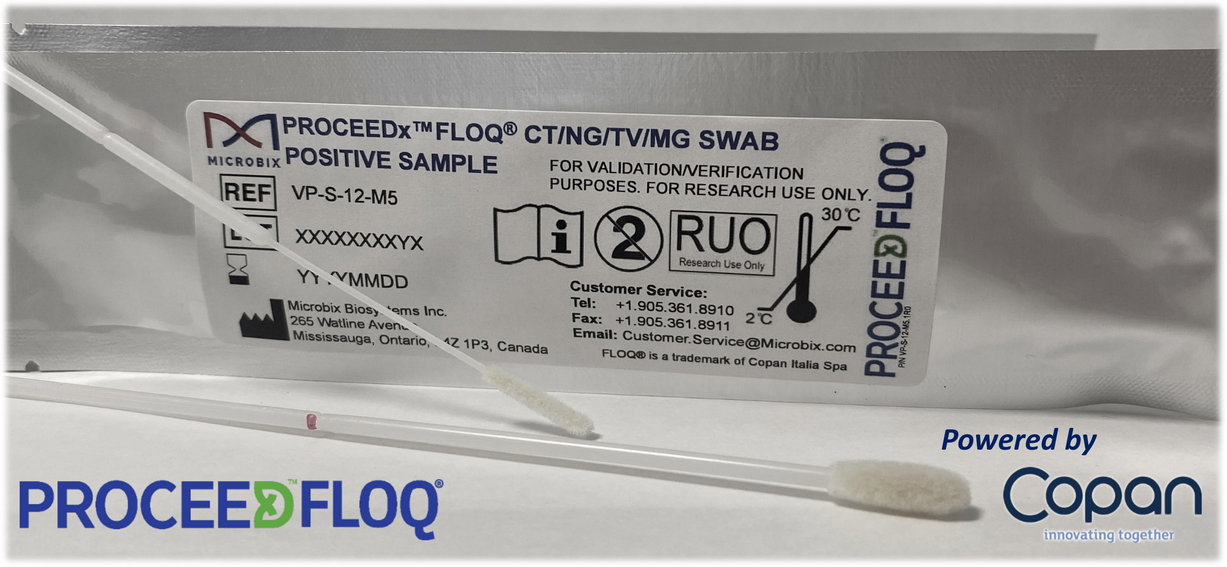
Evaluating the Performance of Emerging STI Point of Care Assays Using Novel, Room Temperature Stable CT/NG/TV/MG Positive Swab Quality Control Materials

A-363

S. Rivers [1], P. Zhelev [1], M. Thakur [1], A. Alagic [1], J. Li[1], C. Randall [1], M. Luscher [1], K. Hughes [1]

[1]*Microbix Biosystems – Mississauga, ON, Canada*

AACC, Anaheim, CA. July 24-27TH 2023



INTRODUCTION

The emergence of Point of Care tests that detect Sexually Transmitted Infections (STIs) is critical for screening and diagnostic programs in low-resource and remote settings. Point of Care tests that are designed to simultaneously detect *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), *Trichomonas vaginalis* (TV), and *Mycoplasma genitalium* (MG) promote rapid diagnosis and early treatment of the most common etiological agents causing STIs. Along with the roll-out and use of these tests, there is a growing need for complex multi-analyte quality control materials that are stable at room temperature and challenge test performance by identifying result deviations, lot-to-lot variability and routine laboratory workflow errors. Microbix developed a whole-workflow multiplex quality control desiccated on a Copan FLOQSwab® that is stable at 2-30°C and contains inactivated whole-genome target pathogens. The objective of this study is to evaluate sample performance with Point of Care diagnostic platforms that are currently in development and commercial IVD tests that are routinely used in the laboratory.

MATERIALS & METHODS

Whole-Workflow External Quality Control

CT/NG/TV/MG desiccated on a Copan FLOQSwab®

- Native, inactivated – *Chlamydia trachomatis* Serovar L2, strain 434
- Native, inactivated – *Neisseria gonorrhoeae* strain B5025
- Native, inactivated– *Trichomonas vaginalis* strain C-1:NIH
- Synthetic, whole genome – *Mycoplasma genitalium* modified G37 genome
- Human cells

Evaluate Sample Performance

- **High and medium-throughput IVD and LDT platforms/assays**
- **POCT IVD platforms**
- **Point of Care IVD assay in final stages of development**

RESULTS

Table 1: CT/NG/TV/MG Swab Positive Performance with Commercial Assays and Assays in Development

Manufacturer	Assay	Target Analytes			
		CT	NG	TV	MG
Seegene	Novaplex™ CT/NG/TV/MG Assay	+	+	+	+
BOSCH / aprimeo diagnostics	Vivalytic STI Assay	+	+	+	+
Abbott	Alinity m STI Assay	+	+	+	+
Cepheid	Xpert® CT/NG Assay	+	+	NA	N/A
	Xpert® TV Assay	N/A	N/A	+	N/A
BD	BD MAX™ CT/GC/TV Assay	+	+	+	N/A
Unable to disclose **IVD Assay is in final stages of development*	CT/NG/TV/MG qPCR	+	+	+	+
LDT qPCR QuantStudio (QS5 and QS 12K)	CT/NG/TV/MG qPCR	+	+	+	+

CONCLUSION

The CT/NG/TV/MG whole genome multiplex formulation desiccated on a Copan FLOQSwab® is an advantageous prospective quality control material that is stable at room temperature and supports the clinical use and accuracy of emerging STI assays, including the most challenging Point of Care test formats. The formulation showed acceptable performance on multiple platforms, thereby demonstrating excellent commutability for use as verification/validation, External Quality Assessment, and ongoing quality control material. Additionally, the dry swab format offers great practicality for monitoring assay performance in low-resource and remote settings.

ACKNOWLEDGEMENTS

We would like to acknowledge that the data used in the poster was provided by:
Aprimeo Diagnostics, Pfungstadt, Germany
Abbott, Illinois, USA
Simple Laboratories, Illinois, USA

CONTACT US

Pavel Zhelev, Director, Product Management
Email: Pavel.Zhelev@microbix.com