Closing Diagnostic Gaps in Respiratory Infections: A 40-Target Multiplex PCR Assay for Comprehensive Pathogen Detection

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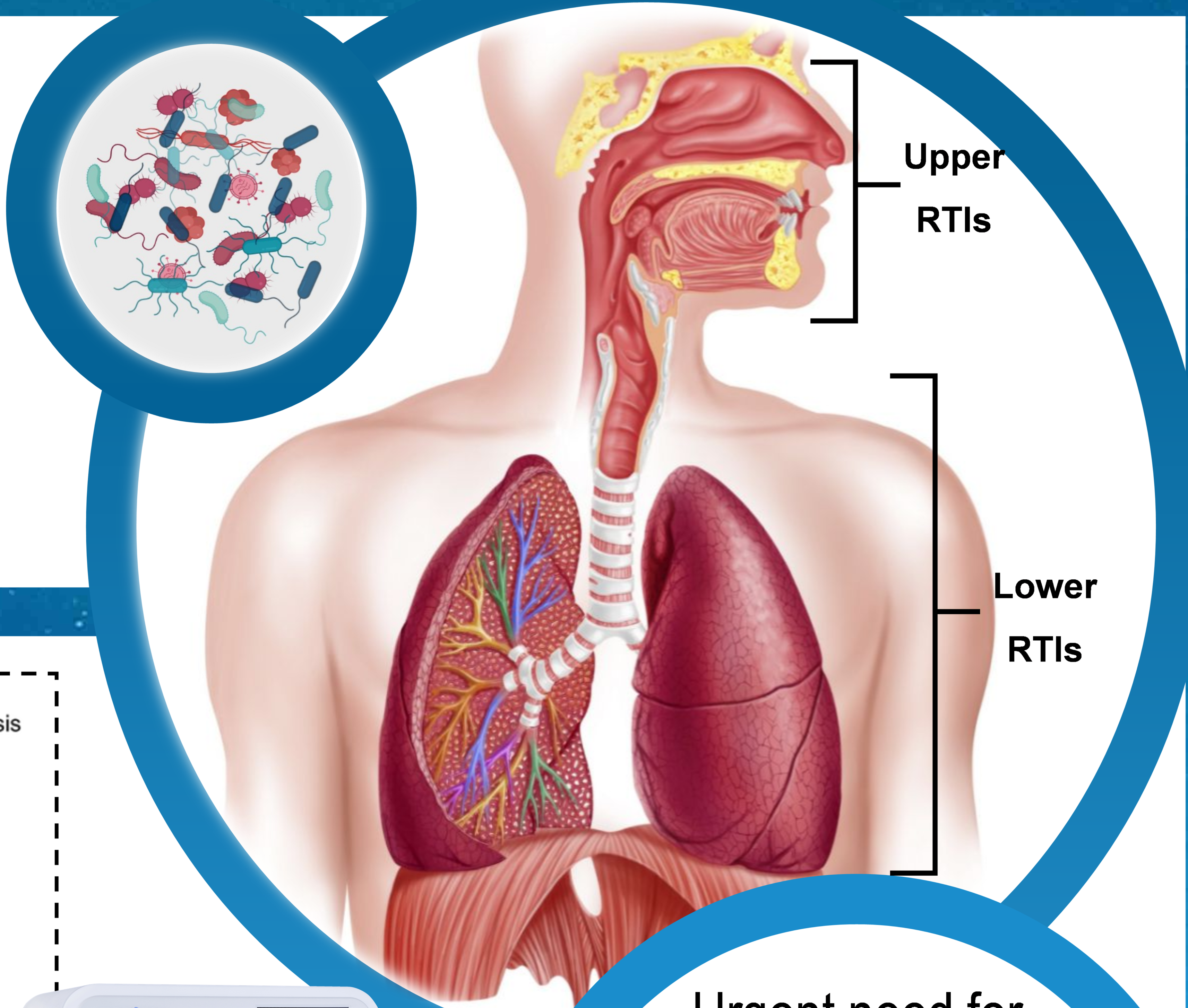
INTRODUCTION

