

Accreditation Certificate

Naas General Hospital

Pathology Laboratory, Naas, Co. Kildare

Medical Testing Laboratory

Registration number: 259MT

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: 13:04:2010

Date of last renewal of accreditation: 13:04:2010

Expiry date of this certificate of accreditation: 13:04:2015

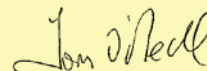
This Accreditation shall remain in force until further notice subject to continuing compliance with INAB accreditation criteria, ISO/IEC 15189 and any further requirements specified by the Irish National Accreditation Board.

Manager:



Dr. Adrienne Duff

Chairperson:



Mr. Tom O'Neill

Issued on 13 April 2010

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

NAAS GENERAL HOSPITAL

Medical Testing Laboratory

<i>Initial Registration Date :</i>	13-April - 2010
<i>Postal Address:</i>	Blood Transfusion Laboratory 13-Apr-2010
<i>(Address of other locations as they apply)</i>	Haematology Laboratory 31-May-2011 Biochemistry Laboratory 25-Oct-2011 Microbiology Laboratory 25-Oct-2011
	Naas Co Kildare
<i>Telephone:</i>	+353 (045) 843046
<i>Fax:</i>	+353 (045) 843096
<i>E-mail:</i>	pat.flynn1@hse.ie
<i>Contact Name:</i>	Mr Pat Flynn
<i>Facilities:</i>	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
- 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.

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



Naas General Hospital 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
1020	Immunohaematology	ABO & Rh(D) typing <i>Whole Blood</i>	Ortho BioVue manual method.
.01	Blood grouping including ABO, Rh(D)		Manual method in tubes. Ortho Autovue automated method. NGH/BB/SOP/004
.03	Blood Group antibody screen	Antibody Screening <i>Plasma</i>	Ortho BioVue manual method. Manual method in tubes. Ortho Autovue automated method. NGH/BB/SOP/006
.04	Identification of blood group antibodies	Antibody Identification <i>Plasma</i>	Ortho BioVue manual method. Manual method in tubes NGH/BB/SOP/007
.05	Determination of compatibility of donor units using appropriate techniques including the investigation of transfusion reactions	Red Cell Compatibility testing <i>Plasma</i>	Ortho BioVue manual method. Manual method in tubes. NGH/BB/SOP/010

Note: Naas General Hospital has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (S.I.No. 360 of 2005 and S.I. No. 547 of 2006)

Scope of Accreditation



Naas General Hospital 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
1020 Immunohaematology .06 Red cell phenotyping	Antigen Typing of red cells	Ortho BioVue manual method. Manual method in tubes NGH/BB/SOP/009
.99 Miscellaneous Tests Direct Antiglobulin Test (DAT) for detection of sensitized cells	Direct Antiglobulin Test (DAT) Red Blood Cells	Ortho BioVue manual method. Manual method in tubes Ortho Autovue automated method. NGH/BB/SOP/008

Note: Naas General Hospital has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (S.I.No. 360 of 2005 and S.I. No. 547 of 2006)

Scope of Accreditation



Naas General Hospital Medical Testing Laboratory

Permanent Laboratory:
Category A

Biochemistry Department

INAB Classification Number (P9)	Test /Assay name	Specimen type	Method	Equipment	SOP
1061 GENERAL CHEMISTRY <i>.01 Analytes in general use in cardiac, liver function, lipid, renal & other profiles & metabolic studies</i>	Alanine Amino Transferase (ALT)	Serum/Plasma	IFCC (w/o PP activation)	Roche SWA	NGH/BIO/SOP/022
	Albumin	Serum/Plasma	Bromocresol Green	Roche SWA	NGH/BIO/SOP/023
	Alcohol	Serum/Plasma	Enzymatic	Roche SWA	NGH/BIO/SOP/033
	Alkaline Phosphate (ALP)	Serum/Plasma	IFCC Colorimetric	Roche SWA	NGH/BIO/SOP/024
	Amylase	Serum/Plasma	Enzymatic / IFCC	Roche SWA	NGH/BIO/SOP/025
	Asparate Amino Transferase (AST)	Serum/Plasma	IFCC (w/o PP activation)	Roche SWA	NGH/BIO/SOP/026
	Bilirubin - Total	Serum/Plasma	Colorimetric	Roche SWA	NGH/BIO/SOP/044
	Calcium	Serum/Plasma	O-Cresolphthalein	Roche SWA	NGH/BIO/SOP/027
	Chloride	Serum/Plasma	Indirect ISE	Roche SWA	NGH/BIO/SOP/028
	Cholesterol	Serum/Plasma	CHOD-PAP	Roche SWA	NGH/BIO/SOP/029
	Creatine Kinase (CK)	Serum/Plasma	Liquid acc to IFCC	Roche SWA	NGH/BIO/SOP/032
	Creatinine	Serum/Plasma	Jaffe	Roche SWA	NGH/BIO/SOP/031
	C Reactive Protein (CRP)	Serum/Plasma	Immunoturbidimetric	Roche SWA	NGH/BIO/SOP/030
	Gamma Glutamyl Transferase (GGT)	Serum/Plasma	IFCC	Roche SWA	NGH/BIO/SOP/034
	Glucose	Serum/Plasma	Hexokinase	Roche SWA	NGH/BIO/SOP/035
	High Density Lipoprotein (HDL)	Serum/Plasma	Enzymatic	Roche SWA	NGH/BIO/SOP/036
	Lactate Dehydrogenase (LDH)	Serum/Plasma	UV Assay	Roche SWA	NGH/BIO/SOP/037
	Lithium	Serum	Randox	Roche SWA	NGH/BIO/SOP/038
	Low Density Lipoprotein (LDL)	Serum/Plasma	Calculated	Roche SWA	NGH/BIO/SOP/020
	Magnesium	Serum/Plasma	Colorimetric	Roche SWA	NGH/BIO/SOP/039

