Ambient-Stable Air-Dryable qPCR Enzyme for STI Diagnosis: Analytical Performance and Operational Advantages

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Introduction

Sexually transmitted infections (STIs) represent a major and growing public health burden worldwide, with significant gynecological, obstetric, and epidemiological consequences.[1] Quantitative PCR (qPCR) assays are the analytical gold standard for STI diagnosis due to their high sensitivity, specificity, and robustness, enabling accurate detection of pathogens such as Chlamydia trachomatis, Neisseria gonorrhoeae, Mycoplasma genitalium, Trichomonas vaginalis, HSV-1/2, and Ureaplasma spp.[2] Despite their analytical superiority, most qPCR assays rely on cold-chain–dependent reagents, which severely limits deployment in decentralized laboratories and resource-limited settings.[3] There is a critical need for cold-chain–free molecular solutions without compromising analytical performance.

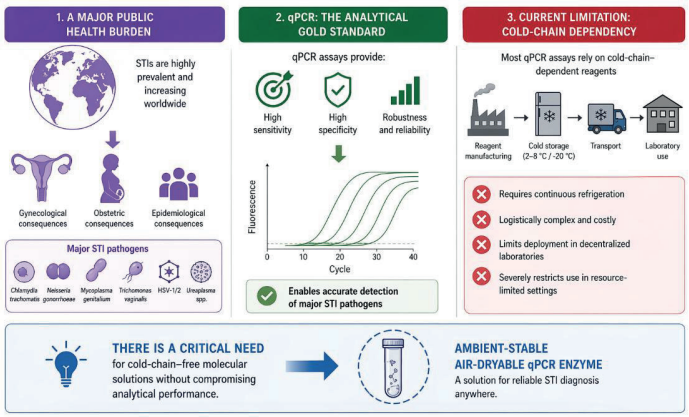


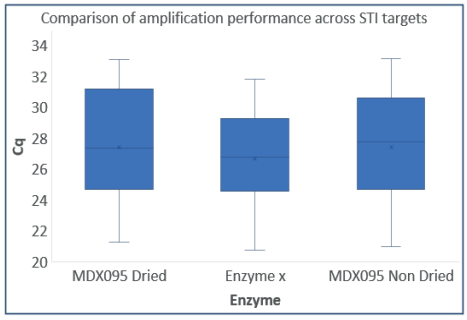
Figure 1: Conceptual Overview of Cold-Chain Limitations and Ambient-Stable qPCR Solutions

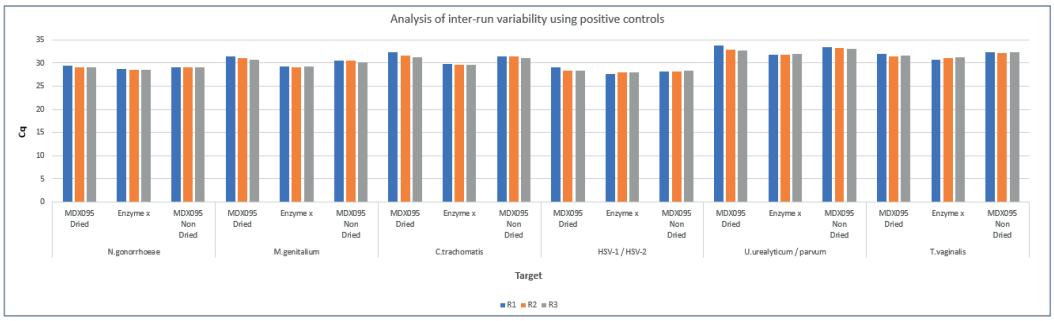
Methods

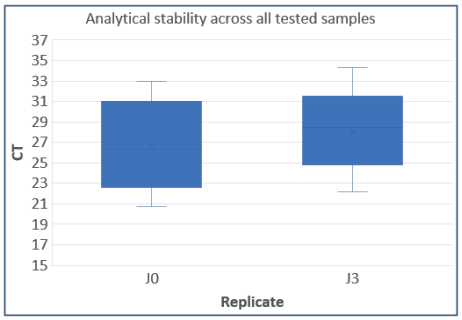
Multiplex qPCR assays were performed in parallel using two enzymes under fully harmonized conditions, including one from Meridian Bioscience, the air-dryable RT-qPCR Mix (reference MDX095). Primer and probe sequences used for all targets were those supplied in the UltraGene Assay STD9 (Ref 11374007) (ABL Diagnostics (Marseille, France)). Reagent concentrations and thermal cycling parameters were identical for all reactions, and a single unified qPCR cycling program was applied. Performance was evaluated using a panel of clinically characterized samples. Comparative analysis was based on Cq value distribution, inter-assay reproducibility and analytical sensitivity. Stability of the air-dried formulation was assessed following extended storage at ambient temperature, without refrigeration or dry ice.

Results

The air-dryable qPCR enzyme demonstrated analytical performance strictly comparable to that of the reference enzyme across all evaluated sexually transmitted infection targets. Cq value distributions between the two formulations showed minimal and consistent variation, indicating equivalent amplification efficiency and analytical behavior. Inter-assay reproducibility remained high and comparable between both enzymes across independent runs, as assessed using three technical replicates (R1, R2, R3). Furthermore, the air-dried formulation maintained stable analytical performance throughout extended storage at ambient temperature, with no detectable Cq drift or loss of sensitivity when evaluated at day 0 (J0) and after three days of storage (J3).







Conclusions

This study demonstrates that an air-dryable qPCR enzyme achieves full analytical equivalence to conventional cold-chain–dependent enzymes while offering robust stability at ambient temperature. By removing logistical barriers associated with reagent storage and transport, this technology enables broader access to molecular STI diagnostics, supports decentralized testing strategies, and strengthens public health responses to STI transmission worldwide.

References

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[2] Caruso G et.al. Current and future trends in the laboratory diagnosis of sexually transmitted infections. International Journal of Environmental Research and Public Health. 2021;18(3):1038. PMCID: PMC7908473.
[3] Lind K et al. Vacuum oven drying: a cost-effective way of producing field-deployable reagents for real-time PCR. Molecular Biotechnology. 2025;67:237–245.PMID: 38081563.