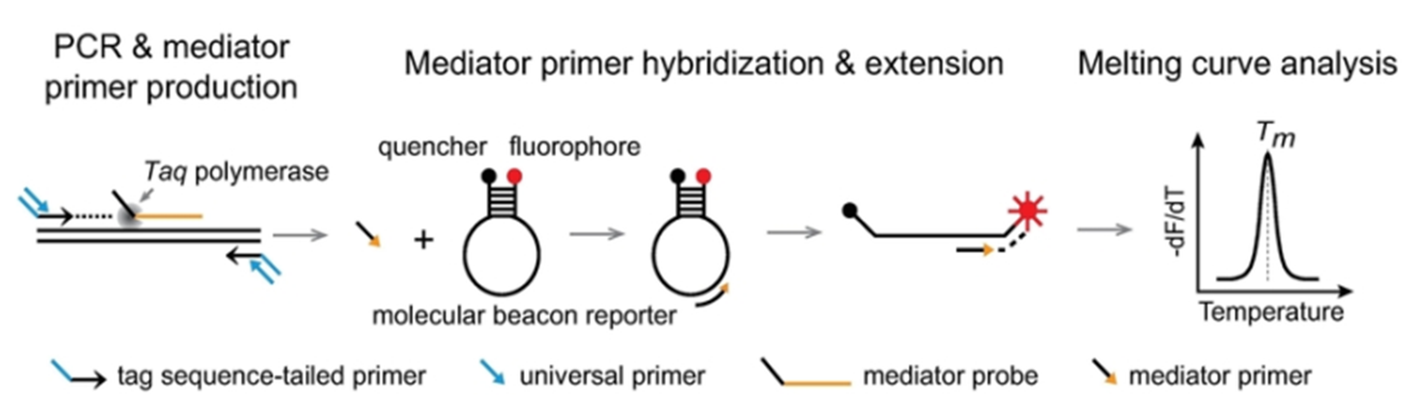
Respiratory tract infections (RTIs) remain a major global health burden, with **upper RTIs** accounting for more than **12.8 billion** cases annually and **lower RTIs** responsible for **2.4 million** deaths worldwide [1,2]. This burden is further compounded by the emergence of pathogens such as SARS-CoV-2, influenza A/B, and their novel variants, as well as the frequent occurrence of bacterial co-infections.



Urgent need for **rapid and comprehensive RTI diagnostics** to support clinical decision-making and antimicrobial stewardship.

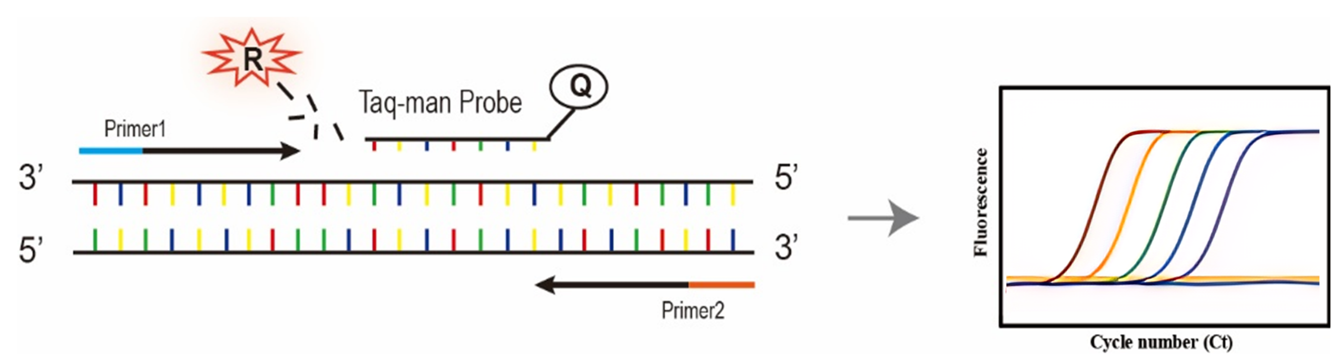
MATERIALS & METHODS

MeltArray



Two-dimensional tag-based detection using a combination of fluorescence channels and melting temperatures [3].

Real-time PCR



Quantitative detection based on qPCR technology using TaqMan probes.

RESULTS & DISCUSSION

- **Detects 32 pathogens** via unique fluorescent channels and T_m values.
- **Quantifies 8 bacterial** species by real-time PCR Ct values.
- Quantification is essential for assessing colonizing bacterial species in immuno-compromised patients.