Scope of Accreditation



Naas General Hospital

Medical Testing Laboratory

Biochemistry Department

Permanent Laboratory:

Category A

INAB Classification Number (P9)	Test /Assay name	Specimen type	Method	Equipment	SOP
1061 GENERAL CHEMISTRY <i>.01 Analytes in general use in cardiac, liver function, lipid, renal & other profiles & metabolic studies</i>	Paracetamol	Serum/Plasma	Enzymatic	Roche SWA	NGH/BIO/SOP/021
	Phosphate - inorganic	Serum/Plasma	Ammonium Molybdate	Roche SWA	NGH/BIO/SOP/040
	Potassium	Serum/Plasma	Indirect ISE	Roche SWA	NGH/BIO/SOP/041
	Protein- Total	Serum/Plasma	Biuret	Roche SWA	NGH/BIO/SOP/045
	Salicylate	Serum/Plasma	Ferric Nitrate	Roche SWA	NGH/BIO/SOP/042
	Sodium	Serum/Plasma	Indirect ISE	Roche SWA	NGH/BIO/SOP/043
	Triglycerides	Serum/Plasma	GPO-PAP	Roche SWA	NGH/BIO/SOP/046
	Urea	Serum/Urine	Urease	Roche SWA	NGH/BIO/SOP/047
	Uric Acid	Serum/Urine	Uricase	Roche SWA	NGH/BIO/SOP/048
1061 GENERAL CHEMISTRY .10	Vancomycin	Serum	FPIA	Abbott AxSYM	NGH/MIC/SOP/032
	Gentamicin	Serum	FPIA	Abbott AxSYM	NGH/MIC/SOP/032
	Haemoglobin	EDTA Blood	HPLC	Menarini HA8160	NGH/BIO/SOP/065
	PSA - total	Plasma/serum	Immunoassay	Roche SWA	NGH/BIO/SOP/055
	T4-free	Plasma/serum	Immunoassay	Roche SWA	NGH/BIO/SOP/063
	Thyroid stimulating hormone (TSH)	Plasma/serum	Immunoassay	Roche SWA	NGH/BIO/SOP/064

Scope of Accreditation



Naas General Hospital
Medical Testing Laboratory
Haematology Department

Permanent Laboratory:
 Category A

INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	Equipment	SOP
1030 HAEMATOLOGY .01 BLOOD COUNTS	White Cell Count	Blood	Flow Cytometry Light Scatter	CD Sapphire CD 3700	NGH/HAEM/SOP/003 NGH/HAEM/SOP/004 NGH/HAEM/SOP/005
	Red Cell Count	Blood	Flow Cytometry (Optical and Impedence)	CD Sapphire CD 3700	NGH/HAEM/SOP/003 NGH/HAEM/SOP/004 NGH/HAEM/SOP/005
	Haemoglobin	Blood	Absorption Spectrophotometry	CD Sapphire CD 3700	NGH/HAEM/SOP/003 NGH/HAEM/SOP/004 NGH/HAEM/SOP/005
	Haematocrit	Blood	Calculated from Red Cell Count and MCV	CD Sapphire CD 3700	NGH/HAEM/SOP/003 NGH/HAEM/SOP/004 NGH/HAEM/SOP/005
	Mean Cell Volume	Blood	Flow Cytometry	CD Sapphire CD 3700	NGH/HAEM/SOP/003 NGH/HAEM/SOP/004 NGH/HAEM/SOP/005
	MCH	Blood	Calculated from Haemoglobin and Red Cell Count	CD Sapphire CD 3700	NGH/HAEM/SOP/003 NGH/HAEM/SOP/004 NGH/HAEM/SOP/005
	MCHC	Blood	Calculated from Haemoglobin, MCV and Red Cell Count	CD Sapphire CD 3700	NGH/HAEM/SOP/003 NGH/HAEM/SOP/004 NGH/HAEM/SOP/005
	Platelet Count	Blood	Flow Cytometry (Optical and Impedence)	CD Sapphire CD 3700	NGH/HAEM/SOP/003 NGH/HAEM/SOP/004 NGH/HAEM/SOP/005

