

Schedule of Accreditation



Organisation Name	St Vincent's Healthcare Group (DAC)
Trading As	
INAB Reg No	192MT
Contact Name	Anne Dickinson
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Contact Phone No	01 2213695
Email	A.Dickinson@st-vincent's.ie
Website	
Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	22/04/2008
Scope Classification	Microbiology and virology
Scope Classification	Blood Transfusion Science
Scope Classification	Immunology
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	SVPH Satellite	St Vincent's Private Hospital, Merrion Road, Dublin 4, Dublin, Ireland

	Laboratory	
2	Head Office	St Vincent's Healthcare Group, Elm Park, Dublin, D4

Scope of Accreditation

Head Office

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	Manual Method in tubes	CE		ISO15189 5.5, LP-BTR-008
	Blood Grouping (ABO & RhD Typing), Blood Transfusion Service Red Blood Cells; Confirming ABO and RhD group and donor units	Whole Blood, Red Blood Cells	Manual Method in tubes	CE		ISO15189 5.5, LP-BTR-008
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods	Blood Grouping (ABO & RhD Typing), Antibody Screening	Whole Blood	IH500 Analyser	CE		ISO15189, LP-BTR-IH500
	Blood Grouping (ABO & RhD Typing), Antibody Screening, Blood Transfusion Service Red Blood	Whole Blood, Red Blood Cells	IH500 Analyser	CE		ISO15189, LP-BTR-IH500

	Cells; Confirming ABO and RhD group and donor units.					
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening	Plasma	IAT Manual Method using gel cards and tube technique	CE		ISO15189 5.5, LP-BTR-018
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		Manual method using Gel IAT and enzyme, and Tube method using IAT	CE		ISO15189 5.5, LP-BTR-019
	LISS Alloadsorption		Antibody Adsorption	CE		ISO15189 5.5, LP-BTR-023, LP-BTR-017
1020 Transfusion science - .05 Cross match compatible donor units	Serological crossmatch testing. Compatibility analysis for the release of compatible blood by electronic means		Manual method of crossmatching in tubes and gel technique, Electronic Crossmatching.	CE		ISO15189 5.5, LP-BTR-028, LP-BTR-028A
1020 Transfusion science - .06 Red cell phenotyping	Antigen Typing	Red Blood Cells	Manual method in tubes and cards	CE		ISO15189 5.5, LP-BTR-027
1020 Transfusion science - .07 Antibody elution	Antibody Elution Testing of EDTA specimens	EDTA		CE		ISO15189 5.5, LP-BTR-024
1020 Transfusion science - .09 Direct antiglobulin test	Direct Antiglobulin Testing	Red Blood Cells	manual method with monospecific gel cards	CE		ISO15189 5.5, LP-BTR-015
1020 Transfusion science - .99 Miscellaneous tests	Blood Transfusion Service Red Blood Cells; Confirming ABO and RhD group and donor units		Manual Method using tubes, automated method using gel cards	CE		ISO15189 5.5, LP-BTR-009

Note: St. Vincent's University 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). It also provides Haemovigilance and Traceability services to another site, further details available in the SLA between the accredited medical testing laboratory and the relevant site.

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	Cut up; Tissue Processing; Embedding; Microtomy; Automated and Manual Haematoxylin and Eosin Staining; Coverslipping **2,4	Human Tissue	Leica ASP6025, Peloris 2, Peloris 3, Leica HistoCore Embedding Centre, Leica RM2550 Microtomes, Tissue Tek 5 Embedding Centre, Diamond Pathology Saw.	Based on standard method		ISO15189 5.5/ LP-HIS-EMBED/ LP-HIS-DICBX/ SVUH Histopathology Manual/ LP-HIS_SPREQMIN/ LP-HIS-SPECREC/ LP-HIS-FRESHINF/ LP-HIS-SPDISSECT/ LP-HIS-FRESHBRE/ LP-HIS-FRESHKID/ LP-HIS-FRESHLN/ LP-HIS-FRESHBMX/ LP-HIS-FRESHNER/ LP-HIS-FRESHSKX/ LP-HIS-FAXITRON/ LP-HIS-DIGFAXITRON/ LP-HIS-GROSPHOTO/ LP-HIS-CLINMCON/ LP-HIS-BMX/ LP-HIS-DECAL/ LP-HIS-BRCHECK/ LP-HIS-POC/ LP-HIS-RADIOACT/ LP-HIS-BIOPAN/ LP-HIS-AMPPROC/ LP-HIS-LIQINT/ LP-HIS-MCLASS1/ LP-HIS-PRFORMAL/ LP-HIS-SECTPAR
1051 Histopathology - .02 Processing fresh specimens for frozen section examination	Cut Up; Frozen Section cryotomy and staining **2,4		Leica CM1900 cryostat	Based on standard method		ISO15189 5.5/ LP-HIS-FRESHFS/ LP-HIS-LIQINT/ LP-HIS-MCLASS1
1051 Histopathology - .03 Histochemistry	Automated H&E		Prisma Automated Slide Stainer and G2 Coverslipper	Based on Standard method		ISO15189 5.5/ LP-HIS-INTQC/ LP-HIS-SECTW/ LP-HIS-PRISMA/ LP-HIS-