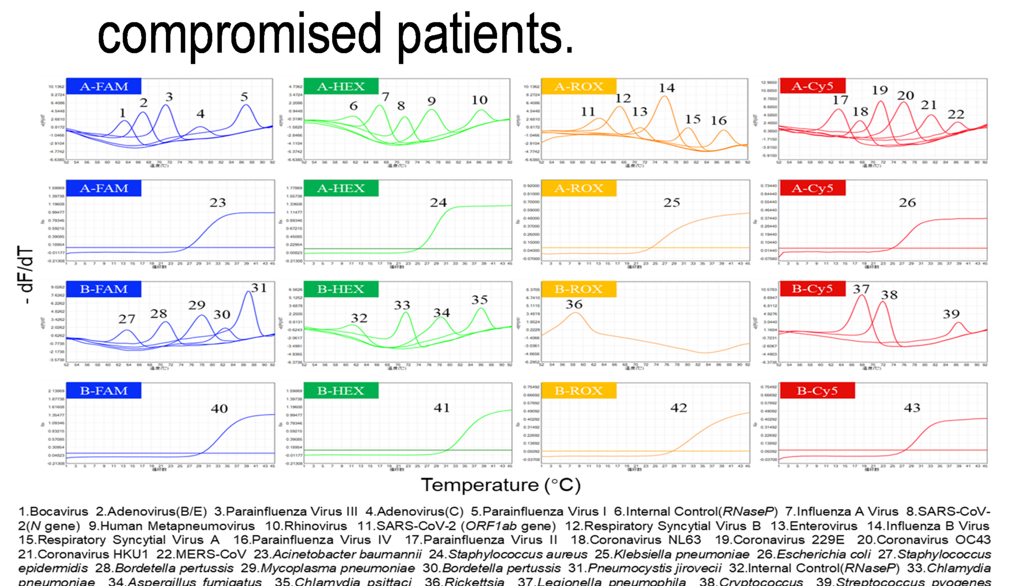


Figure 1. Typical result of RPP-40 for MeltArray and real-time PCR.

- **Clinical trial:** 1,036 oropharyngeal (OP) swabs and 3 simulated swabs (MERS-CoV diluted in negatives).
- RPP-40 assay **fully automated on SLAN qPCR / Sanity 2.0s**.
- Results in **≤2.5 h**, minimal hands-on time.
- LOD **<500 copies/mL** for all targets.

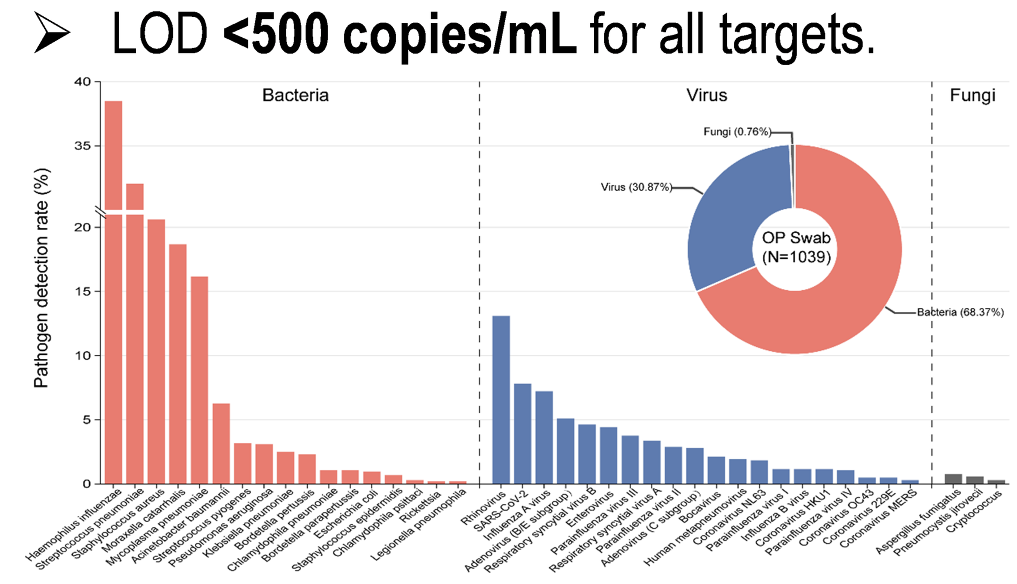


Figure 2. Clinical evaluation of RPP-40 in OP swab samples.

