Schedule of Accreditation

Organisation Name	Blackrock Clinic Ltd
Trading As	
INAB Reg No	212MT
Contact Name	Naomi Fynes
Address	Rock Road, Blackrock, Dublin
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Website	http://www.blackrock-clinic.ie
Accreditation Standard	ISO 15189
Date Initially Awarded	17/02/2009
Scope Classification	Microbiology and virology
Scope Classification	Blood Transfusion Science
Scope Classification	Haematology
Scope Classification	Histopathology and cytopathology
Scope Classification	Chemical pathology
Services available to the public[1]	Yes

[1] Refer to document on interpreting INAB Scopes of Accreditation

Sites from which accredited services are delivered		
(the detail of the accredited services delivered at each site are on the Scope of Accreditation)		
	Name	**Address**
1	Blackrock Clinic Laboratory RCSI	Smurfit Building, Beaumont Campus, Dublin 9, Dublin, D09YD60
2	Blackrock Clinic Laboratory	Rock Road, Blackrock, Dublin, A94E4X7

Scope of Accreditation

Blackrock Clinic Laboratory

Blood Transfusion Science

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1020 Transfusion science - .01 Blood grouping including ABO, Rh(D) and other antigens by manual methods	Blood grouping (ABO & RhD) Typing	Red Blood Cells	Manual Method, Automated Method using Gel Cards	Standard Method	N/A	LM-BT-0016, LP-BT-0041
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening	Plasma	Manual Method ,Automated Method using Gel Cards	Standard Method	N/A	LM-BT-0016, LP-BT-0041
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		Manual method using Gel IAT and enzyme cards	Standard Method	N/A	LM-BT-0005
1020 Transfusion science - .05 Cross match compatible donor units	Antigen Typing	Red Blood Cells	Manual method using Gel Cards	Standard Method	N/A	LM-BT-0009
	Crossmatch Testing	Plasma	Manual method using Gel Cards, Eletronic Issue	Standard Method	N/A	LM-BT-0010 & EXT-BT-0055
	Direct Antiglobulin Test	Red Blood Cells	Automated testing using Gel Cards	Standard Method	N/A	LM-BT-0011
			Manual method using Gel Cards	Standard Method	N/A	LM-BT-0011

a. The hospital blood bank has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (S.I. 360/2005 and S.I. 547/2006)

Chemical Pathology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Technique	Equipment/Range of Measurement	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1061 Clinical Chemistry - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies	Alanine Aminotransferase (ALT) **1,2,3,4	Plasma	NADH (with P-5'-P)	Architect c8000	Standard Method	LM-BIO-0004
	Albumin	Serum/Lithium heparin	Bromocresol Green	Abbott Architect C8000	Standard Method	LM-BIO-0004
	Alkaline Phosphatase (ALP) **1,2,3,4	Plasma	Para-nitrophenyl Phosphate	Architect c8000	Standard Method	LM-BIO-0004
	Amylase **1,2,3,4		CNPG3 Substrate Enzymatic	Architect c8000	Standard Method	LM-BIO-0004
	Asparate Aminotransferase (AST) **1,2,3,4,		Enzymatic	Architect c8000	Standard Method	LM-BIO-0004
	Bilirubin Total **1,2,3,4,		Diazonium salt	Architect c8000	Standard Method	LM-BIO-0004
	BNP **1,2,3,4		CMIA	Architect i2000SR	Standard Method	LM-ENDO-0002
	C Reactive Protein **1,2,3,4		Immunoturbidimetric	Architect c8000	Standard Method	LM-BIO-0004
	Calcium **1,2,3,4	Plasma / Urine	Arsenazo III	Architect c8000	Standard Method	LM-BIO-0004
	Carbon Dioxide **1,2,3,4	Plasma	PEP Carboxylase Enzymatic	Architect c8000	Standard Method	LM-BIO-0004
	Cholesterol **1,2,3,4		Enzymatic	Architect c8000	Standard Method	LM-BIO-0004
	Creatine Kinase **1,2,3,4,		Enzymatic	Architect c8000	Standard Method	LM-BIO-0004
	Creatinine (Enzymatic) **1,2,3,4	Plasma /Urine	Enzymatic	Architect c8000	Standard Method	LM-BIO-0004
	eGFR	Not applicable	Calulation	Not applicable	Standard Method	LM-BIO-0004
	Electolytes Na+ K+ Cl **1,2,3,4	Plasma /Urine	Ion selective electrode (indirect)	Architect c8000	Standard Method	LM-BIO-0004
	Gamma Glutamyl Transferase (GGT) **1,2,3,4	Plasma	Enzymatic	Architect c8000	Standard Method	LM-BIO-0004
	Glucose **1,2,3,4	Plasma/CSF	Hexokinase	Architect c8000	Standard Method	LM-BIO-0004
	HDL-cholesterol **1,2,3,4	Plasma	Accelerator Selective Detergent	Architect c8000	Standard Method	LM-BIO-0004
	High Sensitivity Troponin I **1,2,3,4		CMIA	Architect i2000SR	Standard Method	LM-ENDO-0002
	Lactate Dehydrogenase (LDH) **1,2,3,4		Enzymatic	Architect c8000	Standard Method	LM-BIO-0004

