

# Schedule of Accreditation



Organisation Name	Blackrock Clinic Ltd
Trading As	
INAB Reg No	212MT
Contact Name	Naomi Fynes
Address	Rock Road, Blackrock, Dublin
Contact Phone No	01 2064358
Email	naomi.fynes@blackrock-clinic.com
Website	<a href="http://www.laboratory.blackrock-clinic.ie">http://www.laboratory.blackrock-clinic.ie</a>
Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	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 <sup>1</sup>	Yes

<sup>1</sup> Refer to document on interpreting INAB Scopes of Accreditation

Sites from which accredited services are delivered		
	Name	Address
1	Blackrock Clinic Laboratory	Rock Road, Blackrock, Dublin, Ireland, 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	Whole blood	Grifols DG Gel Card Technology Column agglutination technology	CE./Based on standard method	N/A	LM-BT-0017 LP-BT-0047 EXT-BT-0077
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods			Grifols DG Gel Card Automated System Column agglutination technology	CE/ Based on standard method	N/A	LM-BT-0017 LP-BT-0047 EXT-BT-0077
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening	Plasma	Grifols Manual and Automated Gel Card Systems Column agglutination technology	CE/Based on standard method	N/A	LM-BT-0017 LP-BT-0047 EXT-BT-0077
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		Grifols Manual and Automated Gel Card Systems	CE/ based on standard method	N/A	LM-BT-0019 LP-BT-0047 EXT-BT-0077

			Column agglutination technology			
1020 Transfusion science - .05 Cross match compatible donor units	Crossmatch testing		Grifols Manual and Automated Gel Card Systems Electronic issue	CE/ based on standard method	N/A	LM-BT-0010 EXT-BT-0055 LP-BT-0047 EXT-BT-0077
1020 Transfusion science - .06 Red cell phenotyping	Antigen Typing	Red Blood Cells	Grifols Manual and Automated Gel Card Systems	CE/ based on standard method	N/A	LM-BT-0018 LP-BT-0047 EXT-BT-0077
1020 Transfusion science - .09 Direct antiglobulin test	Direct antiglobulin test (DAT)		Automated Method using Eflexis Grifols DG Gel Card System  Manual Method using Grifols DG Gel Card System	CE/ based on standard method	N/A	LM-BT-0021 LP-BT-0047 EXT-BT-0077
<i>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)</i>						

## 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	Adjusted Calcium **1,2,3,4	Plasma	Calculated	Architect c8000	CE	LM-BIO-0004
	Alanine Aminotransferase (ALT) **1,2,3,4		NADH (with P-5'-P)	Architect c8000	CE	LM-BIO-0004
	Albumin **1,2,3,4		Bromocresol Green	Abbott Architect C8000	CE	LM-BIO-0004
	Alkaline Phosphatase (ALP) **1,2,3,4		Para-nitrophenyl Phosphate	Architect c8000	CE	LM-BIO-0004
	Amylase **1,2,3,4		CNPG3 Substrate Enzymatic	Architect c8000	CE	LM-BIO-0004
	Asparate Aminotransferase (AST) **1,2,3,4,		Enzymatic	Architect c8000	CE	LM-BIO-0004
	Bilirubin Total **1,2,3,4,		Diazonium salt	Architect c8000	CE	LM-BIO-0004
	C Reactive Protein (CRP) **1,2,3,4		Immunturbidimetric	Architect c8000	CE	LM-BIO-0004
	Calcium **1,2,3,4		Plasma / Urine	Arsenazo III	Architect c8000	CE
	Carbon Dioxide **1,2,3,4	Plasma	PEP Carboxylase Enzymatic	Architect c8000	CE	LM-BIO-0004
Cholesterol **1,2,3,4	Enzymatic		Architect c8000	CE	LM-BIO-0004	

