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Clinical performance of a fully automated real-time PCR assay for the detection of *Chlamydophila pneumonia*, *Legionella pneumophila* and *Mycoplasma pneumoniae* in human bronchoalveolar lavage under IVDR

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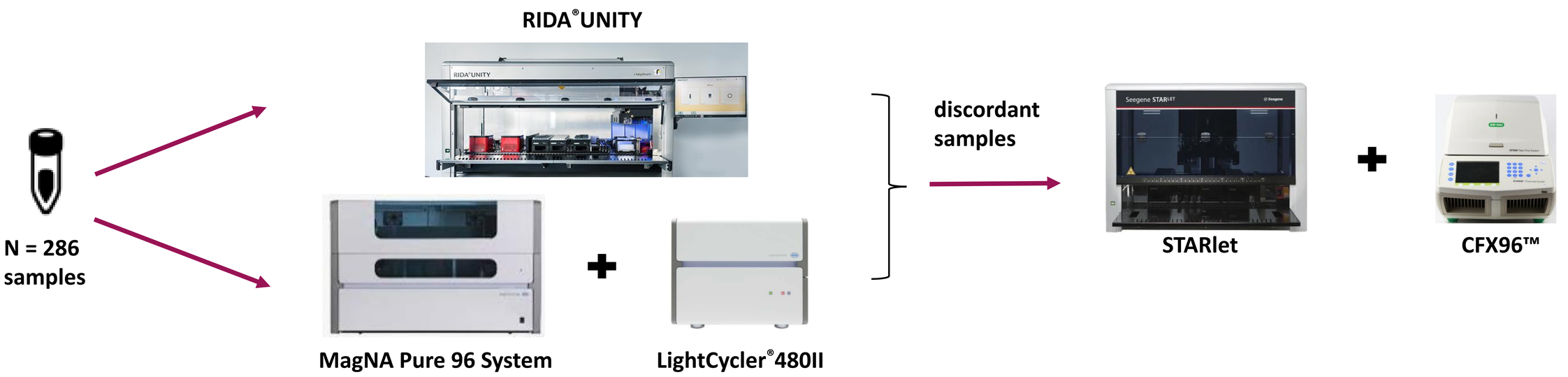
Introduction

The RIDA®UNITY platform is a fully automated system that enables a high sample throughput with low hands-on time. The study aimed to evaluate the qualitative clinical performance of the RIDA®UNITY CAP Bac (R-Biopharm AG), which detects *Chlamydophila pneumonia*, *Legionella pneumophila*, and *Mycoplasma pneumoniae* in human bronchoalveolar lavage performed on the RIDA®UNITY Platform. The clinical performance of this assay was compared to the RIDA®GENE CAP Bac assay (R-Biopharm AG).

Methods

286 retrospective bronchoalveolar lavages from persons with signs and symptoms of community-acquired pneumonia (CAP) were tested for the qualitative detection of *Chlamydophila pneumonia*, *Legionella pneumophila*, and *Mycoplasma pneumonia* using the RIDA®UNITY CAP Bac assay in comparison to the RIDA®GENE CAP Bac assay. The RIDA® UNITY assay was performed on the integrated, fully automated RIDA®UNITY Platform. For the RIDA®GENE assay, the samples were extracted using the MagNa Pure 96 system (Roche) and the Real-time PCR was performed on the LightCycler®480II (Roche). Discrepant results were resolved using the Allplex™ Respiratory Panel 4 (Seegene). For this purpose, the samples were extracted with STARlet (Seegene) and the PCR was performed on the CFX96™ (BioRad).



Figur 1: Study design

Results

A total of 286 samples were tested. All samples tested during the study with the RIDA®UNITY CAP Bac assay produced valid results, with detectable IC signals. Exclusively, 3 samples were repeatedly excluded from the RIDA®UNITY during the extraction process due to the high viscosity of the samples. The treatment of the BAL samples with dithiothreitol according to the routine procedure led to valid results. After analyzing the discrepant results with the Allplex™ Respiratory Panel 4, a sensitivity of 100% for *Chlamydophila pneumonia*, *Legionella pneumophila*, and *Mycoplasma pneumonia* was obtained. The specificity for *Chlamydophila pneumonia*, *Legionella pneumophila* was 100% and 99.6% for the *Mycoplasma pneumonia* for the RIDA®UNITY test, respectively.

Table 1 a) - c): Results of the clinical performance evaluation after resolution of discrepant results. a) *Chlamydophila pneumonia* b) *Legionella pneumophila* c) *Mycoplasma pneumoniae*

a)

		RIDA®GENE + Allplex™ Respiratory Panel 4 *Chlamydophila pneumonia*		
		Positive	Negative	Total
RIDA®UNITY *Chlamydophila pneumonia*	Positive	28	0	28
	Negative	0	258	258
	Total	28	258	286
Sensitivity (95% CI)		100% (87.8% - 100%)		
Specificity (95% CI)		100% (98.6% - 100%)		

b)

		RIDA®GENE + Allplex™ Respiratory Panel 4 *Legionella pneumophila*		
		Positive	Negative	Total
RIDA®UNITY *Legionella pneumophila*	Positive	62	0	62
	Negative	0	224	224
	Total	62	224	286
Sensitivity (95% CI)		100% (94.2% - 100%)		
Specificity (95% CI)		100% (98.4% - 100%)		

c)

		RIDA®GENE + Allplex™ Respiratory Panel 4 *Mycoplasma pneumoniae*		
		Positive	Negative	Total
RIDA®UNITY *Mycoplasma pneumoniae*	Positive	38	1	39
	Negative	0	247	247
	Total	38	248	286
Sensitivity (95% CI)		100% (90.7% - 100%)		
Specificity (95% CI)		99.6% (97.8% - 100%)		

After testing the discrepant samples, all but one sample could be resolved by the secondary reference, the Allplex™ Respiratory Panel 4. All discordant samples prior to resolution of the discrepancy were weakly positive and had a ct-value above 28.

Conclusion

In this study, the RIDA®UNITY CAP Bac and the RIDA®GENE CAP Bac delivered perfectly comparable results. The comparison of the two tests showed excellent sensitivity and specificity for all targets. Due to the outstanding performance and high diagnostic value of the RIDA®UNITY CAP Bac on the RIDA®UNITY platform, it offers a valuable addition for diagnostics. It is well suited for the direct, qualitative detection and differentiation of pneumonia in human bronchoalveolar lavage.

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