	LDL-cholesterol **1,2,3,4		Enzymatic	Architect c8000	Standard Method	LM-BIO-0004
	Magnesium **1,2,3,4		Enzymatic	Architect c8000	Standard Method	LM-BIO-0004
	Osmolality	Plasma/Urine	Freezing Point Depression	Advanced Micro Osmometer Model 3320	Standard Method	LM-BIO-0005
	Phosphorus **1,2,3,4	Plasma	Colorimetric Phosomolybdate	Architect c8000	Standard Method	LM-BIO-0004
	Total Protein **1,2,3,4		Colorimetric	Architect c8000	Standard Method	LM-BIO-0004
	Triglyceride **1,2,3,4		Enzymatic	Architect c8000	Standard Method	LM-BIO-0004
	Urea Nitrogen **1,2,3,4		Urease	Architect c8000	Standard Method	LM-BIO-0004
	Uric Acid **1,2,3,4		Uricase	Architect c8000	Standard Method	LM-BIO-0004
	Urinary/CSF Protein **1,2,3,4	Urine/CSF	Turbidimetric Assay Benzethonium chloride	Architect c8000	Standard Method	LM-BIO-0004
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Total Protein **1,2,3,4	Plasma	Colorimetric	Architect c8000	Standard Method	LM-BIO-0004
	Triglyceride **1,2,3,4		Enzymatic	Architect c8000	Standard Method	LM-BIO-0004
	Urea Nitrogen **1,2,3,4		Urease	Architect c8000	Standard Method	LM-BIO-0004
	Uric Acid **1,2,3,4		Uricase	Architect c8000	Standard Method	LM-BIO-0004
	Urinary/CSF Protein **1,2,3,4	Urine/CSF	Turbidimetric Assay Benzethonium chloride	Architect c8000	Standard Method	LM-BIO-0004
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Gentamicin **1,2,3,4	Plasma/Serum	Particle Enhanced Turbidimetric Assay	Architect i2000SR	Standard Method	LM-BIO-0004
	Vancomycin **1,2,3,4		Particle Enhanced Turbidimetric Assay	Architect i2000SR	Standard Method	LM-BIO-0004
1061 Clinical Chemistry - .20 Hormones	Free T4 **1,2,3,4		CMIA	Architect i2000SR	Standard Method	LM-ENDO-0002
	FSH **1,2,3,4		CMIA	Architect i2000SR	Standard Method	LM-ENDO-0002
	LH **1,2,3,4		CMIA	Architect i2000SR	Standard Method	LM-ENDO-0002
	TSH **1,2,3,4		CMIA	Architect i2000SR	Standard Method	LM-ENDO-0002
1061 Clinical Chemistry - .40 Iron studies	Ferritin **1,2,3,4		CMIA	Architect i2000SR	Standard Method	LM-ENDO-0002
	Iron **1,2,3,4		Ferene	Architect c8000	Standard Method	LM-BIO-0004
	Transferrin **1,2,3,4		Immunoturbidimetric	Architect c8000	Standard Method	LM-BIO-0004
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate **1,2,3,4		CMIA	Architect i2000SR	Standard Method	LM-ENDO-0002
	Vitamin B12 **1,2,3,4		CMIA	Architect i2000SR	Standard Method	LM-ENDO-0002
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	CA 125 **1,2,3,4		CMIA	Architect i2000SR	Standard Method	LM-ENDO-0002
	CA 153 **1,2,3,4		CMIA	Architect i2000SR	Standard Method	LM-ENDO-0002

