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95% OVERALL SUCCESS RATE IN A FIRST INTERNATIONAL PILOT STUDY

Mycoplasma genitalium, Drug Resistance, Nucleic Acid Detection; Introducing a New External Quality Assessment Scheme

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BACKGROUND

Mycoplasma genitalium (Mgen) is classified as a sexually transmitted disease and is commonly treated with macrolide-based antibiotics. Due to the widespread presence of macrolide resistance in Europe, the 2021 European Guidelines[1] recommend testing for macrolide resistance mutations in all positive specimens of Mgen. As rapid molecular tests for Mgen drug resistance have been developed, laboratories need appropriate external quality assessment (EQA) schemes to meet the quality control requirements. Labquality, an international EQA provider, has introduced a new EQA scheme *Mycoplasma genitalium*, drug resistance, nucleic acid detection, to support the quality control of nucleic acid tests (NAT) incorporating detection of mutations associated with macrolide resistance for Mgen.

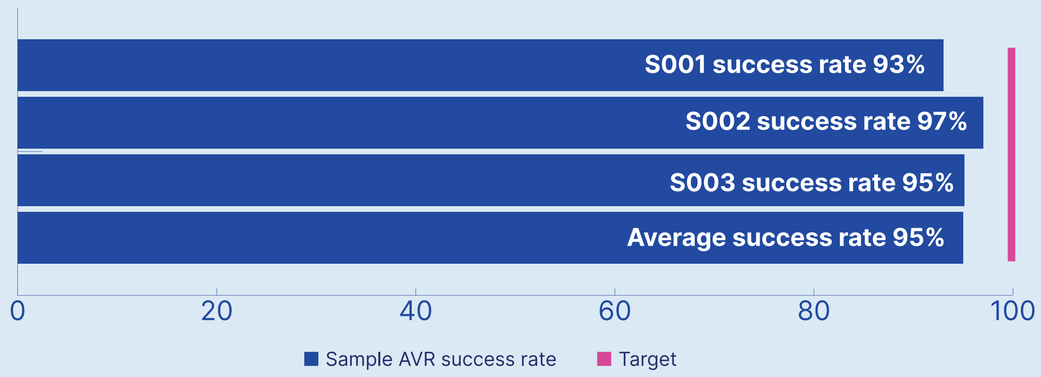
CONCLUSIONS

- The newly developed macrolide resistant Mgen positive samples as well as the negative sample used for this pilot study are homogeneous, stable, and well suited for use as EQA samples based on the results of this study.
- The performance of the participants and the tests used in this pilot study were excellent with an overall success rate of 95%.
- The guidance for reporting results must be specified to avoid unnecessary errors.
- **The high response rate indicates a need for this EQA scheme for molecular assays for detection of Mgen/macrolide resistance.**

RESULTS

Test name	*M. genitalium*	*M. genitalium* + MRAM detection
Abbott Alinity m STI Assay	+	
BioCorp BC-Mycoplasma	+	
ELITechGroup Macrolide-R/MG ELITe MGB Kit	+	+
Hain Lifescience FluoroType STI	+	
Hologic Aptima M. genitalium assay	+	
In-house (4 tests)	+	(2 of 4 tests)
Seegene Allplex CT/NG/MG/TV Assay	+	
Seegene Allplex MG & AziR Assay	+	+
Seegene Allplex STI Essential Assay Q (MH, UU)	+	
SpeedDx ResistancePlus® MG	+	+
SpeedDx ResistancePlus® MG FleXible	+	+
TIB MOLBIOL/Roche LightMix Modular Mycoplasma Macrolide	+	+
Xema Mycoplasma genitalium	+	

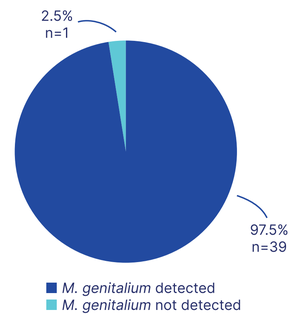
38/44 participants reported their results using altogether 12 different commercial and 4 in-house laboratory developed nucleic acid detection tests. Two laboratories reported results of two different tests. Macrolide resistance was reported by 30 participants using 5 different commercial and 2 in-house tests. MRAM=macrolide resistance-associated mutation (nucleotide exchange in 23S rRNA of *M. genitalium*, *Escherichia coli* numbering).