							G2COVER
	Automated special stains using the ARTISAN: PAS, PASD, Perls, Trichrome, Reticulin, Jones' Methenamine Silver, Grocotts (fungi & pneumocystis), Congo Red, Ziehl Neelson		Dako Artisan Link Pro Special Stainer	CE marked			ISO15189 5.5/ LP-HIS-ARTISANPRO/ LP-HIS-EQASP
	H&E, Shikata, Haemotoxylin Shikata, Gram, Van Gieson, AB/PAS, Millers Elastin, Alcian Blue, Rubeanic Acid, MSB, Oil Red O		Manual	Based on standard method			ISO15189 5.5/ LP-HIS-H&EMAN/ LP-HIS-SHIKO/ LP-HIS-GRAM/ LP-HIS-VANG/ LP-HIS-AB/PAS/ LP-HIS-MILLER/ LP-HIS-AB/ LP-HIS-RUB/ LP-HIS-MSB/ LP-HIS-ORO
1051 Histopathology - .04 Histological interpretation-medical renal pathology	1051.04.41 Medical Renal Pathology and 1051.04.42 Breast Screening. Diagnostic Interpretation and reporting of human tissue specimens. Specialist areas EXCLUDED: Paediatric Pathology, Perinatal Pathology, Neuropathology. Specialist Areas INCLUDED: Medical Renal Pathology, Breast Screening Pathology		Consultant Microscope				ISO15189 5.5/ LP-HIS-REPPER-2/ LP-HIS-REPOR/PR
1051 Histopathology - .09 Immunohistochemistry	AE1/3 **2,4		Ventana Benchmark Ultra	CE marked			ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
	AE1/3-D2-40 Dual Stain **2,4		Ventana Benchmark Ultra	CE marked			ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
	ALK (NSCLC) **2,4		Ventana Benchmark XT	CE marked			ISO15189 5.5/ LP-HIS-VENTBENCHMARKXT
	Androgen Receptor **2,4		Ventana Benchmark Ultra	CE marked			ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA

BAP1 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
BCI2 **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOOMNIS
BCI6 **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOOMNIS
BCL10	Ventana Benchmark Ultra	Based on standard method, not CE marked	ISO15189 5.5/ LP-HIS-VENTBENCHMARKULTRA
BEREP4 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
Beta-Catenin **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
BRAF V600E **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
Calponin **2,4	Ventana Benchmark XT	CE marked	ISO15189 5.5/ LP-HIS-VENTBENCHMARKXT
Calretinin **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD10 (SP67) **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD10 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD117 **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOOMNIS
CD138 **2,4	Dako Omnis Immunostainer		ISO15189 5.5/ LP-HIS-DAKOOMNIS
CD15 (MMA) **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD15 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD20 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD23 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD246 (ALK1) **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOOMNIS
CD246 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA

CD3 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD30 **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOOMNIS
CD31 **2,4	Ventana Benchmark XT	CE marked	ISO15189 5.5/ LP-HIS-VENTBENCHMARKXT
CD34 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD4 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD45 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD5 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD56 (MRQ-42) **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD56 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD68 **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOOMNIS
CD79a (SP18) **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD79a **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD8 **2,4	Ventana Benchmark XT	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKXT
CDX2 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
Chromogranin **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/ LP-HIS-VENTBENCHMARKULTRA
CK20 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/ LP-HIS-VENTBENCHMARKULTRA
CK5/6 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/ LP-HIS-VENTBENCHMARKULTRA
CK7 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/ LP-HIS-VENTBENCHMARKULTRA
CMV **2,4	Ventana Benchmark XT	CE marked	ISO15189 5.5/ LP-HIS-VENTBENCHMARKXT
C-myc	Ventana Benchmark	Not CE marked,	ISO15189 5.5/ LP-HIS-

		XT	based on standard method		VENTBENCHMARKXT
	Cyclin D1 **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/ LP-HIS-VENTBENCHMARKULTRA
	D2-40 **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
	Desmin **2,4	Ventana Benchmark XT	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKXT
	DOG1 **2,4	Dako Omnis Immunostainer	CE marked		ISO15189 5.5/LP-HIS-DAKOOMNIS
	EBV (In situ hybridisation, ISH) **2,4	Dako Omnis Immunostainer	CE marked		ISO15189 5.5/ LP-HIS-DAKOCISH
	E-Cadherin **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
	EMA **2,4	Ventana Benchmark XT	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKXT
	ER (SP1) **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
	ERG **2,4	Dako Omnis Immunostainer	CE marked		ISO15189 5.5/ LP-HIS-DAKOOMNIS
	Gastrin **2,4	Dako Omnis Immunostainer	CE marked		ISO15189 5.5/ LP-HIS-DAKOOMNIS
	GATA-3 **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
	GCDFP-15 **2,4	Ventana Benchmark XT	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKXT
	Glutamine Synthetase **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
	Glypican 3 **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
	H. Pylori **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
	Heat Shock Protein 70 **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
	Hepar **2,4	Ventana Benchmark XT	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKXT
	Her2neu (45B) **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA

Her2neu **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
HMB45 **2,4	Ventana Benchmark XT	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKXT
HSV1 **2,4	Ventana Benchmark XT	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKXT
Insulin **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOOMNIS
Kappa (ISH) **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOCISH
Ki67 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
Lambda (ISH) **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOCISH
Melan A **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
MLH1 **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOOMNIS
MSH2 **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOOMNIS
MSH6 **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOOMNIS
Muc 4 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
Mum-1 **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOOMNIS
Napsin A **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
OCT4 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
Oestrogen Receptor **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
p-16 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
P5045/ Racemase/ AMACR **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
P53 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
P63 **2,4	Ventana Benchmark	CE marked	ISO15189 5.5/LP-HIS-

	Ultra			VENTBENCHMARKULTRA
p63-AE1/3 Dual Stain **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
p63-Ker5/6 Dual Stain **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
PAX5 **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
PAX8 (EP311) **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
PAX8 **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
PD-L1 (22C3) **2,4	Dako Omnis Immunostainer	CE marked		ISO15189 5.5/ LP-HIS-DAKOOMNIS
PD-L1 (SP263) **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
PMS2 **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
PRAME (ERP 20330) **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
Progesterone Receptor **2,4	Dako Omnis Immunostainer	CE marked		ISO15189 5.5/ LP-HIS-DAKOOMNIS
PSA **2,4	Dako Omnis Immunostainer	CE marked		ISO15189 5.5/ LP-HIS-DAKOOMNIS
ROS1 **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
S100 **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
SMA **2,4	Ventana Benchmark XT	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKXT
SOX-10 **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
SSR2A	Ventana Benchmark Ultra	Not CE marked, based on standard method		ISO15189 5.5/ LP-HIS-VENTBENCHMARKULTRA
Stat 6 **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
Succinate Dehydrogenase (SDHB)	Ventana Benchmark Ultra	Based on standard method, not CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA

	Synaptophysin **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
	TdT (Terminal Deoxynucleotidyl Transferase) **2,4		Dako Omnis Immunostainer	CE marked		ISO15189 5.5/ LP-HIS-DAKOOMNIS
	Trypsin		Dako Omnis Immunostainer	Based on standard method, not CE marked		ISO15189 5.5/ LP-HIS-DAKOOMNIS
	TTF-1 **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
	TTF-1-Napsin A Dual Stain **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
	Vimentin **2,4		Ventana Benchmark XT	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKXT
	WT-1 **2,4		Dako Omnis Immunostainer	CE marked		ISO15189 5.5/ LP-HIS-DAKOOMNIS
1051 Histopathology - .10 Fluorescence in situ hybridisation	FISH Her2 **2,4	Human Tissue/ Slide	Dako Omnis Immunostainer	CE		ISO15189 5.5/ LP-HIS-DAKOOMNIS
1051 Histopathology - .99 Miscellaneous tests	Direct Immunofluorescence DIF	Human Tissue	Manual Technique	CE		ISO15189 5.5/ LP-HIS-DIFTEC
1052 Cytopathology - .02 Non gynaecological cytology	Exfoliative and FNA cytology	Urinary Cytology, Serous Fluid Cytology, Respiratory Cytology and FNAs	Thin Prep 2000, Leica ST5020			ISO15189 5.5/ LP-HIS-CYT/ LP-HIS-EBUS/ LP-HIS-PRCTFNA/ LP-HIS-TISSUE/ LP-HIS-PAPAUTO/ LP-HIS-PAPMAN/ LP-HIS-CMGG
1052 Cytopathology - .05 Immunocytochemistry	AE1/3 **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
	AE1/3-D2-40 dual stain **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
	ALK (NSCLC) **2,4		Ventana Benchmark XT	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKXT
	Androgen Receptor **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
	BAP1 **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
	BCI2 **2,4		Dako Omnis Immunostainer	CE marked		ISO15189 5.5/LP-HIS-DAKOOMNIS

BCI6 **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/LP-HIS-DAKOOMNIS
BCL10	Ventana Benchmark Ultra	Based on standard method, not CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
BEREP4 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
Beta-Catenin **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
BRAF V600E **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
Calponin **2,4	Ventana Benchmark XT	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKXT
Calretinin **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD10 (SP67) **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD10 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD117 **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOOMNIS
CD138 **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOOMNIS
CD15 (MMA) **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD15 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD20 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD23 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD246 (ALK1) **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/LP-HIS-DAKOOMNIS
CD246 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD3 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD30 **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOOMNIS

CD31 **2,4		Ventana Benchmark XT	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKXT
CD34 **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD4 **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD45 **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD5 **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD56 (MRQ-42) **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD56 **5,6		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD68 **2,4		Dako Omnis Immunostainer	CE marked		ISO15189 5.5/ LP-HIS-DAKOOMNIS
CD79a (SP18) **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD79a **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CD8 **2,4		Ventana Benchmark XT	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKXT
CDX2 **2,4		Dako Omnis Immunostainer	CE marked		ISO15189 5.5/ LP-HIS-DAKOOMNIS
Chromogranin **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CK20 **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CK5/6 **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CK7 **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
CMV **2,4		Ventana Benchmark XT	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKXT
C-myc		Ventana Benchmark XT	Not CE marked, based on standard method		ISO15189 5.5/ LP-HIS-VENTBENCHMARKXT
Cyclin D1 **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA

