Evaluation of TRU Legionella®, a new rapid test for detection of *Legionella pneumophila* serogroup 1 antigen in urine samples

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Introduction

LD is an acute pneumonia caused by *Legionella* spp., which are responsible for 2 to 5% of community-acquired pneumonias. More than 90% of LD cases are caused by *L. pneumophila*, and 70 to 80% of these belong to serogroup type 1.

Objectives

The aim of our study was to evaluate the ability of a new antigen test (TRU Legionella assay, Meridian Bioscience, Cincinatti, USA) to diagnose Legionnaires' Disease (LD) using frozen urine samples from a well-described sample of patients with and without LD. The results were compared with those obtained with the Binax NOW urinary antigen test.

Methods

We studied a panel of frozen nonconcentrated urine samples collected between 2000 and 2011 and were stored at -70°C until processing was performed.

We included 139 urine samples from 139 patients with LD (cases). A case of confirmed Legionella pneumonia was defined according to the European Working Group on Legionella Infections (EWGLI) criteria (www.ewgli.org).
The specificitiy of the test was determined by using urine samples collected from 73 patients with respiratory tract infections other than Legionella infections. The laboratory test results for these patients were as follows: *Streptococcus pneumoniae* (40 patients), *Haemophilus influenzae* (9 patients), *Moraxella catarrhalis* (2 patients), *Staphylococcus aureus* (3 patients), *Escherichia coli* (2 patients), *Acinetobacter baumannii* (1 patient), *Streptococcus pyogenes* (2 patients), *Mycobacterium tuberculosis* (2 patients), and *Pneumocystis jirovecii* (1 patient). Eleven patients who had a

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Results

Results are shown in table 1. The sensitivities and specificities were 73.4% and 100%, respectively, for TRU Legionella test; and 77.0% and 100%, respectively, for the Binax NOW urinary antigen test. All discrepant results tested positive for *L.pneumophila* anitigen in Binax EIA.

Table: Results of Binax NOW and TRU Legionella tests after 15/20 minutes and 1 hour of incubation.

	No. of patients with a positive test result/total number of patients (%)	
	20/15 min	1 hour
LD (cases)		
TRU Legionella®	102/139 (73%)	112/139 (81%)
NOW®	107/139 (77%)	113/139 (81%)
RTI other than LD (controls)		
TRU Legionella®	0/73 (0%)	0/73 (0%)
NOW®	0/73 (0%)	0/73 (0%)

The sensitivity of the TRU Legionella test increased to 80.6% (112/139) if tests were reexamined after 60 minutes of incubation. Prolonged incubation did not effect the specificity in both tests.

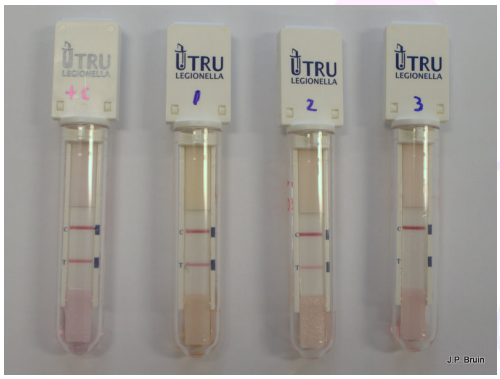

Figure: Picture of the TRU Legionella assay. +C: positive control sample; 1 and 2: positive patient samples; 3: negative patient sample.

Conclusion

The study provided data showing that the TRU Legionella test has a high degree of sensitivity and specificity, with a sensitivity that increased with incubation time. The two assays evaluated have similar performance characteristics and are suitable for the rapid diagnosis of LD.

In this evaluation all LD-positive patients were infected with *L. pneumophila* serogroup 1, making it difficult to draw any conclusions about the assay's ability to detect *L. pneumophila* infections caused by other serogroups or *Legionella* species.