

Accreditation Certificate

Cruinn Diagnostics Ltd Trading as CruinnCal

5B/6B Hume Centre, Parkwest Industrial Park, Clondalkin, Dublin12

Calibration Laboratory

Registration number: 279C

is accredited by the Irish National Accreditation Board (INAB) to undertake calibration as detailed in the Schedule bearing the Registration Number detailed above, in compliance with the International Standard ISO/IEC 17025:2005 2nd Edition

"General Requirements for the Competence of Testing and Calibration Laboratories"


*(This Certificate must be read in conjunction with the annexed
Schedule of Accreditation)*

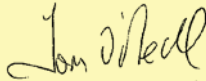
Date of award of accreditation: 15:02:2011

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

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

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.

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)

Permanent Laboratory:
Category A, B, D

CRUINN DIAGNOSTICS LTD

T/A Cruinnca

Balance & Volumetric and Temperature Calibration Laboratory

Initial Accreditation Date : 15-February-2011
Postal Address: Unit 5B/6B Hume Centre,
Parkwest Industrial Park,
Clondalkin, Dublin 12
Telephone: +353 (1) 6297400
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E-mail: info@cruinn.ie
Contact Name: Joe Featherstone
Sinead Reidy
Facilities: Public calibration service

Schedule of Accreditation



Permanent Laboratory:
 Category A, B, 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.

Calibration Categories:

- Category A:** Permanent calibration laboratory where the laboratory is erected on a fixed location for a period expected to be greater than three years.
- Category B:** Site calibration 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 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 that is performed on site by individuals and organisations that do not have a permanent calibration laboratory. Calibration 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 Calibration Procedure Used:

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

Laboratory users wishing to obtain assurance that calibration results are reliable and carried out to the Irish National Accreditation Board criteria should insist on receiving an accredited calibration certificate.

Users should contact the laboratory directly to ensure that this schedule of accreditation is current. INAB will on request verify the status and scope.

Scope of Accreditation



Cruinn Diagnostics Ltd T/A CruinnCal

Permanent Laboratory:
Category A

Volumetric Calibration Laboratory

(Nominal temperature for calibration work: 18-25°C)

INAB Classification number (P9) Measured quantity	Range of measurement	Calibration and measurement capability expressed as an uncertainty *	Method and remarks
130 Volumetric Equipment .02 Specialist Laboratory Volumetric Apparatus <i>Single Channel Pipettes</i>	1µl ≤ v ≤ 5µl	± 0.09µl	For water delivered from piston and/or plunger operated volumetric apparatus using the gravimetric method based ISO 8655 and documented in-house methods CALB-015, CALB-019 and CALB-020
	5µl < v ≤ 10µl	± 0.11µl	
	10µl < v ≤ 20µl	± 0.16µl	
	20µl < v ≤ 50µl	± 0.27µl	
	50µl < v ≤ 100µl	± 0.61µl	
	100µl < v ≤ 200µl	± 0.8µl	
	200µl < v ≤ 500µl	± 2.5µl	
	500µl < v ≤ 1,000µl	± 4.3µl	
	1,000µl < v ≤ 2,500µl	± 8.7µl	
	2,500µl < v ≤ 5,000µl	± 22.0µl	
5,000µl < v ≤ 10,000µl	± 75.0µl		

*** Notes:**

1. In accordance with INAB policy, uncertainties are calculated for an estimated confidence level of not less than 95%.
2. Calibration and measurement capability expressed as an uncertainty (±) to be reported in compliance with EA-4/02, "Expression of the Uncertainty of Measurement in Calibration".

Scope of Accreditation



Cruinn Diagnostics Ltd T/A CruinnCal

Permanent Laboratory:
Category B

Volumetric Calibration Laboratory

(Nominal temperature for calibration work: 18-25°C)

INAB Classification number (P9) Measured quantity	Range of measurement	Calibration and measurement capability expressed as an uncertainty *	Method and remarks
130 Volumetric Equipment .02 Specialist Laboratory Volumetric Apparatus <i>Single Channel Pipettes</i>	2µl ≤ v ≤ 10µl	± 0.13µl	For water delivered from piston and/or plunger operated volumetric apparatus using the gravimetric method based ISO 8655 and documented in-house methods CALB-015, CALB-019 and CALB-020
	10µl < v ≤ 20µl	± 0.16µl	
	20µl < v ≤ 50µl	± 0.27µl	
	50µl < v ≤ 100µl	± 0.61µl	
	100µl < v ≤ 200µl	± 0.8µl	
	200µl < v ≤ 500µl	± 2.5µl	
	500µl < v ≤ 1,000µl	± 4.3µl	
	1,000µl < v ≤ 2,500µl	± 8.7µl	
	2,500µl < v ≤ 5,000µl	± 22.0µl	
5,000µl < v ≤ 10,000µl	± 75.0µl		

*** Notes:**

1. In accordance with INAB policy, uncertainties are calculated for an estimated confidence level of not less than 95%.
2. Calibration and measurement capability expressed as an uncertainty (±) to be reported in compliance with EA-4/02, "Expression of the Uncertainty of Measurement".

Scope of Accreditation



Cruinn Diagnostics Ltd T/A CruinnCal

Permanent Laboratory:
Category D

Balance Calibration Laboratory

(Nominal temperature for calibration work: 18-25°C)

INAB Classification number (P9) Measured quantity	Range of measurement	Calibration and measurement capability expressed as an uncertainty *	Method and remarks
121 Weighing Devices			Documented in-house procedure CALB 029, based on EURAMET cg-18
.01 Precision Laboratory Balances	1mg - 5g 5g - 20g 20g - 50g	0.024mg 0.045mg 0.074mg	OIML Class E2 Weights
.02 Industrial Balances	50g - 100g 100g - 200g 200g - 500g 500g - 1200g 1g - 100g 100g - 200g 200g - 600g 600g - 1000g 1000g - 2000g 2000g - 5000g 5000g - 11000g	0.14mg 0.27mg 0.73mg 2.8mg 0.21mg 0.46mg 2.8mg 3.1mg 24mg 25mg 277mg	OIML Class F1 Weights

*** Notes:**

1. In accordance with INAB policy, uncertainties are calculated for an estimated confidence level of not less than 95%.
2. Calibration and measurement capability expressed as an uncertainty (\pm) to be reported in compliance with EA-4/02, "Expression of the Uncertainty of Measurement in Calibration".

Scope of Accreditation



Cruinn Diagnostics Ltd T/A CruinnCal

Permanent Laboratory:
Category D

Temperature Calibration Laboratory

(Nominal temperature for calibration work: 23±5 °C)

INAB Classification number (P9) Measured quantity	Range of measurement	Calibration and measurement capability expressed as an uncertainty *	Method and remarks
510 Temperature Controlled Enclosures	-90°C ≤ Tn ≤ +130°C Using PT100 probes	± 0.09°C	Temperature mapping and calibration of temperature controlled enclosures
.01 Ovens, refrigerators, freezers and baths	-20 °C ≤ Tn ≤ +130°C Using wireless thermistor based data loggers	± 0.12°C	In-house procedure CALB 017
.02 Incubators			EN 60068-3-5:2002
.04 Industrial freezers			EN 60068-3-11:2007

*** Notes:**

1. In accordance with INAB policy, uncertainties are calculated for an estimated confidence level of not less than 95%.
2. Calibration and measurement capability expressed as an uncertainty (±) to be reported in compliance with EA-4/02, "Expression of the Uncertainty of Measurement in Calibration".