D2-40 **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
Desmin **2,4	Ventana Benchmark XT	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKXT
DOG1 **2,4	Dako Omnis Immunostainer	CE marked		ISO15189 5.5/ LP-HIS-DAKOOMNIS
EBV (In Situ hybridisation, ISH) **2,4	Dako Omnis Immunostainer	CE marked		ISO15189 5.5/ LP-HIS-DAKOCISH
E-Cadherin **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
EMA **2,4	Ventana Benchmark XT	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKXT
ER (SP1) **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
ERG **2,4	Dako Omnis Immunostainer	CE marked		ISO15189 5.5/ LP-HIS-DAKOOMNIS
Gastrin **2,4	Dako Omnis Immunostainer	CE marked		ISO15189 5.5/ LP-HIS-DAKOOMNIS
GATA-3 **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
GCDFP-15 **2,4	Ventana Benchmark XT	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKXT
Glutamine Synthetase **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/ LP-HIS-BENCHMARKULTRA
Glypican 3 **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/ LP-HIS-VENTBENCHMARKULTRA
H. Pylori **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
Heat Shock Protein 70 **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
Hepar **2,4	Ventana Benchmark XT	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKXT
Her2neu (45B) **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
Her2neu **2,4	Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
HMB45 **2,4	Ventana Benchmark XT	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKXT

HSV1 **2,4	Ventana Benchmark XT	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKXT
Insulin **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOOMNIS
Kappa (ISH) **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOCISH
Ki67 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
Lambda (ISH) **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOCISH
Melan A **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
MLH1 **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOOMNIS
MSH2 **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOOMNIS
MSH6 **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOOMNIS
Muc 4 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
Mum-1 **2,4	Dako Omnis Immunostainer	CE marked	ISO15189 5.5/ LP-HIS-DAKOOMNIS
Napsin A **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
OCT4 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
Oestrogen Receptor **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
p-16 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
P5045/Racemase/AMAC **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
P53 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
P63 **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
p63-AE1/3 dual stain **2,4	Ventana Benchmark Ultra	CE marked	ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
p63-Ker5/6 dual stain	Ventana Benchmark	CE marked	ISO15189 5.5/LP-HIS-

**2,4		Ultra			VENTBENCHMARKULTRA
PAX 8 (EP311) **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
PAX5 **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
PAX8 **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
PD-L1 (22C3) **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
PD-L1 (SP263) **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
PMS2 **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
PRAME **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
Progesterone Receptor **2,4		Dako Omnis Immunostainer	CE marked		ISO15189 5.5/ LP-HIS-DAKOOMNIS
PSA **2,4		Dako Omnis Immunostainer	CE marked		ISO15189 5.5/ LP-HIS-DAKOOMNIS
ROS1 **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
S100 **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
SMA **2,4		Ventana Benchmark XT	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKXT
SOX-10 **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
SSR2A		Ventana Benchmark Ultra	Not CE marked, based on standard method		ISO15189 5.5/ LP-HIS-VENTBENCHMARKULTRA
Stat 6 **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
Succinate Dehydrogenase (SDHB)		Ventana Benchmark Ultra	Based on standard method, not CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
Synaptophysin **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
TdT (Terminal Deoxynucleotidyl		Dako Omnis Immunostainer	CE marked		ISO15189 5.5/ LP-HIS-DAKOOMNIS

	Transferase) **2,4					
	Trypsin		Dako Omnis Immunostainer	Based on standard method, not CE marked		ISO15189 5.5/ LP-HIS-DAKOOMNIS
	TTF-1 **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
	TTF-1-Napsin A dual stain **2,4		Ventana Benchmark Ultra	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKULTRA
	Vimentin **2,4		Ventana Benchmark XT	CE marked		ISO15189 5.5/LP-HIS-VENTBENCHMARKXT
	WT-1 **2,4		Dako Omnis Immunostainer	CE marked		ISO15189 5.5/ LP-HIS-DAKOOMNIS
1055 Molecular pathology - .01 Assay for somatic variants in DNA sequence(s)	Assays for somatic variants in DNA sequences: Semi-automated BRAF/ NRAS mutation testing	Human tissue and cytology cell blocks	Semiautomated BRAF/ NRAS mutation testing: Roche Lightcycler 480 11 Real Time PCR analyser	CE		ISO15189 5.5/ LP-HIS-MICRODIS/ LP-HIS-DNACOBAS/ LP-HIS-NRASBRAFTTEST
	Assays for somatic variants in DNA sequences: Semi-Automated EGFR mutation testing		Semiautomated EGFR mutation testing: Roche Lightcycler 480 11 Real Time PCR analyser	CE		ISO15189 5.5/ LP-HIS-MICRODIS/ LP-HIS-DNACOBAS/ LP-HIS-EGFRTEST
	Assays for somatic variants in DNA sequences: Semi-automated KRAS mutation testing		Semiautomated KRAS mutation testing: Roche Lightcycler 480 11 Real Time PCR analyser	CE		ISO15189 5.5/ LP-HIS-MICRODIS/ LP-HIS-DNACOBAS/ LP-HIS-KRASTEST

