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Clinical assessment of a fully automated RT-PCR assay for the qualitative detection of parainfluenza virus 1, 3 and 2/4 in human nasal/throat swabs under IVDR

Jasmin Köffer[1], Melissa Kolb[1], Charlene Eckel[1], Ulrich Eigner[1]

[1]MVZ Labor Dr. Limbach & Kollegen GbR, Heidelberg, Germany

MVZ Labor Dr. Limbach HEIDELBERG

Introduction

The RIDA®UNITY platform is a fully automated system that enables a high sample throughput with low hands-on time. The RIDA®UNITY Parainfluenza test, performed on the RIDA®UNITY platform, is a multiplex real-time RT-PCR for the direct qualitative detection and differentiation of parainfluenza 1, parainfluenza 3 and parainfluenza 2/4. In the current study we evaluated the qualitative clinical performance of the RIDA®UNITY Parainfluenza test (R-Biopharm AG) in comparison to the RIDA®GENE Parainfluenza assay (R-Biopharm AG) in untreated human nasal/throat swabs.

Methods

In total, 317 retrospective swabs from persons with signs and symptoms of acute respiratory infections were tested with the RIDA®UNITY Parainfluenza assay for the qualitative detection of parainfluenza virus 1,3 and 2/4 in comparison to the RIDA®GENE Parainfluenza 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 Pure 96 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, the routine results measured with various PCR methods were used for resolution.

Figur 1: Study design

Results

A total of 317 samples were tested with both assays. 3 samples were repeatedly invalid and were excluded from the analysis. After analyzing the discrepancies, the results showed excellent agreement between the RIDA®UNITY test and the RIDA®GENE assay. A PPA of 96.6% was achieved for parainfluenza 1, 93.1% for parainfluenza 3 and 97.7% for parainfluenza 2/4 with the RIDA®UNITY assay. The NPA for parainfluenza 1 and 3 is 99.6% and for parainfluenza 2/4 100% for the RIDA®UNITY assay.

a)

		RIDA®GENE Parainfluenza 1 + Routine		
		Positive	Negative	Total
RIDA®UNITY Parainfluenza 1	Positive	84	1	85
	Negative	3	226	229
	Total	87	227	314
Positive Percent Agreement (95% CI)		**96.6%** (90.3 – 99.3%)		
Negative Percent Agreement (95% CI)		**99.6%** (97.6 - 100%)		

b)

		RIDA®GENE Parainfluenza 3 + Routine		
		Positive	Negative	Total
RIDA®UNITY Parainfluenza 3	Positive	81	1	82
	Negative	6	226	232
	Total	87	227	314
Positive Percent Agreement (95% CI)		**93.1%** (85.6 – 97.4%)		
Negative Percent Agreement (95% CI)		**99.6%** (97.6 - 100%)		

c)

		RIDA®GENE Parainfluenza 2/4 + Routine		
		Positive	Negative	Total
RIDA®UNITY Parainfluenza 2/4	Positive	84	0	84
	Negative	2	228	230
	Total	86	228	314
Positive Percent Agreement (95% CI)		**97.7%** (91.9 – 99.7%)		
Negative Percent Agreement (95% CI)		**100%** (98.4 - 100%)		

Table 1 a) - c): Results of the clinical performance evaluation after resolution of discrepant results. a) Parainfluenza 1 b) Parainfluenza 3 and c) Parainfluenza 2/4

Overall, the majority results of discrepant cases for parainfluenza occurred due to negative results RIDA®UNITY Parainfluenza, while RIDA®GENE Parainfluenza detected the same samples as low positive (Ct >31), suggesting a higher analytical sensitivity of the RIDA®GENE Parainfluenza workflow.

Conclusion

The automated RIDA®UNITY Parainfluenza assay and the manual RIDA®GENE Parainfluenza assay delivered comparable results. Due to the excellent performance and the convenient automated workflow of the RIDA®UNITY Parainfluenza on the RIDA®UNITY platform, this test offers an excellent and suitable addition to routine molecular diagnostics.

Contact: jasmin.koeffer@labor-limbach.de

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