A New External Quality Assessment Program for Laboratories that Detect *H. pylori* and Antimicrobial Resistant Markers Using Nucleic Acid Amplification Test Methods

Pavel Zhelev[1], Sydney Rivers[1], Heidi Berghäll[2] , Kristel Virtanen[2], Kati Luiro[2] , Qudus Aguda[1], Mehak Thakur[1], Amer Alagic[1], Mark Luscher[1], and Ken Hughes[1]

[1] *Microbix Biosystems Inc, Mississauga, Canada*
[2] *Labquality, Helsinki, Finland*

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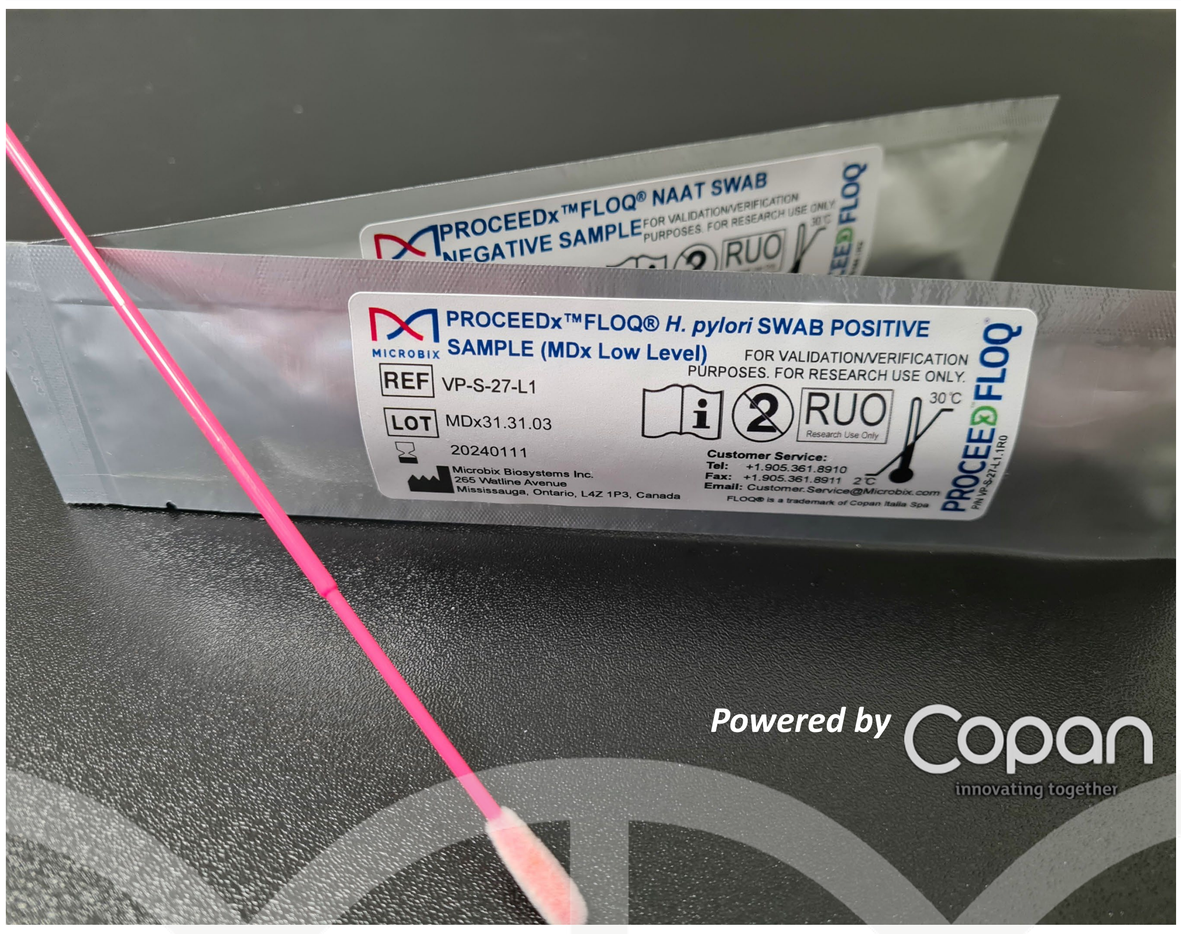

INTRODUCTION

Helicobacter pylori (*H. pylori*) infection affects approximately half of the world's population and continues to pose a serious threat to human health with the rise of antibiotic resistant strains[1,2]. Consequently, there is an urgent need for screening and diagnostic programs that accurately detect *H. pylori* infections and its antibiotic resistant markers[2]. Conventional microbiological diagnosis is based on culture; however, this technique has limitations as it is challenging to isolate the bacterium from gastric biopsy specimens and has prolonged turnaround times[2]. The emergence of non-invasive molecular diagnostic tests has become significant to promote rapid diagnosis and early treatment.

