

# Accreditation Certificate

## Cruinn Diagnostics Ltd. Trading as CruinnCal

5B/6B Hume Centre, Parkwest Industrial park, Clondalkin, Dublin 12

### Testing Laboratory

Registration number: 281T

is accredited by the Irish National Accreditation Board (INAB) to undertake testing as detailed in the Schedule bearing the Registration Number detailed above, in compliance with the International Standard ISO/IEC 17025:2005 2<sup>nd</sup> Edition "General Requirements for the Competence of Testing and Calibration Laboratories"  
*(This Certificate must be read in conjunction with the Annexed Schedule of Accreditation)*

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Date of award of accreditation: 15:02:2011

Date of last renewal of accreditation: 15:02:2011

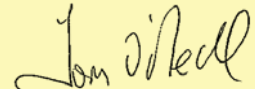
Expiry date of this certificate of accreditation: 15:02:2016

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This Accreditation shall remain in force until further notice subject to continuing compliance with INAB accreditation criteria, ISO/IEC 17025 and any further requirements specified by the Irish National Accreditation Board.

Manager: 

Dr Adrienne Duff

Chairperson: 

Mr Tom O'Neill

Issued on 15 February 2011

Organisations are subject to annual surveillance and are re-assessed every five years. The renewal date on this Certificate confirms the latest date of renewal of accreditation. To confirm the validity of this Certificate, please contact the Irish National Accreditation Board.

The INAB is a signatory of the European co-operation for Accreditation (EA) Testing Multilateral Agreement (MLA) and the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

# Schedule of Accreditation



(Annex to Accreditation Certificate)

Site Laboratory:  
Category D

**Cruinn Diagnostics Ltd.**  
**Trading as CruinnCal**

## Mechanical Testing Laboratory

*Initial Registration Date :* 15-February-2011  
*Postal Address:* 5B/6B Hume Centre,  
Parkwest Industrial Park,  
Clondalkin,  
Dublin 12  
*Telephone:* +353 (1) 6297422  
*Fax:* +353 (1) 6297401  
*E-mail:* [info@cruinn.ie](mailto:info@cruinn.ie)  
[Calibration@cruinn.ie](mailto:Calibration@cruinn.ie)  
*Contact Name:* Joe Featherstone (Technical Manager)  
Sinead Reidy (Quality Manager)  
*Facilities:* Public Testing Service

# Schedule of Accreditation



Site Laboratory:  
 Category D

THE IRISH NATIONAL ACCREDITATION BOARD (INAB) is the Irish body for the accreditation of organisations including laboratories.

Laboratory accreditation is available to testing and calibration facilities operated by manufacturing organisations, government departments, educational institutions and commercial testing/calibration services. Indeed, any organisation involved in testing, measurement or calibration in any area of technology can seek accreditation for the work it is undertaking.

Each accredited laboratory has been assessed by skilled specialist assessors and found to meet criteria which are in compliance with ISO/IEC 17025 or ISO/IEC 15189 (medical laboratories). Frequent audits, together with periodic inter-laboratory test programmes, ensure that these standards of operation are maintained.

## Testing and Calibration Categories:

- Category A:** Permanent laboratory calibration and testing where the laboratory is erected on a fixed location for a period expected to be greater than three years.
- Category B:** Site calibration and testing that is performed by staff sent out on site by a permanent laboratory that is accredited by the Irish National Accreditation Board.
- Category C:** Site calibration and testing that is performed in a site/mobile laboratory or by staff sent out by such a laboratory, the operation of which is the responsibility of a permanent laboratory accredited by the Irish National Accreditation Board.
- Category D:** Site calibration and testing that is performed on site by individuals and organisations that do not have a permanent calibration/testing laboratory. Testing may be performed using
- (a) portable test equipment
  - (b) a site laboratory
  - (c) a mobile laboratory or
  - (d) equipment from a mobile or site laboratory

## Standard Specification or Test Procedure Used:

The standard specification or test procedure that is accredited is the issue that is current on the date of the most recent visit, unless otherwise stated.

## Glossary of Terms

### Facilities:

- Public calibration/testing service:** Commercial operations which actively seek work from others.
- Conditionally available for public calibration/testing:** Established for another primary purpose but, more commonly than not, is available for outside work.
- Normally not available for public calibration/testing:** Unavailable for public calibration/testing more often than not.

Laboratory users wishing to obtain assurance that calibration or test results are reliable and carried out to the Irish National Accreditation Board criteria should insist on receiving an accredited calibration certificate or test report. Users should contact the laboratory directly to ensure that this scope of accreditation is current. INAB will, on request, verify the status and scope.

# Scope of Accreditation



## Cruinn Diagnostics Ltd. (CruinnCal) Mechanical Testing Laboratory

Site Laboratory:  
Category D

INAB Classification number (P9)	Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1169	<b>Controlled Environments</b>	Testing to determine the performance characteristics detailed below:	In House Cruinn SOPS Based on relevant sections of the following standards
.01	Laminar Flow Workstations.		EN 12469: 2000 ISO 14644:Part 1:1999 ISO 14644:Part 3:2005
.02	Microbiology Safety Cabinets, Class I, II and III.	Airflow velocity (0.25 m/s- 1.5 m/s)	EN 14175-4:2004 BS5726:2005 BS 7258: Part 1: 1994 BS 7258: Part 3:1994
.03	Fume Hoods/Cupboards	HEPA Filter and Seal Integrity Test	BS 7989:2001 Annex 1 of EudraLex Good Manufacturing Practice.
.99	Other Air Handling Systems (Including) Balance Enclosures. PCR Cabinets. Clean Zones and Clean Air Devices. Fan (HEPA) Filter Units. Local Exhaust Ventilation Devices. Isolators. Chemical Safety Cabinets.	Operator Protection Factor Test (using the Ki-Discus method)  Particle Counting  Airflow Visualisation Test	