	CA 19.9 **1,2,3,4		CMIA	Architect i2000SR	Standard Method	LM-ENDO-0002
	CEA **1,2,3,4		CMIA	Architect i2000SR	Standard Method	LM-ENDO-0002
	Free PSA **1,2,3,4	Serum	CMIA	Architect i2000SR	Standard Method	LM-ENDO-0002
	Total PSA **1,2,3,4		CMIA	Architect i2000SR	Standard Method	LM-ENDO-0002
1061 Clinical Chemistry - .61 Hb A1c	HBA1C	EDTA Blood	Enzymatic	Architect c8000	Standard Method	LM-BIO-0004 and LP-BIO-0008
1061 Clinical Chemistry - .65 Pregnancy tests – qualitative	Total Beta HCG	Serum/Plasma	CMIA	Abbott Architect C8000	Standard Method	LM-ENDO-0002

b Point of care testing, ISO 22870

The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratories approved and documented procedures.
Note 1 - Range may be extended for the test
Note 2 – New parameters / tests may be added
Note 3 – New matrices may be added
Note 4 – Changes to equipment / kits where the underlying methodology does not change
For further details please refer to the laboratories 'Master list of Flexible scope changes', available directly from the laboratory.

Chemical Pathology

Category: B

Medical pathology field - Test	Test/assay	Specimen Type	Technique	Equipment/Range of Measurement	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1061 Clinical Chemistry - .06 Blood pH and gas tensions	Blood Gas and pH	Whole Blood	Electrochemical	RAPIDpoint 500	Standard Method	LP-POC-0007
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Blood Gas Electrolytes, Hematocrit, Haemoglobin and Metabolites		Electrochemical	RAPIDpoint 500	Standard Method	LP-POC-0007
1061 Clinical Chemistry - .65 Pregnancy tests – qualitative	HCG	Urine	CIA	Siemens Clinitek Status	Standard Method	LM-POC-0004

b Point of care testing, ISO 22870

The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratories approved and documented procedures.
Note 1 - Range may be extended for the test
Note 2 – New parameters / tests may be added
Note 3 – New matrices may be added
Note 4 – Changes to equipment / kits where the underlying methodology does not change
For further details please refer to the laboratories 'Master list of Flexible scope changes', available directly from the laboratory.