The laboratory is accredited for a flexible scope of testing in the following categories

- 1 Range of measurement may be extended
- 2 Parameters may be added
- 3 Test matrices may be added
- 4 Equipment/kit

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
1040 Immunology - .02 Qualitative investigation of immunoglobulins G,A,M and D in body fluids	Immunofixation electrophoresis	Serum or Urine	Immunofixation electrophoresis on the Sebia Hydrasys 2	CE	Serum detection programme has a limit of detection of 0.06-0.25g/l, BJP programme has a limit of detection of 1-5mg/dl	ISO15189 5.5/ LP-IMM-IFX
1040 Immunology - .04 Allergen - specific IgE	Allergen Specific IgE	Serum	Allergen – specific IgE: Specific IgE to a range of allergens are measured on the Phadia250	CE	0.0-100kUA/L	ISO15189 5.5/ LP-IMM-PHADIA
1040 Immunology - .10 Rheumatoid factor - quantitative assays	Rheumatoid Factor (RF)		IgM RF measured by immunoassay on the Phadia250	CE	0.6 to >= 200 IU/ml	ISO15189 5.5/ LP-IMM-PHADIA
1040 Immunology - .12 Detection of autoantibodies in body fluids and biopsy material	Anti GBM antibodies		Detected by immunoassay on the Phadia250	CE	1.5 to >= 680 IU/ml	ISO15189 5.5/ LP-IMM-PHADIA
	Anti-Cardiolipin Antibodies (ACA): ACA IgG and ACA IgM		Detected by Immunoassay on the Phadia 250	CE	IgG ACA 0.5 - >=418 GPL-U/ml IgM ACA 0.9 - >=472 MPL-U/ml	ISO15189 5.5, LP-IMM-PHADIA
	Anti-CCP antibodies		Detected by immunoassay on the Phadia250	CE	0.4-340 U/ml	ISO15189 5.5/ LP-IMM-PHADIA
	Anti-dsDNA antibodies		Detected by immunoassay on the Phadia250	CE	0.5-379 IU/ml	ISO15189 5.5/ LP-IMM-PHADIA
		Screen at 1/20 by IIF on C. luciliae (werfen)	CE	0.5-379 IU/l	ISO15189 5.5/ LP-IMM-QUANTA3000	

		using the Quantalyser 3000 (Werfen)			
Anti-ENA antibodies		Detected by immunoassay on the Phadia250	CE	0.09-55 (ratio)	ISO15189 5.5/LP-IMM-PHADIA
Anti-ENA Profile including: Anti-Ro, Anti-La, Anti-SmD, Anti-U1RNP, Anti-Scl-70S, Anti-Jo-1, Anti-CENP		Detected by immunoassay on the Phadia250	CE	Measuring Ranges: Anti-Ro: 0.3 - >/= 240U/ml, Anti-La: 0.4 - >/= 320U/ml, Anti-SmD: 0.7 - >/= 330U/ml, Anti-U1RNP: 0.3 - >/= 240U/ml, Anti-Scl-70S: 0.6 - >/= 240U/ml, Anti-Jo-1: 0.3 - >/= 240U/ml, Anti-CENP: 0.4 - >/= 240U/ml	ISO15189 5.5, LP-IMM-PHADIA
		Detected by immunoassay on the Phadia250	CE	Measuring Ranges: Anti-Ro: 0.3 - >/= 240U/ml, Anti-La: 0.4 - >/= 320U/ml, Anti-SmD: 0.7 - >/= 330U/ml, Anti-U1RNP: 0.3 - >/= 240U/ml, Anti-Scl-70S: 0.6 - >/= 240U/ml, Anti-Jo-1: 0.3 - >/= 240U/ml, Anti-CENP: 0.4 - >/= 240U/ml	ISO15189 5.5, LP-IMM-PHADIA
Anti-LKM antibodies		Screen at 1/20 by IIF on composite block of liver, kidney, stomach (Werfen) using the Quantalyser 3000 (Werfen)	CE		ISO15189 5.5/ LP-IMM-QUANTA3000
Anti-mitochondrial antibodies		Screen at 1/20 by IIF on composite block of liver, kidney, stomach (Werfen) using the Quantalyser 3000 (Werfen)	CE		ISO15189 5.5/ LP-IMM-QUANTA3000
Anti-MPO antibodies		Detected by immunoassay on the Phadia250	CE	0.2-134 IU/ml	ISO15189 5.5/ LP-IMM-PHADIA

