Evaluation of the *Legionella V*-TesT Coris® in comparison to the BinaxNOW to detect the *Legionella* serogroup 1 antigen in urine samples

D-108

E. DE WITTE, K. LOENS, C. LAMMENS, J. ALMIRALL, H. GOOSSENS AND M. Ieven
University Hospital Antwerp, Edegem, Belgium

M. Ieven
Lab. Microbiology
Antwerp University Hospital
Wilrijkstraat 10
B-2650 Edegem-Antwerp
Tel +32 3 821 36 44
Fax +32 3 825 42 81
Email: greet.ieven@uza.be

BACKGROUND

Legionnaires' disease is a serious pneumonia mostly (90%) caused by *Legionella pneumophila* which includes several serotypes with serogroup 1 accounting for 70% of all infections. It's a laboratory diagnosis that can be made on respiratory samples by culture, immunofluorescence and PCR or on (paired) serum samples by serology. The disadvantages are the relative lack of productive sputum in these patients and the invasive procedure to obtain respiratory specimens such as BAL for diagnosis by culture and PCR and the retrospective character of serology. The current urinary antigen tests have the advantage to obtain a rapid diagnosis with a high sensitivity (70-90%) and specificity (>95%). Even though they only detect the serogroup 1 antigen, urine antigen detection is recommended in patients with severe CAP or where this infection is suspected.

AIM

Recently a new direct assay, the *Legionella V*-tesT was developed by Coris Bioconcept (see *Fig. 1*). We evaluated the performance and user friendliness of this new assay for the detection of *Legionella pneumophila* serogroup 1 antigen in urine by comparing the results of the *V*-tesT with those obtained by the BinaxNOW *Legionella* urinary antigen test (Inverness).

Fig 1: *The Legionella V-tesT*

METHODS

Clinical specimens

We investigated 129 previously collected and frozen urine samples from patients with lower respiratory tract infections (see *table 1*).

N°	Collected from…
61	patients with symptoms of pneumonia during a *Legionella* outbreak • 34 from the Hospital of Mataró (Spain) • 27 from the Legionellosis outbreak in Kapellen (Belgium)
68	patients with LRTI other than *Legionella* enrolled during the European GRACE study (Barcelona, Mataro, Poland and Utrecht)

Table 1: *The urine samples collected for the evaluation of the V-tesT Legionella.*

Urinary antigen tests

The *V*-tesT and BinaxNOW *Legionella* are direct antigen tests to detect the *Legionella pneumophila* serogroup 1 antigen in urine samples. Specifications of both products are summarized in *table 2*.

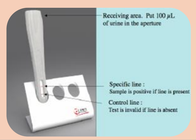
***Legionella* test**	***V*-tesT**	**BinaxNOW**
Principle	Immunochromatographic assay	
N° of tests/kit	10 or 20	12 or 22
Controls	+ and – control solution	+ and – control swab
Additional reagent	No	Citrate/phosphate + Tween 20 and azide
TAT	15'	15'
Image		

Table 2: *Properties of the V-tesT and BinaxNOW Legionella.*

RESULTS

Of the 129 urine samples tested, 41 were found positive (32%) with the BinaxNOW. Performance results of the *V*-tesT in comparison to the BinaxNOW are shown in *table 3*.

Legionella	**BinaxNOW**			**Performance**
***V*-TesT**	-	+	Total	*Sensitivity*
-	86	1	87	97.6
+	2	40	42	*Specificity*
Total	88	41	129	97.7

Table 3: *Performance results of the Legionella V-tesT.*

The two apparent false positives and one false negative were confirmed as true *Legionella* infections by the Biotest *Legionella* and by positive culture, positive PCR on sputum and/or serology.

In comparison to the true clinical status of the patient the BinaxNOW yielded one false negative more than the *V*-TesT resulting in a sensitivity of 95.3% and 97.7% respectively.

The TAT was comparable for the two assays but the new *V*-tesT could be used directly on the urine specimen, while the BinaxNOW required two additional steps: adding reagent and sealing the device.

CONCLUSIONS

- The *Legionella V*-TesT has comparable performance characteristics to those of the BinaxNOW.
- Due to its simplicity it facilitates urgent testing.
- We evaluated it as an even more user-friendly test.