Evaluation of automated mariPOC® multianalyte antigen detection test

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Introduction

mariPOC® (ArcDia International Oy Ltd) is the first random-access test system (IVD CE) that allows automated and rapid multianalyte detection of respiratory pathogens at the point-of-care (Figures 1 and 2). The majority of positive results are reported in 20 minutes. Low positive and negative samples are reported at two hours.

The objective of this prospective open study was to evaluate the performance of the mariPOC® for the diagnosis of respiratory viruses in comparison with the direct fluorescent antibody assay (DFA). Both nasopharyngeal aspirates (NPAs) and swab samples were evaluated.

Experimental

✓ Study period from October 4, 2011 to February 29, 2012
✓ 241 NPAs and 193 swab samples collected from patients with symptoms of respiratory illness – at the emergency department, or – from those who were hospitalized in pediatric, pulmonary, or in the department for hematologic malignancies, or – who were treated in the intensive care unit
✓ 283 patients
   – 124 children below 5 years old
   – 144 adults (among them 79 patients older than 65 years old)
✓ PCR (Department of Virology, University of Turku, Finland) was used for discrepant samples

Results

The results for RSV and influenza A virus using NPAs are shown in Table 1. mariPOC® found six other pathogens from NPAs (3 adeno- and 3 meta-pneumoviruses) and DFA found five (3 adeno- and 2 parainfluenza viruses).

mariPOC® tests from NPAs had mean analytical specificity of 99.8 % and clinical specificity of 98.4 %. With swab samples sensitivities were close to 70 %, and mean analytical and clinical specificity were 99.2 % and 93.6 %, respectively. Lower specificity for the swab samples was due to a few problematic samples that gave multiple positive results. mariPOC® reported correctly all samples of a quality assurance round (Labquality, Helsinki, Finland).

Conclusions

✓ The performance of mariPOC® was similar in all age groups tested.
✓ The system provides convenient multianalyte analysis without delay right at the patients’ bedside and in busy emergency departments
✓ It allows patient cohort-grouping and helps to prevent nosocomial infections.
✓ The system can utilize either NPAs or swab samples.
✓ Lower sensitivity obtained in our study for the swab samples emphasizes adequate sample quality and the importance of training of nurses who collect specimens.
✓ The possibility to diagnose metapneumovirus and the use of the database of the analyser for epidemiological surveys are additional advantages.
✓ In established laboratory settings with highly skilled personnel, DFA remains preferable due to its high analytical resolution.