Creatine Kinase **1,2,3,4,		Enzymatic	Architect c8000	CE	LM-BIO-0004	
Creatinine (Enzymatic) **1,2,3,4	Plasma /Urine	Enzymatic	Architect c8000	CE	LM-BIO-0004	
Creatinine Clearance *1,2,3,4	Plasma and Urine	Calculated	Architect c8000	CE	LM-BIO-0004	
eGFR	Not applicable	Calculation	Not applicable	CE	LM-BIO-0004	
Electrolytes Cl **1,2,3,4	Plasma	Ion selective electrode (indirect)	Architect c8000	CE	LM-BIO-0004	
Electrolytes K+ **1,2,3,4	Plasma /Urine	Ion selective electrode (indirect)	Architect c8000	CE	LM-BIO-0004	
Electrolytes Na+ **1,2,3,4		Ion selective electrode (indirect)	Architect c8000	CE	LM-BIO-0004	
Gamma Glutamyl Transferase (GGT) **1,2,3,4	Plasma	Enzymatic	Architect c8000	CE	LM-BIO-0004	
Glucose **1,2,3,4	Plasma/CSF	Hexokinase	Architect c8000	CE	LM-BIO-0004	
HDL-cholesterol **1,2,3,4	Plasma	Accelerator Selective Detergent	Architect c8000	CE	LM-BIO-0004	
High Sensitivity Troponin I **1,2,3,4		CMIA	Architect i2000SR	CE	LM-ENDO-0002	
Lactate Dehydrogenase (LDH) **1,2,3,4		Enzymatic	Architect c8000	CE	LM-BIO-0004	
LDL-cholesterol **1,2,3,4		Enzymatic	Architect c8000	CE	LM-BIO-0004	
Magnesium **1,2,3,4		Enzymatic	Architect c8000	CE	LM-BIO-0004	
NT ProBNP **1,2,3,4		CMIA	Architect i2000SR	CE	LM-ENDO-0002	
Osmolality		Serum/Urine	Freezing Point Depression	Advanced Micro Osmometer Model 3320	CE	LM-BIO-0005
Phosphorus **1,2,3,4		Plasma	Colorimetric Phosomolybdate	Architect c8000	CE	LM-BIO-0004
Total Protein **1,2,3,4	Colorimetric		Architect c8000	CE	LM-BIO-0004	
Triglyceride **1,2,3,4	Enzymatic		Architect c8000	CE	LM-BIO-0004	

	Urea Nitrogen **1,2,3,4		Urease	Architect c8000	CE	LM-BIO-0004
	Uric Acid **1,2,3,4		Uricase	Architect c8000	CE	LM-BIO-0004
	Urinary/CSF Protein **1,2,3,4	Urine/CSF	Turbidimetric Assay Benzethonium chloride	Architect c8000	CE	LM-BIO-0004
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Gentamicin **1,2,3,4	Plasma	CMIA	Architect i2000SR	CE	LM-BIO-0004
	Vancomycin **1,2,3,4		CMIA	Architect i2000SR	CE	LM-BIO-0004
1061 Clinical Chemistry - .20 Hormones	Follicle Stimulating Hormone (FSH) **1,2,3,4	Plasma/Serum	CMIA	Architect i2000SR	CE	LM-ENDO-0002
	Free T4 (FT4) **1,2,3,4	Plasma	CMIA	Architect i2000SR	CE	LM-ENDO-0002
	Luteinizing Hormone (LH) **1,2,3,4	Serum	CMIA	Architect i2000SR	CE	LM-ENDO-0002
	Parathyroid Hormone (PTH) *1,2,3,4		CMIA	Architect i2000SR	CE	LM-ENDO-0002
	Thyroid-Stimulating Hormone (TSH) **1,2,3,4	Plasma	CMIA	Architect i2000SR	CE	LM-ENDO-0002
	Total Beta HCG **1,2,3,4	Serum	CMIA	Architect i2000SR	CE	LM-ENDO-0002
1061 Clinical Chemistry - .40 Iron studies	Ferritin **1,2,3,4	Plasma/Serum	CMIA	Architect i2000SR	CE	LM-ENDO-0002
	Iron **1,2,3,4	Plasma	Ferene	Architect c8000	CE	LM-BIO-0004
	Transferrin **1,2,3,4		Immunoturbidimetric	Architect c8000	CE	LM-BIO-0004
	Transferrin saturation *1,2,3,4		Calculated	Architect c8000	CE	LM-BIO-0004
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate **1,2,3,4	Plasma/Serum	CMIA	Architect i2000SR	CE	LM-ENDO-0002
	Vitamin B12 **1,2,3,4		CMIA	Architect i2000SR	CE	LM-ENDO-0002
1061 Clinical Chemistry - .47 Vitamin assays	25-OH Vitamin D **1,2,3,4	Serum	CMIA	Architect i2000SR	CE	LM-ENDO-0002

