

Accreditation Certificate

Coombe Women & Infants University Hospital

Pathology Department, Dublin 8

Testing Laboratory

Registration number: 218MT

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: 17:02:2009

Date of last renewal of accreditation: 17:02:2009

Expiry date of this certificate of accreditation: 17:02:2014

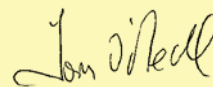
This Accreditation shall remain in force until further notice subject to continuing compliance with INAB accreditation criteria, ISO/IEC 15189 and any further requirements specified by the Irish National Accreditation Board.

Manager: _____



Dr Adrienne Duff

Chairperson: _____



Mr Tom O'Neill

Issued on 15 March 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

COOMBE WOMEN & INFANTS UNIVERSITY HOSPITAL

Medical Testing Laboratory

<i>Initial Registration Date :</i>	Blood Transfusion Department : 17-February-2009 Cytopathology Department: 17-February-2009 Haematology: 7-September-2010 Histopathology Department: 7-September-2010 Microbiology Department: 03-April-2012
<i>Postal Address:</i> <i>(Address of other locations as they apply)</i>	Pathology Department Coombe Women & Infants University Hospital Cork Street Dublin 8
<i>Telephone:</i>	+353 (1) 4085678
<i>Fax:</i>	+353 (1) 4085676
<i>E-mail:</i>	mring@coombe.ie
<i>Contact Name:</i>	Ms Martina Ring
<i>Facilities:</i>	Normally not available for Public testing

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



Coombe 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 .01	Immunohaematology Blood grouping, including ABO and Rh(D)	ABO and RhD grouping of blood Ab/Ag reaction <i>Red Cells/ Plasma</i>	TT-IDGELST-P (Automated Gel method) TT-ABORHDIAMED-P (Semi-Automated Gel method)
1020 .03	Immunohaematology Blood group antibody screen	Antibody screening Ab/Ag reaction <i>Plasma</i>	TT-IDGELST-P (Automated Gel method) TT-ABSCRDIAMED-P (Semi-Automated gel method)
1020 .04	Immunohaematology Identification of blood group antibodies	Antibody identification Ab/Ag reaction <i>Plasma</i>	TT-ABIDDIAMED-P (Manual Gel method)
1020 .05	Immunohaematology Determination of compatibility of donor units using appropriate techniques including the investigation of transfusion reactions	Compatibility testing <i>Plasma/cells</i>	TT-XMDIAMED-P (Manual Gel method)

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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 Ab/Ag reaction <i>Red Cells</i>	TT-PHENO-P (Gel and Tube Technique)
1020 Immunohaematology .99 Miscellaneous tests	Direct Coombs Test <i>Red Cells</i>	TT-IDGELST-P (Automated Gel method) TT-NBATORH-I (Semi-Automated Gel method)
1020 Immunohaematology .99 Miscellaneous tests	Antibody Titre <i>Plasma</i>	TT-ABTITRE-P (Manual Gel method)

Note: Coombe Women & Infants University Hospital, Transfusion Medicine Department, Cork Street, Dublin 8 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).

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INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1030 Haematology .01	Full Blood Counts Automated	HH-RUBY-C HH-3200-C
1030 .02	Visual Examination of Blood Films Manual	PATH-HAE-PPG-2
1030 .03	Erythrocyte Sedimentation Rate Manual	HH-ESR-C
1030 .05	Automated Differential Leucocyte count	HH-RUBY-C
1030 .06	Automated Reticulocytes counts	HH-RETAUTO-C
1030 .09	Examination for Malarial Parasites Manual	HH-IDMALARIAP-C
1030 .03	Kleihauer (Test for foetal Hb) Manual	HH-FMHIMMU-C

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INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1030 Haematology .41	Coagulation Screen (PT, APTT, Fibrinogen) Automated	HH-STAGO-C
1030 .41	Lupus Anticoagulant Automated	HH-LA-C
1030 .99 Fetomaternal haemorrhage	Estimation of FMH by Flow Cytometry Semi-Automated	HH-FMH-P

