

Accreditation Certificate

Reagecon Diagnostics Ltd

Shannon Free Zone, Shannon, Co. Clare

Calibration Laboratory

Registration number: 265C

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: 12:07:2010

Date of last renewal of accreditation: 23:11:2011

Expiry date of this certificate of accreditation: 23:11:2016

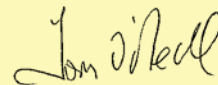
This Accreditation shall remain in force until further notice subject to continuing compliance with INAB accreditation criteria, ISO/IEC 17025 and any further requirements specified by the Irish National Accreditation Board.

Manager:



Dr Adrienne Duff

Chairperson:



Mr Tom O'Neill

Issued on 23 November 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

Site Laboratory:

Category B

REAGECON DIAGNOSTICS LTD

Balance, Volumetric and Temperature Calibration Laboratory

Initial Accreditation Date : 12-July-2010
Postal Address: Shannon Free Zone,
Shannon,
Co. Clare
Telephone: +353 (061) 472622
Fax: +353 (061) 472642
E-mail: john.okeefe@reagecon.ie
Contact Name: Mr John O'keefe
Facilities: Public calibration service

Schedule of Accreditation



Permanent Laboratory: Cat A
 Site Laboratory: Cat B

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



Reagecon Diagnostics Ltd

Site Laboratory:

Category B

Balance Calibration Laboratory

(Environmental Conditions: Relative Humidity: 25 - 75%, Temperature: +10°C - +30°C, Pressure: 800 - 1050 hPa)

| 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 methods: |
| .01 Precision laboratory balances | 1mg - 5g | 0.049mg | CAL-TS 8,9,11,14,15,22,26,31,32,37 (a) (b),38,41, 85, 86, 104, 108 Using OIML Class E2 from 1mg to 600g, Using Class F1 from 100g to 5kg Using Class M1: 5 x 20kg and 6 x 10kg |
| | 5g - 20g | 0.088mg | |
| | 20g - 100g | 0.13mg | |
| .02 Industrial balances | 100g - 200g | 0.20mg | |
| | 200g - 500g | 0.40mg | |
| .03 Industrial Weighing applicances | 500g - 600g | 0.66mg | |
| | 100g - 1kg | 1.6mg | |
| | 1kg - 2kg | 3.1mg | |
| | 2kg - 5kg | 7.7mg | |
| | 5kg - 10kg | 16mg | |
| | 1kg - 10kg | 0.16g | |
| | 10kg - 20kg | 0.31g | |
| 20kg - 50kg | 0.77g | | |
| | 50kg - 100kg | 1.6g | |
| | 100kg - 160kg | 2.5g | |

*** 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



Reagecon Diagnostics Ltd

Permanent Laboratory:
Category A

Volumetric Calibration Laboratory

(Nominal temperature for calibration work: 15°C -30°C±0.5°C)

| INAB Classification number (P9) Measured quantity | Range of measurement | Calibration and measurement capability expressed as an uncertainty * | Method and remarks |
|---|----------------------|--|---|
| 130 Volumetric Equipment | | | Documented in-house methods: |
| .02 Special laboratory volumetric apparatus <i>Single channel pipettes</i> | 5 - 10 µL | 0.15 µL | CAL-TS 5,8,9,11,12,13,14, 15,20,21,22,23,31,33,37 (a) (b),40,41,42,46,85, 86,104 |
| | 10 - 20 µL | 0.15 µL | |
| | 20 - 100 µL | 0.45 µL | |
| | 100 - 200 µL | 0.70 µL | |
| | 200 - 500 µL | 2.0 µL | |
| | 500 - 1000 µL | 4.0 µL | |
| | 1000 - 2,000 µL | 10 µL | |
| | 2,000 - 5,000 µL | 30 µL | |
| <i>Multichannel Pipettes</i> | 5,000 - 10,000 µL | 50 µL | CAL-TS 5,8,9,11,12,13,14, 15,20,21,22,23,31,33,37 (a) (b),40,41,42,46,85, 86,104 For water delivered from piston and/or plunger operated volumetric apparatus. |
| | 10 - 20 µL | 0.45 µL | |
| | 20 - 100 µL | 0.60 µL | |
| | 100 - 200 µL | 0.70 µL | |
| | 200 - 300 µL | 2.0 µL | |

