

PROFLOW™ LUA RE-LAUNCH AND EVALUATION UPDATE

Pro-Lab Diagnostics are pleased to advise the availability of the Proflow™ Legionella Urinary Antigen test. Evaluation kits are now available; please see enclosed request form.

In addition to the original trial at the Scottish Haemophilus, Legionella, Meningococcus and Pneumococcus Reference Laboratory (SHLMPRL) we have now completed an extensive UK ring trial with the help of ten recognised NHS laboratories across the UK offering the customer a confidence level required for such a test. We are extremely grateful to the laboratories involved.

UK RING TRIAL

Due to the low prevalence of *Legionella pneumophila* it was deemed pertinent to conduct a larger trial in order to establish performance data based on routine samples and the normal low prevalence of positivity (2-5%). 327 routine clinical samples were tested across 10 UK hospital laboratories. Results were compared to the BinaxNOW® LUA test and any discrepant results were sent for confirmation at the Respiratory and Vaccine Preventable Bacteria Reference Unit (RVPBRU).

During the ring trial five laboratories tested the tested Proflow™ LUA kit using samples sent from the United Kingdom National External Quality Assessment Service (UK NEQAS). For the September 2014 distribution these samples consisted of one LUA positive and one LUA negative sample per laboratory. The Proflow™ LUA kit gave correct results for all tests.

COMBINED PERFORMANCE CHARACTERISTICS

(excluding UK NEQAS samples)

		Expected Result		
		Positive	Negative	Total
Proflow™ LUA	Positive	54	2	56
	Negative	1	520	521
	Total	55	522	577

Prevalence of L. pneumophila in normal population is approx. 2-5%.

This combined data shows 9.5% prevalence; please consider the impact on statistical analysis.

Sensitivity = 98.2%

Positive Predictive Value = 96.4%

Specificity = 99.6%

Negative Predictive Value = 99.8%

USER FEEDBACK

Kettering General Hospital: *“The test is very easy to perform and needs no additional reagents, which is a bonus. The results are comparable with our current method so we are very happy with it.”*

Airedale Hospital: *“The product instructions were clear and the cartridges were easy to use.”*

The Whittington Hospital: *“The test device was extremely simple to use and we had no problems from an ergonomics point of view.”*