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INAB Classification number (P9) Materials/products tested		Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1052 .01	Cytopathology Gynaecological (cervical)	Stained LBC slide sample	CC-IMAGER-P (Semi - Automated scanning of stained slide preparation)
1052 .01	Cytopathology Gynaecological (cervical)	Stained LBC slide sample	CC-REVIEWSCOPEOP-P CC-CXSMRSCREEN-P CC-REPORTCODES-I (Semi -Automated screening of stained slide preparation)
1052 .01	Cytopathology Gynaecological (cervical)	Stained LBC slide sample	CC-CXMRSRSCREEN-P CC-REPORTCODES-I CC-PATHREF-P (Manual screening of stained slide preparation)
1052 .01	Cytopathology Gynaecological (cervical)	Liquid Based Cytology (LBC)	CC-SAMPREG-P CC-TP3OP-P (Programmed Automated Slide preparation)

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INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1052 Cytopathology .01 Gynaecological (cervical)	Liquid Based Cytology (LBC)	CC-TP20P-P CC-REPBLOODSMR-P (Programmed Semi Automated Slide preparation)
1052 Cytopathology .01 Gynaecological (cervical)	Unstained LBC sample slide for PAP staining	CC-SAKURADRS2000-P CC-TISSUETEKGLC550-P CC-STAINCHECK-P (Programmed automated application of reagents)

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INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1051 Histopathology .01 Histopathology of biopsy material from: Cervix	Specimen Reception Cut-Up Tissue Processing Embedding Microtomy Automated Haematoxylin and Eosin Staining Mounting/ Coverslipping	PATH-HISTO-PPG-18 PATH-HISTO-PPG-19 PATH-HISTO-PPG-20 PATH-HISTO-PPG-21 PATH-HISTO-PPG-22 PATH-HISTO-PPG-23 PATH-HISTO-PPG-24
.01 Histopathology of biopsy material from: Fallopian Tubes	Specimen Reception Cut-Up Tissue Processing Embedding Microtomy Automated Haematoxylin and Eosin Staining Mounting/ Coverslipping	PATH-HISTO-PPG-18 PATH-HISTO-PPG-19 PATH-HISTO-PPG-20 PATH-HISTO-PPG-21 PATH-HISTO-PPG-22 PATH-HISTO-PPG-23 PATH-HISTO-PPG-24
.01 Histopathology of biopsy material from: Ovary	Specimen Reception Cut-Up Tissue Processing Embedding Microtomy Automated Haematoxylin and Eosin Staining Mounting/ Coverslipping	PATH-HISTO-PPG-18 PATH-HISTO-PPG-19 PATH-HISTO-PPG-20 PATH-HISTO-PPG-21 PATH-HISTO-PPG-22 PATH-HISTO-PPG-23 PATH-HISTO-PPG-24

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INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1051 Histopathology .01 Histopathology of biopsy material from: Uterus	Specimen Reception Cut-Up Tissue Processing Embedding Microtomy Automated Haematoxylin and Eosin Staining Mounting/ Coverslipping	PATH-HISTO-PPG-18 PATH-HISTO-PPG-19 PATH-HISTO-PPG-20 PATH-HISTO-PPG-21 PATH-HISTO-PPG-22 PATH-HISTO-PPG-23 PATH-HISTO-PPG-24
.01 Histopathology of biopsy material from: Trophoblastic Disease of Pregnancy	Specimen Reception Cut-Up Tissue Processing Embedding Microtomy Automated Haematoxylin and Eosin Staining Mounting/ Coverslipping	PATH-HISTO-PPG-18 PATH-HISTO-PPG-19 PATH-HISTO-PPG-20 PATH-HISTO-PPG-21 PATH-HISTO-PPG-22 PATH-HISTO-PPG-23 PATH-HISTO-PPG-24
.01 Histopathology of biopsy material from: Placenta	Specimen Reception Cut-Up Tissue Processing Embedding Microtomy Automated Haematoxylin and Eosin Staining Mounting/ Coverslipping	PATH-HISTO-PPG-18 PATH-HISTO-PPG-19 PATH-HISTO-PPG-20 PATH-HISTO-PPG-21 PATH-HISTO-PPG-22 PATH-HISTO-PPG-23 PATH-HISTO-PPG-24
.02 Immediate frozen section diagnosis	Tissue processing	PATH-HISTO-PPG-42

