

Capillary Array 50cm 3500 Dx

REF	4404684
SN	L512IA400
	2013-08-27

TEST	SPECIFICATION	RESULT
Capillary Leak Test Each array is tested to assure absence of leaks.		
Leak Test	No Leaks	PASS
Capillary Plug Test Each array is tested to assure absence of plugged capillaries.		
Plug Test	No Plugged Capillaries	PASS
Fluorescence Background Test Each array is tested to assure background fluorescence is within specification.		
Fluorescence Background Test	Conforms to Specification	PASS
Capillary Mapping Test Each array is tested to verify that capillary inlet and outlet spatial positioning correspond.		
Mapping Test	Conforms to Specification	PASS

When used with the 3500 Dx series systems, this device meets the requirements of Directive 98/79/EC on In Vitro Diagnostic Medical Devices and complies with QSR 21CFR820.

**ISO13485:2003
 REGISTERED**

Singapore

IVD



Quality Assurance Manager



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