



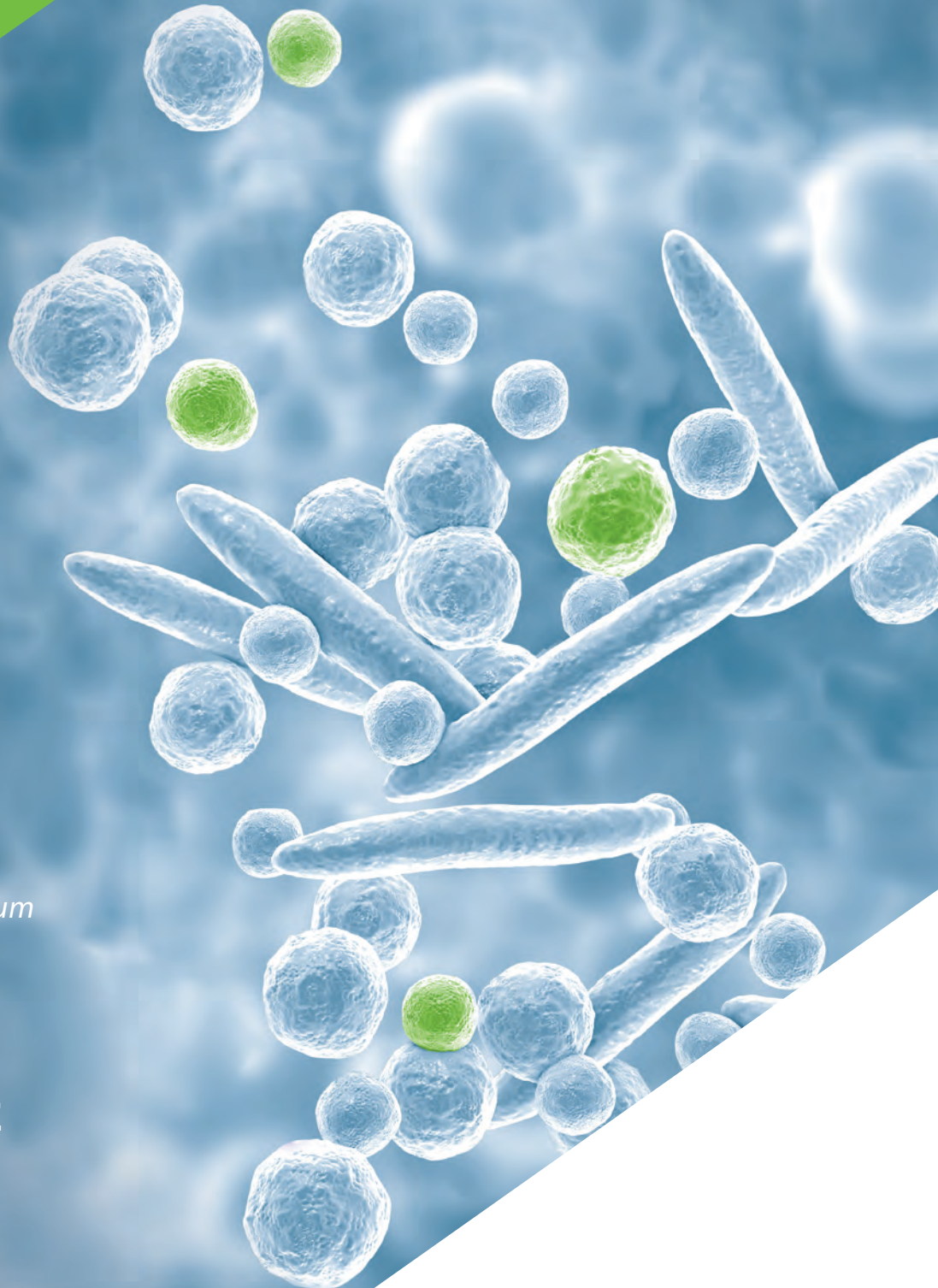
Molecular Diagnostics

Macrolide-R/MG ELITe MGB® KIT

Assay for *Mycoplasma genitalium* &
Macrolide resistance

Real-Time PCR

MGB



INNOVATIVE ASSAY

design for *M. genitalium*
and resistance to
macrolide detection

HIGHEST PERFORMANCE

assay

SIMPLIFIED WORKFLOW

in combination with
the ELITe InGenius® system

The rate of patients infected with *Mycoplasma genitalium* resistant to macrolide, a first line antibiotic treatment, is dramatically increasing worldwide. An accurate detection is crucial to provide an appropriate patient treatment and prevent the transmission of antibiotics resistant infections.

Macrolide-R/MG ELITe MGB® Kit is an innovative PCR assay designed to detect *Mycoplasma genitalium* and mutations responsible for macrolide-resistance as recommended by new European guideline. In combination with ELITe InGenius, Macrolide-R/MG ELITe MGB® Kit is the first CE-IVD assay available with a sample-to-result solution to simultaneously detect *M. genitalium* and its resistance to macrolide.

UNIQUE ASSAY DESIGN

- Detection in one single reaction of ***M. genitalium***, and 5 mutations: **A2058G, A2059G, A2058T, A2058C, A2059C** associated to macrolide resistance by Real-Time PCR and melt-curve analysis
- Dual probe test design targeting the *M. genitalium* 23S rRNA gene
- Industry-leading MGB technology embedded

HIGHEST PERFORMANCE

Sample	<i>M. genitalium</i> Analytical Sensitivity	<i>M. genitalium</i> Diagnostic Sensitivity	<i>M. genitalium</i> Diagnostic Specificity	Macrolide-R Diagnostic Sensitivity	Macrolide-R Diagnostic Specificity
Urine	247 CFU/mL	100% (33/33)	100% (30/30)	100% (30/30)	100% (24/24)

SIMPLIFIED WORKFLOW

- Fully automated solution to perform all the steps of MDx, from extraction to result analysis
- Direct loading of urine, and transport media without pre-treatment
- Limited hands-on time: less than 2 minutes per sample
- Screening or reflex testing from *M. genitalium* positive eluate obtained with **STI PLUS ELITe MGB Kit** for *C. trachomatis*, *N. gonorrhoeae*, *M. genitalium*, and *T. vaginalis* detection

EFFICIENT DIAGNOSIS

- Laboratory testing workflow improvement in comparison to other molecular solutions available
- Rapid, and accurate diagnosis of *M. genitalium* combined with patient guide therapy
- Quick patient information and appropriate treatment decision to limit complications, and the risk of transmission

Ordering information

Reference	Product	Quantity
RTS401ING-48	Macrolide-R/MG ELITe MGB® Kit (MG and Macrolide resistance)	48 tests
CTR401ING	Macrolide-R/MG ELITe Positive Control	12 tests
RTS400ING	STI PLUS ELITe MGB® Kit (CT/NG/MG/TV)	96 tests
CTR400ING	STI PLUS ELITe Positive Control	12 tests
CTRCPE	Internal Control	48 tests

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.

WORLDWIDE OFFICES

Please contact your sales representative for terms, conditions and product availability in your country.



ELITechGroup is certified by DEKRA and applies a quality management system in compliance with ISO 9001:2015 and EN ISO 13485:2016

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