- Clinical performance analysis showed an overall concordance rate of 98.36–100% between RPP-40 and mNGS.

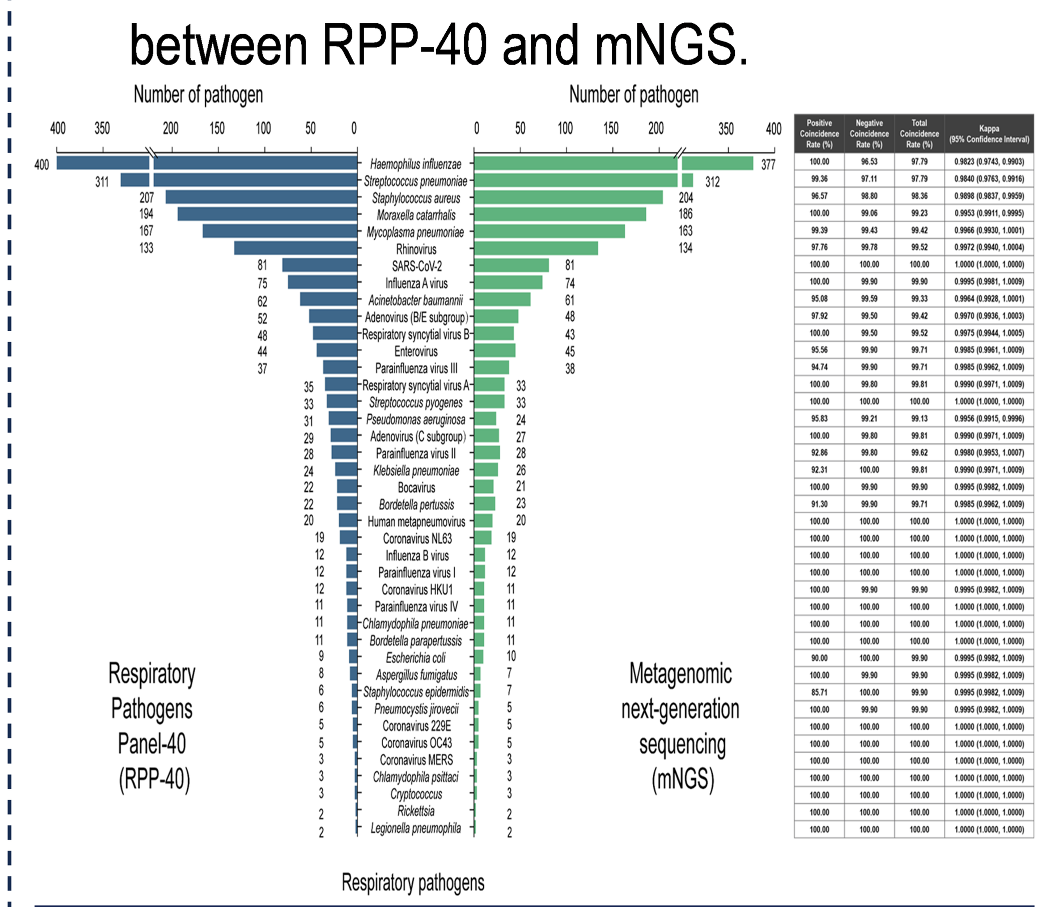


Figure 3. Comparative analysis of test results between RPP-40 and mNGS.

CONC.

The **RPP-40 assay** fills critical gaps in respiratory diagnostics by offering a robust, rapid, and scalable solution for comprehensive detection of respiratory pathogens. Its automation-ready design and high diagnostic accuracy make it well-suited for both routine clinical use and outbreak-response scenarios, aligning with global priorities for enhanced RTI management and evidence-based antimicrobial prescribing.

References: [1]. Kyu *et al. Lancet Infect Dis* 2025; [2]. Safiri *et al. Front Public Health* 2023; [3]. Huang *et al. PNAS* 2022.

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