

Schedule of Accreditation



Organisation Name	HSE Cork University Hospital
Trading As	Laboratory Medicine, Cork University Hospital
INAB Reg No	333MT
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Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	09/06/2015
Scope Classification	Microbiology and virology
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	Head Office	Laboratory Quality Manager, Laboratory Medicine, Cork University Hospital, Wilton, Cork

Scope of Accreditation

Head Office

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 Transaminase (ALT) ¹²³⁴	Plasma/Serum	TRIS	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	Albumin ¹²³⁴	Plasma/Serum /Urine	Bromocresol Green Turbidimetry (Urines)	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	Alkaline Phosphatase (ALP) ¹²³⁴	Plasma/Serum	IFCC	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	Ammonia ¹²³⁴	Plasma	Enzymatic	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	Amylase ¹²³⁴	Plasma/Serum /Urine	IFCC	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	Angiotensin converting enzyme (ACE) ¹²³⁴	Serum	FAPGG	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420

Aspartate aminotransferase (AST) ¹²³⁴	Plasma/Serum	TRIS	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
Bicarbonate ¹²³⁴		Enzymatic	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
Bile Acids ¹²³⁴	Serum	Enzymatic	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
Calcium ¹²³⁴	Plasma/Serum /Urine	Colorimetric	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
Calculated Globulin ¹²³⁴	Serum	Calculated Parameter	n/a	Based on Standard Method	INS-CUH-PAT-126
Chloride ¹²³⁴	Plasma/Serum /Urine	Indirect ISE	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
Cholesterol ¹²³⁴	Plasma/Serum	Enzymatic	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
Creatine Kinase (CK) ¹²³⁴		IFCC	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
Creatinine ¹²³⁴		Enzymatic	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
Direct Bilirubin ¹²³⁴		Diazo	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
Gamma-glutamyl transpeptidase (GGT) ¹²³⁴		IFCC	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
Glucose (Fasting/Random) ¹²³⁴		Plasma	Enzymatic	Beckman Coulter AU5832	CE Marked Assay
HDL Cholesterol ¹²³⁴	Plasma/Serum	Enzymatic	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
Lactate Dehydrogenase (LDH) ¹²³⁴		IFCC	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
Lactate ¹²³⁴	Plasma	Enzymatic	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
Magnesium ¹²³⁴	Plasma/Serum /Urine	Colorimetric	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420

	Osmolality ¹²³⁴	Serum/Urine	Freezing Point measurement	Advanced Micro-Osmometer Model 2020	CE Marked Assay	PPG-CUH-PAT-195
	Phosphate ¹²³⁴	Plasma/Serum /Urine	Ammonium Molybdate	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	Potassium ¹²³⁴		Indirect ISE	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	Sodium ¹²³⁴		Indirect ISE	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	Total Bilirubin ¹²³⁴	Plasma/Serum	Diazo Method	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	Total Protein ¹²³⁴		Colorimetric	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	Triglyceride ¹²³⁴		GPO-PAP	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	Urate ¹²³⁴	Plasma/Serum /Urine	Enzymatic	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	Urea ¹²³⁴		Enzymatic	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	Urinary Protein ¹²³⁴	Urine	Pyrogallol Red	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	A1-Antitrypsin ¹²³⁴	Serum	Immunoturbidimetric	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	Anti-Thyroid Peroxidase Ab's ¹²³⁴		CMIA	Beckman DXI 800 /DxI 9000	CE Marked Assay	PPG-CUH-PAT-4036
	Ceruloplasmin ¹²³⁴		Immunoturbidimetric	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	C-Reactive Protein (CRP) ¹²³⁴	Plasma/Serum	Immunoturbidimetric	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	Free Kappa Light Chains ¹²⁴	Serum	Immunoturbidimetric	Optilite IE700	CE Marked Assay	PPG-CUH-PAT-99
	Free Lambda Light Chains ¹²⁴		Immunoturbidimetric	Optilite IE700	CE Marked Assay	PPG-CUH-PAT-99
	Haptoglobin ¹²³⁴		Immunoturbid-imetric	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420

	Insulin-like Growth Factor 1 (IGF1) ¹²³⁴		Immunoassay	IDS-isys	CE Marked Assay	PPG-CUH-PAT-265
	NTproBNP ¹²³⁴		CMIA	Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263
	Procalcitonin ^{**1,2,3,4}		Immunoassay	Beckman Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4036
	Troponin I (hs) ¹²³⁴		CMIA	Beckman Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4036
1061 Clinical Chemistry - .03 Proteins, qualitative and semiquantitative analysis	Bence-Jones Protein ¹²³⁴	Urine	Electrophoresis	Sebia Hydrasys II	CE Marked Assay	PPG-CUH-PAT-222
	Paraprotein Type (Serum) ¹²³⁴	Serum	Immuno-fixation	Sebia Hydrasys	CE Marked Assay	PPG-CUH-PAT-219
	Protein Electrophoresis ¹²³⁴		Electrophoresis	Sebia Capillarys III	CE Marked Assay	PPG-CUH-PAT-1403
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Carbamazepine ¹²³⁴		EMIT	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	C-peptide ^{**1234}	Serum/plasma	Chemiluminescent	Dxl 800	CE Marked Assay	PPG-CUH-PAT-4037
	Cyclosporin ¹²³⁴	Whole Blood	CMIA	Architect i 1000 System	CE Marked Assay	PPG-CUH-PAT-263
	Digoxin ¹²³⁴	Serum	Enzymatic	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	Lithium ¹²³⁴		Colorimetric	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	Methotrexate ¹²³⁴		CMIA	Abbott Architect i1000SR System Automated Immunoassay	CE Marked Assay	PPG-CUH-PAT-206
	Paracetamol ¹²³⁴		Enzymatic	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	Phenobarbitone ¹²³⁴		EMIT	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
Phenytoin ¹²³⁴	EMIT	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420		

	Tacrolimus ¹²³⁴	Whole Blood EDTA	CMIA	Abbott Architect i1000SR System Automated Immunoassay	CE Marked Assay	PPG-CUH-PAT-206	
	Theophylline ¹²³⁴	Serum	EMIT	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420	
	Valproate ¹²³⁴		EMIT	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420	
1061 Clinical Chemistry - .14 Alcohol for non-legal purposes	Alcohol ¹²³⁴	Serum/Urine	EMIT	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420	
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Salicylate ¹²³⁴	Serum	Enzymatic	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420	
1061 Clinical Chemistry - .20 Hormones	Cortisol ¹²³⁴		CMIA	Beckman Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4036	
	Follicle-stimulating hormone (FSH) ¹²³⁴		CMIA	Beckman Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4036	
	Free T3 ¹²³⁴		CMIA	Beckman Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4036	
	Free T4 ¹²³⁴		CMIA	Beckman Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4036	
	Growth Hormone ¹²³⁴		CMIA	IDS-isys	CE Marked Assay	PPG-CUH-PAT-265	
	Insulin ^{**1234}		Serum/plasma	Chemiluminescent	Dxl 800	CE Marked Assay	PPG-CUH-PAT-4037
	Luteinizing hormone (LH) ¹²³⁴		Serum	CMIA	Beckman Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4036
	Oestradiol ¹²³⁴			CMIA	Beckman Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4036
	Parathyroid hormone (PTH) ¹²³⁴		EDTA-Plasma	CMIA	Beckman DXI 800 /Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4036
	Progesterone ¹²³⁴	Serum	CMIA	Beckman DXI 800 /Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4037	
	Prolactin ¹²³⁴		CMIA	Beckman Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4036	
	Sex Hormone-Binding Globulin ¹²³⁴		CMIA	Beckman DXI 800 /Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4037	
	Testosterone ¹²³⁴		CMIA	Beckman DXI 800 /Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4036	

	Thyroid-stimulating hormone (TSH) ¹²³⁴
1061 Clinical Chemistry - .40 Iron studies	Iron ¹²³⁴
	Transferrin ¹²³⁴
1061 Clinical Chemistry - .47 Vitamin assays	Vitamin D ¹²³⁴
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Alphafetaprotein ¹²³⁴
	Ca125 ¹²³⁴
	Ca15-3 ¹²³⁴
	Ca19-9 ¹²³⁴
	Carcinoembryonic Antigen (CEA) ¹²³⁴
	Human chorionic gonadotropin ¹²³⁴
	PSA (Total) ¹²³⁴
1061 Clinical Chemistry - .80 Quantitative investigation of immunoglobulins G, A, M and in body fluids	IgA ¹²³⁴
	IgG ¹²³⁴
	IgM ¹²³⁴
1061 Clinical Chemistry - .86 C3 and C4	Complement C3 ¹²³⁴
	Complement C4 ¹²³⁴
1061 Clinical Chemistry - .99 Miscellaneous tests	%Iron Saturation ¹²³⁴

