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Evaluation of the Solana Influenza A+B assay during the Swiss influenza outbreak season 2016/17

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Influenza is a contagious respiratory illness caused by influenza virus A and B. Diagnosis of the influenza virus is of high importance for both hospital hygiene and patient management. Therefore, rapid, minimal hands-on time and economically viable molecular testing systems are needed, esp. in influenza peak seasons. The Solana Influenza A+B Assay (Quidel) is a newly available, recently FDA cleared isothermal NAT-amplification assay. Here, we present the outcome of an evaluation-study performed during the 2016/17 epidemic Swiss influenza season and show the performance characteristics of the Solana Influenza A+B assay compared to two other, well-established testing systems.

Material and Methods

423 freshly obtained nasopharyngeal swab specimens (Copan UTM™ Viral Transport Media) from adult patients admitted to the accident and emergency unit of the university hospital of Bern, Switzerland, were prospectively analyzed. Solana and Xpert assays were performed in parallel for all samples. Non-concordent results were repeated using the Influenza A/B r-gene assay. All assays were performed according to the manufacurers instructions. For extraction, a Biomerieux NUCLISENS® EASYMAG® System using 400ul original material eluted in 110ul Buffer was used. RT-PCR was performed on a Roche LightCycler® II z480.

	Xpert Xpress FLU/RSV +	Xpert Xpress FLU/RSV -	Influenza A/B r-gene +
Solana Influenza A+B +	130	0	nd
Solana Influenza A+B -	14	279	14

Systems

	Xpert Xpress Flu/RSV	Solana Influenza A+B Assay	Influenza A/B r-gene
Assay:			
Manufacturer:	**Cepheid Inc.**	**Quidel Inc.**	**Biomérieux**
Format:	conventional rt-RT-PCR	isothermal RT-Helicase-Dep. Amplification	conventional rt-RT-PCR
Extraction:	• on-board extraction	• separate lysis step	• separate extraction step
Assay Runtime:	• 20/30 minutes	• 40 minutes	• 90 minutes
Preparatory work:	• <5 minutes	• 10 minutes	• variable (>90 min.)
Interpretation:	• automatic	• automatic	• manual
Single cont. Testing:	• yes	• (yes) Device is blocked during run	• no (in our setting)
Hands-on time:	• very low	• low	• high
Manual complexity:	• very low	• medium	• high

Results and Conclusion

All obtained results represent Influenza A virus (IFA). No IFB were detected in the 2016/17 season. Compared to Xpert Xpress Flu/RSV and Influenza A/B r-gene, the Solana Influenza A+B achieved a sensitivity of 90.3% (95% CI: 84.3% to 94.6%) and a specificity of 100.00 % (95% CI: 98.6% to 100.0%). This reflects a PPV of 100.0% and NPV of 95.2% (95% CI: 92.3% to 97.0%) for this test in the analyzed study group. The 14 specimens where IFA was not detected by the Solana assay had C(t) values between 34.5 and 36.9 (mean 35.7) in the Influenza A/B r-gene assay and are therefore all considered to be low-positive specimens. The Xpert Xpress Flu/RSV and Influenza A/B r-gene showed congruent results for these samples.

The Solana Influenza A+B Assay offers in terms of its performance characteristics, ease-of-use and economic viability a middleground between the rapid, low-labor, all-in-one but expensive Xpert Xpress Flu/RSV system and the conventional Influenza A/B r-gene real time PCR assay regarding the turn-around time, hands-on-time and overall cost efficiency. However, in our hands, these benefits came with a slight trade-off in sensitivity for low positive samples.

Declaration of interest: Solana Influenza A+B Assay Kits used for this study were provided free of charge by Quidel Inc.