*** 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



Reagecon Diagnostics Ltd

Site Laboratory:

Category B

Volumetric Calibration Laboratory

(Nominal temperature for calibration work: 15°C -30°C±0.5°C)

| INAB Classification number (P9) Measured quantity | Range of measurement | Calibration and measurement capability expressed as an uncertainty * | Method and remarks |
|--|--|---|--|
| 130 Volumetric Equipment | | | Documented in-house methods: |
| .02 Special Laboratory volumetric apparatus <i>Single and multichannel pipettes</i> | *5 -10 µL 10 - 20 µL 20 - 100 µL 100 - 200 µL 200 - 300 µL *300-1000 µL *1,000 - 2,000 µL *2,000 - 5,000 µL *5,000 - 10,000 µL * single channel pipettes only | 0.15 µL 0.45 µL 0.60 µL 0.70 µL 2.0 µL 4.0 µL 10 µL 30 µL 50 µL | CAL-TS 5,8,9,11,13,14, 15,20,21,22,23,31,36,37 (a) (b) (c),40,41,42,43, 44,45,46,80,85,86,104 For water delivered from piston and/or plunger operated volumetric apparatus. |
| | | | |
| | | | |

*** 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



Reagecon Diagnostics Ltd

Permanent Laboratory:

Category A¹

Category B²

Temperature Calibration Laboratory

(Nominal temperature for calibration work: 10-30±5°C)

| INAB Classification number (P9) Measured quantity | Range of measurement | Calibration and measurement capability expressed as an uncertainty * | Method and remarks |
|---|----------------------|--|--|
| 501 Calibration of temperature measuring equipment ¹ | - 45°C to + 140°C | ± 0.05°C | Documented in-house methods: CAL-TS5, -TS49, -TS50, -TS51, -TS52, -TS53, -TS54, -TS62, -TS63, -TS64, -TS65, -TS66, -TS67, -TS68, -TS69, -TS72, -TS85, -TS86, -TS101, -TS104. |
| .41 Digital temperature indicator system | 140°C to 400°C | ± 0.13°C | |
| <i>Digital thermometer with probes</i> | 400°C to 650°C | ± 0.30°C | |
| | 650°C to 700°C | ± 1.40°C (plus resolution of indicator) | |
| 510 Temperature control enclosures ² | -196°C to 0°C | ±0.4°C | Temperature mapping and calibration of temperature controlled enclosure in-house procedures: CAL-TS15, -TS49, -TS50, -TS51, -TS52, -TS54, -TS56, -TS57, -TS59, -TS60, -TS61, -TS65, -TS67, -TS70, -TS71, -TS72 |
| .01 Ovens, refrigerators, freezers, baths | - 45°C to +140°C | ±0.24 (PRTs) ±0.29°C (thermocouples) | |
| .02 Incubators | 140°C to 400°C | ±0.32°C | |
| .04 Industrial freezers | 400°C to 650°C | ±0.43°C | |
| | 650°C to 700°C | ±1.42°C | |
| .03 Autoclaves and sterilising ovens | 700°C to 1200°C | ±4.2°C | |
| | +80°C to 140°C | ± 0.31°C | CAL-TS15, -TS49, -TS50, -TS51, -TS52, -TS54, -TS56, -TS57, -TS59, -TS60, -TS61, -TS65, -TS67, -TS70, -TS71, -TS72, -TS87A, -TS87B, -TS101, -SW |

*** 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



Reagecon Diagnostics Ltd

Permanent Laboratory:
 Category A¹
 Category B²

Temperature Calibration Laboratory

(Nominal temperature for calibration work: 10-30±5° C)

| INAB Classification number (P9) Measured quantity | Range of measurement | Calibration and measurement capability expressed as an uncertainty * | Method and remarks |
|--|---|--|-----------------------|
| Time Interval | Time interval: 0 to 180 minutes 3 Hrs to 24 Hrs | ± 0.6 seconds ± 0.6 seconds | Procedure CAL - SW |

*** 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".