CMIA	Beckman Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4036
Ferrazine	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
Immunoturbid-imetric	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
CMIA	Beckman Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4036
CMIA	Beckman Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4036
CMIA	Beckman Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4036
CMIA	Beckman DXI 800 /Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4036
CMIA	Beckman DXI 800 /Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4037
CMIA	Beckman DXI 800 /Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4037
CMIA	Beckman Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4036
CMIA	Beckman DXI 800 /Dxl 9000	CE Marked Assay	PPG-CUH-PAT-4037
Immunoturbidimetric	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
Immunoturbidimetric	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
Immunoturbidimetric	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
Immunoturbidimetric	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
Immunoturbidimetric	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
Calculated Parameter	n/a	Based on Standard Method	INS-CUH-PAT-126

24 Hour Urinary Amylase ¹²³⁴	Urine	Calculated Parameter	n/a	Based on Standard Method	INS-CUH-PAT-126
24 Hour Urinary Magnesium ¹²³⁴		Calculated Parameter	n/a	Based on Standard Method	INS-CUH-PAT-126
24 Hour Urinary Phosphate ¹²³⁴		Calculated Parameter	n/a	Based on Standard Method	INS-CUH-PAT-126
24 Urinary Urea ¹²³⁴		Calculated Parameter	n/a	Based on Standard Method	INS-CUH-PAT-126
24hr Urinary Calcium ¹²³⁴		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
24hr Urinary Chloride ¹²³⁴		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
24HR Urinary Creatinine ¹²³⁴		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
24hr Urinary Microalbumin ¹²³⁴		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
24hr Urinary Potassium ¹²³⁴		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
24hr Urinary Protein ¹²³⁴		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
24hr Urinary Sodium ¹²³⁴		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
24hr Urinary Urate ¹²³⁴		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
Adjusted Calcium ¹²³⁴	Serum	Calculated Parameter	n/a	Based on Standard Method	INS-CUH-PAT-126
Amy:Creat Clearance Ratio ¹²³⁴	Urine	Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
Androgen Index ¹²³⁴	Serum	Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
Ca:Creat Clearance Ration ¹²³⁴	Urine/Serum	Calculated Parameter	n/a	Annals of Clinical Biochemistry 2004; 41:441-458	INS-CUH-PAT-126
Calcium Excretion ¹²³⁴		Calculated Parameter	n/a	Annals of Clinical Biochemistry 2004; 41:441-458	INS-CUH-PAT-126

	Creatinine Clearance ¹²³⁴		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
	CSF Glucose ¹²⁴	CSF	Enzymatic	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	CSF Lactate ¹²⁴		Enzymatic	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	CSF Total Protein ¹²⁴		Pyrogallol Red	Beckman Coulter AU5832	CE Marked Assay	PPG-CUH-PAT-1420
	Estimated GFR	Serum	Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
	Kappa/Lamda ratio		Calculated parameter	n/a	Based on standard method	INS-CUH-PAT-126
	Kappa: Lambda Ratio ¹²³⁴		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
	LDL Calculation ¹²³⁴		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
	Microalbumin Creatinine Ratio ¹²³⁴	Urine	Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
	Ur. Protein /Creat. ratio ¹²³⁴		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
	UTP:Creat Ratio ¹²³⁴		Calculated Parameter	n/a	BMI 1998; 316: 504-9	INS-CUH-PAT-126

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*

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.

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 - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies	Creatinine**1234	Whole Blood	Amperometry via enzymatic reactions	Abbott iStat Alinity/18-1768 umol/L	CE Marked	PPG-CUH-PAT-5028
	POC Creatinine**1234		Amperometry via enzymatic reactions	Abbott iStat Alinity/18-1768 umol/L	CE Marked Assay	PPG-CUH-PAT-5028
1061 Clinical Chemistry - .05 CO-oximetry	COHb**1234	Whole Blood taken into Heparinised Blood Gas syringe: Arterial, Venous, Capillary	Siemens RP500 /CO-Oximetry	CE Marked Assay	0 - 100%	PPG-CUH-PAT-5006
	Hb**1234		Siemens RP500 /CO-Oximetry	CE Marked Assay	5 - 20.63 g/dl	PPG-CUH-PAT-5006
	HHb**1234		Siemens RP500 /CO-Oximetry	CE Marked Assay	0 - 100%	PPG-CUH-PAT-5006
	MetHb**1234		Siemens RP500 /CO-Oximetry	CE Marked Assay	0 - 100%	PPG-CUH-PAT-5006
	O2 Saturation (Blood Gas**1234)		Siemens RP500 /CO-Oximetry	CE Marked Assay	0 - 100%	PPG-CUH-PAT-5006
	O ² Hb**1234		Siemens RP500 /CO-Oximetry	CE Marked Assay	0 - 100%	PPG-CUH-PAT-5006
	SO ² **1234		Siemens RP500 /CO-Oximetry	CE Marked Assay	0 - 100%	PPG-CUH-PAT-5006

1061 Clinical Chemistry - .06 Blood pH and gas tensions	Base excess**1234	Whole blood taken into heparinised syringe: Arterial, venous, capillary	Siemens RP500/Potentiometry	CE Marked Assay	n/a	PPG-CUH-PAT-5006
	H+**1234	Whole Blood taken into Heparinised Blood Gas syringe: Arterial, Venous, Capillary	Siemens RP500, Siemens RL1240 /Potentiometry	CE Marked Assay	196.663 - 20.543 nmol/L	PPG-CUH-PAT-5006
	HCO3**1234	Whole blood taken into heparinised syringe: Arterial, venous, capillary	Siemens RP500/Potentiometry	CE Marked Assay	n/a	PPG-CUH-PAT-5006
	pCO2**1234	Whole Blood taken into Heparinised Blood Gas syringe: Arterial, Venous, Capillary	Siemens RP500, Siemens RL1240 /Potentiometry	CE Marked Assay	2.277 - 19.157 kPa	PPG-CUH-PAT-5006
	pH**1234		Siemens RP500, Siemens RL1240 /Potentiometry	CE Marked Assay	6.709 - 7.688 pH units	PPG-CUH-PAT-5006
	pO2**1234		Siemens RP500, Siemens RL1240 /Amperometry	CE Marked Assay	6.977 - 60.743 kPa	PPG-CUH-PAT-5006
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Chloride**1234		Siemens RP500 /Direct ISE	CE Marked Assay	72 - 125 mmol/L	PPG-CUH-PAT-5006
	Glucose**1234		Siemens RP500 /Amperometry	CE Marked Assay	1.47 - 35.8 mmol/L	PPG-CUH-PAT-5006
	Ionized Calcium**1234		Siemens RP500 /Potentiometry	CE Marked Assay	0.537 - 2.883 mmol/L	PPG-CUH-PAT-5006
	Lactate**1234		Siemens RP500 /Amperometry	CE Marked Assay	0.553 - 17.14 mmol/L	PPG-CUH-PAT-5006
	Neonatal Bilirubin**1234		Siemens RP500 /Potentiometry	CE Marked Assay	34 - 403.7 umol/L	PPG-CUH-PAT-5006
	Potassium**1234		Siemens RP500/Direct ISE	CE Marked Assay	1.496 - 11.163 mmol/L	PPG-CUH-PAT-5006

	Sodium**1234	Whole Blood taken into Heparinised Blood Gas Syringe /Capillary or Serum Sample	Siemens RP500 /Direct ISE	CE Marked Assay	111.93 - 164.3 mmol/L	PPG-CUH-PAT-5006
1061 Clinical Chemistry - .99 Miscellaneous tests	Estimated GFR**1234	Whole Blood	Calculated parameter	Abbott iStat Alinity/0-60 mL/min/1.73m2	CE Marked	PPG-CUH-PAT-5028
			Calculated parameter	Abbott iStat Alinity/0-60 mL/min/1.73m2	CE Marked Assay	PPG-CUH-PAT-5028

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

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.

