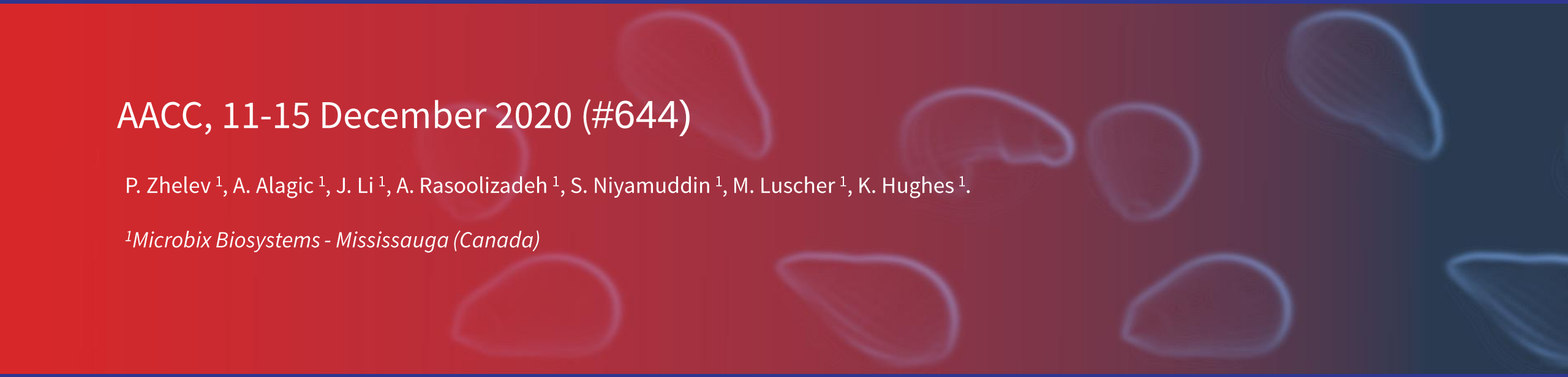
Novel *Mycoplasma genitalium* (Mgen) and AMR Mgen A2059G Materials for use in a Cross-Platform NAAT Quality Control



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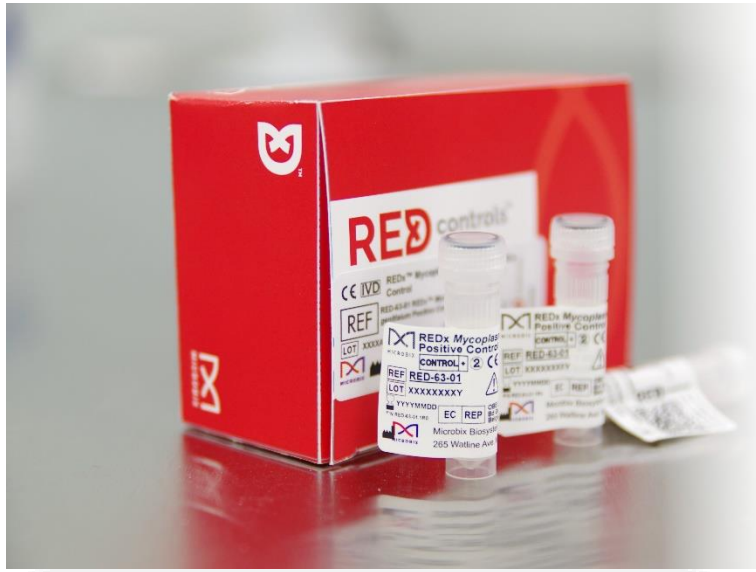
OBJECTIVES

To demonstrate the performance of novel *Mycoplasma genitalium* (Mgen) and antimicrobial resistant (AMR) Mgen A2059G materials, designed as liquid formulations for use on multiple, full genotyping commercially available nucleic acid amplification testing (NAAT) platforms. *Mycoplasma genitalium* NAAT is emerging as a cornerstone triage method for sexually transmitted infection evaluation in the infected population. Furthermore, with the introduction of antimicrobial resistant Mgen evaluation in this population, NAAT is needed and becoming mandatory in certain geographies. However, currently available NAAT on the market is affected by the lack of proper AMR Mgen quality control (QC) material and may impact timely testing and patient diagnosis.

MATERIALS AND METHODS



REDx™ M. genitalium (Mgen) Positive Controls (IVD) and PROCEEDx™ Mgen Positive Samples (RUO) contain modified Mycoplasma genitalium G37 whole bacterial genome and human cells. PROCEEDx™ Mgen A2059G (RUO) contains modified Mycoplasma genitalium whole bacterial genome with the A2059G macrolide resistance mutation in the 23S rRNA gene, and human cells. All products are formulated in a widely accepted sample transport medium.

The products are stable at 2-8°C for one year and contain all the diagnostic targets normally found in a patient specimen sample; such as bacterial DNA, RNA, and proteins. The presence of human cells in the preparations allow for representation of human housekeeping genes (such as HBB) if sample adequacy control is needed.

The products were evaluated by using a three-step approach; first with internal validation of sample performance using the Diagenode S-DiaMGTV™ and S-DiaMGRes™ tests, followed by performance verification by “end users”, and last by validation at multiple Original Equipment Manufacturer (OEM) laboratories.