	Anti-neutrophil cytoplasmic antibodies (ANCA)	Screen at 1/20 by indirect immunofluorescence (IIF) on ethanol fixed neutrophils (Werfen) using the Quantalyser 3000 (Werfen)	CE		ISO15189 5.5/ LP-IMM-QUANTA3000
	Anti-Nuclear Antibody (ANA)	Screen at 1/80 by IIF on HEp2 (Werfen) using the Quantalyser 3000 (Werfen)	CE		ISO15189 5.5/ LP-IMM-QUANTA3000
	Anti-Parietal Cell antibodies	Screen at 1/20 by IIF on composite block of liver, kidney, stomach (Werfen) using the Quantalyser 3000 (Werfen)	CE		ISO15189 5.5/ LP-IMM-QUANTA3000
	Anti-PDH antibodies (AMA-M2 subtype)	Detected by ELISA using the DS2 ELISA processor	CE	0-200IU/ml	ISO15189 5.5/ LP-IMM-DS2
	Anti-PR3 antibodies	Detected by immunoassay on the Phadia250	CE	0.6 to >=177 IU/ml	ISO15189 5.5/ LP-IMM-PHADIA
	Anti-smooth muscle antibodies	Screen at 1/20 by IIF on composite block of liver, kidney, stomach (Werfen) using the Quantalyser 3000 (Werfen)	CE		ISO15189 5.5/ LP-IMM-QUANTA3000
	Anti-tissue transglutaminase (Anti-tTG) antibodies	Detected by immunoassay on the Phadia250	CE	0.2 to >=128 U/ml	ISO15189 5.5/ LP-IMM-PHADIA
	IgA-anti-endomysial antibody (EMA)	Screen at 1/10 by IIF on monkey oesophagus (Werfen) using the Quantalyser 3000 (Werfen)	CE		ISO15189 5.5/ LP-IMM-QUANTA3000
1040 Immunology - .54 Tryptase	Tryptase	Measurement of tryptase levels using ThermoFisher ImmunoCAP Tryptase on the Phadia 250 instrument (ThermoFisher)	CE	1.0 - 200ug/l	ISO15189 5.5/ LP-IMM-PHADIA

1040 Immunology - .99 Miscellaneous tests	Cyclosporine	Whole blood (EDTA)	CMA on Abbott Architect	CE	18-1500 ng/ml	ISO15189 5.5/ LP- IMM-ARCHITECT
	Tacrolimus		CMA on Abbott Architect	CE	2.0-30 ng/ml	ISO15189 5.5/ LP- IMM-ARCHITECT

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
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)	Preparation of films; Gram stains Microscopic Examination of clinical specimens; Cell Counts and Gram stains	Gram stains: Wound swabs (of specific type), body fluids, tissues, sputum, BAL, isolates from culture plats, genital swabs. Cell Counts: CSF, body fluids, urine.		standard method		ISO15189 5.5/ LP-MIC-GRAM LP-MIC-CSF/ LP-MIC-BOFYFL/ LP-MIC-URINE/ LP-MIC-SPUT/ LP-MIC-BAL
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .04 Microscopic examination for mycobacteria	Auromine-Rhodamine stain for AFB on Clinical Specimens	Sputum, BAL, Body fluids, CSF, Tissue		standard method		ISO15189/ LP-MIC-STAIN/ LP-MIC-TB/ LP-MIC-AFB STAIN
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	CPE/ ESBL Screens	Rectal swab			N/A	ISO15189 5.5 LP-MIC-CRE/ESBL
	CRE/ ESBL screens				N/A	ISO15189 5.5 LP-MIC-CRE/ESBL
	Culture of General Bacteria on agar based culture media	Urine, faeces, sputum, BAL, AWO, bone marrow, CSF, body fluids, wound swabs, tissue,		standard method		ISO15189 5.5/ LP-MIC-URINE/ LP-MIC-SVRE/ LP-MIC-FAEC/ LP-MIC-TISS/ LP-MIC-BILE/ LP-

		ulcers, genital swabs, throat, eyes, ears, IV tips, MRSA and VRE screens				MIC-SPUT/ LP-MIC-CAPD/ LP-MIC-BAL/ LP-MIC-CORNEA/ LP-MIC-SINUS/ LP-MIC-HPGA/ LP-MIC-GEN/ LP-MIC-MRSA/ LP-MIC-THROAT/ LP-MIC-IVA/ LP-MIC-SKIN/ LP-MIC-BODYFL/ LP-MIC-PUS/ LP-MIC-CSF/ LP-MIC-MOUTH/ LP-MIC-ULCER/ LP-MIC-EAR/ LP-MIC-NOSE/ LP-MIC-EYE/ LP-MIC-PSORE
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 on agar based culture media	Dermatology, BAL, AWO, tissues, ears, devices, mouth, HVS, sputum, throat, urine				ISO15189 5.5/ LP-MIC-DERM (dermatology)/ LP-MIC-BAL/ LP-MIC-SINUS (AWO)/ LP-MIC-GEN (HVS)/ LP-MIC-THROAT/ LP-MIC-EAR/ LP-MIC-MOUTH/ LP-MIC-TISS (tissue/ devices)/ LP-MIC-SPUT/ LP-MIC-URINE
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .03 Culture of mycobacteria	Culture of mycobacterium using liquid based and agar based media	Sputum, BAL, Body fluids, CSF, Tissue	Automated liquid culture using Biomerieux MBACT. Manual TB culture using LJ slopes/ BCSA plates	Liquid Culture: CE marked. Solid Culture: Standard method		ISO15189 5.5/ LP-MIC-TB
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .02 Particle agglutination	Latex Tests: For Staph aureus and for BHS Lancefield grouping (as identification or partial identification of cultured bacteria)		BioRad Pastorex Strep and BioRad Pastorex Staph Plus	CE marked kits		ISO15189
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and	C. diff Quik Chek Complete	Faeces	Membrane enzyme immunoassay for the simultaneous detection of C. difficile glutamate	CE	N/A	ISO15189 5.5/ LP-MIC-FCD

