

Legionella V-Test

Rapid diagnostic test for *in vitro* detection of *Legionella pneumophila* antigen in urine

- Easy to use
- Easy to read
- Rapid format (15')
- Specific
- Sensitive
- Safe

Legionnaires' disease includes pneumonia and is the major clinical manifestation of *Legionella* infection although extrapulmonary infection and non-pneumonic disease like Pontiac fever occur. *L. pneumophila* is responsible for approximately 90% of infections, and of these, over 80% are due to serogroup 1.

Legionella species can survive in a wide range of conditions, and temperature is a critical determinant for *Legionella* proliferation, which makes it often present in cooling towers and

potable hot water systems. The disease is transmitted via aspiration of aerolized water containing the bacteria, and there is no evidence for direct person-to-person transmission.

The mortality rate of untreated patients is as high as 25%.

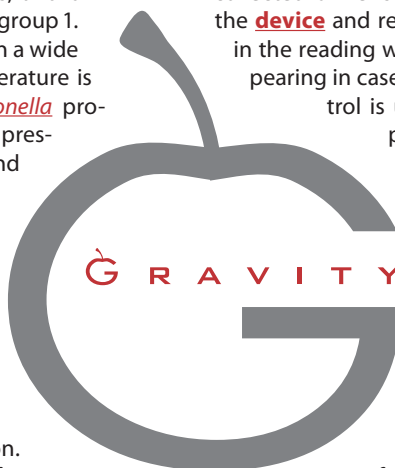
Antigen detection in urine has proved to be sensitive and is thus widely used for detection of *Legionella* infection. We have developed a new *Legionella* antigen detection assay based on colloidal gold nanoparticles with antibodies directed

against LPS of *L. pneumophila serogroup 1*. This proprietary sandwich-type assay is a ready-to-use test that does not require dilution of urine with a reaction buffer. Liquid sample moves by gravity along the stick within a specific designed device. Freshly collected urine is simply deposited on the top of the device and result is observed after 15 minutes

in the reading window, the upper purple line appearing in case of a positive test. A build-in control is used as migration control (lower purple line). **Legionella V-Test** is

an antigen detection assay that has been validated in two different reference laboratories against a market leader ICT test and against PCR techniques. Specificity of 100% was evaluated on 113 urine samples from patients with non-*Legionella* lower respiratory tract infections. The sensitivity in both studies ranges from 87% to 100% according to the reference technique. In conclusion, our

Legionella V-Test antigen detection assay in urine shows very good sensitivity and specificity. The test is rapid, very simple to use, and is appropriate for the detection of *L. pneumophila* serogroup 1 infection due to its 100% positive predictive value, and its very high detectability.



Performance of the Legionella V-Test

The Legionella V-Test has been evaluated in 2 different laboratories (Spain and The Netherlands).

• Performance compared to ICT competitor (n = 108) - Spanish study

The Spanish validation was conducted on 108 urine samples and the results show a perfect match with those obtained by the market leader test as well as regarding sensitivity and specificity parameters.

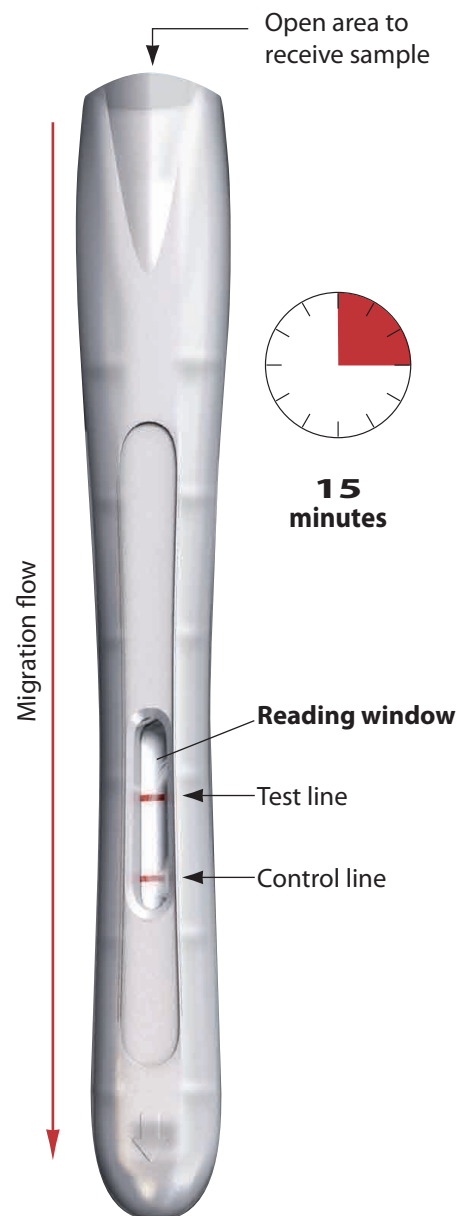
Specificity	100% (96/96)
Sensitivity	100% (12/12)
PPV	100% (12/12)
NPV	100% (96/96)
Accuracy	100% (108/108)

• Performance according to the clinical status of samples (n = 40) - Dutch study

The Dutch study was conducted on a panel of urine from patients with proven legionellosis (radiological signs, culture, PCR, EIA) as well as on samples of patients with respiratory infections other than *L. pneumophila* (e.g., *S. pneumoniae*).

Specificity	100% (17/17)
Sensitivity	87% (20/23)
PPV	100% (20/20)
NPV	85% (17/20)
Accuracy	92,5% (37/40)

A third study is currently carried out at the laboratory of Bacteriology, Center of Biologie and Pathologie at Lyon (France).



Ordering Information

Enteric range (25 tests)

Description	Code
Rota-Strip	C-1001
Adeno-Strip	C-1002
40/41 Adeno-Strip	C-1003
Combi-Strip	C-1004
Crypto-Strip	C-1005
O157 Coli-Strip (20 tests)	C-1011
Giardia-Strip	C-1013
GastroVir-Strip	C-1016
Crypto/Giardia Duo-Strip	C-1018

Respiratory range (25 tests)

Description	Code
RSV Respi-Strip	C-1006
Adeno Respi-Strip	C-1009
Influ-A Respi-Strip	C-1010
Influ-A&B Respi-Strip	C-1012
Legionella V-Test*	C-1815

Gastric range (25 tests)

Description	Code
Pylori-Strip	C-1019

All our products are also available in packaging of 10 tests, and in packaging of 20 tests, individually packed.

*Only available in 10 or 20 tests.



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