hydrosense®

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HYDROSENSE ONE TEST – CERTIFICATE OF CONFORMANCE

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

Key Specifications	Unaided	Hollow Fibre Filtration
	(a)	(b)
Limit of detection / CFU/L	100,000	100
Typical Recovery / %	n/a	20-100

a) Limit of detection by comparison to ISO11931, ATCC 33152 grown in aqueous environment testing in clean water samples. Note CFU counts and antigen presence do not always correlate - as they are measuring different physical parameters.

b) 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 the laboratory conditions.

Diagnostic Sensitivity	80%
Species Detected	*Legionella pneumophila* Serogroup 1
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 as with all testing methods, including lab culture testing, 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 and Quality Control

The Hydrosense® ONE *Legionella pneumophila* test strip is manufactured under ISO 13485 and ISO 9001 within a facility adhering to the principles of GMP. Quality controls are in place to ensure traceability of components, and conformance to specifications. Each batch is tested for conformance to specification by Express Micro Science (UKAS accredited Legionella testing laboratory).

Physical:	Labelling, Contents & Test assembly	PASS
Performance:	Negative water samples (Hard, soft, tap & cooling tower)	PASS
	Cross reaction (x15 common water bacteria)	PASS
	Cross reaction (x6 non SG-1 L.p. serogroups)	PASS
	Positive testing (x9 L.p. SG-1 subgroups)	PASS

Country of Origin

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

Batch Details

Batch No:	12345	Expiry:	MM/YYYY
Tested By:	Paul Moffat (Express Micro Science)	Date:	DD/MM/YY
Released By:	Richard Campbell (Technical Director)	Date:	DD/MM/YY