Evaluation of new immunofluorescence lateral flow test for *Legionella pneumophila* serogroup 1 antigen detection in urine samples

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OBJECTIVES

To determine the sensitivity and specificity of the *Legionella* FIA test (Sofia. QUIDEL, San Diego, USA) for the *L. pneumophila* serogroup 1 antigen detection, comparing the results with EIA (Bartels Trinity,Biotech, Ireland) and ICT (Binax Now. Maine. USA) methods, in both non-concentrated and concentrated urine samples.

MATERIAL AND METHODS

• Retrospective study:

- Group 1: 50 patients with clinical and radiological signs of pneumonia, and microbiologically confirmed as *L. pneumophila* etiology.

- Group 2: 25 specimens from patients with pneumonia due to *Streptococcus pneumoniae;* and 25 urine samples from patients with no clinical or radiological evidence of pneumonia and with urinary tract infections.

• The test is a lateral flow assay based on an advanced immunofluorescence technology for rapid detection of *L.pneumophila* serogroup 1 antigen in urinary samples. The results are read by means a fluorescence detector.

• The Sofia test was compared with the previous EIA Bartels and with the ICT Binax results.

• Pre-treatment of the urine samples:

- 50 non-concentrated urine with 5 minutes boiling step

- 31 non-concentrated urine without 5 minutes boiling step

-50 urine concentrated by centrifugal selective ultrafiltration (Amicon-Ultra. Millipore)

• In order to evaluate the analytical sensitivity of the SOFIA test in comparison with the other immunological tests, 10 positive samples randomly selected were tested after be diluted 1:2, 1:4, 1:8, 1:16, 1:32 and 1:64, with PBS.

RESULTS

Table 1. Sensitivity of the evaluated technique in both non-concentrated and concentrated urine samples, and comparison with the values obtained by Bartels EIA and ICT Binax in the same samples.

SAMPLES	SOFIA	Bartels EIA	ICT Binax
Non-concentrated urine (without boiling step)	90.3% (28/31)	77.4% (24/31)	71% (22/31)
Non-concentrated urine (with boiling step)	96% (48/50)	84% (42/50)	82% (41/50)
Concentrated urine	98% (48/49)	100% (50/50)	95.9% (47/49)

Table 2. Specificity of the evaluated technique in both non-concentrated and concentrated urine samples, and comparison with the values obtained by Bartels EIA and ICT Binax in the same samples.

SAMPLES	SOFIA	Bartels EIA	ICT Binax
Non-concentrated urine (without boiling step)	98% (49/50)	98% (49/50)	100% (50/50)
Non-concentrated urine (with boiling step)	100% (50/50)	100% (50/50)	100% (50/50)
Concentrated urine	95.9% (47/49)	100 % (49/49)	100 % (49/49)

The differences between SOFIA and Binax in non-concentrated urine without and with pre-treatment were statistically significant (p=0.031 and p=0.03, respectively), in contrast the differences between SOFIA and EIA Bartels were not statistically significant (p=0.219 and p=0.125, respectively).

Table 3. Concordance (%) and agreement (Cohen's Kappa) between SOFIA and the other immunological tests, when using non-concentrated urine samples, considering the group study.

SAMPLES	SOFIA vs ICT Binax	SOFIA vs ELISA Bartels
Non-concentrated urine (without boiling step)	63.3% (0.415)	63.3% (0.306)
Non-concentrated urine (with boiling step)	88.0% (0.451)	86.0% (0.303)

Table 4 Results obtained in the analytical sensitivity testing by SOFIA in comparison with the results obtained by Bartels EIA and ICT Binax.

Nº of sample	SOFIA	Bartels EIA	ICT Binax
1	1:32	1:8	<1:2
2	1:2	1:2	<1:2
3	>1:64	1:16	1:4
4	1:8	1:8	1:2
5	1:16	1:8	1:4

Nº of sample	SOFIA	Bartels EIA	ICT Binax
6	1:16	1:16	1:4
7	1:8	1:4	1:2
8	1:16	1:16	1:4
9	1:16	1:16	1:4
10	1:8	1:2	1:4

CONCLUSIONS

SOFIA, using NCU, obtained higher sensitivity than EIA Bartels and ICT Binax. The thermic pre-treatment of the urine samples increase the specificity of SOFIA test without affecting the sensitivity. SOFIA has higher analytical sensitivity than both EIA Bartels and ICT Binax. SOFIA using NCU, obtained comparable sensitivity than EIA Bartels and ICT Binax using CU. Therefore, it is possible to avoid the concentration step when SOFIA test is used. SOFIA is a real alternative method for diagnosing *L.pneumophila* pneumonia.

Fundació Institut d'Investigació en Ciències de la Salut Germans Trias i Pujol

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