Certificate Number
AU Q00333

Australian Government

Department of Health
Therapeutic Goods Administration

Conformity Assessment Certificate

Full Quality Assurance Procedures

This is to certify that the quality management system described below complies with the relevant provisions of Schedule 3, Part 1 (excluding clause 1.6) of the *Therapeutic Goods (Medical Devices) Regulations 2002*. Certification is based on an assessment of the Full Quality Management System, applied at each stage of medical device manufacture, from the design of a device until its final inspection before being supplied.

Manufacturer Name: Cellabs Pty Ltd

Manufacturer Address: Unit 7/27 Dale Street
BROOKVALE NSW 2100
Australia

Commencement Date: 19 September 2014

Certificate Expiry Date: 19 September 2019

This certificate has effect at all times from the commencement date, until the end of the period specified in the certificate (expiry date), or unless it has been suspended or revoked.

This certificate is issued under Section 41EE of the *Therapeutic Goods Act 1989* by:

Peter Kaylock
Signed electronically
Delegate of the Secretary
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia

Australian Government

Department of Health
Therapeutic Goods Administration

Scope of Certificate

Manufacturer Facilities

	Name and Address	Scope
1.	Unit 7/27 Dale Street BROOKVALE NSW 2100 Australia	Full manufacturing of diagnostic kits- design, production, packaging, labelling, final release, warehousing and dispatch.

Device Categories

	Description	Limitations (if applicable)
1.	Chlamydia IVDs	
2.	Cryptosporidium IVDs	
3.	Multi-parasite IVDs	
4.	Pneumocystis IVDs	
5.	Toxoplasma IVDs	
6.	Plasmodium (malaria) IVDs	
7.	Wuchereria/Brugia (filariasis) IVDs	
8.	Entameoba (ameobiasis) IVDs	
9.	Trypanosoma IVDs	
10.	Toxocara IVDs	
11.	Giardia IVDs	