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	Vitamin B12**1234	Serum	Chemiluminescent Immunoassay	Beckman Coulter DXi800	CE Marked Assay	PPG-CUH-PAT-501
	White Cell Count ¹²³⁴ Red Cell Count ¹²³⁴ Haemoglobin ¹²³⁴ Haematocrit ¹²³⁴ Mean Cell Volume ¹²³⁴ MCH ¹²³⁴ MCHC ¹²³⁴ Platelet Count ¹²³⁴	Whole Blood in EDTA	Fluorescent flow Cytometry, Hydrodynamic focusing Light scatter Impedance	XN series	CE Marked Assay	PPG-CUH-PAT-403 PPG-CUH-PAT-1571
1030 Haematology - .02 Visual examination of blood films	Differential white cell, red cell morphology and platelet checks ¹²³⁴	Whole blood – films	May Grunwald and Giemsa staining	SP1000i Microscope SP10	CE Marked Assay	PPG-CUH-PAT-471 PPG-CUH-PAT-473 PPG-CUH-PAT-475
1030 Haematology - .03 Erythrocyte sedimentation rate	Automated ESR ¹²³⁴	Whole Blood in EDTA	Westgren based Sedimentation rate	Starrs Compact ESR (Interrliner and RS)	CE Marked Assay	PPG-CUH-PAT-404
1030 Haematology - .05 Automated differential leucocyte counts	Neutrophils, Lymphocytes, Monocytes, Eosinophils and Basophils ¹²³⁴		Fluorescent flow Cytometry, Hydrodynamic focusing Light scatter, Impedance	XN series	CE Marked Assay	PPG-CUH-PAT-403 PPG-CUH-PAT-1571 PPG-CUH-PAT-1971
1030 Haematology - .06 Automated reticulocyte counts	Automated Reticulocyte count ¹²³⁴		Fluorescent flow Cytometry Impedance	XN series	CE Marked Assay	PPG-CUH-PAT-403 PPG-CUH-PAT-1571 PPG-CUH-PAT-1971

1030 Haematology - .08 Blood film examinations involving special staining procedures	Iron Stain ¹²³⁴	Bone marrow film	Perl's Prussian Blue	Manual	Based on a standard method	PPG-CUH-PAT-476
1030 Haematology - .09 Examination of malarial parasites	Examination for malaria parasites ¹²³⁴	Whole Blood in EDTA	May Grunwald and Giemsa manual staining and Kits	Manual and Screen Carestart Ag Screen	CE Marked Assay	PPG-CUH-PAT-272
	Malaria**3,4	Whole blood EDTA	PCR	Alethia PCR bench top analyser	CE Marked Assay	PPG-CUH-PAT-272
1030 Haematology - .20 Bone marrow examination	Bone Marrow ¹²³⁴	Bone marrow film	May-Grunwald/ Giemsa stain	SP 1000i, Microscope SP-10 Manual	CE Marked Assay	PPG-CUH-PAT-476 PPG-CUH-PAT-471 PPG-CUH-PAT-473 PPG-CUH-PAT-475 PPG-CUH-PAT-476 PPG-CUH-PAT-1971
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Sickle cell test ¹²³⁴ Haemoglobin Electrophoresis on the HYDRASYS System ¹²³⁴ Hb Variants and β Thalassaemia Screen ¹²³⁴	Whole Blood in EDTA	Haemoglobin Solubility test Electrophoresis	Clin Tech Sickle Cell Kit HYDRASYS System Tosoh G8	CE Marked Assay	PPG-CUH-PAT-458 PPG-CUH-PAT-457 PPG-CUH-PAT-453
			High Performance Liquid Chromatography HPLC			
1030 Haematology - .36 Screening tests for G6Pd	G6PD screen ¹²³⁴		Fluorescence spot test Ultraviolet, kinetic determination of G6PDH	UV Lamp	CE Marked Assay	PPG-CUH-PAT-455
1030 Haematology - .40 Limited haemostasis related tests	ACTIN FSL ¹²³⁴	Plasma – Citrate	Clotting	CS-2500, CS-5100	CE Marked Assay	PPG-CUH-PAT-425 PPG-CUH-PAT-1972
	Activated Protein C Resistance ¹²³⁴		Clotting	CS-2500, CS-5100	CE Marked Assay	PPG-CUH-PAT-425 PPG-CUH-PAT-1972
	Anti Xa Heparin assay ¹²³⁴		Chromogenic	CS-2500, CS-5100	CE Marked Assay	PPG-CUH-PAT-424 PPG-CUH-PAT-1972

Anti-Thrombin III Assay ¹²³⁴		Chromogenic	CS-2500, CS-5100	CE Marked Assay	PPG-CUH-PAT-425 PPG-CUH-PAT-1972	
Cardiolipin Antibody ¹²³⁴	Serum sample	Immunoassay	DS2	CE Marked Assay	PPG-CUH-PAT-438 PPG-CUH-PAT-440	
Chromogenic Factor VIII ^{**1234}	Plasma - Citrate	Chromogenic	Sysmex CS analysers (CS5100 and CS2500)	CE Marked Assay	PPG-CUH-PAT-398	
Direct Oral Anti-Coagulant (DOAC's)- Rivaroxiban and Apixiban ^{**1234}	Sodium Citrate	Chromogenic	Sysmex CS analysers (CS5100 and CS2500)	CE Marked Assay	PPG-CUH-PAT-592	
DVVT: Lupus Anticoagulant ¹²³⁴	Plasma – Citrate	Clotting	CS-2500, CS-5100	CE Marked Assay	PPG-CUH-PAT-425 PPG-CUH-PAT-1972	
Factor assays - Intrinsic Factor VIII, IX, XI, XII ¹²³⁴		Clotting	CS-2500, CS-5100	CE Marked Assay	PPG-CUH-PAT-422 PPG-CUH-PAT-1972	
Factor assays –Extrinsic Factor II, VII, X ¹²³⁴		Clotting	CS-2500, CS-5100	CE Marked Assay	PPG-CUH-PAT-421 PPG-CUH-PAT-1972	
Free Protein S ¹²³⁴		Immunoassay	CS-2500, CS-5100	CE Marked Assay	PPG-CUH-PAT-425 PPG-CUH-PAT-1972	
Protein C Assay ¹²³⁴		Chromogenic	CS-2500, CS-5100	CE Marked Assay	PPG-CUH-PAT-425 PPG-CUH-PAT-1972	
Thrombophilia Screen ¹²³⁴		Chromogenic and clotting	CS-2500, CS-5100	CE Marked Assay	PPG-CUH-PAT-425 PPG-CUH-PAT-1972	
vW screen: Antigen ¹²³⁴ Ristocetin cofactor ¹²³⁴		Immunoassay Aggregometry	CS-2500, CS-5100	CE Marked Assay	PPG-CUH-PAT-434 PPG-CUH-PAT-435 PPG-CUH-PAT-1972	
Beta 2 Glycoprotein 1 Antibody ¹²³⁴		Serum sample	Immunoassay	DS2	CE Marked Assay	PPG-CUH-PAT-438 PPG-CUH-PAT-439

