

## ACCREDITATION CERTIFICATE

### *Reagecon Diagnostics Ltd.*

*Shannon Free Zone, Shannon, Co. Clare*

#### Testing Laboratory

#### Registration Number

**012T**

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 only be read in conjunction with the Annexed Schedule of Accreditation)*

Date of award of Accreditation: 04:04:2002

Date of last renewal of Accreditation: 20:07:2006

Expiry Date of this certificate of Accreditation: 20:07:2011

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: *Tom Dempsey*  
Mr Tom Dempsey

Chairperson: *Máire Walsh*  
Dr Máire Walsh

Issued on 20<sup>th</sup> July 2006

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.

Wilton Park House  
Wilton Place  
Dublin 2

Tel: 353-1-607 3003  
Fax: 353-1-607 3109  
Email: [inab@inab.ie](mailto:inab@inab.ie)  
<http://www.inab.ie>



Permanent Laboratory:  
Category A

## ***Schedule of Accreditation***

# **REAGECON DIAGNOSTICS LTD**

### ***Chemical Testing Laboratory***

**Initial Accreditation Date: 20-12-1990**

<b>Postal Address:</b>	Shannon Free Zone Shannon Co Clare
<b>Telephone:</b>	353 -61-472622
<b>Fax:</b>	353 -61-472642
<b>Contact Name:</b>	Ms M Reddan
<b>Facilities:</b>	Not normally available for public testing

**THE IRISH NATIONAL ACCREDITATION BOARD (INAB) is the Irish organisation for the accreditation of laboratories and certification bodies.**

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 undertaking 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.

#### 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.

#### 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

- portable test equipment
- a site laboratory
- a mobile laboratory or
- 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.

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.

# REAGECON DIAGNOSTICS LTD



## Chemical Testing Laboratory

Permanent Laboratory:  
Category A

### SCOPE OF ACCREDITATION

INAB Classification number	Type of test/properties measured	Standard specifications
Materials/products tested	Range of measurement	Equipment/techniques used
<b>795 LABORATORY REAGENTS</b>		Documented In-House Method by Electrometry:-
<b>Aqueous Buffer Solutions</b>	pH 1 to 3 from ± 0.02 pH 4 to 10 from ± 0.01 pH 11 to 13 from ± 0.05	TPPHB
<b>Standard Buffer Solutions</b>	pH1.6 to 10 from ± 0.01	
<b>Blood Gas Buffer</b>	pH 6.8 to 7.4 from ± 0.01	
<b>Solid Buffers</b>	pH 4 to 10 from ± 0.02	
<b>Aqueous General Reagents</b>	pH 0 to 14 from ± 0.1	TPPHG
		Documented In-House Methods based on ASTM E200-97 (a) (See Note 1)
<b>Sodium Thiosulphate by redox reaction</b>	0.01N to 1.0N ± 0.1%	TPATRX1
<b>Iodine by redox reaction</b>	0.1N to 1.0N ± 0.1%	TPATRX2
<b>Acetous Perchloric Acid</b>	0.1M ± 0.2%	TPAHCLO
<b>Silver Nitrate by argentometric titration</b>	0.05 – 1.0N ± 0.2%	TPAGNO
<b>EDTA by compleximetric titration</b>	0.02 to 2.0N ± 0.2%	TPEDTA

# REAGECON DIAGNOSTICS LTD



## Chemical Testing Laboratory

Permanent Laboratory:  
Category A

### SCOPE OF ACCREDITATION

INAB Classification number	Type of test/properties measured	Standard specifications
Materials/products tested	Range of measurement	Equipment/techniques used
795 Laboratory Reagents (cont/d)		Documented In-House volumetric methods based on methods from Vogel: Quantitative Inorganic Analysis, 4th Edition:-
<b>Chloride Solutions</b>	0.01N to 0.09N      ± 0.5% 0.1N to 4N            ± 0.2%	TPATPPT1
<b>Acid Solutions</b>		
<b>Monobasic Acids</b>	{ 0.02M - 10.0 M      ± 0.1% 0.01M - 0.024M      ± 0.2%	TPATA
<b>Dibasic Acids</b>	0.025 - 10.0 M      ± 0.1%	
<b>Base Solutions</b>		
<b>Hydroxide Ion</b>	{ 0.02M - 0.049 M      ± 0.2% 0.05M - 10.0 M      ± 0.1%	TPATB
<b>General reagents</b>	Conductivity 5 to 500,000 µS/cm ±1% Conductivity at 1.3 µS/cm ±0.05 µS/cm	TPCOND

Note 1. ASTM: American Society for Testing and Materials