Product Name (used in the study)	Catalogue	Strain	Volume
RED controls *M. genitalium* **Positive Control**	RED-63-01	G37	1 mL
PROCEED *M. genitalium* **Positive Sample**	VP-63-01		
PROCEED **Mgen A2059G Positive Sample**	VP-63-02	A2059G	

RED controls™ PROCEED™

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RESULTS

1. Internal analytical performance and validation study.

1a. Analytical performance of REDx™ *M. genitalium* Positive Control.

MICROBIX	Mgen Positive (qPCR) diagenode						HBB Gene Cepheid					
	First set			Second set			First set			Second set		
	Result	SD	CV	Result	SD	CV	Result	SD	CV	Result	SD	CV
Lot#1	+++	0.33	1.31%	+++	0.40	1.58%	+++	0.29	0.96%	+++	0.15	0.50%
	+++			+++			+++			+++		
	+++			+++			+++			+++		
Lot#2	+++	0.12	0.49%	+++	0.40	1.55%	+++	0.15	0.51%	+++	0.59	1.91%
	+++			+++			+++			+++		
	+++			+++			+++			+++		
Lot#3	+++	0.32	1.28%	+++	0.21	0.82%	+++	0.06	0.19%	+++	0.25	0.83%
	+++			+++			+++			+++		
	+++			+++			+++			+++		
Total SD	**0.4**						**0.4**					
Total CV [%]	**1.4%**						**1.2%**					

1 b. Internal validation study.

- NAAT detection of REDx™ *M. genitalium* Positive Control

OEM	Test	Platform	Target	Mgen G37
diagenode	**S-DiaMGTV™**	qPCR (Ct)	DNA	+++
	S-DiaMGRes™	qPCR (Ct)	DNA	+++

- NAAT detection of detection of PROCEEDx™ *M. genitalium A2059G* Positive Sample

OEM	Test	Platform	Target	Mgen A2059G
diagenode	**S-DiaMGTV™**	qPCR (Ct)	DNA	-
	S-DiaMGRes™	qPCR (Ct)	DNA	+++

Legend/ Symbol	Test detection range
-	Negative
+	Low positive
++	Medium positive
+++	High positive

2. OEM validation studies.

2a. NAAT detection of REDx™ *M. genitalium* Positive Control.

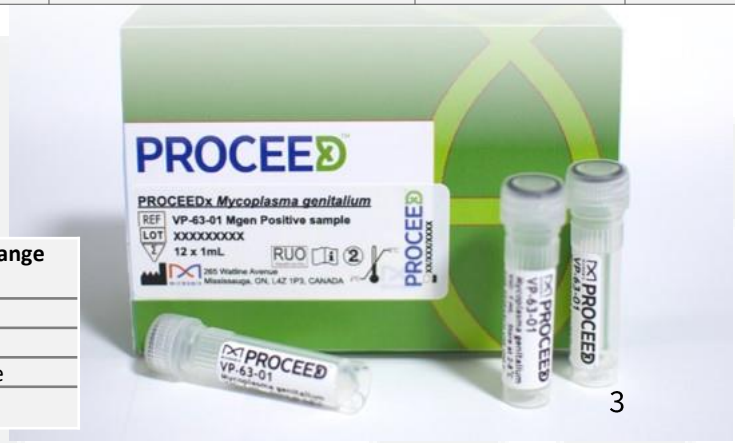
OEM	Test	Platform	Target	Mgen G37
Roche	**cobas® TV/MG**	qPCR (Ct)	DNA	+++
HOLOGIC	**Aptima MG Assay**	TMA (RLU)	RNA	+++
SpeeDx	**ResistancePlus MG**	qPCR (Ct)	DNA	+++
ELITechGroup	**STI PLUS ELITe MGB®Kit**	qPCR (Ct)	DNA	+++
Seegene	**Allplex™ CT/NG/MG/TV**	DPO qPCR (Ct)	DNA	+++

2b. NAAT detection of PROCEEDx™ *M. genitalium A2059G* Positive Sample

OEM	Test	Platform	Target	Mgen A2059G
SpeeDx	**ResistancePlus MG**	qPCR (Ct)	DNA	+++
Seegene	**Allplex™ MG & AziR**	DPO qPCR (Ct)	DNA	+++

3. Performance verification study with Lab Developed Test (LDT).

Laboratory	Test	Platform	Target	Mgen G37
Quest Diagnostics	**Lab Developed Test**	qPCR (Ct)	DNA	+++



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CONCLUSIONS

Novel Mgen and Antimicrobial Resistant (AMR) Mgen materials formulated in a widely accepted sample transport medium demonstrate excellent compatibility with several OEM platforms utilizing TMA, qPCR and TOCE-DPO detection methods. Further, the internal validation studies demonstrated high reproducibility and lot to lot repeatability of the materials. The low variability allows Lab Developed Tests (LDTs) to use the samples as daily run controls by following the Westgard rules, in addition to internal validation and verification of test performance.

The successful detection of various DNA and RNA targets demonstrates the achievement of constructing cross-platform compatible whole genome Mgen and AMR Mgen samples for use as prospective quality controls.

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