented workflow**

**Batch Workflow**
- Run 1: 150 min
  - 12 Patients - Plasma
  - 12 Extractions
  - 12 PCR CMV
- Run 2: 105 min
  - 12 PCR EBV
- Run 3: 105 min
  - 12 PCR BKV

**36 reactions in approx. 6h Time-to-result oriented workflow**
Intelligent Software

1. **User Management**
   - Individual login and roles (audit trail)

2. **Assay Programming**
   - Open & Closed modes
   - CE-IVD assay locked & User-defined protocol
   - Custom Panel saving

3. **Reagent Management**
   - Traceability on screen and reports
   - Inventory manager tracks reagent block test configuration, setup, usage, expiry

4. **Run Setup & Monitoring**
   - Bi-Directional LIS, bar-coded materials
   - Graphical loading guidance
   - Indicates progress, time left & curves in real time

5. **Assay Calibration**
   - Stores curves of multiple Cal & reagent lots
   - Manages bar-code entry, approval, expiry

6. **Assay Controls (QC)**
   - Stores multiple Control & reagent lots
   - Levy Jennings (Quant), CT plots (Qual)

7. **Reports**
   - Run results summary
   - Custom report by track or patient (optional plots)
   - Setup, Cal, & Control reports
ELITe InGenius™

ELITe InGenius – Reliable, flexible sample-to-result solution that enables workflow optimization, effective resource allocation and gives accurate and timely results.