1030 Haematology - .41 General haemostasis related tests	Prothrombin Time PT ¹²³⁴ International Normalised Ratio INR ¹²³⁴ Thromborel**1,2,3,4 Activated Partial Thromboplastin Time APTT and Ratio ¹²³⁴ Fibrinogen ¹²³⁴ D-Dimer ¹²³⁴	Plasma – Citrate	Clotting Clotting Immuno assay Immuno-turbidmetric	CS-5100 CS-2500 Centrifuge	CE Marked Assay	PPG-CUH-PAT-442 PPG-CUH-PAT-1972
1030 Haematology - .45 Tests of platelet function	Platelet Aggregometry ¹²³⁴	Whole blood Plasma – Citrate	Optical Impedance	PFA 100 PAP-8	CE Marked Assay	PPG-CUH-PAT-437 PPG-CUH-PAT-436
1030 Haematology - .55 Iron studies	Serum Ferritin ¹²³⁴	Serum sample	Chemiluminescent immunoassay	Dxl 800	CE Marked Assay	PPG-CUH-PAT-501
1030 Haematology - .57 Screening test for infectious mononucleosis	Clearview IM Screening Test for Infectious Mononucleosis ¹²³⁴	EDTA	Heterophile Antibody	Alere IM II Kit	CE Marked Assay	PPG-CUH-PAT-480
1030 Haematology - .58 Vitamin B12 and folate (serum and red cell)	Serum Folate ¹²³⁴	Serum sample	Chemiluminescent immunoassay	Dxl 800	CE Marked Assay	PPG-CUH-PAT-501
	Serum Vitamin B12** ¹²³⁴		Chemiluminescent immunoassay	Dxl 800	CE Marked Assay	PPG-CUH-PAT-501
1030 Haematology - .70 Immunophenotyping	Cell Surface Markers ¹²³⁴ CD2, CD3, CD4,CD5, CD7, CD8, CD10, CD11b, CD11c, CD13, CD14, CD15, CD16, CD19, CD20, CD22, CD23,CD25,CD27,CD28, CD33, CD34, CD35, CD36, CD38, CD42a CD43,CD45, CD56, CD57, CD61, CD64, CD71, CD79b,CD81,, CD103, CD105, CD117,CD200, CD203, CD138, CD235a, CD300 CD305,B2M, HLADR, Kappa, Lambda, IgM, TCR a/b, TCR g/d ¹²³⁴	Whole Blood in EDTA or Bone Marrow in EDTA/RPMI	Flow Cytometry	FACS Lyse Wash Assistant (LWA) FACS Lyric, FACS Duet	CE Marked Assay	PPG-CUH-PAT-496 PPG-CUH-PAT-499 PPG-CUH-PAT-1975 PPG-CUH-PAT-1973

	Intracellular Markers ¹²³⁴ cyCD3, cyCD79a, cyIgM, TdT, MPO, Kappa, Lambda ¹²³⁴ CD4 Assay ¹²³⁴ CD3/8/45/4 ¹²³⁴					
	Enumeration of CD34 cells ¹²³⁴	Whole Blood in EDTA	Flow Cytometry	FACS Lyric	CE Marked Assay	PPG-CUH-PAT- 1973
	Multiset Immune Monitoring CD3, CD4, CD8, CD19, CD16/56 ¹²³⁴ CD4 Assay ¹²³⁴ CD3/8/45/4 ¹²³⁴		Flow Cytometry	FACS Duet, FACS Lyric,	CE Marked Assay	PPG-CUH-PAT- 499 PPG-CUH-PAT- 1975 PPG-CUH-PAT- 1973
1030 Haematology - .80 Molecular genetic studies	Factor V Leiden and Prothrombin gene mutation**3,4	Whole Blood in EDTA – DNA extracted	PCR	Cobas 480, PCR /MagNA Pure 24 (new MagNA Pure 24 analyser)	CE Marked Assay	PPG-CUH-PAT- 1572 PPG-CUH-PAT- 1247 PPG-CUH-PAT- 1570
1030 Haematology - .99 Miscellaneous tests	Hb A1c ¹²³⁴	Whole Blood in EDTA	High Performance Liquid Chromatography HPLC	Tosoh G8 (new Tosoh G8 analyser)	CE Marked Assay	PPG-CUH-PAT- 451 PPG-CUH-PAT- 452
	Intrinsic factor antibody ¹²³⁴	Serum sample	Chemiluminescent immunoassay	Dxl 800	CE Marked Assay	PPG-CUH-PAT- 501
	Pregnancy test ¹²³⁴	Urine	Chromographic Immunoassay	Alere HCG Cassette	CE Marked Assay	PPG-CUH-PAT- 456

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

Head Office

Haematology

Category: B

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 - .99 Miscellaneous tests	HbA1c	Whole Blood	Latex agglutinaion/spectrophotometry	DCA Vantage/ 4-130 mmol/L	CE Marked Assay	PPG-CUH-PAT-5030
	POC HbA1c**1234		Inhibition of latex agglutination/spectrophotometry	DCA Vantage/4-130 mmol/l	CE Marked Assay	PPG-CUH-PAT-5030
<p><i>The laboratory is accredited for a flexible scope of testing in the following categories</i></p> <p>1 Range of measurement may be extended</p> <p>2 Parameters may be added</p> <p>3 Test matrices may be added</p> <p>4 Equipment/kit</p>						

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	Coverslipping	Stained slides	Automated & Manual Automated coverslipper	Based on standard method	Qualitative test	PPG-CUH-PAT-622
	Cut up	Human Tissue	Manual (Knives, scalpels, dyes etc)	Based on standard method	Qualitative test	PPG-CUH-PAT-565 PPG-CUH-PAT-1118 PPG-CUH-PAT-552 PPG-CUH-PAT-600 PPG-CUH-PAT-684 PPG-CUH-PAT-685 PPG-CUH-PAT-642 PPG-CUH-PAT-918 PPG-CUH-PAT-949 PPG-CUH-PAT-690 PPG-CUH-PAT-691 PPG-CUH-PAT-1102 PPG-CUH-PAT-1108
	Embedding	Paraffin infiltrated	Embedding Centre & Cold Plate Manual	Based on standard method	Qualitative test	PPG-CUH-PAT-569
	H & E Staining **Change to Haematoxylin and Eosin reagents In addition new stainer in Neuropathology	Paraffin wax tissue sections	Staining machine Automated	Based on standard method	Qualitative test	PPG-CUH-PAT-622 PPG-CUH-PAT-989

	Microtomy	Paraffin wax blocks	Semi-automated microtome	Based on standard method	Qualitative test	PPG-CUH-PAT-590
	Muscle biopsy	Muscle	Manual Cryostat Microtome Stainer Bond III	Based on standard method	Qualitative test	PPG-CUH-PAT-951
	Nerve biopsy	Nerve	Manual Cryostat Microtome Stainer Fluorescent Microscope Electron Microscope Bond III	Based on standard method	Qualitative test	PPG-CUH-PAT-952
	Tissue processing	Formalin fixed	Automated Vacuum Infiltration Processor	Based on standard method	Qualitative test	PPG-CUH-PAT-626
1051 Histopathology - .02 Processing fresh specimens for frozen section examination	Frozen section/smear **Change to Haematoxylin and Eosin reagents	Human Tissue	Cryostat Cryotomy	Based on standard method	Qualitative test	PPG-CUH-PAT-576
1051 Histopathology - .03 Histochemistry	6. Immunohistochemistry**24: Bond Polymer Refine Detection Kit**24	Human Tissue	Immunostaining Bond III	CE	Qualitative test	PPG-CUH-PAT-926
	7. Immunohistochemistry**24: Dako Envision Detection Kit**24		Manual Immunostaining PT Module	CE	Qualitative test	PPG-CUH-PAT-926
	AFB/ZN* *New counterstain; change from Green to Blue	Glass slides – tissue sections & smears	Dako Artisan™ Link Pro Special Staining system	CE Marked	Qualitative test	PPG-CUH-PAT-622
	Alcian Blue/PAS		Dako Artisan™ Link Pro Special Staining system	CE Marked	Qualitative test	PPG-CUH-PAT-622
	Biebrich Scarlet		Manual	Standard Method	Qualitative test	PPG-CUH-PAT-622
	Congo Red		Manual	Standard Method	Qualitative test	PPG-CUH-PAT-622

Elastic Van Gieson (EVG)		Manual	Standard Method	Qualitative test	PPG-CUH-PAT-622
Gallyas		Manual	Standard Method	Qualitative test	PPG-CUH-PAT-989
Gram		Manual	Standard Method	Qualitative test	PPG-CUH-PAT-989
Grocott's Methenamine Silver		Dako Artisan™ Link Pro Special Staining system	CE Marked	Qualitative test	PPG-CUH-PAT-622
H&E **Change to Haematoxylin and Eosin reagents		Manual	Standard Method	Qualitative test	PPG-CUH-PAT-622
Haematoxylin Van Gieson (HVG)		Manual	Standard Method	Qualitative test	PPG-CUH-PAT-989
Immunohistochemistry Antibodies**24 AE1-3 , AFP, ALK NSCLC , Alk1, AMACR/P504S, AMACR/P63/34βE12 , Arginase , β-Catenin, BCL-2, BCL-6 , BER-4, BOB-1 , BRAF, CA IX, Caldesmon, Calcitonin, Calretinin, CAM 5.2 CD1a , CD3, CD4, CD5, CD7, CD8, CD10, CD15 , CD20, CD21 CD23, CD30, CD31 , CD34, CD43, CD45/CLA, CD56, CD57, CD68, CD79a, CD99 CD117/C-KIT, CD138, CDX2, CEA Poly , Chromogranin A, CK 5/6, CK7 , CK19 , CK20, CMV, c-myc, CYCLIN D1 , D2-40 / Podoplanin, DESMIN , Dog-1 EBER/EBV, EMA, E-Cad, ER, ERG, GATA 3, Glycophorin A,	0.05 Immunocytochemistry Human Tissue Non-gynae cytology Immunohistochemistry: ICC on Cell Blocks and cytocentrifuged samples.	Automated Ventanna Benchmark Ultra Immunostainer	CE	Qualitative test	PPG-CUH-PAT-665