Haematology

Category: A

Medical pathology field - Test	Test/Assay	Specimen Type	Technique	Range of Measurement/Equipment	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1030 Haematology - .01 Blood counts	Full Blood Count with automated differential leucocyte count	EDTA Blood	Automated	Beckman Coulter Unicel DxH 800	Standard Method	LM-HAEM-0025, LP-HAEM-0013
1030 Haematology - .02 Visual examination of blood films	Blood Film Examination and differential leucocyte count		Manual Microscopy	Microscope	Standard Method	LM-HAEM-0017, LM-HAEM-0018, LP-HAEM-0004
1030 Haematology - .03 Erthrocyte sedimentation rate	Erythrocyte Sedimentation Rate	Sodium Citrate/EDTA	Automated Sedimentation	Diesse Vesmatic	Standard Method	LM-HAEM-0011, LP-HAEM-0011
1030 Haematology - .05 Automated differential leucocyte counts	Full Blood Count with automated differential leucocyte count	EDTA Blood	Automated	Beckman Coulter Unicel DxH 801	Standard Method	LM-HAEM-0025, LP-HAEM-0013
1030 Haematology - .09 Examination of malarial parasites	Examination for Malarial Parasites		Manual Microscopy Immuno-Chromatographic Kit	Microscope	Standard Method	LM-HAEM-0010, LM-HAEM-0012
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time	Sodium Citrate	Photo optical detection	ACL Top	Standard Method	LM-HAEM-0024, LP-HAEM-0012
	D Dimer		Enzyme Linked Fluorescence	Mini Vidas	Standard Method	LM-HAEM-0022, LP-HAEM-0011
	Fibrinogen		Photo optical detection	ACL Top	Standard Method	LM-HAEM-0023, LP-HAEM-0012
	Prothrombin Time		Photo optical detection	ACL Top	Standard Method	LM-HAEM-0024, LP-HAEM-0012
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious Mononucleosis Screen	EDTA Blood, Serum / Plasma	Manual Immunoassay	N/A	Standard Method	LM-HAEM-0016

Histopathology and Cytopathology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1051 Histopathology - .01 Processing fixed specimens for Histopathological testing	Automated and Manual Haematoxylin and Eosin Staining	Human tissue	Leica Multistainer	Standard Method	N/A	LM-HIST-0007 & LP-HIST-0047
	Cover Slipping		Leica Coverslipper	Standard Method	N/A	LM-HIST-0008 & LP-HIST-0035
	Cut Up		KMA Downdraft Cut Up Bench	Standard Method	N/A	LM-HIST-0003 & LP-HIST-0028
	Embedding		Histostar Embedding Centre	Standard Method	N/A	LM-HIST-0005 & LP-HIST-0038
	Microtomy		Microtome	Standard Method	N/A	LP-HIST-0029 & LM-HIST-0006
	Tissue Processing		Shandon Excelsior Tissue Processors	Standard Method	N/A	LM-HIST-0002 & LM-HIST-0004 & LP-HIST-0026 & LP-HIST-0049
1051 Histopathology - .02 Processing fresh specimens for frozen section examination	Cut Up		Microflow Safety Cabinet	Standard Method	N/A	LM-HIST-0011 & LP-HIST-0034 & LM-HIST-0001 & LP-MICRO-0019
	Frozen Section Cryotomy and staining		Leica Cryostat	Standard Method		LP-HIST-0034
1051 Histopathology - .03 Histochemistry	Cover Slipping Automated and Manual		Leica Coverslipper	Standard Method	N/A	LP-HIST-0047 & LP-HIST-0008
	Slide Issue		Leica DMLB2 Multihead Microscope	Standard Method	N/A	LP-HIST-0005 & LP-HIST-0030
	Special stains – automated: H&E (Tissue) Papanicolaou Stain Giemsa Stain Periodic Acid-Schiff's (PAS) counterstain Special stains – manual: Alcian Blue Stain Giemsa Stain for Helicobacter Pylori Giemsa Stain for bacteria Grocott Stain Haematoxylin-Van Gieson Stain Highman's Congo Red Stain Masson Trichrome Stain Masson Fontana Stain Mauritus Scarlet Blue		Leica Multistainer	Standard Method	N/A	LM-HIST-0007

	Stain Miller's Elastin Stain Periodic Acid-Schiff (PAS) Stain Perl's Prussian Blue Stain Reticulin Stain Von Kossa Stain Ziehl Neelsen (Kinyouin) Stain					
1051 Histopathology - .04 Histological interpretation-medical renal pathology	Diagnostic Interpretation and reporting of Human tissue specimens Specialist areas excluded: Medical Renal Pathology Paediatric Pathology Perinatal Pathology Neuropathology Breast screening Pathology		Microscope	Standard Method	N/A	LP-HIST-0003 LP-HIST-0006 LP-HIST-0009 LP-HIST-0016
1051 Histopathology - .09 Immunohistochemistry	34BE12		Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
	Alpha-Methylacyl-CoA Racemase (AMACR)		Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
	BCL-2		Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
	BCL-6		Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
	BER-EP4		Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
	CALRETININ		Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica

				BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CAM5.2	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CD10	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CD117	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CD138	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CD15	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CD20	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CD21	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CD23	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III

				immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CD3	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CD30	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CD31	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CD34	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CD4	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CD45	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CD5	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CD56	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry

				platform LM-HIST-0012 Immunohistochemistry Method
CD68	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CD79A	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CD8	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CDX2	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CHROMGRANIN A	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CYCLIN D1	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CYTOKERATIN 19	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CYTOKERATIN 20	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform

				LM-HIST-0012 Immunohistochemistry Method
CYTOKERATIN 5/6	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
CYTOKERATIN 7	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
DESMIN	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
E-CADHERIN	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
EPITHELIAL MEMBRANE ANTIGEN	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
HMB45	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
Immunohistochemistry staining methods	Bond Max III	CE	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
KI67	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012

				Immunohistochemistry Method
MelA	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
MLH1	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
MSA	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
MSH2	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
MSH6	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
MULTICYTOKERATIN (AE1/3)	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
MUM1	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
P16	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012

				Immunohistochemistry Method
P53	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
P63	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
PMS2	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
PROSTATE SPECIFIC ACID PHOSPHATASE (PSAP)	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
PROSTATE SPECIFIC ANTIGEN (PSA)	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
S100	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
SMOOTH MUSCLE ACTIN (SMA)	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
SYNAPTOPHYSIN	Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012

						Immunohistochemistry Method
	TTF1		Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
	VIMENTIN		Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
	WILM'S TUMOUT		Bond Max III	Based on standard method	N/A	LP-HIST-0051 Operation of the Leica BOND Max III immunohistochemistry platform LM-HIST-0012 Immunohistochemistry Method
1052 Cytopathology - .02 Non gynaecological cytology	Cytology Sample Preparation and Description	Human Tissue or Fluid	Thin Prep 2000	Standard Method	N/A	LM-HIST-0010 & LP-HIST-0039
	Diagnostic Interpretation and reporting of non-gynae samples Registration and labelling Gross description Thin Prep Direct smears Cell blocks Processing Embedding Microtomy Storage Disposal		Thin Prep 2000, Shandon Excelsior Tissue Processors, Histostar Embedding Centre, Microtome, Leica Multistainer	Standard Method	N/A	LP-HIST-0001 LP-HIST-0004 LP-HIST-0008 LP-HIST-0013 LP-HIST-0014 LP-HIST-0016 LM-HIST-0005 LM-HIST-0006 LM-HIST-0010

Microbiology and Virology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1011 Macroscopic examination and description	Macroscopic examination and description of specimens	Sputum, CSF, Faeces, Sterile fluids	Manual	Manual Macroscopic examination and description of specimens	N/A	LM-MICRO-0017 LP-MICRO-0021 LP-MICRO-0022 LP-MICRO-0026
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .01 Microscopic examination for general bacteriology purposes (including enumeration and description of human cells)	Microscopic examination of General Bacteriology	All swabs BAL Respiratory Specimens CSF CAPD Fluids Faeces Colonic Aspirates Fluids Corneal Scrapings Tissues Biopsies Artificial devices Urine	Light Microscope	Microscopic examination with or without fixation and staining with dyes for enumeration and description of bacteria	N/A	LM-MICRO-0070
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .02 Microscopic examination for parasites	Microscopic examination for Parasites	Faeces Worms Sellotape slides Duodena/Jejunal aspirates Urine Liver and spleen aspirates Sputum Bile CSF	Light Microscope	Microscopic examination with or without fixation and staining with dyes for enumeration and description of parasites	N/A	LM-MICRO-0070
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .03 Microscopic examination for fungi	Microscopic examination for Fungi	Faeces Worms Sellotape slides Duodena/Jejunal aspirates Urine Liver and spleen aspirates Sputum Bile CSF Skin Hair Nail	Light Microscope	Microscopic examination with or without fixation and staining with dyes for enumeration and description of parasites	N/A	LM-MICRO-0070
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	Culture of general bacteria	Aqueous/Vitreous fluids Corneal Scrapings	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods.	N/A	LM-MICRO-0035

