MOLECULAR DIAGNOSTICS

Coagulation ELITe MGB® Kit

Multiplex Real-Time PCR Assay for the Detection of Factor V, Factor II, and MTHFR Variants

**HIGH-PERFORMANCE** assay for the detection of Factor V, Factor II and MTHFR variants

**Simplified** workflow in combination with the ELITe InGenius® system

**Comprehensive** test menu
Venous thromboembolism is a major and global health issue that annually concerns more than 1.5 million people, with an economic burden estimate at €3.07 billion only in Europe. The combination of acquired and genetic risk factors, such as the Factor V Leiden coagulation gene variant, influence the susceptibility to thrombosis and embolisms. Effective prevention strategies, including the assessment of genetic factors in individuals with history of thrombosis, are required to improve patient management and reduce the economic burden.

**Coagulation ELITe MGB® Kit** is a genetic assay, to detect and differentiate by real-time PCR amplification & melt-curve analysis, Factor V Leiden, Factor II G20210A and MTHFR C677T variants. In association with ELITe InGenius, a fully automated sample-to-result system, the Coagulation ELITe MGB® Kit is an advanced molecular solution for the allelic detection of the main variants associated with higher risk of venous thrombosis.

### Highest performance assay
- Multiplex assay for the simultaneous detection of the Factor V Leiden, Prothrombin Factor II G20210A, and MTHFR C677T single nucleotide polymorphisms
- Industry leading-MGB technology embedded
- Excellent clinical performance: 98.5%, 100%, and 100% sensitivity and 100% specificity respectively for Factor V Leiden, Factor II G20210A and MTHFR C677T variants

### Simplified workflow
- Fully automated, cassette based sample-to-result solution to perform all the steps of genetic testing
- Limited hands-on-time: less than 2 minutes per sample
- Direct loading of patient sample in primary tubes
- Optimize set-up, without any manual pipetting steps required during the whole process
- Storage of extracted nucleic acid for retesting, archiving or additional molecular testing

### Comprehensive ELITe InGenius menu
- First CE-IVD genetic test available on the ELITe InGenius system
- Best-in-class CE-IVD menu for transplant pathogen monitoring, healthcare associated infections, meningitis respiratory infections, and sexual transmitted diseases.*
- Real open capability to increase the menu breadth with complementary Laboratory Developed Tests or other tests of interest according to the specific lab’s requirements

### Ordering information

<table>
<thead>
<tr>
<th>Reference</th>
<th>Product</th>
<th>Quantity</th>
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<tbody>
<tr>
<td>RSTD00ING</td>
<td>Coagulation ELITe MGB® Kit</td>
<td>96 tests</td>
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<tr>
<td>CTRD00ING</td>
<td>Coagulation ELITe Positive Control</td>
<td>12 tests</td>
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ELITechGroup Molecular Diagnostics, a major innovator in the molecular diagnostics market, offers comprehensive real-time PCR products and solutions for diagnosis and monitoring of viral and microbiological infections.

*Submission pending

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ELITechGroup is certified by DEKRA and applies a quality management system in compliance with ICO 9001:2008 and ISO 13485:2012