appropriate techniques - .03 Enzyme immunoassay,			dehydrogenase antigen (GDH) and toxins A and B			
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods,	MecA testing to aid in the identification of MRSA	Bacterial isolate	Alere PBP2a SA Culture colony Test	CE marked	N/A	ISO15189 5.5/LP-MIC-AST
		Bacterial isolates	Alere PBP2a SA Culture colony Test	CE marked	N/A	ISO15189 5.5/LP-MIC-AST
	Resist-5 O.K.N.V.I Detection of Carbapenemase in bacterial culture		RESIST-5 O.K.N.V.I	CE marked	N/A	ISO15189 5.5/LP-MIC-AST
	Resist-5 O.K.N.V.I Detection of Carbapenemase in bacterial culture for the identification of query CPE isolates	Bacterial Isolates	RESIST-5 O.K.N.V.I	CE marked	N/A	ISO15189 5.5/LP-MIC-AST
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	CPE Identification of query CPE isolates from clinical and screening samples		Cepheid GeneXpert	CE marked	N/A	ISO15189 5.5/ LP-MIC-AST LP-MIC-GENEXPERT
	Detection of Influenza A, B and RSV	Viral Swab - nose or throat	Cepheid GeneXpert	CE marked	N/A	ISO15189 5.5/ LP-MIC-FLU LP-MIC-GENEXPERT
	Detection of MTB Complex and Rifampicin resistance	Sputum, BAL	Cepheid GeneXpert	CE	N/A	ISO15189 5.5/ LI-MIC-XPERTTB, LP-MIC-TB
	Detection of SARS-CoV-2	Nasopharyngeal swabs	Abbott Alinity M	CE	N/A	ISO15189 5.5/ LP-MIC-ALINITYSARS2
			Cepheid GeneXpert	CE	N/A	ISO15189 5.5/ LP-MIC-XPERTSARS
Luminex Aries	CE	N/A	ISO15189 5.5/ LP-MIC-LUMINEXSARS			

			Roche FLOW using Primer Design Genesig SARS-CoV-2 assay	CE	N/A	ISO15189 5.5/ LP-MIC-FLOWSARS2
	Detection of SARS-CoV2/ Flu A/ Flu B/ RSV - Alinity Four Plex		Abbott Alinity M	CE	N/A	ISO15189 5.5/ LP-MIC-ALINITYM
	Detection of SARS-Co-V-2/Flu A/ Flu B/ RSV		Cepheid GeneXpert	CE	N/A	ISO15189 5.5/ LP-MIC-GXSARS/FLU/RSV
	Molecular detection of faeces bacterial (and parasitic Cryptosporidium and Giardia) enteric pathogens including C. difficile	Faeces	EntericBio Gastro Panel 2 and EntericBio C. difficile using EntericBio Workstation and lightcycler	CE marked kits		ISO15189 5.5/ LP-MIC-FAEC/ LP-MIC-FCD
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	Automated Identification of Gram positive and Gram negative bacteria on Biomerieux Vitek 2 (automated system)		Biomerieux Vitek 2	CE marked		ISO15189 5.5/ LP-MIC-AST/ LP-MIC-VITEK2
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .03 Identification of fungi by microscopic morphology	Microscopic identification of significant moulds		Morphology and Microscopic examination (lactphenol blue)	standard method		ISO15189 5.5/ LP-MIC-DERM/ LP-MIC-STAIN
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy	Automated identification of organisms (bacteria and yeast) using Biomerieux Vitek MS		Biomerieux VitekMS	CE marked		ISO15189 5.5/ LP-MIC-ID/ LP-MIC-VITEK2/ LP-MIC-AST
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	Anerobic bacteria: Gradient MIC strips using EUCAST guidelines		Manual susceptibility testing by MIC strips using Eucast guidelines	standard method		ISO15189 5.5/ LP-MIC-AST
	General aerobic/CO2/microareophilic bacteria: Automated		Automated susceptibility testing using Vitek 2. Manual	Vitek 2: CE marked		ISO15189 5.5/ LP-MIC-AST/ LP-MIC-VITEK2

	susceptibility testing, manual susceptibility testing by disks and MIC strips using EUCAST guidelines		sensitivities standard method using Eucast Guidelines			
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts	Yeasts: Automated susceptibility testing using CLSI guidelines		Automated susceptibility testing for Candida using Vitek 2	Vitek 2: CE marked		ISO15189 5.5/ LP-MIC-AST
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .05 Other categories of organism (as specified)	mCim (modified carbapenemase inactivation method)	Bacterial Isolate	Modified manual susceptibility testing (non EUCAST guidelines)	Standard method	N/A	ISO15189 5.5/ LP-MIC-AST/ LI-MIC-CREREP

