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Evaluation of the clinical performance of a fully automated RT-PCR assay for the qualitative detection of RSV and hMPV in human nasal/throat swabs and bronchoalveolar lavage under IVDR

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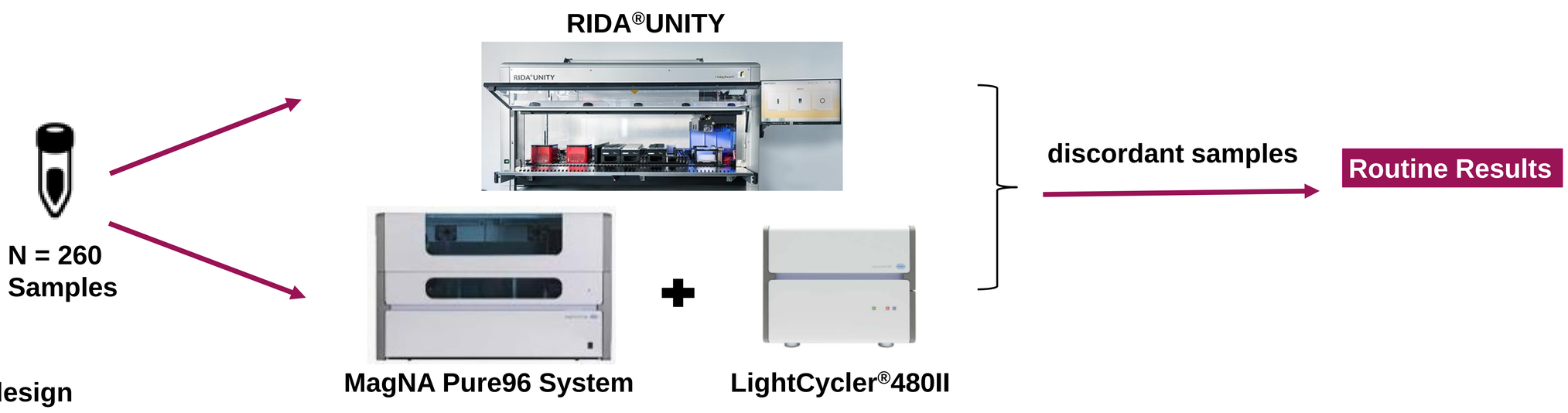
Introduction

The RIDA®UNITY platform is a fully automated system that enables a high sample throughput with low hands-on time. The RIDA®UNITY RSV & hMPV test, performed on the RIDA®UNITY platform, is a multiplex real-time RT-PCR for the direct qualitative detection and differentiation of respiratory syncytial virus (A/B) and human metapneumovirus (A/B). This study was conducted for evaluation of the qualitative clinical performance of the RIDA®UNITY RSV & hMPV test (R-Biopharm AG) in untreated human nasal/throat swabs and bronchoalveolar lavage (BAL). The clinical performance characteristics of this assay were compared to those of the RIDA®GENE RSV & hMPV assay (R-Biopharm AG).

Methods

In total, 260 retrospective swabs and BALs from persons with signs and symptoms of acute respiratory infections were tested with the RIDA®UNITY RSV (A/B) & hMPV (A/B) in comparison to the RIDA®GENE RSV (A/B) & hMPV (A/B) assay. The samples were tested in a non-interventional, monocentric, cross-sectional fashion and samples were completely anonymized. The RIDA®UNITY test was performed on the integrated fully automated RIDA®UNITY platform. For the RIDA®GENE assay the samples were extracted with the MagNA Pure96 system (ROCHE) and the PCR was performed on the LightCycler®480II (ROCHE). Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) were assessed. In case of discrepancies, routine results were used for resolution. The routine result was measured with the Allplex™ Respiratory Panel (Seegene).



Figur 1: Study design

Results

After resolution of discrepant results, for the RIDA®GENE RSV & hMPV assay 98 of the 260 samples were tested positive and 162 samples were tested negative for RSV. For hMPV the RIDA®GENE tested 89 samples positive and 171 negative. Within the measurement, 11 discrepant results for RSV and 8 discrepant results for hMPV occurred. After analyzing the discrepancies, the results showed excellent agreement between the RIDA®UNITY test and the RIDA®GENE assay. A PPA of 91.8% was achieved for RSV and 89.9% for hMPV with the RIDA®UNITY assay combined in Swab and BAL. The NPA for RSV and hMPV is 100% for the RIDA®UNITY assay combined in Swab and BAL.

a)

		RIDA®GENE RSV + Routine (Swab & BAL)		
		Positive	Negative	Total
RIDA®UNITY RSV (Swab & BAL)	Positive	90	0	90
	Negative	8	162	170
	Total	98	162	260
Positive Percent Agreement (95% CI)		**91.8%** (84.5 – 96.4%)		
Negative Percent Agreement (95% CI)		**100%** (97.6 - 100%)		

b)

		RIDA®GENE hMPV + Routine (Swab & BAL)		
		Positive	Negative	Total
RIDA®UNITY hMPV (Swab & BAL)	Positive	80	0	80
	Negative	9	171	180
	Total	89	171	260
Positive Percent Agreement (95% CI)		**89.9%** (81.7 – 95.3%)		
Negative Percent Agreement (95% CI)		**100%** (97.9 - 100%)		

Table 1 a) & b): Results of the clinical performance evaluation after resolution of discrepant results. a) RSV (Swab & BAL) b) hMPV (Swab & BAL)

Overall, the majority results of discrepant cases for RSV & hMPV occurred due to negative results using RIDA®UNITY RSV & hMPV, while RIDA®GENE RSV & hMPV detected the same samples as low positive (Ct >32), suggesting a higher sensitivity of the RIDA®GENE RSV & hMPV workflow.

Conclusion

In this comparison, the RIDA®UNITY RSV & hMPV showed very good performance for the direct, qualitative detection and differentiation of RSV and hMPV in human nasopharyngeal swabs and BAL samples. In addition, the automated RIDA®UNITY platform offers a convenient workflow for the molecular diagnostic routine laboratory.

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