Associated Infections menu

ELITE InGenius

Comprehensive, Fast, and Flexible Sample-to-Result Solution for **Healthcare Associated Infections** and **Antimicrobial Resistance** Testing







ELITe InGenius®, a **Comprehensive** sample-to-result solution for Healthcare Associated Infections testing



ELITe MGB® line, a **SUPERIOR CE-IVD** menu to prevent nosocomial infections and tackle antimicrobial resistance

This innovative molecular diagnostics solution features capabilities not available on other systems.

Fully automated and highly flexible, ELITe InGenius is designed to simplify testing workflow enabling laboratories to perform multiple and independent PCR in parallel simply on demand, with less than 2 minutes hands-on time.

Additionally, ELITe InGenius offers laboratories a superior and unique HAI menu including a complete range of antibiotics resistance testing in Gram negative bacteria with CRE, ESBL, and Colistin assays.

Unprecedented flexibility and full automation

- Fully automated from extraction to result Full flexibility in PCR testing: analysis
- Full flexibility in patient sample processing:
- 1 to 12 samples independently processed
- Direct loading of transport media without pre-treatment
- Mix and match all kinds of sample matrices within one run
- Storage of extracted nucleic acid in individual tubes for multiple and reflex testing, sequencing, or archiving

- Suitable for HAI emergency and batch testing
- Mix and match any real-time PCR assays on
- Up to 4 parallel or reflex PCR from one single

• Adaptable to any HAI testing scenarios:

- Infection diagnosis,
- Confirmation of positive samples obtained with culture

Patient screening,

C. difficile **ELITe MGB® Kit** Toxin A Toxin B, including NAP1/BI/027

100% sensitivity 98% specificity

Open Channel

Laboratory developed tests, & others tests of



* RUO version, CE-IVD available in 2019

interest

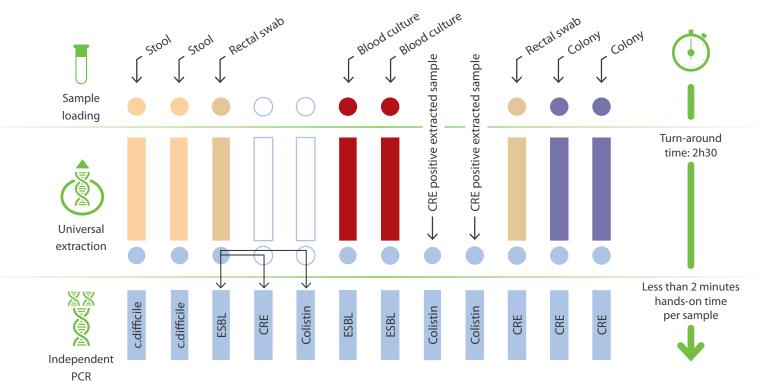
100% specificity





- Monoreagent, ready-to-use format to save time and guarantee result accuracy
- Unlimited menu capability in combination with other ELITechGroup assays and laboratory developed tests within one run
- Compatible with open instruments: All PCR reagents can be used on both sample-to-result and conventional PCR systems

ELITe InGenius workflow



MRSA/SA **ELITe MGB® Kit**

Including mecC

98.9% sensitivity 100% specificity

CR Mix BI Suffer Up S.p.A. Cu Submit Up S.p.A. Cu S.p.A.





ESBL

ELITe MGB® Kit

99.5% sensitivity

97.8% specificity

99.7% sensitivity 98% specificity



mcr-1

mcr-2

OXA 48

VIM, IMP, NDM

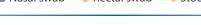
CTX M-1

CTX M-9



100% sensitivity



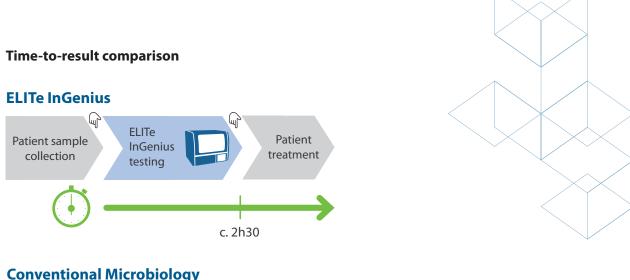


- Focused **multiplexed** real-time PCR assays
- Designed with industry-leading, proprietary Minor Groove Binder (MGB) technology
- Developed with our **extensive experience** and long-lasting expertise in design, optimization, and validation of PCR assays