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 **1,2,4	Serum	Calculation	Roche Cobas 6000/ APEX iLab (Calculation)	CE	ISO15189 5.5/ LP-SAT-ROCHE/ LP-CHEM-CALC
	Alanine Aminotransferase (ALT) **1,2,3,4		Colourimetric	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	Alkaline Phosphatase **1,2,3,4		Colourimetric	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	Amylase **1,2,3,4		Enzymatic Colourimetric	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	Aspartate Aminotransferase (AST) **1,2,3,4		Colourimetric	Roche Cobas 6000	CE	ISO15189 5.5, LP-SAT-ROCHE
	Bilirubin - Total **1,2,3,4		Colourimetric	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	C Reactive Protein **1,2,3,4		particle enhanced immunoturbidometric assay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	Calcium **1,2,3,4		Photometric	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	Carbon Dioxide **1,2,3,4		Photometric	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	Chloride **1,2,3,4		ISE	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	Cholesterol **1,2,3,4		Enzymatic Colourimetric Assay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	CKD-EPI GFR		Calculation	Roche Cobas	CE	ISO15189 5.5/ LP-

**1,2,4		6000/ APEX iLab (Calculation)		SAT-ROCHE/ LP- CHEM-CALC
Creatine Kinase **1,2,3,4	Photometric	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
Creatinine (Enzymatic) **1,2,3,4	enzymatic method measured photometrically	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
eGFR **1,2,4	Calculated	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
FT3 **1,2,3,4	competitive immunoassay using electrochemiluminescence	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
FT4 **1,2,3,4	competitive immunoassay using electrochemiluminescence	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
Gamma Glutamyl Transferase (GGT) **1,2,3,4	Enzymatic colourimetric assay	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
Glucose **1,2,3,4	Photometric	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
HDL and LDL Cholesterol **1,2,3,4	Homogeneous enzymatic colourimetric test	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
Iron **1,2,3,4	Colourimetric	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
Lactate Dehydrogenase **1,2,3,4	Enzymatic assay	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
Lipid Calculations**1,2,4 including: Non-HDL Cholesterol (NHDLC) and Total Cholesterol: HDL Cholesterol Ratio (TCHDR)	Calculation	Roche Cobas 6000/ APEX iLAB (calculation)	CE	ISO15189 5.5/ LP- CHEM-CALC
Magnesium **1,2,3,4	Colourimetric end point assay	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
Phosphate **1,2,3,4	Photometric	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
Potassium **1,2,3,4	ISE	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
Sodium **1,2,3,4	ISE	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE

	Total Iron Binding Capacity (TIBC/C) **1,2,4	Calculation	Roche Cobas 6000/ APEX iLAB (calculation)	CE	ISO15189 5.5/ LP-CHEM-CALC
	Triglycerides **1,2,3,4	Enzymatic Colourimetric assay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	Troponin T high sensitivity **1,2,3,4	Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	TSH **1,2,3,4	electrochemiluminescent sandwich Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	Urea **1,2,3,4	Photometric	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	Uric Acid **1,2,3,4	Enzymatic Colourimetric	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Albumin **1,2,3,4	Colourimetric	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	Calculated Globulin **1,2,4	Calculation	Roche Cobas 6000/ APEX iLab (Calculation)	CE	ISO15189 5.5/ LP-SAT-ROCHE/ LP-CHEM-CALC
	IgA **1,2,3,4	immunospectrometric assay using electrochemiluminescence	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	IgE **1,2,3,4	sandwich immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	IgG **1,2,3,4	immunospectrometric assay using electrochemiluminescence	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	IgM **1,2,3,4	immunospectrometric assay using electrochemiluminescence	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	Total Protein **1,2,3,4	immunospectrometric assay using electrochemiluminescence	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
	1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Gentamycin **1,2,3,4	kinetic interaction of microparticles in solution (KIMS)	Roche Cobas 6000	CE
Vancomycin **1,2,3,4		homogeneous enzyme immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE
1061 Clinical Chemistry - .40 Iron studies	Transferrin **1,2,3,4	immunospectrometric assay using electrochemiluminescence	Roche Cobas 6000	CE	ISO15189 5.5/ LP-SAT-ROCHE

	Transferrin Saturation **1,2,4		Calculation	Roche Cobas 6000/ APEX iLab (Calculation)		ISO15189 5.5/ LP- SAT-ROCHE/ LP- CHEM-CALC
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
	Vitamin B12 **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	AFP **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
	CA125 **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
	CA15-3 **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
	CA19-9 **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
	CEA **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
	HCG **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
	PSA **1,2,3,4		Electrochemiluminescent Immunoassay	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE
1061 Clinical Chemistry - .60 Glycohaemoglobins	HbA1c **1,2,3,4	Blood	Turbidimetric Inhibition Immunoassay with TTAB Haemolyzer	Roche Cobas 6000	CE	ISO15189 5.5/ LP- SAT-ROCHE

*For laboratories with a flexible scope, the following footnote applies:
The laboratory is accredited for a flexible scope of testing in the following categories*

- 1 Range of measurement may be extended
- 2 Parameters may be added
- 3 Test matrices may be added
- 4 Equipment/kit