Glypican-3, Granzyme B HEPAR 1, HCG, HER2, HER2 DDISH , H Pylori , HMB45 Inhibin, IgG4 , Ki-67, Ki- 67/Melan-A Mel A, Mel tri-cocktail, MNF 116, MOC31 Mum 1, MPO , Myogenin, Napsin, OCT2, OCT4 P16, P40, P40/TTF1, P57, P53 , P63, P63/CK5/6, Parvovirus, PAX5, PAX8, PD1, PD-L1, Perforin, PLAP, PR, Prostein / P501S, PSA, RCC , SMA, Synapto, S100 , TDT, Thyroglobulin, TTF-1 , WT1 Vimentin , SOX 10, SOX 11, Uroplakin, 34βE12					
Immunohistochemistry*** ²⁴ Detection Kit: 1. Optiview 2. Ultraview 3. Ultraview Red Alkaline phosphatase 4. IView Blue ISH 5. (a) Ultraview Red ISH DIG (b) Ultraview SISH DNP	Human Tissue/Glass slides	Immunostaining Insitu Hybridisation Ventana Ultra	CE	Qualitative test	PPG-CUH-PAT- 669 PPG-CUH-PAT- 580 PPG-CUH-PAT- 680
LFB-Cresyl Violet	Glass slides – tissue sections & smears	Manual	Standard Method	Qualitative test	PPG-CUH-PAT- 989
Luxol Fast Blue(LFB)-H&E		Manual	Standard Method	Qualitative test	PPG-CUH-PAT- 989
Martius Scarlet Blue (MSB)		Manual	Standard Method	Qualitative test	PPG-CUH-PAT- 622
Masson Fontana		Manual	Standard Method	Qualitative test	PPG-CUH-PAT- 622
Masson Trichrome		Manual	Standard Method	Qualitative test	PPG-CUH-PAT- 622

Masson's Trichrome		Dako Artisan™ Link Pro Special Staining system	CE Marked	Qualitative test	PPG-CUH-PAT-622
Muscle stains: ATP 4.2 ATP 4.6 ATP 10.2 Myophosphorylase Cytochrome oxidase Succinic dehydrogenase Myoadenylate deaminase NADH PFK	Fresh Muscle Tissue	Manual Oven	Based on standard method	Qualitative test	PPG-CUH-PAT-988
Oil Red O	Glass slides – tissue sections & smears	Manual	Standard Method	Qualitative test	PPG-CUH-PAT-989
PAS/DPAS		Manual	Standard Method	Qualitative test	PPG-CUH-PAT-989
PASD (Diastase)		Dako Artisan™ Link Pro Special Staining system	CE Marked	Qualitative test	PPG-CUH-PAT-622
Periodic Acid Methenamine Silver (PAM)		Manual	Standard Method	Qualitative test	PPG-CUH-PAT-622
Periodic Acid Schiff (PAS)		Dako Artisan™ Link Pro Special Staining system	CE Marked	Qualitative test	PPG-CUH-PAT-622
Perl's		Dako Artisan™ Link Pro Special Staining system	CE Marked	Qualitative test	PPG-CUH-PAT-622
Rapid Giemsa		Manual	Standard Method	Qualitative test	PPG-CUH-PAT-622
Reticulin		Dako Artisan™ Link Pro Special Staining system	CE Marked	Qualitative test	PPG-CUH-PAT-622
Solochrome cyanine		Manual	Standard Method	Qualitative test	PPG-CUH-PAT-989
Toluidine Blue		Manual	Standard Method	Qualitative test	PPG-CUH-PAT-989
Von Kossa		Manual	Standard Method	Qualitative test	PPG-CUH-PAT-622

	Warthin Starry		Dako Artisan™ Link Pro Special Staining system	CE Marked	Qualitative test	PPG-CUH-PAT-622
1051 Histopathology - .035 Histological Interpretation	Diagnostic Interpretation and reporting of Human tissue specimens Specialist areas excluded: Paediatric Pathology Specialist areas included: (Added as demonstration of EQA participation is presented)	Stained glass slides – Tissue sections	H&E - Special Stains - ICC	Based on standard method	Qualitative test	PPG-CUH-PAT-602
1051 Histopathology - .04 Histological interpretation-medical renal pathology	Histological Interpretation-Medical Renal Pathology	Stained slides Stained ultrathin sections	Manual Diagnostic Interpretation and reporting	Based on standard method	Qualitative test	PPG-CUH-PAT-602
1051 Histopathology - .06 Histological interpretation-perinatal pathology	Perinatal Pathology: Placentas Products of conception Ectopic pregnancies	Stained glass slides – Tissue sections	H&E - Special Stains - ICC	Based on standard method	Qualitative test	PPG-CUH-PAT-602
1051 Histopathology - .07 Histological interpretation-neuropathology	Neuropathology specimens		H&E - Special Stains - ICC	Based on standard method	Qualitative test	PPG-CUH-PAT-602
1051 Histopathology - .08 Histological interpretation-breast screening pathology (Breastcheck programme)	Breast Specimens		H&E - Special Stains - ICC - ISH	Based on standard method	Qualitative test	PPG-CUH-PAT-602
1051 Histopathology - .09 Immunohistochemistry	Immunohistochemistry Antibodies**24 AE1-3 AFP ALK NSCLC Alk1 AMACR/P504S AMACR/P63/34βE12 Arginase β-Catenin BCL-2 BCL-6	Human Tissue	Immunostaining Ventana Benchmark Ultra Immunostainer	CE	Qualitative test	PPG-CUH-PAT-669 PPG-CUH-PAT-580 PPG-CUH-PAT-926

BER-4 BOB-1 BRAF Caldesmon Calcitonin Calretinin CAM 5.2 Carbonic Anhydrase IX Cathepsin K CD1a CD3 CD4 CD5 CD7 CD8 CD10 CD15 CD20 CD21 CD23 CD30 CD31 CD34 CD43 CD45/CLA CD56 CD57 CD68 CD79a CD99 CD117/C-KIT CD138 CDX2 CEA Poly Chromogranin A CK 5/6 CK7 CK19 CK20 C-MYC CMV CYCLIN D1 D2-40 / Podoplanin					
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	DESMIN Dog-1 EBER/EBV EMA E-Cad ER ERG FOX-L2 GATA 3 Glycophorin A Glypican-3 Granzyme B HEPAR 1 HCG HER2 HER2 DDISH HHV-8 H Pylori HMB45 Inhibin IgG4 Ki-67 Ki-67/Melan-A Lysozyme, Mel A Mel tri-cocktail MLH1 MMR/MSH6 MMR/PMS2 MNF 116 MOC31 Mum 1 MPO MSH2 Myogenin Napsin NKX3.1 OCT2 OCT4 P16 P40 P40/TTF1 P57 P53					
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	<p>P63 P63/CK5/6 PAX5 PAX8 Parvovirus PD1 PD-L1 Perforin PLAP PR PRAME Prostein /P501S PSA RCC Sars CoV-2 SMA Synapto S100 TDT Thyroglobulin TTF-1 Uroplakin II WT1 Vimentin SOX 10 SOX 11 34βE12</p>					
	<p>Immunohistochemistry Neuropathology Markers**24: Alpha-synuclein,, ATRX, B- Amyoid (A4), Brachyury, B- APP, C5b-9, GFAP , H3K27M, H3K27me3, HSV 1, IDH1, INI1, MAP2 , MHC1, MBP, Measles, Myosin (fast), Myosin (slow) Myosin (neonatal) , Nestin, NeuN, NF (52/2F11), Olig 2, PHH3, P62, SV40, Tau- AT8, Tau (RD3), Tau (RD4), TDP-Phosphorylated, Toxoplasma, Dystrophin1 ,</p>		<p>Immunostaining Ventana Ultra Bond III</p>	<p>CE</p>	<p>Qualitative test</p>	<p>PPG-CUH-PAT- 669 PPG-CUH-PAT- 580 PPG-CUH-PAT- 926</p>