1061 Clinical Chemistry - .50 Protein and peptide tumour markers	CA 125 **1,2,3,4	Plasma/Serum	CMIA	Architect i2000SR	CE	LM-ENDO-0002
	CA 153 **1,2,3,4		CMIA	Architect i2000SR	CE	LM-ENDO-0002
	CA 19.9 **1,2,3,4		CMIA	Architect i2000SR	CE	LM-ENDO-0002
	CEA **1,2,3,4		CMIA	Architect i2000SR	CE	LM-ENDO-0002
	Free PSA **1,2,3,4	Serum	CMIA	Architect i2000SR	CE	LM-ENDO-0002
	PSA Ratio *1,2,3,4		Calculated	Architect i2000	CE	LM-ENDO-0002
	Total PSA **1,2,3,4		CMIA	Architect i2000SR	CE	LM-ENDO-0002
1061 Clinical Chemistry - .61 Hb A1c	HBA1C **1,2,3,4	EDTA Blood	Enzymatic	Architect c8000	CE	LM-BIO-0004 LP-BIO-0008

**b**

*The hospital pathology laboratory is accredited for the provision of Point of Care testing in accordance with ISO 15189:2012 and ISO 22870:2017, for the tests identified in category B.*

*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 - .05 CO-oximetry	COHb	Whole Blood	Co-oximetry	RAPIDpoint 500	CE	LP-POC-0007
	MetHb		Co-oximetry	RAPIDpoint 500	CE	LP-POC-0007
	O2Hb		Co-oximetry	RAPIDpoint 500	CE	LP-POC-0007
	Total Haemoglobin		Co-oximetry	RAPIDpoint 500	CE	LP-POC-0007
1061 Clinical Chemistry - .06 Blood pH and gas tensions	pCO2	Whole Blood	Potentiometric	RAPIDpoint 500	CE	LP-POC-0007
	pH		Potentiometric	RAPIDpoint 500	CE	LP-POC-0007
	pO2		Amperometric	RAPIDpoint 500	CE	LP-POC-0007
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Chloride	Whole Blood	Potentiometric	RAPIDpoint 500	CE	LP-POC-0007
	Glucose		Amperometric	RAPIDpoint 500	CE	LP-POC-0007
	Ionised Calcium		Potentiometric	RAPIDpoint 500	CE	LP-POC-0007
	Lactate		Amperometric	RAPIDpoint 500	CE	LP-POC-0007
	Potassium		Potentiometric	RAPIDpoint 500	CE	LP-POC-0007
	Sodium		Potentiometric	RAPIDpoint 500	CE	LP-POC-0007
1061 Clinical Chemistry - .65 Pregnancy tests – qualitative	HCG	Urine	CIA	Siemens Clinitek Status	CE	LM-POC-0004
1061 Clinical Chemistry - .76 Simple side tests for	Glucose	Whole Blood	Electrochemical	Abbott Freestyle Pro Meter	CE	LM-POC-0013



biochemical and immunological analytes						
	Ketones		Electrochemical	Abbott Freestyle Pro Meter	CE	LM-POC-0013

*b*  
*The hospital pathology laboratory is accredited for the provision of Point of Care testing in accordance with ISO 15189:2012 and ISO 22870:2017, for the tests identified in category B.*