Fast, and actionable results when time matters

- Superior alternative to conventional microbiology workflow:
- Faster answers by shortening the time-toresult from several days to just 2h30
- Easy-to-operate with minimal hands-on
- Higher sensitivity, and accurate results
- **Proven technology:** Mean Time Before Failure higher than 13 months

- **complex** Cost-effective solution for hospitals:
 - Significant reduction of patients' isolation, and length of hospitalization
 - Infection prevention and control
 - Better antibiotic stewardship
 - Improve patient management with faster and appropriate treatment decision





Human Intervention



Fact sheet



Healthcare Associated Infections (HAI) and antimicrobial resistance (AMR) are major global health issues worldwide with adverse impacts on healthcare facilities, patients and societies. Amongst several measures, like infection control or antibiotics stewardship, the use of rapid molecular tools in hospital laboratories is vital to address this rising problem.

HAI burden -



of hospitalized patients will acquire at least one HAI

1/3 of intensive care unit patients

will acquire at least one HAI



of HAI in long-term acute care settings

are caused by antibiotic resistant bacteria⁽¹⁾

C. difficile and MRSA/SA impact

172,000

c. difficile infections each year in Europe



€3,000 M

of deaths within 40% the 3 months after diagnosis(2)



171,200

MRSA infections in Europe in 2008(3)



€380 M

5.400 deaths



Antimicrobial resistance threat





worldwide are attributable

to antimicrobial resistance





Based on scenarios of rising drug resistance,



0 million deaths

= 1 person every 3 seconds



\$100 trillion⁽¹⁾



ELITechGroup delivers unparalleled solutions for Healthcare Associated Infections testing based on the ELITe MGB® line, a unique and high-performance range of real-time PCR assays. In combination with ELITe InGenius, a highly flexible sample-to-result solution, laboratories and hospitals gain significant benefits in terms of quality of results, efficiency, productivity, and costs:

- Workflow simplification
- Fast and accurate results
- Infection prevention and control

- Better patient management
- High economic impact
- Adaptability to laboratory testing needs

Additionally, CE-IVD validated with conventional PCR systems and compatible with most of extraction, and thermal cyclers available on market, the ELITe MGB® line offers laboratories a unique configuration adapted to every laboratory workflow and throughput needs.



| Product Name | Quantity | Reference |
|-------------------------------------|----------|-----------|
| C. difficile ELITe MGB® Kit | 100 | M800358 |
| C. difficile ELITe Positive Control | 12 | M800373 |
| MRSA/SA ELITe MGB® Kit | 100 | M800351 |
| MRSA/SA ELITe Positive Control | 12 | M800356 |
| CRE ELITe MGB® Kit | 96 | RTS200ING |
| CRE ELITe Positive Control | 12 | CTR200ING |
| ESBL ELITe MGB® Kit | 96 | RTS201ING |
| ESBL ELITe Positive Control | 12 | CTR201ING |
| Colistin ELITe MGB® Kit | 96 | RTS202ING |
| Colistin ELITe Positive Control | 12 | CTR202ING |



A pioneer in PCR technologies for more than 20 years, ELITechGroup is a leading PCR innovator with the revolutionary Minor Groove Binder (MGB) technology and has become today a global solution provider for Molecular Diagnostics. Our culture of innovation, combined with the highest manufacturing quality standard and long-lasting collaborations with customers and international working groups enables us to design and manufacture superior sensitivity and specificity real-time PCR assays for infectious disease testing, immunocompromised patient monitoring, antibiotic resistance control, oncohematology, and genetic testing.



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