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Evaluation of two point-of-care (POC) multiplex PCR's as a rapid screening tool for respiratory syndromes.

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A. Coussee[1], L. Florin[1], W. Vandewal[1], J. Robbrecht[1], K. Maelegheer[1]
[1]Department of Laboratory Medicine, AZ Sint-Lucas, Bruges, Belgium

BACKGROUND

POC molecular tests for respiratory tract diseases have the potential to improve patient management and antimicrobial stewardship. [2]

It can also provide a solution to obtain fast and reliable results in urgent situations. [3]

METHODS

Method comparison of 2 POC RMP analyzers of viral pathogens available in both assays:

- RPP12 kit on the Sanity 2.0 System (Zeesan, China): 9 viral and 3 bacterial pathogens
- Respiratory Panel 1.0 on the FlashDx-1000-E platform (FlashDx, China): 8 viral and 1 bacterial pathogen

Inclusion of 27 nasopharyngeal samples, previously positive for at least one pathogen analyzed in routine (Respiratory panel 1A, 2 & 3 on STARlet platform Seegene, South-Korea).

Analytical evaluation: sensitivity & specificity
Feasibility: evaluation of pre-analytical, analytical and post-analytical phases

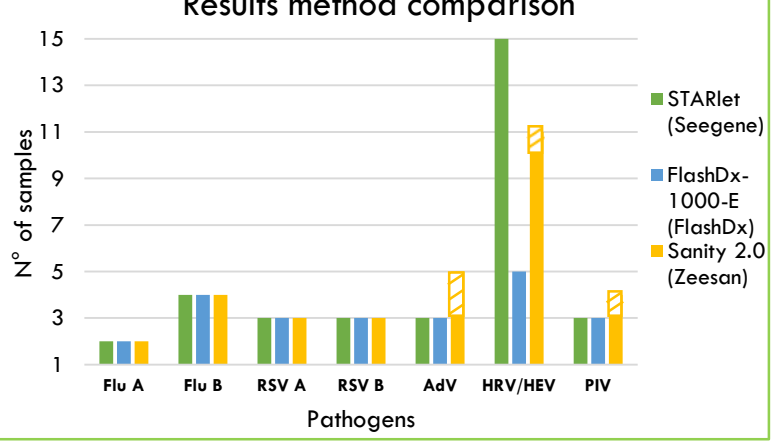

Figure 1: Results method comparison (Influenza A Virus (Flu A), Influenza B Virus (Flu B), Respiratory Syncytial Virus A/B (RSV A/RSV B), Adenovirus (AdV), Human Rhinovirus (HRV), Human Enterovirus (HEV), Parainfluenza Virus 1, 2 and 3 (PIV))

REFERENCES

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[4] Principi N, Zampiero A et al. Prospective evaluation of Rhinovirus infection in healthy young children. Journal of Clinical Virology. 2015;66;83-89.
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OBJECTIVES

Method comparison of 2 POC analyzers for a respiratory tract infections multiplex PCR (RMP) detecting the most common respiratory pathogens:

- Analytical evaluation
- Assessment of their feasibility

RESULTS

- All samples positive on the STARlet platform (Seegene) for FLU A & B, RSV A & B, AdV and PIV were confirmed on both POC devices.
- **FlashDx-1000E (FlashDx):**
  - Missed 9 weak HEV/HRV positive samples.
  - Higher Ct-values for all targets compared to Seegene
  - Single sample analysis
  - Analysis time +/- 1h
- **Sanity 2.0 (Zeesan):**
  - Additionally detected AdV (2 samples), HRV/HEV (1 sample), and PIV (1 sample)
  - Missed 5 weak HRV/HEV positive samples
  - No Ct-values visible for user
  - Samples are batched in groups of 4
  - Analysis time +/- 2h30
- Both POC devices scored equally well in terms of ease of handling.

CONCLUSIONS

✓ Both platforms are sufficiently **user-friendly** as rapid screening tools for respiratory syndromes.

! **Sensitivity issues** with HRV/HEV detection were reported in both assays

→ Limited clinical impact.[4]

→ Difficult to include all serotypes of HEV/HRV in a single PCR[5]

! **Specificity problems** with Sanity 2.0 (Zeesan) need to be further investigated and corrected

→ Potentially false positive results due to fluorescence-interference?

⇒ **Respiratory Panel 1. (FlashDx)** seems to meet the necessary requirements for accuracy, ease of use and TAT, although some important respiratory pathogens (e.g. human Metapneumovirus (hMPV)) are missing in this panel