*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 Electrical Impedance VCS technology Calculations	Beckman Coulter Unicel DxH 800	CE	LM-HAEM-0025 LP-HAEM-0013
1030 Haematology - .02 Visual examination of blood films	Blood Film Examination and differential leucocyte count		Microscopy	Microscope	Standard Method	LM-HAEM-0017 LM-HAEM-0018 LP-HAEM-0004
1030 Haematology - .03 Erythrocyte sedimentation rate	Erythrocyte Sedimentation Rate	Sodium Citrate/EDTA	Automated Sedimentation	Diesse Vesmatic	CE	LM-HAEM-0011 LP-HAEM-0011
	Erythrocyte Sedimentation Rate (ESR)		Sedimentation	Westegren (Manual)	CE based on standard method	LM-HAEM-0011
1030 Haematology - .05 Automated differential leucocyte counts	Full Blood Count with automated differential leucocyte count	EDTA Blood	Automated Electrical Impedance VCS technology Calculations	Beckman Coulter Unicel DxH 800	CE	LM-HAEM-0025 LP-HAEM-0013
1030 Haematology - .09 Examination of malarial parasites	Examination for Malarial Parasites		Staining/ Microscopy/ Calculation/ Chromatographic Kit	Microscope	CE	LM-HAEM-0010 LM-HAEM-0012
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time APTT/APTT ratio	Sodium Citrate	Photo optical detection Calculation	ACL Top	CE	LM-HAEM-0024 LP-HAEM-0012
	D Dimer		Enzyme Linked Fluorescence	Mini Vidas	CE	LM-HAEM-0022 LP-HAEM-0011

	Fibrinogen		Photo optical detection	ACL Top	CE	LM-HAEM-0023 LP-HAEM-0012
	Prothrombin Time PT/INR		Photo optical detection Calculation	ACL Top	CE	LM-HAEM-0024 LP-HAEM-0012
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious Mononucleosis Screen	EDTA Blood Plasma	Manual Immunoassay	Clearview IM II Kit	CE	LM-HAEM-0016

# Blackrock Clinic Laboratory

## 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/ Automated stainer/ Manual	CE/ based on standard Method	N/A	LM-HIST-0007 LP-HIST-0047
	Cover Slipping		Leica Coverslipper/ Automated coverslipping	CE/ Based on Standard Method	N/A	LM-HIST-0008 LP-HIST-0035
	Cut Up		KMA Downdraft Cut Up Bench	Based on Standard Method	N/A	LM-HIST-0003 LP-HIST-0028 LM-HIST-0002
	Embedding		Histostar Embedding Centre/ Manual	Based on Standard Method	N/A	LM-HIST-0005 LP-HIST-0038
	Microtomy		Microtome/ Manual	Based on Standard Method	N/A	LP-HIST-0029 LM-HIST-0006
	Tissue Processing		Excelsior AS Tissue Processors/ Automated Vacuum Infiltration Processor	CE	N/A	LM-HIST-0002 LM-HIST-0004 LP-HIST-0049
1051 Histopathology - .02 Processing fresh specimens for frozen section examination	Cut up of frozen section		Microflow Safety Cabinet/ Manual	CE/ Based on Standard Method	N/A	LM-HIST-0011 LP-HIST-0034 LM-HIST-0001 LP-MICRO-0019
	Frozen section cryotomy and staining		Leica Cryostat/ Cryotomy	Based on Standard Method	N/A	LP-HIST-0034
1051 Histopathology - .03 Histochemistry	Alcian Blue Stain		Manual Method	Based on Standard Method	N/A	LM-HIST-0007

	Giemsa stain for bacteria		Manual Method	Based on Standard Method	N/A	LM-HIST-0007
	Giemsa stain for helicobacter pylori		Manual Method	Based on Standard Method	N/A	LM-HIST-0007
	Giemsa Stain Periodic Acid-Schiff's (PAS) counterstain		Leica Multistainer/ automated stainer	Standard Method	N/A	LM-HIST-0007
	Grocott stain		Manual Method	Based on Standard Method	N/A	LM-HIST-0007
	Haematoxylin -Van Gieson Stain		Manual Method	Based on Standard Method	N/A	LM-HIST-0007
	Highman's Congo Red Stain		Manual Method	Based on Standard Method	N/A	LM-HIST-0007
	Masson Fontana Stain		Manual Method	Based on Standard Method	N/A	LM-HIST-0007
	Masson Trichrome Stain		Manual Method	Based on Standard Method	N/A	LM-HIST-0007
	Mauritus Scarlet Blue Stain		Manual Method	Based on Standard Method	N/A	LM-HIST-0007
	Miller's Elastin Stain		Manual Method	Based on Standard Method	N/A	LM-HIST-0007
	Periodic Acid -Schiff (PAS) Stain		Manual Method	Based on Standard Method	N/A	LM-HIST-0007
	Perl's Prussian Blue Stain		Manual Method	Based on Standard Method	N/A	LM-HIST-0007
	Reticulin Stain		Manual Method	Based on Standard Method	N/A	LM-HIST-0007
	Von Kossa Stain		Manual Method	Standard Method	N/A	LM-HIST-0007
	Ziehl Neelsen (Kinyouin) Stain		Manual Method	Based on Standard Method	N/A	LM-HIST-0007
1051 Histopathology - .035 Histological Interpretation	Diagnostic Interpretation and reporting of Human tissue specimens Specialist areas		Microscope/ Microscopy	Based on Standard Method	N/A	LP-HIST-0003 LP-HIST-0046