Scope of Accreditation



Naas General Hospital
Medical Testing Laboratory
Haematology Department

Permanent Laboratory:
 Category A

INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	Equipment	SOP
1030 HAEMATOLOGY <i>.02 Visual examination of blood films</i>	Includes: Neutrophils	Blood Film	Staining/Microscopy	Hematek Stainer Nikon Microscopes	NGH/HAEM/SOP/020
	Lymphocytes Monocytes	Blood Film	Staining/Microscopy	Hematek Stainer Nikon Microscopes	NGH/HAEM/SOP/020
	Eosinophils Basophils Precursor cells Platelets	Blood Film	Staining/Microscopy	Hematek Stainer Nikon Microscopes	NGH/HAEM/SOP/020
	Red Cell Morphology	Blood Film	Staining/Microscopy	Hematek Stainer Nikon Microscopes	NGH/HAEM/SOP/020
1030 HAEMATOLOGY <i>.05 Automated differential leucocyte counts</i>	Neutrophil Count	Blood	Flow Cytometry Light Scatter	CD Sapphire CD 3700	NGH/HAEM/SOP/003 NGH/HAEM/SOP/004 NGH/HAEM/SOP/005
	Lymphocyte Count	Blood	Flow Cytometry Light Scatter	CD Sapphire CD 3700	NGH/HAEM/SOP/003 NGH/HAEM/SOP/004 NGH/HAEM/SOP/005
	Monocyte Count	Blood	Flow Cytometry Light Scatter	CD Sapphire CD 3700	NGH/HAEM/SOP/003 NGH/HAEM/SOP/004 NGH/HAEM/SOP/005
	Eosinophil Count	Blood	Flow Cytometry Light Scatter	CD Sapphire CD 3700	NGH/HAEM/SOP/003 NGH/HAEM/SOP/004 NGH/HAEM/SOP/005
	Basophil Count	Blood	Flow Cytometry Light Scatter	CD Sapphire CD 3700	NGH/HAEM/SOP/003 NGH/HAEM/SOP/004 NGH/HAEM/SOP/005
<i>.06 Automated reticulocyte counts</i>	Reticulocyte Count	Blood	Fluorescence Flow Cytometry	CD Sapphire	NGH/HAEM/SOP/003 NGH/HAEM/SOP/004

Scope of Accreditation



Naas General Hospital Medical Testing Laboratory

Permanent Laboratory:
Category A

Haematology Department

INAB Classification Number (P9)	Test/Assay Name	Specimen Type	Method	Equipment	SOP
1030 HAEMATOLOGY .41 <i>General haemostasis related tests</i>	Prothrombin Time (PT)	Blood	Photo-Optical Technology	MDA MTX	NGH/HAEM/SOP/011 NGH/HAEM/SOP/013
	International Normalised Ratio (INR)	Blood	Calculation using PT result, mean normal PT and ISI	MDA MTX	NGH/HAEM/SOP/011 NGH/HAEM/SOP/013
	Activated Partial Thromboplastin Time (APTT)	Blood	Photo-Optical Technology	MDA MTX	NGH/HAEM/SOP/011 NGH/HAEM/SOP/013
	Fibrinogen (Clauss)	Blood	Photo-Optical Technology	MDA MTX	NGH/HAEM/SOP/011 NGH/HAEM/SOP/013
	D-Dimer	Blood	Enzyme Linked Fluorescent Assay	mini Vidas	NGH/HAEM/SOP/016