				Visual observation of growth.		
		Artificial devices	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0045
		Aspirates	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0032
		Axilla swab	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0038 LM-MICRO-0042 LM-MICRO-0040
		BAL	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0025
		CAPD Fluid	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0027
		Cerebrospinal Fluid	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0026
		Ear Swab	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0028

		Eye swabs Conjunctival swabs	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0029
		Faeces Colonic aspirates	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0031
		Fluids	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0032
		High Vaginal Swabs Endocervical Swabs Cervical swabs Urethral swabs	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0058
		Mouth Swabs	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0037
		Nasal Swab Groin Swabs	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0038 LM-MICRO-0042
		Pharyngeal swabs	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0044
		Pus	Manual	Manual culture in agar based media	N/A	LM-MICRO-0022

		with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.		
Rectal swabs	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0043 LM-MICRO-0087
Respiratory Specimens	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0041
Skin	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0040
Throat swab	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0044
Tips	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0036
Tissue	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0045
Urine Suprapubic Aspirate	Manual	Manual culture in agar based media with incubation of specimens at	N/A	LM-MICRO-0046

				defined temperatures for defined periods. Visual observation of growth.		
		Wound swabs	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0022 LM-MICRO-0040
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi	Culture of fungi	Bile	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0092
		CSF	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0026
		Faeces	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0031
		Skin Hair Nail	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0033
		Sputum	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	N/A	LM-MICRO-0041
		Urine	Manual	Manual culture in agar based media with incubation of specimens at defined temperatures for	N/A	LM-MICRO-0046

				defined periods. Visual observation of growth.		
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .01 Slide agglutination,	MRSA Confirmation testing	Bacterial Isolate	Mastalex Kit	Particle agglutination	N/A	LM-MICRO-0082
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay,	Clostridium Difficile	Faeces	TechLab C.Diff Quik Chek Complete Kit	Enzyme Immunoassay	N/A	LM-MICRO-0081
	Legionella Pneumophilia Antigen	Urine	BINAX Legionella Urinary Antigen Kit	Enzyme Immunoassay	N/A	LM-MICR0-0073 LM-MICRO-0074
	Streptococcus Pneumonia Urinary Antigen		BINAX Streptococcus pneumoniae Urinary Antigen Kit	Enzyme Immunoassay	N/A	LM-MICR0-0073 LM-MICRO-0074
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	Identification of Organisms	Bacterial and Fungal Isolates	Identification using manual and automated systems	Kits/tests and automated Vitek 2	N/A	LM-MICRO-0017 LP-MICRO-0021 LP-MICRO-0022 LP-MICRO-0026
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy			MALDI-TOF	Mass Spectrometry	N/A	LP-MICRO-0026
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	Measurement of antimicrobial activity in Aerobic and Anaerobic bacteria and application of clinical interpretive criteria		Vitek 2 Compact and Manual	Manual Disc diffusion and Minimum Inhibitory Concentration (MIC) methods. Automated MIC.	N/A	LM-MICRO-0060 LP-MICRO-0021 LP-MICRO-0022
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .07 Chemiluminescent microparticle immunoassay, using CE marked commercial systems	HIV Ag/Ab Syphilis Hep B Surface Ag Hep C	Serum	Abbott Architect i2000SR	CMIA	N/A	LM-ENDO-0002
1029 Miscellaneous - .99 Miscellaneous tests	Investigation of Joint Fluid for the Presence of Crystals	Joint fluid	Manual	Polarising Microscopy	N/A	LM-MICRO-0085