To ensure accurate and reliable testing, contrived specimens are required for External Quality Assessment (EQA) programs, assay validation, sensitivity and specificity assessment, laboratory personnel training, and routine quality control. However, existing liquid matrix formats frequently fall short in providing the required stability. The target degradation (antigen and nucleic acid) can compromise sample integrity, impeding accurate assessments of laboratory competency, especially in Point-of-Care Testing (POCT) setups.

AIM

Microbix Biosystems Inc. collaborated with Labquality to create a pilot EQA program for laboratories that perform nucleic acid amplification tests (NAATs) for *H. pylori* and antimicrobial resistant detection. To address the challenges associated with formulating stable liquid EQA samples, Microbix developed an inactivated whole-process *H. pylori* positive swab sample, which was then used to evaluate the performance of various *H. pylori* NAATs that were conducted by laboratories across Europe. The objective of this study is to highlight the outcomes of a newly developed *H. pylori* EQA program using a novel sample format to preserve sample integrity.

METHODS

Microbix designed and developed a whole-process *H. pylori* positive swab sample that resembles patient specimens. The positive sample was formulated with native *H. pylori* that was heat inactivated, stabilized and desiccated on a Copan FLOQSwab® to ensure stability at room temperature. Blinded positive and negative samples were shipped to seventeen laboratories across Europe for assessment, of which thirteen responded.

Table 1: Samples Used in the Pilot EQA Program

Product Name	Cat. No	Intended Use
H. pylori Swab Positive Sample (MDx Low Level) PT PROCEEDFLOQ	PT-S-27-L1 / VP-S-27-L1	Blinded EQA sample / Research Use Only sample
NAAT Swab Negative Sample PT PROCEEDFLOQ	PT-S-99-M4 / VP-S-99-M4	Blinded EQA sample / Research Use Only sample

RESULTS

All participants correctly detected *H. pylori* positive and negative samples with their respective assays, except for one laboratory that received an invalid result when testing the blinded negative sample. Laboratories used their choice of elution buffer and volumes ranged from 0.5mL to 3mL.

Table 2: Summary of EQA Pilot Study

13 Laboratories	7 Assays/platforms	Positive Sample Average Success Rate 100%	Negative Sample Average Success Rate 92.3%

Table 3: *H. pylori* Swab Positive Sample (NAAT Low Level) Performance

Manufacturer	Assay	No. of Participants	Target Analytes	
			H. pylori	Resistance to Clarithromycin
Seegene	Allplex™ H. pylori & ClariR Assay	1	+	-
MOBIDIAG	Amplidiag® H. pylori+ClariR Assay	3	+	-
r-biopharm	RIDAGENE *Helicobacter pylori* Assay	3	+	-
DNA-TECHNOLOGY	Helicobacter pylori REAL-TIME PCR Detection Kit	1	+	N/A
BIOCORP a novo nordisk company	BC-H pylori Assay	2	+	N/A
Biometrics Quality of life	LightGene H. pylori Assay	1	+	N/A
Laboratory	In-House PCR	2	+	-

CONCLUSION

Microbix and Labquality launched a pilot EQA program for laboratories that detect *H. pylori* and antimicrobial resistant markers using NAATs. The results demonstrate that the novel swab-based *H. pylori* positive sample format is stable and cross-platform compatible, rendering the design suitable for EQA programs, assay verification/validation studies, laboratory personnel training, and ongoing quality control. Subsequent initiatives will focus on designing stable clarithromycin-resistant swab-based samples to enhance the comprehensiveness and effectiveness of EQA programs within the realm of *H. pylori* detection.

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CONTACT US

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

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