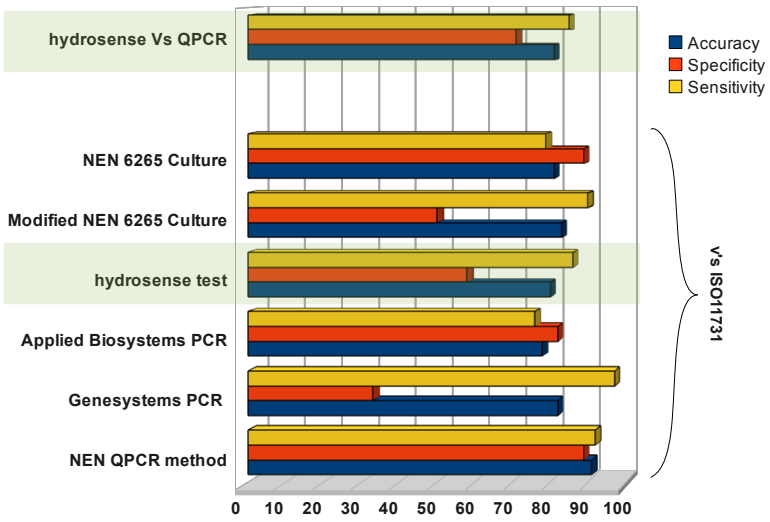
VALIDATION OF LEGIONELLA FIELD TEST™

The test utilises the principle of immunochromatography to detect the presence of *Legionella pneumophila* serogroup 1 antigen in a water sample. The test may be used directly on the water sample or combined with filtration to achieve better levels of detection. The test is intended for use in the field with minimal levels of operator training, and requiring no other specialist equipment. This technology has been widely applied to the detection and diagnosis of disease, including Legionnaires' Disease in humans [1].

Kiwa Water Research

The "industrial" version of the product using hollow fibre filtration was evaluated by Kiwa Water Research, Netherlands as part of a multi-site, evaluation of several novel *Legionella* test methods. [2]

"In view of its high level of accordance with the results of Q-PCR and the ISO 11731 method and given the speed and simplicity of the test, [this method] would appear to be a useful addition to the set of instruments available to the process operator responsible for the daily management of cooling water systems. The method's specificity makes it a useful addition to ATP measurements, colony number measurements or dip slides that are already used for monitoring water systems. The method' speed and simplicity make it exceptionally interesting for monitoring in emergencies."

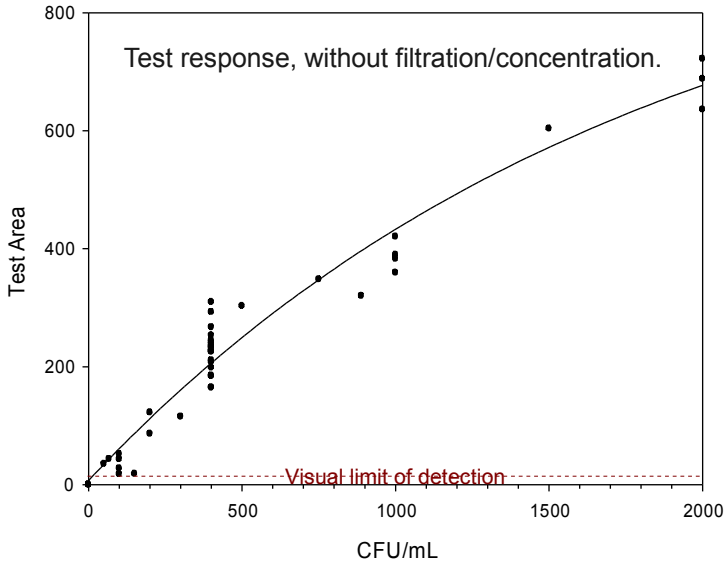


International Water Conference

Leading industrial water treatment company, Nalco, presented its validation of the hydrosense® Legionella Field Test™ at the peer reviewed Industrial Water Conference 2008, in Chicago. [3]

Samples spiked with Lp sg1		Culture (ISO11731)		
		+ve	-ve	Total
This method	+ve	81	65	146
	-ve	20	16	36
	Total	101	81	182

Diagnostic sensitivity was determined to be 80.2%



"96% repeatability was obtained with 91% reproducibility."

"the [confidence] of detecting 100 cfu/L L. pneumophila sg 1 in the water sample was 92-100 % [using hollow fibre filtration]."

References

[1] C Guerrero, CM Toldos, G Yagüe, C Ramírez, T Rodríguez, M Segovia; "Comparison of Diagnostic Sensitivities of Three Assays for Detection of *Legionella pneumophila* Serogroup 1 Antigen in Urine"; J.Clin. Micro. (2004), 42(1) p. 467-468

[2] F Oesterholt, D van der Linde, B Wallings, H Veenendaal "A new method of screening cooling water and process water for *Legionella pneumophila*" KWR 2009.004; May 2009 Report: A307531

[3] N Polwart, R Grant, H Barnes, E Holmes, T Lindley, A Cooper; "A Field Test for Rapid Detection of *Legionella pneumophila* serogroup 1 in Water Samples" Proceedings of IWC Conference, Chicago (2008).

CERTIFICATE OF CONFORMANCE

The hydrosense® Legionella Field Test™ has been tested to ensure conformance with the published specification.

Key specifications

ANALYTICAL SENSITIVITY

	Unaided	Membrane Filtration	Hollow Fibre Filtration
	(a)	(b)	(c)
LIMIT OF DETECTION / cfu/L	100,000	100	100
TYPICAL RECOVERY / %	n/a	25-60	20-100

(a) Limit of detection by comparison to ISO11731, ATCC 33552 grown in aqueous environment tested in clean water samples. Note cfu counts and antigen presence do no always correlate well - as they are measuring different physical parameters.
(b) Theoretical Mathematical Limit of Detection, as described in the HSE ACOP (L8) / ISO11731, assuming 1L of water processed using "Domestic Legionella Field Test". Recovery rates for clean water under laboratory conditions.
(c) Theoretical Mathematical Limit of Detection, as described in the HSE ACOP (L8) / ISO11731, assuming 250 mL of water processed using "Industrial Legionella Field Test". Recovery rates for clean water under laboratory conditions.

DIAGNOSTIC SENSITIVITY / % 80

SPECIES DETECTED LEGIONELLA PNEUMOPHILLA SEROGROUP 1 *(all known subtypes)*

SHELF LIFE 18 MONTHS FROM DATE OF MANUFACTURE

Intended use

This product is NOT intended for clinical or medical diagnostic use.
This product is intended for use as part of an overall water treatment, management, and risk reduction approach and should not be used as the sole method of preventing outbreaks of Legionellosis.

CE marking

This product does not fall within the auspices of the European Directives providing for CE marking. The product is therefore not CE marked.

Manufacture & quality control

The hydrosense® Legionella Field Test™ is manufactured under ISO9001:2008 within a facility adhering to the principles of GMP. Quality controls are in place to ensure traceability of components, and conformance to specifications, including sensitivity and specificity.

Country of origin

This product is manufactured in the United Kingdom (UK).

Batch details

BATCH NUMBER	**XXXXX**	
EXPIRY DATE	**DD-MMM-YYYY**	
TESTED BY	**S. DYER**	
APPROVED FOR RELEASE BY	**DR NEIL POLWART, COO**	**DD/MM/YY**
SIGNED		

Manufacturer

ALBAGAIA LIMITED (SC 204853)
29 Regent Terrace,Edinburgh,
EH7 5BS, United Kingdom
www.albagaia.com www.hydrosense.biz