	Dystrophin2, Dystrophin 3, Alpha-sarcoglycan, Beta-sarcoglycan, Gamma-sarcoglycan, Dystroglycan, Dysferlin, Merosin, Spectrin, Caveolin3, Collagen VI, Emerin, Lamin A/C, Alpha-subunit, ACTH, TSH, GH, PRO, LH, FSH , GH, SF1, TPIT, Pit-1					
1051 Histopathology - .11 Chromogenic / bright-field in situ hybridisation	Chromogenic in situ hybridisation method**24 List of probes specific to each laboratory EBER Her-2 DDISH Kappa Lambda/λ		Immunostaining Ventana Ultra	CE	Qualitative test	PPG-CUH-PAT-669 PPG-CUH-PAT-580 PPG-CUH-PAT-680
1051 Histopathology - .12 Electron microscopy	Electron Microscopy: Preparation and Cut up Fixation and Processing Microtomy and Staining EM Diagnostic Interpretation		Manual Ultramicrotomy Manual Staining Electron Microscopy Rotator, Fumehood Fridge 60°oven Ultramicrotome Fumehood Electron Microscope	Based on standard method	Qualitative test	PPG-CUH-PAT-570 PPG-CUH-PAT-571 PPG-CUH-PAT-568 PPG-CUH-PAT-600
1051 Histopathology - .13 Molecular testing	Assay for Somatic Variants in DNA sequences**24		Idylla Cobas KRAS, NRAS, EGFR, BRAF. ALK, ROS, RET, MET	CE	Qualitative test	PPG-CUH-PAT-1101 PPG-CUH-PAT-1103 PPG-CUH-PAT-1104
	MSI (PCR Assay)**24	FFPE Tissue	"Biocartis Idylla DNA extraction and PCR method for MSI"	CE marked assay	Qualitative test	PPG-CUH-PAT-1101 PPG-CUH-PAT-1103
	NGS Sequencing	FFPE Tissue and Plasma	Genexus Ion Torrent Next Generation Sequencer	Standard Method	n/a	PPG-CUH-PAT-1121

1051 Histopathology - .14 Detection of immune complexes in body fluids and biopsy material	Direct Immunofluorescence for skin, renal and nerve biopsies: IgG-FITC, IgA-FITC, IgM-FITC, C3-FITC, C1q-FITC, Kappa-FITC, Lambda-FITC, Fibrin-FITC	Human Tissue	Direct Immuno- fluorescence, Fluorescent microscope	Standard Method	Qualitative method	PPG-CUH-PAT-687
	Direct Immunofluorescence for skin, renal and nerve biopsies: IgG-FITC, IgG4-FITC IgA-FITC, IgM-FITC, C3-FITC, C1q-FITC, Kappa-FITC, Lambda-FITC, Fibrin-FITC Indirect Immunofluorescence: C4d, FITC secondary antibody (polyclonal rabbit anti mouse)		Direct Immuno- fluorescence, Fluorescent microscope Indirect Immuno- fluorescence	Standard Method	Qualitative method	PPG-CUH-PAT-687
	Direct Immunofluorescence for skin, renal and nerve biopsies: Poly-FITC, IgG-FITC, IgG4-FITC, IgA-FITC, IgM-FITC, C3-FITC, C1q-FITC, Kappa-FITC, Lambda-FITC, Fibrin-FITC		Direct Immuno- fluorescence, Fluorescent microscope	Standard Method	Qualitative method	PPG-CUH-PAT-687

	Indirect Immunofluorescence: C4d, FITC secondary antibody (polyclonal rabbit anti mouse)		Indirect Immunofluorescence			
	Paraneoplastic screen**24 (to include new Ravo PNS-14 kit)	Serum	Manual Indirect immunofluorescence & Immunoblot	Standard Method	Qualitative method	PPG-CUH-PAT-901
1052 Cytopathology - .02 Non gynaecological cytology	Cytopathology, Non-gynae cytology: Preparation	Joint fluids, Respiratory, FNA, Serous Fluids, Urines, CSF, Other fluids, Cell Blocks	LBC Cyto centrifugation Direct Smear Thin Prep 2000 Stat spin Cytocentrifuge	Based on standard method	Qualitative test	PPG-CUH-PAT-37 PPG-CUH-PAT-665 PPG-CUH-PAT-664 PPG-CUH-PAT-689 PPG-CUH-PAT-923
	Non-gynae cytology: Coverslipping		Automated Acetate Sakura Tissue Tek Film Coverslipper	Based on standard method	Qualitative test	PPG-CUH-PAT-622
	Non-gynae cytology: Staining PAP and Giemsa Special Stains ICC **Change to Haematoxylin reagent for PAP stain		Manual & Automated staining Manual Giemsa (Rapid) Leica Autostainer (PAP)	Based on standard method	Qualitative test	PPG-CUH-PAT-622 PPG-CUH-PAT-580
1052 Cytopathology - .04 Cytopathological interpretation	Non-gynae cytology: Cytological interpretation		Microscopic & word processing APEX LIMS	Based on standard method	Qualitative test	PPG-CUH-602

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

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)	Microscopic examination of General bacteriology ¹²³⁴	Urine Sputum Brocheoalveolar Lavage Swabs Abscess and pus specimens Tissues and biopsies Intravascular cannulae and associated specimens Normally sterile body fluids Bone and associated soft tissue Prosthetic joint specimens Aqueous and vitreous humour, corneal scrapings Antral washout, sinus aspirate, sinus washout Aspirates from: Bartholin's gland Fallopian tube Tubo-ovarian abscess Pouch of Douglas fluid Intra-uterine contraceptive device	Light/ Fluorescent microscope	Based on standard method	Qualitative test	PPG-CUH-PAT-776 PPG-CUH-PAT-759 PPG-CUH-PAT-750 PPG-CUH-PAT-751 PPG-CUH-PAT-753 PPG-CUH-PAT-754 PPG-CUH-PAT-707 PPG-CUH-PAT-709 PPG-CUH-PAT-706

		(IUCD) Semen Blood Cultures Bone Marrow CSF CSF Shunts Peritoneal Dialysis Fluid				
	Urine Microscopy automated**234	Urine	UF5000/ Flow cytometry for automated urine microscopy	CE Marked Assay	WCC,RCC <20 to >1000 per ul. Semi-quantitative for Bacteria, Yeast, Casts and Epithelial Cells	PPG-CUH-PAT-776
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 of Parasites ¹²³⁴	Faeces Duodenal aspirates Sellotape slides Aspirates Worm/ larvae, Urine	Light/ Fluorescent microscope	Based on standard method	Qualitative test	PPG-CUH-PAT-725
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 of Fungi ¹²³⁴	Hair, Nail, Skin	Light/ Fluorescent microscope	Based on standard method	Qualitative test	PPG-CUH-PAT-761
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	Microscopic examination of Mycobacteria **234	Sputum, Brochoalveolar Lavage /Bronchial washings, Blood or bone marrow, CSF, body fluids, aspirates, pus, Skin / tissue biopsy / post-mortem specimens, Sputum, Urine	Light/ Fluorescent microscope	Based on standard method	Qualitative test	PPG-CUH-PAT-766
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for	Culture of General Bacteria ¹²³⁴	Urine Sputum Brochoalveolar Lavage	Bactec FX blood culture instrument, Culture media	Based on standard method	Qualitative test	PPG-CUH-PAT-776 PPG-CUH-PAT-759 PPG-CUH-PAT-750 PPG-CUH-PAT-751

<p>growth - .01 Culture of general bacteria</p>		<p>Swabs Abscess and pus specimens Tissues and biopsies Intravascular cannulae and associated specimens Normally sterile body fluids Bone and associated soft tissue Prosthetic joint specimens Aqueous and vitreous humour, corneal scrapings Antral washout, sinus aspirate, sinus washout Aspirates from: Bartholin's gland Fallopian tube Tubo-ovarian abscess Pouch of Douglas fluid Intra-uterine contraceptive device (IUCD) Semen Blood Cultures Sterile Fluids Bone Marrow CSF CSF Shunts Peritoneal Dialysis Fluid Faeces</p>				<p>PPG-CUH-PAT-753 PPG-CUH-PAT-754 PPG-CUH-PAT-707 PPG-CUH-PAT-709 PPG-CUH-PAT-706 PPG-CUH-PAT-721</p>
	<p>Microscopic examination of General bacteriology¹²³⁴</p>		<p>Bactec FX blood culture instrument, Culture media</p>	<p>Based on standard method</p>	<p>Qualitative test</p>	<p>PPG-CUH-PAT-776 PPG-CUH-PAT-759 PPG-CUH-PAT-750 PPG-CUH-PAT-751 PPG-CUH-PAT-753 PPG-CUH-PAT-754</p>

