

Accreditation Certificate

Zentra Lab Ltd

Sims Building, Clonskeagh Road, Clonskeagh, Dublin 14

Medical Testing Laboratory

Registration number: 245MT

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 15189:2007 2nd Edition

"Medical laboratories - Particular requirements for quality and competence"

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

Date of award of accreditation: 27:10:2009

Date of last renewal of accreditation: 27:10:2009

Expiry date of this certificate of accreditation: 27:10:2014

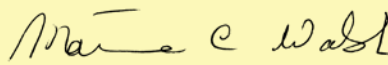
This Accreditation shall remain in force until further notice subject to continuing compliance with INAB accreditation criteria, ISO/IEC 15189 and any further requirements specified by the Irish National Accreditation Board.

Manager:



Dr Adrienne Duff

Chairperson:



Dr Máire Walsh

Issued on 27 October 2009

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)

Permanent Laboratory:
Category A

ZENTRA LAB LTD

Medical Testing Laboratory

Initial Registration Date : 27-October -2009
Postal Address: Sims Building, Clonskeagh Road
(Address of other locations as they apply) Clonskeagh
Dublin 14
Telephone: +353 (1) 2080717
E-mail: Kevin.marron@zentralab.ie
Contact Name: Dr Kevin Marron
Facilities: Public testing service

Schedule of Accreditation



Permanent Laboratory:
 Category A

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



Zentra Lab Ltd

Medical Testing Laboratory

Permanent Laboratory:
Category A

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1016 Serology of Infection .02 General serological testing	Qualitative screening test for HIV Serum for screening purposes only HIV Ag/Ab combo Reference Ranges S/CO ≥ 1.0 REACTIVE S/CO 0.90- <1.0 Grayzone S/CO <0.90 NEGATIVE	ZL-LP-0014 Automated Method, Abbott Architect
1016 Serology of Infection .02 General serological testing	Qualitative screening test for Hep B SAg Serum for screening purposes only Hep B Surface Antigen Reference Ranges S/CO <1.0 NEGATIVE S/CO ≥ 1.0 REACTIVE	ZL-LP-0014 Automated Method, Abbott Architect

Scope of Accreditation



Zentra Lab Ltd

Medical Testing Laboratory

Permanent Laboratory:
Category A

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1016 .02 Serology of Infection General serological testing	Qualitative screening test for Hep B Core Antibody Serum for screening purposes only Hep B Core Reference Ranges S/CO 1.001-3.000 NEGATIVE S/CO 0.000-1.000 REACTIVE S/CO >3.000 Invalid	ZL-LP-0014 Automated Method, Abbott Architect
1016 .02 Serology of Infection General serological testing	Qualitative screening test for Hep C Serum for screening purposes only Hep C Antibody Reference Ranges S/CO <1.0 NON-REACTIVE S/CO >1.0 REACTIVE	ZL-LP-0014 Automated Method, Abbott Architect
1016 .02 Serology of Infection General serological testing	Quantitative screening test for Rubella IgG	ZL-LP-0014 Automated Method, Abbott Architect

Scope of Accreditation



Zentra Lab Ltd

Medical Testing Laboratory

Permanent Laboratory:

Category A

INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1016 Serology of Infection .02 General serological testing	Qualitative screening for Syphilis Serum for screening purposes only Syphilis Antibody References Ranges S/CO <1.0 NON-REACTIVE S/CO >= 1.0 REACTIVE	ZL-LP-0014 Automated Method, Abbott Architect
	Qualitative screening for HTLV I/II Serum for screening purposes only HTLV I/II Antibody References Ranges S/CO <1.0 NON-REACTIVE S/CO >= 1.0 REACTIVE	ZL-LP-0014 Automated Method, Abbott Architect

NOTE: Any positive virology results are referred to the National Virus Reference Laboratory for confirmatory analysis. Zentra Lab Ltd does not provide confirmatory testing services.