Evaluation of Legionella K-set®, a lateral flow test for the detection of Legionella pneumophila serogroup 1 antigens in urine samples.

Aubin Souche, Anne-Gaëlle Ranc, Ghislaine Descours, Christophe Ginevra, Gerard Lina, Sophie Jarraud, Laetitia Beraud
French National Reference Centre of Legionella, Centre de Biologie Est, Hospices Civils de Lyon, Bron, France Contact: laetitia.beraud@chu-lyon.fr

Introduction / Objectives

Legionella pneumophila serogroup 1 antigen detection in urine samples (US) is widely used for the early diagnosis of Legionnaires’ disease (LD). The tests used have to be easy and quick (less than 30 minutes) to perform, and demonstrate good performances. Automated reading allows traceability and reduces the operator’s subjectivity.

The aim of this study was to evaluate the Legionella K-set® test (Coris BioConcept, Gembloux, Belgium) in comparison with the BinaxNOW® Legionella Urinary Antigen Card (UAC) (Alere, Scarborough, Maine, USA) on concentrated urine samples, according to Coris Bioconcept and French National Reference Centre’s recommendations. The evaluation of a strip reader prototype (Coris BioConcept strip reader prototype) was realised at the same time.

Methods

The automated reading was based on intensity ratio between sample strip and control strip. An urine sample was positive if this ratio was over 0.070.

200 prospective fresh urine samples submitted for Legionella urinary antigen detection (September – December 2015)

Concentration

Centrifugation at 4000 g for 10 min using Amicon Ultra-4 Ultracel-10k (Amicon Ultra, Millipore Corporation Bedford, Mass)

50 frozen urine samples from confirmed Legionnaire’s disease (20°C, 2008-2012)

Results

Table 1. Visual reading and automated reading results of Legionella K-set® test on concentrated US compared to BinaxNOW® UAC.

<table>
<thead>
<tr>
<th>Legionella K-set® test (Coris Bioconcept)</th>
<th>Visual Reading</th>
<th>Automatic Reading</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>200</td>
<td>0</td>
</tr>
<tr>
<td>+</td>
<td>49</td>
<td>48</td>
</tr>
<tr>
<td>Total</td>
<td>201</td>
<td>48</td>
</tr>
</tbody>
</table>

a : One positive sample with BinaxNOW® UAC was negative with Legionella K-set® at 15 min with both readings. After 3 hours, Legionella K-set® test was positive with a weak strip by visual reading but the result remained negative by automatic reading

b : One sample was negative only by automatic reading. By visual reading, a weak strip was observed.

After heating all positive US were confirmed except 3 of them, which were not interpretable because of lack or weak control strip. These errors were due to migration defect but the sample strips were strongly positive.

All discrepant results with Legionella K-set® test were confirmed positive by EIA.

Regarding our results, Legionella K-set® on concentrated US detected 49 out of 50 positive US. Among 200 prospective US, no difference were noticed in comparison to BinaxNOW® UAC. The heat treatment led to 3 migration defects.

To conclude, performances of Legionella K-set® test in concentrated US are close to the ones of BinaxNOW® UAC. The test is easy to use and to read. The reader prototype has to be improved and more urines samples are needed before defining the optimal cut-off.

Conclusion

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