						PPG-CUH-PAT-707 PPG-CUH-PAT-709 PPG-CUH-PAT-706 PPG-CUH-PAT-721
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 ¹²³⁴	Urine Sputum Brocheoalveolar Lavage Swabs Abscess and pus specimens Tissues and biopsies Intravascular cannulae and associated specimens Normally sterile body fluids Bone and associated soft tissue Prosthetic joint specimens Aqueous and vitreous humour, corneal scrapings Antral washout, sinus aspirate, sinus washout Aspirates from: Bartholin's gland Fallopian tube Tubo-ovarian abscess Pouch of Douglas fluid Intra-uterine contraceptive device (IUCD) Semen Blood Cultures Sterile Fluids Bone Marrow CSF	Bactec FX blood culture instrument, Culture media	Based on standard method	Qualitative test	PPG-CUH-PAT-776 PPG-CUH-PAT-759 PPG-CUH-PAT-750 PPG-CUH-PAT-751 PPG-CUH-PAT-753 PPG-CUH-PAT-754 PPG-CUH-PAT-707 PPG-CUH-PAT-709 PPG-CUH-PAT-706 PPG-CUH-PAT-761

		CSF Shunts Peritoneal Dialysis Fluid Hair, Nail, Skin				
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .03 Culture of mycobacteria	Culture of Mycobacteria **234	BAL/Bronchial washings, Blood or bone marrow, CSF, body fluids, aspirates, pus, Gastric lavage fluid, Laryngeal swabs / Other swabs, Skin / tissue biopsy / post-mortem specimens, Sputum, Urine	MB/ BacT Alert Bactec FX MB/ BacT Alert liquid media (update to formula) Solid media (RGM)	Based on standard method CE marked Media	Qualitative test	PPG-CUH-PAT-764 PPG-CUH-PAT-766 PPG-CUH-PAT-707
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods,	Coris RESIST-5 O.K.NVI**234	Isolate	Immunochromatography	CE Marked assay	Qualitative test	PPG-CUH-PAT-843
	Detection of Rotavirus and Adenovirus Antigens in Faecal Samples ¹²³⁴	Faeces	Immunochromatographic Kit	CE marked assay	Qualitative test	PPG-CUH-PAT-726
	Legionella Urinary Antigen ¹²³⁴	Urine	Immunochromatographic Kit	CE marked assay	Qualitative test	PPG-CUH-PAT-832
	TBCheck MPT64 **234	bacteria grown in liquid medium	MPT64 kit cartridge Immunochromatographic method	CE marked assay	Qualitative test	PPG-CUH-PAT-1956
	Urinary Pneumococcal Antigen ¹²³⁴	Urine	Immunochromatographic Kit	CE marked assay	Qualitative test	PPG-CUH-PAT-832
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .01 Nucleic acid probe hybridization, CE marked commercial systems	ePlex® Respiratory Pathogen Panel 2 (RP2) **234	Nose and/or Throat swabs in VTM, UTM or equivalent	GenMark ePlex® system	CE marked assay	Qualitative test	PPG-CUH-PAT-3059

1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Biofire® FilmArray® Meningitis/Encephalitis panel **234	CSF	FilmArray Torch	CE Marked assay	Qualitative test	PPG-CUH-PAT-3047
	Biofire® FilmArray® Respiratory panel**234	Nose and/or Throat swabs in VTM, UTM or equivalent	Biofire Film Array Torch	CE Marked assay	Qualitative test	PPG-CUH-PAT-3047
	Cepheid GeneXpert® system MTB/RIF Ultra**234	sputum samples or concentrated sediments from induced or expectorated sputum	Cepheid GeneXpert® DX system Real time PCR platform	CE marked assay	Qualitative test	PPG-CUH-PAT-718
	GeneXpert® Real time PCR for Influenza A, Influenza B,RSV and SARS CoV-2**234	Swab or NPA	Cepheid GeneXpert® DX system Real time PCR platform	CE marked assay	Qualitative test	PPG-CUH-PAT-718
	GeneXpert® Real time PCR for Xpert® Carba-R**234	Rectal swab or Isolate	Cepheid GeneXpert® DX system Real time PCR platform	CE marked assay	Qualitative test	PPG-CUH-PAT-718
	Real Time PCR for Chlamydia trachomatis**234	Urine Endocervical Swab High Vaginal Swab	Real Time PCR Roche Cobas 4800	CE marked assay	Qualitative test	PPG-CUH-PAT-738
	Real Time PCR for Influenza A, Influenza B, Metapneumovirus, RSV**234	Nose or Throat swabs (Virocult), Nasopharyngeal aspirates, Bronchoalveolar lavage and Sputum	Real Time PCR Magna Pure 24 Cobas 480Z Module	CE marked assay	Qualitative test	PPG-CUH-PAT-1951 PPG-CUH-PAT-1955
	Real Time PCR for Investigation of Faeces Specimens for Astrovirus **234	Faeces	Real Time PCR EntericBio Detection System epmotion 5070 instrument LightCycler® 480 Real-time PCR system	CE Marked assay	Qualitative test	PPG-CUH-PAT-719

Real Time PCR for Investigation of Faeces Specimens for Clostridium difficile**234		EntericBio Detection System epmotion 5070 instrument LightCycler® 480 Real-time PCR system	CE marked assay	Qualitative test	PPG-CUH-PAT-719
		Real Time PCR GeneXpert	CE Marked assay	Qualitative test	PPG-CUH-PAT-718
		EntericBio Detection System epmotion 5070 instrument LightCycler® 480 Real-time PCR system	CE marked assay	Qualitative test	PPG-CUH-PAT-719
		Real Time PCR GeneXpert	CE Marked assay	Qualitative test	PPG-CUH-PAT-718
Real Time PCR for Investigation of Faeces Specimens for Norovirus**234		EntericBio Detection System epmotion 5070 instrument LightCycler® 480 Real-time PCR system	CE marked assay	Qualitative test	PPG-CUH-PAT-719
		Real Time PCR GeneXpert	CE Marked assay	Qualitative test	PPG-CUH-PAT-718
Real Time PCR for Investigation of Faeces Specimens for Salmonella, Shigella, Campylobacter sp, VTEC, and Cryptosporidium parvum/hominis Giardia**234		EntericBio Detection System Epmotion 5070 instrument LightCycler® 480 Real-time PCR system	CE marked assay	Qualitative test	PPG-CUH-PAT-719
Real Time PCR for Neisseria gonorrhoeae**234	Urine Endocervical Swab High Vaginal Swab	Real Time PCR Roche Cobas 4800 Cepheid GeneXpert®Dx System	CE marked assay	Qualitative test	PPG-CUH-PAT-738 PPG-CUH-PAT-718