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INAB Classification number (P9) Materials/products tested		Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1051	Histopathology	Cut-Up	PATH-HISTO-19 PATH-HISTO-25
.01	Diagnostic pathology of: cervix, fallopian tubes, ovary, uterus, trophoblastic disease of pregnancy and placenta	Tissue Disgnosis and Reporting	
.01	Special stains	Millers Elastin Phosotungstic acid haematoxylin Perls Prussian Blue PAS Stain / Diastase PAS stain Gram Twort Massons Trichrome Ziehl Neelsen Alcian Blue / PAS stain Alcian Blue Congo Red Haematoxylin Van Gieson Martius Scarlett Blue	PATH-HISTO-PPG-7 PATH-HISTO-PPG-15 PATH-HISTO-PPG-10 PATH-HISTO-PPG-11 PATH-HISTO-PPG-13 PATH-HISTO-PPG-14 PATH-HISTO-PPG-12 PATH-HISTO-PPG-40 PATH-HISTO-PPG-9 PATH-HISTO-PPG-16 PATH-HISTO-PPG-41 PATH-HISTO-PPG-8

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INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1051 Histopathology .03 Immunohistochemical Investigation	Automated Immunohistochemical Tissue Staining Actin AE1/AE3 Alpha Feto Protein Bcl-2 Calretinin CEA CD3 CD10 CD15 CD20 CD30 CD56 hPL P57 Kip2	PATH-HISTO-PPG-17

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INAB Classification number (P9) Materials/products tested	Type of test/properties measured Range of measurement	Standard specifications Equipment/techniques used
1051 Histopathology	CD31	PATH-HISTO-PPG-17
	CD34	PATH-HISTO-PPG-17
.03 Immunohistochemical Investigation	CD45	PATH-HISTO-PPG-17
	CD68	PATH-HISTO-PPG-17
	CD138	PATH-HISTO-PPG-17
	Chromogranin A	PATH-HISTO-PPG-17
	CK5/6	PATH-HISTO-PPG-17
	CK7	PATH-HISTO-PPG-17
	CK20	PATH-HISTO-PPG-17
	Collagen IV	PATH-HISTO-PPG-17
	Desmin	PATH-HISTO-PPG-17
	EMA	PATH-HISTO-PPG-17
	GFAP	PATH-HISTO-PPG-17
	HCG	PATH-HISTO-PPG-17
	Inhibin	PATH-HISTO-PPG-17
	Mib-1	PATH-HISTO-PPG-17
	MCM3	PATH-HISTO-PPG-17
	P16	PATH-HISTO-PPG-17
	P53	PATH-HISTO-PPG-17
	PLAP	PATH-HISTO-PPG-17
	S100	PATH-HISTO-PPG-17
	Vimentin	PATH-HISTO-PPG-17

