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Evaluation of the clinical performance of an enzyme-linked immunosorbent assay and an immunochromatographic lateral flow assay for the detection of *Mycobacterium tuberculosis* infection in human plasma samples

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Introduction

The RIDASCREEN® TB (R-Biopharm AG) is an enzyme-linked immunosorbent assay for the indirect detection of *M. tuberculosis* infection (including disease) and is intended for use in conjunction with risk assessment, radiographic examinations and other clinical and laboratory findings. The RIDA®QUICK TB (R-Biopharm AG) is a manual immunochromatographic rapid test for the direct quantitative detection of interferon gamma induced protein 10 (IP-10) from human plasma samples from individuals with suspected *Mycobacterium tuberculosis* infection (including disease). In this study, the qualitative clinical performance of the RIDASCREEN® TB and RIDA®QUICK TB assay in human plasma samples was evaluated according to Regulation (EU) 2017/746 (IVDR). Therefore, the clinical performance characteristics of these assays were compared with the culture result and the medical history.

Methods

In this study a total of 339 samples were tested, including 133 pretested for active tuberculosis, 11 samples with knowledge about medical history of LTBI/inactive TB and 195 negative samples. A set of 7 tubes (4 for the QuantiFERON®-TB Gold Plus assays and 3 for the RIDASCREEN® TB assay and the RIDA®QUICK TB assay) were tested for each patient.

Both ELISA assays were processed manually and extinctions were measured on the DYNEX DSX® at 450/620 nm. For the RIDASCREEN® TB the OD results were calculated through the RIDASOFT Software to determine the end results. The RIDA®QUICK TB assay was analyzed on the RIDA®Q3 lateral flow reader.

The clinical performance characteristics of these assays were compared with the culture result and the medical history. Additionally the results were compared with the QuantiFERON®-TB Gold Plus (Qiagen).

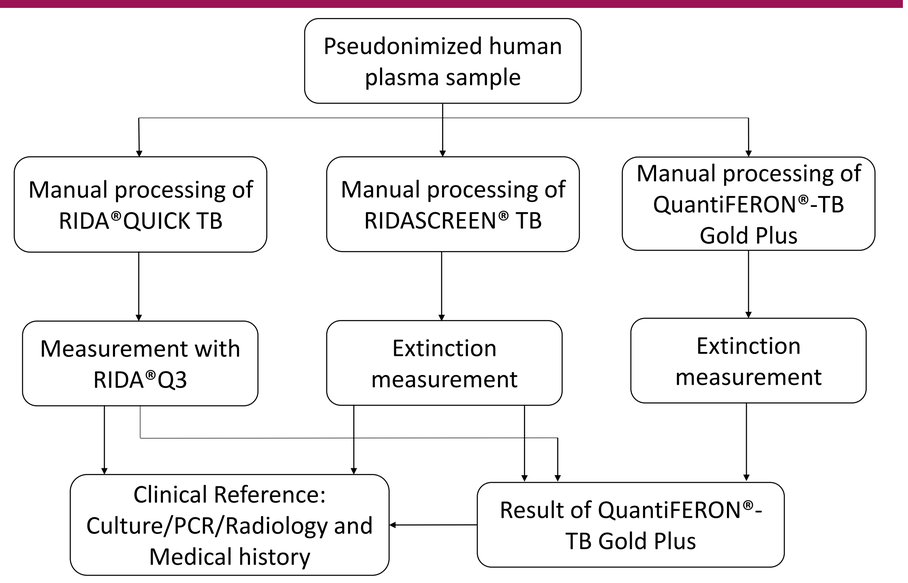

Figure 1: Study design

Results

In total 339 samples were tested. Eleven samples were taken from latent/inactive patients (LTBI), which were excluded from the analysis due to the small size of the patient group. After analyzing the samples and compared to the clinical reference we obtained a relative sensitivity of 85.2% for the RIDASCREEN® TB and 80.0% for the RIDA®QUICK TB Test. For the QuantiFERON®-TB Gold Plus the relative sensitivity was 71.6%. Relative Specificity was above 90.3% for all three tests.

Compared to QuantiFERON®-TB Gold Plus, the relative sensitivity was 96.9% for RIDASCREEN® TB and 94.9% for RIDA®QUICK TB.

Relative Specificity was 86.9% for RIDASCREEN® TB and 88.8% for the RIDA®QUICK TB.

Both assays performed very well, with only a few invalid samples: no invalid samples for RIDASCREEN® TB and 2 invalid samples for RIDA®QUICK TB.

Table 1 a) & b): Results of the clinical performance evaluation. a) against Clinical Reference: Culture/PCR/Radiology and Medical history b) against QuantiFERON®-TB Gold Plus

a)

		RIDASCREEN® TB			RIDA®QUICK TB			QuantiFERON®-TB Gold Plus		
		Positive	Negative	Total	Positive	Negative	Total	Positive	Negative	Total
Clinical Reference: Culture/PCR/Radio-logy and Medical history	Positive	109	19	128	104	26	130	91	36	127
	Negative	18	167	185	16	168	184	10	181	191
	Total	127	186	313	120	194	314	101	217	318
Relative Sensitivity (95% CI)		85.2% (77.8% - 90.8%)			80.0% (72.1% - 86.5%)			71.6% (62.98% - 79.29%)		
Relative Specificity (95% CI)		90.3% (85.1% - 94.1%)			91.3% (86.3% - 94.9%)			94.8% (90.58% - 97.46%)		

b)

		RIDASCREEN® TB			RIDA®QUICK TB		
		Positive	Negative	Total	Positive	Negative	Total
QuantiFERON®-TB Gold Plus	Positive	95	3	98	94	5	99
	Negative	27	179	206	23	183	206
	Total	122	182	304	117	188	305
Relative Sensitivity (95% CI)		96.9% (91.3% - 99.4%)			94.9% (88.9% - 98.3%)		
Relative Specificity (95% CI)		86.9% (81.5% - 91.2%)			88.8% (83.7% - 92.8%)		

Conclusion

The RIDASCREEN® TB and the RIDA®QUICK TB were evaluated in this study. Both assays provided high sensitivity and specificity when compared to the clinical reference and a very good diagnostic agreement with the QuantiFERON®-TB Gold Plus Assay. The sensitivity in active patients was higher compared to the reference assay. Both assays offer a good alternative in diagnosis of persons with suspected *Mycobacterium tuberculosis* infection. In addition, the use of the rapid test is an excellent way of providing an initial indication of a disease.

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