



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 205818 Advanced Biotech Pty Ltd - Clinical chemistry hormone IVDs

**ARTG entry for** Medical Device Included - IVD Class 2  
**Sponsor** Advanced Biotech Pty Ltd  
**Postal Address** 24- 1045 Doncaster Road, Doncaster East, VIC, 3109  
Australia  
**ARTG Start Date** 8/02/2013  
**Product Category** Medical Device Class 2  
**Status** Active  
**Approval Area** 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
Seratec GmbH	Ernst Ruhstrat strasse 5 D-37079 GOTTINGEN, , Germany

### Products

#### 1 . Clinical chemistry hormone IVDs

Product Type	IVD	Effective Date	8/02/2013
<b>GMDN</b>	CT850 Clinical chemistry hormone IVDs		
<b>Intended Purpose</b>	For the qualitative and/or quantitative determination of clinical chemistry hormones in a clinical specimen.		

### Specific Conditions

No Specific Conditions included on Record

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