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INAB Classification Number (P9)		Test/ Assay Name	Specimen Type	Method	Equipment	SOP
1011 BACTERIOLOGY	.01 .03 .04	BLOOD CULTURE	Blood	BacT Alert Blood Culture instrument Microscopy Culture Sensitivity	BacT Alert	MM-BLOODCULTURES-P.DOC
	.01 .02 .03 .04	CSF CULTURE	CSF	Culture/ Sensitivity Microscopy	Manual	MM-CSF-P.DOC
	.02 .04 .05	Umbilical Culture	Swab	Culture/ Sensitivity Microscopy	Manual	MM-UMB-P.DOC
	.02 .04 .05	Faeces Culture	Faeces or rectal swab	Culture/ Sensitivity	Manual	MM-FAECES-P.DOC
	.02 .04 .05	Ear Culture	Ear Swab	Culture/ Sensitivity	Manual	MM-EAR-P.DOC
	.01 .02 .03 .04 .05	Eye Culture	Eye Swab	Culture/ Sensitivity	Manual	MM-EYE-P.DOC
	.01 .02 .03 .04 .05	Oral Culture	Swab	Culture/ Sensitivity	Manual	MM-ORAL-P.DOC
	.02 .04 .05	Nasal Culture	Swab	Culture/ Sensitivity	Manual	MM-NASAL-P.DOC
	.02 .04 .05	Upper Respiratory tract secretions	ETT secretions	Culture/ Sensitivity	Manual	MM-SPUTA-P.DOC

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INAB Classification Number (P9)	Test/ Assay Name	Specimen Type	Method	Equipment	SOP	
1011 BACTERIOLOGY	.02 .04 .05	Throat Culture	Throat Swab	Culture/ Sensitivity	Manual	MM-THROAT- P.DOC
	.02 .04 .05	Superficial Wound Culture	Swabs	Culture Sensitivity	Manual	MM-SS-P.DOC
	.02 .04 .05	Skin spot or canula site	Swabs	Culture Sensitivity	Manual	MM-SS-P.DOC
	.02 .04 .05	Skin rash	Swabs	Culture Sensitivity	Manual	MM-SS-P.DOC
	.02 .04 .05	Interventricular cannulae UAC UVC iv and PICC lines	Tip of line	Culture Sensitivity	Manual	MM-CANNULAE- C.DOC
	.01 .02 .04 .05	HVS Placenta pairs	Swab	Culture/ Sensitivity	Manual	MM-GENITAL- P.DOC
	.01 .02 .03 .04 .05	Genital -HVS, LVS and Endocervical	Throat Swab	Microscopy Culture/ Sensitivity	Manual	MM-GENITAL- P.DOC
	.01 .02 .03 .04 .05	IUCD/ Genital abscess / fluid	Coil, pus or fluid in sterile container	Culture/ Sensitivity	Manual	MM-GENITAL- P.DOC MM-WOUND- P.DOC
	.02 .03 .04 .05	Sputum Culture	Sputum	Culture/ Sensitivity	Manual	MM-SPUTA-P.DOC
	.02 .04 .05	EBM or breast swab	Milk Or swab	Culture sensitivity	Manual	MM-BREAST- P.DOC

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INAB Classification Number (P9)	Test/ Assay Name	Specimen Type	Method	Equipment	SOP	
1011 BACTERIOLOGY	.02 .04 .05	Perineal / Episiotomy Wound Culture	Swab	Culture sensitivity	Manual	MM-WOUND- P.DOC
	.01 .02 .03 .04 .05	Abscess, pus and fluids	Swab, pus or fluids in sterile container	Culture sensitivity	Manual	MM-WOUND- P.DOC
	.04	Disk sensitivity	Susceptibility	Plate culture	Manual	MM-SENS-P.DOC
	.04	MIC-Etest	MIC	Plate culture	Manual	MM-SENS-P.DOC
	.04	MIC-VITEK	MIC	Automated	VITEK2com pact	MM-SENS-P.DOC
	.02 .03 .04 .05	Urine -MSU, U, CCU, PU and U culture and sensitivity	Urine	Microscopy Culture Sensitivity	Manual	MM-URINALYSIS- P.DOC
1019 Miscellaneous	.01	Semen analysis	Semen analysis	Microscopy	Manual	MM-SEMEN-I.DOC
1090 Medical Practise Pathology	.02	Urinary hCG	Urine	Kit	Manual	
	.15	Urine -MSU, U, CCU, PU and U culture and sensitivity	Urine	Microscopy Culture Sensitivity	Manual	MM-URINALYSIS- P.DOC