Scope of Accreditation



Naas General Hospital
Medical Testing Laboratory

Permanent Laboratory:
 Category A

Microbiology Department

INAB Classification Number (P9)	Test/ Assay Name	Specimen Type	Method	Equipment	SOP	
1011 BACTERIOLOGY	.01 .02 .03 .04	BLOOD CULTURE	Blood	BacT Alert Blood Culture instrument Microscopy Culture Sensitivity	BacT Alert 3D System	NGH/MIC/SOP/031
	.01 .02 .03 .04	CSF CULTURE	CSF	Culture/ Sensitivity Microscopy	Manual	NGH/MIC/SOP/034
	.01 .02 .03 .04	FLUID CULTURES	Amniotic Fluid Ascitic Fluid Bursa Fluid Pericardial Fluid Peritoneal Fluid Pleural Fluid Synovial Fluid	Microscopy Culture/ Sensitivity	Manual	NGH/MIC/SOP/052

Scope of Accreditation



Permanent Laboratory:
Category A

Naas General Hospital Medical Testing Laboratory

Microbiology Department

INAB Classification Number (P9)		Test/Assay Name	Specimen Type	Method	Equipment	SOP
1011 BACTERIOLOGY	.02 .04	Faeces Culture	Faeces	Culture/ Sensitivity	Manual	NGH/MIC/SOP/01 0
	.01 .02 .03 .04	Cervical Culture	Cervical Swab	Culture/ Sensitivity Microscopy	Manual	NGH/MIC/SOP/05 1
	.02 .04	Ear Culture	Ear Swab Middle Ear Effusion	Culture/ Sensitivity	Manual	NGH/MIC/SOP/05 0
	.02 .04	Eye Culture	Eye Swab Canalicular Pus	Culture/ Sensitivity	Manual	NGH/MIC/SOP/05 0
	.01 .02 .03 .04	High Vaginal Culture	High Vaginal Swab (HVS) Vaginal Discharge Vulval Swab Labial Swab	Microscopy Culture/ Sensitivity	Manual	NGH/MIC/SOP/05 1
	.01 .02 .03 .04	Low Vaginal Culture	Low Vaginal Swab	Microscopy Culture/ Sensitivity	Manual	NGH/MIC/SOP/05 1
	.02 .04	Mouth Culture	Mouth Swab	Culture/ Sensitivity Microscopy if requested	Manual	NGH/MIC/SOP/05 0
	.02 .04	MRSA Screen	Nasal, Throat, Axilla, Groin, Perineum and other sites depending on clinical information	Culture/ Sensitivity	Manual	NGH/MIC/SOP/03 0
	.02 .04	Nasal Culture	Nasal Swab	Culture/ Sensitivity	Manual	NGH/MIC/SOP/05 0

Scope of Accreditation



Naas General Hospital Medical Testing Laboratory Microbiology Department

Permanent Laboratory:
Category A

INAB Classification Number (P9)	Test/ Assay Name	Specimen Type	Method	Equipment	SOP	
1011 BACTERIOLOGY	.01 .02 .03 .04	Penile Culture	Penile Swab	Microscopy Culture/ Sensitivity	Manual	NGH/MIC/SOP/05 1
	.02 .04	Throat Culture	Throat Swab	Culture/ Sensitivity	Manual	NGH/MIC/SOP/05 0
	.01 .02 .03 .04	Urethral Culture	Urethral Swab	Culture/ Sensitivity Microscopy	Manual	NGH/MIC/SOP/05 1
	.01. 02 .04	Sputum and Associated Specimens culture	Bronchoalveolar Lavage, Sputum and Associated Specimens	Culture/ Sensitivity Microscopy if required	Manual	NGH/MIC/SOP/01 3
	.02 .04	Tip Culture	Intravascular cannulae & associated specimens	Culture/ Sensitivity	Manual	NGH/MIC/SOP/05 3
	.01 .03 .04	Urine Culture	BAG CATCH CSU MSU SUPRA PUBIC	Microscopy Culture/ Sensitivity	Manual	NGH/MIC/SOP/00 1
	.02 .04	Wound Culture	Exudates Pus Swabs	Microscopy if required Culture/ Sensitivity	Manual	NGH/MIC/SOP/05 0
	.02 .04 .99	Clostridium difficile culture	Faeces	Culture/ latex id/ eliza toxin id	Manual	NGH/MIC/SOP/01 2
	.04 .07	Antimicrobial susceptibility testing - Manual CLSI method	Bacterial cultures	CLSI	Manual	NGH/MIC/SOP/08 0
	.04 .07	Antimicrobial susceptibility testing on the BD Phoenix	Bacterial cultures	CLSI	Automated	NGH/MIC/SOP/08 1

Scope of Accreditation



Permanent Laboratory:
Category A

Naas General Hospital
Medical Testing Laboratory

Microbiology Department

INAB Classification Number (P9)		Test/ Assay Name	Specimen Type	Method	Equipment	SOP
1012 PARASITOLOGY	.02	Ova, Cysts & Parasites	Faeces	Microscopy	Manual	NGH/MIC/SOP/011