	Real Time PCR for SARS-CoV-2**234	Nasopharangeal swab,Throat swab	Real time PCR Cobas 6800, MagNA Pure 24 System and LC 480 Light cycler,	CE Marked assay	Qualitative test	PPG-CUH-PAT-4001 PPG-CUH-PAT-1951 PPG-CUH-PAT-1955 PPG-CUH-PAT-1958 PPG-CUH-PAT-1960
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	Identification of Cultured Bacteria and Fungi 1234	Liquid culture medium Isolates from culture medium	Biochemical Characterisation kits	Based on standard method	Qualitative test	PPG-CUH-PAT-859 PPG-CUH-PAT-843
	MAST Uriplus **1234	Urine	MAST Uriplus imagind analyser MAST Uriwell multipoint inoculator MAST Uriplus direct culture identification using biochemical substrates/ chromogenic agar	CE marked assay	No growth, no significant growth or Significant growth with organism identification and susceptibility	PPG-CUH-PAT-3032
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .03 Identification of fungi by microscopic morphology	Identification of Cultured Fungi 1234	Liquid culture medium Isolates from culture medium	Biochemical Characterisation kits	Based on standard method	Qualitative test	PPG-CUH-PAT-761 PPG-CUH-PAT-859 PPG-CUH-PAT-843 PPG-CUH-PAT-865
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy	Identification of Cultured Bacteria 234 (including Mycobacteria)		Mass Spectrometry Bruker Maldi-tof Optimised for Mycobacteria	Based on standard method	Qualitative test	PPG-CUH-PAT-859 PPG-CUH-PAT-843 PPG-CUH-PAT-865
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly	Aerobes, Anaerobes 1234		Qualitative susceptibility testing bioMerieux VITEK 2XL Biomic Manual	Based on standard method	Qualitative test	PPG-CUH-PAT-860 PPG-CUH-PAT-869 PPG-CUH-PAT-864

growing aerobes) - .01 Anaerobes						
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .02 Mycobacteria	Mycobacteria **234		Rifampicin Qualitative susceptibility testing	Based on standard method	Qualitative test	PPG-CUH-PAT-718
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts	Sensititre yeast susceptibility testing **234	Isolate	Broth Microdilution	CE marked assay	Qualitative test	PPG-CUH-PAT-860
	Yeasts 1234	Liquid culture medium Isolates from culture medium	Qualitative susceptibility testing bioMerieux VITEK 2XL Manual	Based on standard method	Qualitative test	PPG-CUH-PAT-860 PPG-CUH-PAT-869
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .05 Other categories of organism (as specified)	MAST Uriplus **1234	Urine	MAST Uriplus imagind analyser MAST Uriwell multipoint inoculator MAST Uriplus breakpoint susceptibility testing.	CE marked assay	No growth, no significant growth or Significant growth with organism identification and susceptibility	PPG-CUH-PAT-3032
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .01 Particle agglutination, using CE marked commercial systems	Anti-Streptolysin (ASO) Latex Agglutination Slide Test 1234	Serum	Particle Agglutination Kit	CE marked assay	Qualitative test	PPG-CUH-PAT-832

	Syphilis Rapid Plasma Reagin (RPR) and Treponema pallidum Particle Agglutination (TPPA) Tests ¹²³⁴	Manual Particle Agglutination (TPPA, RPR)	CE marked assay	Qualitative test	PPG-CUH-PAT-832
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .07 Chemiluminescent microparticle immunoassay, using CE marked commercial systems	Antibodies to Hepatitis B e Antigen (Anti-HBeAg) Assay ¹²³⁴	Architect Chemiluminescent Immunoassay	CE marked assay	Qualitative test	PPG-CUH-PAT-1960
	Antibodies to Hepatitis B Surface Antigen (Anti-HBs) Assay ¹²³⁴	Architect Chemiluminescent Immunoassay	CE marked assay	0 to 1,000 mIU/mL	PPG-CUH-PAT-1960
	Borrelia Burdorferi IgM (Lyme)** ¹²³⁴	Liaison XL Chemiluminescent Immunoassay	CE Marked assay	Qualitative test	PPG-CUH-PAT-1959
	Borrelia Burgdorferi IgG (Lyme) ¹²³⁴	Liaison XL Chemiluminescent Immunoassay	CE marked assay	Qualitative test	PPG-CUH-PAT-1959
	Cytomegalovirus IgG Assay ¹²³⁴	Architect Chemiluminescent Immunoassay	CE marked assay	Qualitative test	PPG-CUH-PAT-1960
	Cytomegalovirus IgM Assay ¹²³⁴	Architect Chemiluminescent Immunoassay	CE marked assay	Qualitative test	PPG-CUH-PAT-1960
	Epstein-Barr Virus VCA IgM Assay ¹²³⁴	Architect Chemiluminescent Immunoassay	CE marked assay	Qualitative test	PPG-CUH-PAT-1960
	Hepatitis A Virus IgG Assay ¹²³⁴	Architect Chemiluminescent Immunoassay	CE marked assay	Qualitative test	PPG-CUH-PAT-1960
	Hepatitis A Virus IgM Assay ¹²³⁴	Architect Chemiluminescent Immunoassay	CE marked assay	Qualitative test	PPG-CUH-PAT-1960

Hepatitis B Core Total Antibody ¹²³⁴ Assay	Architect Chemi-luminescent Immunoassay	CE marked assay	Qualitative test	PPG-CUH-PAT-1960
Hepatitis B e Antigen (HBeAg) ¹²³⁴ Assay	Architect Chemi-luminescent Immunoassay	CE marked assay	Qualitative test	PPG-CUH-PAT-1960
Hepatitis B Surface Antigen (HBsAg) Assay ¹²³⁴	Architect Chemi-luminescent Immunoassay	CE marked assay	Qualitative test	PPG-CUH-PAT-1960
Hepatitis C Virus Antibody (Anti-HCV) Assay ¹²³⁴	Architect Chemi-luminescent Immunoassay	CE marked assay	Qualitative test	PPG-CUH-PAT-1960
Hepatitis C Virus Antigen (HCV Ag) Assay ¹²³⁴	Architect Chemi-luminescent Immunoassay	CE marked assay	Qualitative test	PPG-CUH-PAT-1960
HIV Ag/Ab Combo Assay ¹²³⁴	Architect Chemi-luminescent Immunoassay	CE marked assay	Qualitative test	PPG-CUH-PAT-1960
Measles IgG ^{**1234}	Liaison Chemiluminiscent Immunoassay	CE Marked assay	Qualitative test	PPG-CUH-PAT-1959
Mumps IgG ^{**1234}	Liaison Chemiluminiscent Immunoassay	CE Marked assay	Qualitative test	PPG-CUH-PAT-1959
Parvovirus IgG ^{**1234}	Liaison Chemiluminiscent Immunoassay	CE Marked Assay	Qualitative assay	PPG-CUH-PAT-1959
Parvovirus IgM ^{**1234}	Liaison Chemiluminiscent Immunoassay	CE Marked assay	Qualitative test	PPG-CUH-PAT-1959
Rubella IgG Assay ¹²³⁴	Architect Chemi-luminescent Immunoassay	CE marked assay	0 to 500 IU/mL	PPG-CUH-PAT-1960
Rubella IgM Assay ¹²³⁴	Architect Chemi-luminescent Immunoassay	CE marked assay	Qualitative test	PPG-CUH-PAT-1960
Syphilis Total Antibody Assay ¹²³⁴	Architect Chemi-luminescent	CE marked assay	Qualitative test	PPG-CUH-PAT-1960

			Immunoassay			
	Toxoplasma IgG Assay ¹²³⁴		Architect Chemi-luminescent Immunoassay	CE marked assay	Qualitative test	PPG-CUH-PAT-1960
	Toxoplasma IgM Assay ¹²³⁴		Architect Chemi-luminescent Immunoassay	CE marked assay	Qualitative test	PPG-CUH-PAT-1960
	Varicella-zoster Virus IgG ¹²³⁴		Liaison XL Chemi-luminescent Immunoassay	CE marked assay	Qualitative test	PPG-CUH-PAT-1959
1029 Miscellaneous - .99 Miscellaneous tests	Amikacin Assay ¹²³⁴		Cobas c311 KIMS	CE marked assay	0.8 to 40.0 mg/L	PPG-CUH-PAT-821
	Gentamicin Assay ¹²³⁴		Cobas c311 KIMS	CE marked assay	0.4 to 10.0 mg/L	PPG-CUH-PAT-821
	Tobramycin Assay ¹²³⁴		Cobas c311 KIMS	CE marked assay	0.33 to 10.0 mg/L	PPG-CUH-PAT-821
	Vancomycin Assay ¹²³⁴		Cobas c311 KIMS	CE marked assay	4.0 to 80.0 mg/L	PPG-CUH-PAT-821

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*

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.

Head Office

Microbiology and Virology

Category: B

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
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	SARS-CoV-2, influenza A and influenza B ^{**1234}	Nasopharyngeal swab	Roche Cobas LIAT/ RT-PCR	CE Marked Assay	Qualitative test	PPG-CUH-PAT-5009
<p><i>The laboratory is accredited for a flexible scope of testing in the following categories</i></p> <p><i>1 Range of measurement may be extended</i></p> <p><i>2 Parameters may be added</i></p> <p><i>3 Test matrices may be added</i></p> <p><i>4 Equipment/kit</i></p> <p><i>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.</i></p>						