Flexible, automated sample-to-result opportunistic virus monitoring for transplant care on the myCROBE™ system

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Background Needed

Sexually transmitted infections (STIs) remain a major public health challenge, highlighting the need for accurate and accessible molecular diagnostics. The GeneProof STI Panel was implemented and validated on myCROBE, an automated sample-to-result platform enabling flexible pathogen detection across two clinically relevant specimen types.

myCROBE Introduction

Most sample-to-result systems offer limited viral breadth and do not support flexible, patient-specific target selection within a single automated workflow. We implemented and validated a broad-spectrum STI PCR menu on the myCROBE Fully Automated Sample-to-Result platform, enabling per-sample assay selection without changing the overall workflow.

Multiple specimen testing
Different specimen types processed within the same run

Parallel assay procession
Multiple pathogen targets tested within a single automated run

Integrated automation
Flexible sample-to-result workflow for molecular viral monitoring

Assays and Tests

Assay	CT	NG	MG	MH	UU	UP	GV	TV
Material Validation	✓	✓	✓	✓	✓	✓	✓	✓
Whole system failure test	✓	✓	✓	✓	✓	✓	✓	✓
Cross-reactivity	✓	✓	✓	✓	✓	✓	✓	✓
Interfering substances	✓	✓	✓	✓	✓	✓	✓	✓
On-board stability	✓*							

* On-board stability validated for CT MC.

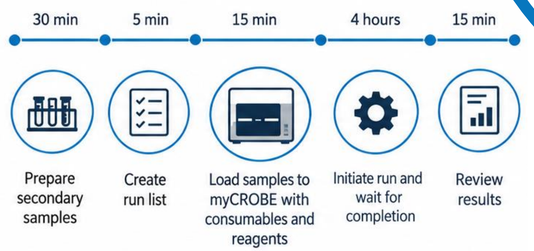


MANUAL OR SEMI-AUTOMATED WORKFLOW



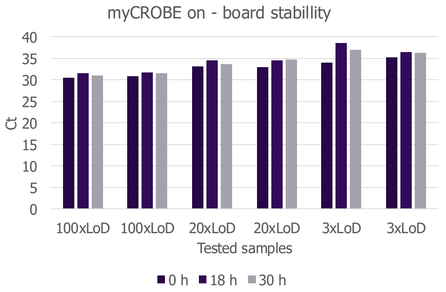
Hands on time: 3 hours 15 min | Walk-away time: 2 hours 15 min (disjointed)

myCROBE WORKFLOW



Hands on time: **50 min** | **Walk-away time: 4 hours (continuous)**

On-board Stability



On-board stability was evaluated using reference material (100×LoD, 20×LoD, 3×LoD). myCROBE PCR kits were tested over 30 hours within a 30-day period, with freezing of assay reagents between runs. **The results support the use of a single MasterMix preparation for up to four runs.**

Interference

Specimen	Swab	Urine
Interferents	Whole blood (2 % (v/v))	Bilirubin 20 mg/dL
	Mucin 60 µg/mL	pH pH4 / pH 9
	Clotrimazole cream 0.25 % (w/v)	Urea 600 mmol/L
	Gel lubricant 0.25 % (w/v)	Glucose 1 %
		Uric acid 1.4 mmol/L
		Albumin 5 %

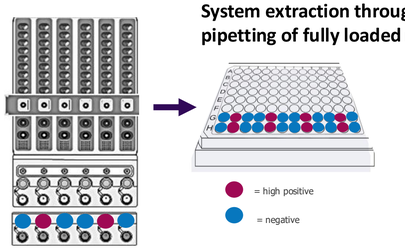
Assay performance was evaluated in the presence of potential interfering substances in validated sample materials at defined concentrations, with multiple targets assessed simultaneously within a single run.

Precision

Variability of concentration	Standard Deviation (Ct)	Coefficient of variation %
Intra-assay	0.282	0.95
Inter-assay	0.325	1.08
Inter-device	0.548	2.04
Inter-lot	0.354	1.19
Total	0.458	1.54

High precision was demonstrated with a total SD of 0.458 log, consistent across days, lots and devices. Fully automated pipetting by the myCROBE system ensured reliable and reproducible performance.

Cross-contamination



Cross-contamination testing was performed using alternating highly positive (Ct ≈ 15) and negative samples across extraction and PCR plate positions under full load conditions.
No cross-contamination was detected in six PCR runs across three myCROBE instruments.

Summary

- Reliable detection of all 8 targets bacterial across 2 clinically relevant specimen types.
- No cross-contamination observed across multiple runs and instruments, demonstrating high analytical reliability.
- Stable reagent performance throughout the entire on-board working period
- Robust assay performance confirmed across a broad panel of potential interfering substances and sample materials.
- Overall, myCROBE PCR kits provide a reliable and robust solution for routine monitoring of opportunistic bacterial infections
- Reliable performance across multiple specimen types and parallel assay processing within a single automated run.
- Consistent assay performance and effective prevention of cross-contamination, even under high viral-load conditions.

Note: Data presented are derived from the GeneProof Chlamydia trachomatis MC PCR Kit and are representative of the sexually transmitted myCROBE PCR kit panel performance.