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INAB Classification Number (P9)		Test/ Assay Name	Specimen Type	Method	Equipment	SOP
1014 Mycology	.03 .04 .05	BLOOD CULTURE	Blood	BacT Alert Blood Culture instrument Microscopy Culture Sensitivity	BacT Alert	MM-BLOODCULTURES-P.DOC
	.03 .04 .05	CSF CULTURE	CSF	Culture/ Sensitivity Microscopy	Manual	MM-CSF-P.DOC
	.03 .04 .05	Umbilical Culture	Swab	Culture/ Sensitivity Microscopy	Manual	MM-UMB-P.DOC
	.03 .04 .05	Faeces Culture	Faeces or rectal swab	Culture/ Sensitivity	Manual	MM-FAECES-P.DOC
	.03 .04 .05	Ear Culture	Ear Swab	Culture/ Sensitivity	Manual	MM-EAR-P.DOC
	.03 .04 .05	Eye Culture	Eye Swab	Culture/ Sensitivity	Manual	MM-EYE-P.DOC
	.03 .04 .05	Oral Culture	Swab	Culture/ Sensitivity	Manual	MM-ORAL-P.DOC
	.03 .04 .05	Nasal Culture	Swab	Culture/ Sensitivity	Manual	MM-NASAL-P.DOC
	.03 .04 .05	Upper Respiratory tract secretions	ETT secretions	Culture/ Sensitivity	Manual	MM-SPUTA-P.DOC

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INAB Classification Number (P9)	Test/ Assay Name	Specimen Type	Method	Equipment	SOP	
1014 MYCOLOGY	.03 .04 .05	Throat Culture	Throat Swab	Culture/ Sensitivity	Manual	MM-THROAT- P.DOC
	.03 .04 .05	Superficial Wound Culture	Swabs	Culture Sensitivity	Manual	MM-SS-P.DOC
	.03 .04 .05	Skin spot or canula site	Swabs	Culture Sensitivity	Manual	MM-SS-P.DOC
	.03 .04 .05	Skin rash	Swabs	Culture Sensitivity	Manual	MM-SS-P.DOC
	.03 .04 .05	Interventricular cannulae UAC UVC iv and PICC lines	Tip of line	Culture Sensitivity	Manual	MM-CANNULAE- C.DOC
	.03 .04 .05	HVS Placenta pairs	Swab	Culture/ Sensitivity	Manual	MM-GENITAL- P.DOC
	.03 .04 .05	Genital -HVS, LVS and Endocervical	Throat Swab	Microscopy Culture/ Sensitivity	Manual	MM-GENITAL- P.DOC
	.03 .04 .05	IUCD/ Genital abscess / fluid	Coil, pus or fluid in sterile container	Culture/ Sensitivity	Manual	MM-GENITAL- P.DOC MM-WOUND- P.DOC
	.03 .04 .05	Sputum Culture	Sputum	Culture/ Sensitivity	Manual	MM-SPUTA-P.DOC
	.03 .04 .05	EBM or breast swab	Milk Or swab	Culture sensitivity	Manual	MM-BREAST- P.DOC

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INAB Classification Number (P9)		Test/ Assay Name	Specimen Type	Method	Equipment	SOP
1014 MYCOLOGY	.03 .04 .05	Perineal / Episiotomy Wound Culture	Swab	Culture sensitivity	Manual	MM-WOUND- P.DOC
	.03 .04 .05	Abscess, pus and fluids	Swab, pus or fluids in sterile container	Culture sensitivity	Manual	MM-WOUND- P.DOC
	.03 .04 .05	Urine -MSU, U, CCU, PU and U culture and sensitivity	Urine	Microscopy Culture Sensitivity	Manual	MM-URINALYSIS- P.DOC