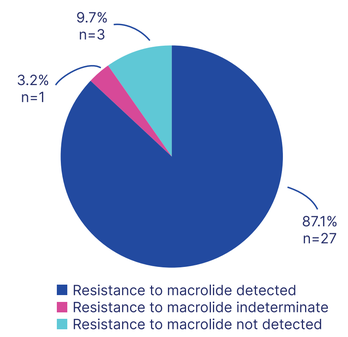
The success rates were 93% for sample S001 (Mgen positive, macrolide resistant, A2058C point mutation), 97% for sample S002 (Mgen positive, macroclide resistant, A2058G point mutation) and 95% for sample S003 (Mgen negative). Most of the deviating results were most likely due to reporting errors and/or misunderstandings in entering the results. The overall success rate was thereby 95%.

Sample S001 Expected result: *M. genitalium* positive, macroclide resistantance detected

S001 *Mycoplasma genitalium*, NAT

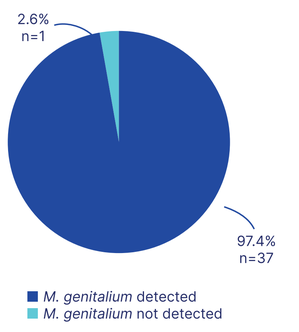


S001 Macrolide susceptibility, NAT

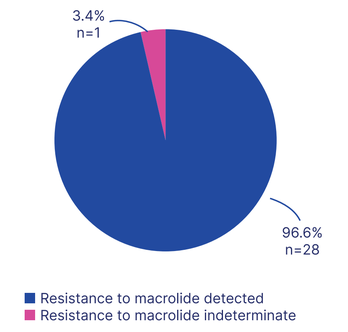


Sample S002 Expected result: *M. genitalium* positive, macroclide resistantance detected

S002 *Mycoplasma genitalium*, NAT

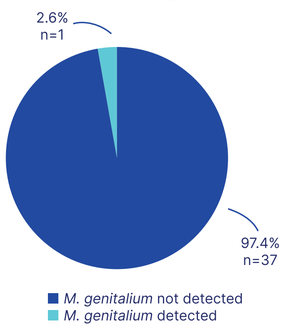


S002 Macrolide susceptibility, NAT

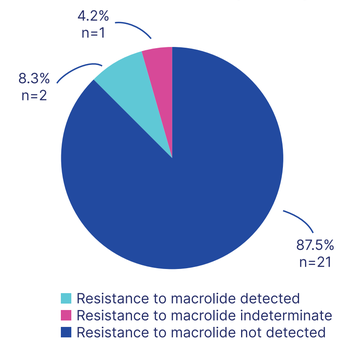


Sample S003 Expected result: *M. genitalium* negative, macroclide resistantance not detected

S003 *Mycoplasma genitalium*, NAT



S003 Macrolide susceptibility, NAT



The expected results for the three samples included in the pilot study and the distribution of the reported results. The participants were allowed to report up to 3 results/sample.

METHODS

- Three patient sample-simulating swab samples containing desiccated preparations of human cells and Mgen with A2058C or A2058G point mutations or only human cells i.e. negative for Mgen developed by Microbix Biosystems, Canada.
- Samples were shipped without temperature control packaging to 44 participating laboratories in 18 different countries.
- Participants were instructed to elute the swabs in a sample collection tube or transport medium (1-3 mL).
- Analysis of nucleic acid detection for Mgen and macrolide resistance was to be performed according to the test manufacturer's instructions.
- Qualitative results of Mgen and macrolide detection, with the option of reporting which point mutation was detected, were to be reported via Labquality's electronic platform LabScala.
- Final reports were distributed to the participants upon closing of the round.

[1]U.S. Jensen, M. Cusini, M. Gomberg, H. Moi, J. Wilson, M. Unemo. 2021 European guideline on the management of *Mycoplasma genitalium* infections. Journal of the European Academy of Dermatology and Venereology Guideline; 2022:36:641-650. https://doi.org/10.1111/jdv.17972.

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