



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	399243	Abacus dx Pty Ltd - Clinical chemistry tumour marker IVDs
<b>ARTG entry for</b>	Medical Device Included - IVD Class 2	
<b>Sponsor</b>	Abacus dx Pty Ltd	
<b>Postal Address</b>	PO Box 446, WATERFORD, QLD, 4133 Australia	
<b>ARTG Start Date</b>	11/11/2022	
<b>Product Category</b>	Medical Device Class 2	
<b>Status</b>	Active	
<b>Approval Area</b>	IVD	

### Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.  
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

### Manufacturers

Name	Address
LGC Clinical Diagnostics Inc	221 US Route 1 Cumberland Foreside, ME, 04110-1345 United States Of America

### Products

#### 1 . Clinical chemistry tumour marker IVDs

<b>Product Type</b>	IVD	<b>Effective Date</b>	11/11/2022
<b>GMDN</b>	CT845 Clinical chemistry tumour marker IVDs		
<b>Intended Purpose</b>	Calibration verification and/or linearity test kits for tumour markers		

### Specific Conditions

No Specific Conditions included on Record

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Public Summary