	excluded: Medical Renal Pathology Paediatric Pathology Perinatal Pathology Neuropathology Breast screening Pathology					
1051 Histopathology - .09 Immunohistochemistry	34BE12 **2,4		Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
	AE 1/3 **2,4		Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
	Alpha-Methylacyl-CoA Racemase (AMACR) **2,4		Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
	BCL-2 **2,4		Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
	BCL-6 **2,4		Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
	BER-EP4 **2,4		Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
	CALRETININ **2,4		Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
	CAM5.2 **2,4		Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
	CD10 **2,4		Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
	CD117 **2,4		Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012

CD138 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
CD15 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
CD20 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
CD21 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
CD23 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
CD3 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
CD30 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
CD31 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
CD34 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
CD4 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
CD45 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
CD5 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
CD68 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012

CD79a **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
CD8 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
CDX2 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
CEA **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
CHROMGRANIN A **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
CYCLIN D1 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
CYTOKERATIN 19 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
CYTOKERATIN 20 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
CYTOKERATIN 5/6 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
CYTOKERATIN 7 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
DESMIN **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
E-CADHERIN **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
EPITHELIAL MEMBRANE ANTIGEN **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012



HMB45 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
Immunohistochemistry staining methods **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
KI67 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
MeIA **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
MLH1 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
MSA **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
MSH2 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
MSH6 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
MUM1 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
NSE *2,4	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 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012

P53 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
P63 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
PMS2 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
PROSTATE SPECIFIC ACID PHOSPHATASE (PSAP) **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
PROSTATE SPECIFIC ANTIGEN (PSA) **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
S100 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
SMOOTH MUSCLE ACTIN (SMA) **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
SYNAPTOPHYSIN **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
TTF1 **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
VIMENTIN **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
WILM'S TUMOUR **2,4	Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012

1051 Histopathology - .11 Chromogenic / bright-field in situ hybridisation	Kappa (ISH)		Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
	Lambda (ISH)		Bond Max III/ Automated Immunostaining	CE	N/A	LP-HIST-0051 LM-HIST-0012
1052 Cytopathology - .02 Non gynaecological cytology	Cytology Sample Preparation and Description automated PAP stain	Human Tissue or Fluid	Thin Prep 2000 Shandon Excelsior Tissue Processor Embedding centre Microtome Leica Multistainer	CE/ Based on Standard Method	N/A	LM-HIST-0010 LP-HIST-0039
1052 Cytopathology - .03 Cytochemistry	Special stains Manual: Perls Grocott ZN PAS Gram MGG	Respiratory fluid, Human Tissue Fluid, FNA, Urine, Cell blocks	Manual	Based on Standard Method	N/A	LM-HIST-0007
1052 Cytopathology - .04 Cytopathological interpretation	Diagnostic interpretation and reporting of non-gynae samples		Microscope/ Microscopy	Based on Standard Method	N/A	LM-HIST-0010 LP-HIST-0001 LM-HIST-0003 LP-HIST-0039 LM-HIST-0007 LM-HIST-0008

*The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's 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 laboratory's 'List of flexible scope changes', available directly from the laboratory.*

*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.*

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
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 Urine	Light Microscope	Microscopic examination with or without fixation and staining with dyes for enumeration and description of parasites	N/A	LM-MICRO-0070