

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	ISO 15189
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	IFCC with PNPP	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Albumin ¹²³⁴	Plasma/Serum /Urine	Bromocresol Green Turbidimetry (Urines)	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Alkaline Phosphatase ¹²³⁴	Plasma/Serum	IFCC	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Ammonia ¹²³⁴	Plasma	Enzymatic	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Amylase ¹²³⁴	Plasma/Serum /Urine	IFCC	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Angiotensin converting enzyme ¹²³⁴	Serum	FAPGG	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Aspartate aminotransferase (AST) ¹²³⁴	Plasma/Serum	IFCC	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Bicarbonate ¹²³⁴		Enzymatic	AU General	CE Marked Assay	PPG-CUH-PAT-121

			Chemistry Analyser		
Bile Acids ¹²³⁴	Serum	Enzymatic	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
Calcium ¹²³⁴	Plasma/Serum /Urine	Colorimetric	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
Calculated globulin	Serum	Calculation	Calculation	Based on Standard Method	INS-CUH-PAT-126
Chloride ¹²³⁴	Plasma/Serum /Urine	Indirect ISE	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
Cholesterol ¹²³⁴	Plasma/Serum	Enzymatic	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
Creatinine Kinase (CK) ¹²³⁴		IFCC	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
Creatinine ¹²³⁴		Enzymatic	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
Direct Bilirubin ¹²³⁴		Diazo	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
Gamma-glutamyl transpeptidase (GGT) ¹²³⁴		IFCC	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
Glucose (Fasting/Random) ¹²³⁴	Plasma	Enzymatic	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
HDL Cholesterol ¹²³⁴	Plasma/Serum	Enzymatic	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
Lactate Dehydrogenase (LDH) ¹²³⁴		IFCC	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
Lactate ¹²³⁴	Plasma	Enzymatic	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
LDL-Cholesterol ¹²³⁴	Plasma/Serum	Calculated	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
Magnesium ¹²³⁴	Plasma/Serum /Urine	Colorimetric	AU General Chemistry Analyser	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	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
Potassium ¹²³⁴		Indirect ISE	AU General	CE Marked Assay	PPG-CUH-PAT-1420

				Chemistry Analyser		
	Sodium ¹²³⁴		Indirect ISE	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Total Bilirubin ¹²³⁴	Plasma/Serum	Diazo Method	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Total Protein ¹²³⁴		Colorimetric	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Triglyceride ¹²³⁴		GPO-PAP	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Urate ¹²³⁴	Plasma/Serum /Urine	Enzymatic	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Urea ¹²³⁴		Enzymatic	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Urinary Protein ¹²³⁴	Urine	Pyrogallol Red	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	A1-Antitrypsin ¹²³⁴	Serum	Immunoturbidimetric	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Anti-Thyroid Peroxidase Ab's ¹²³⁴		CMIA	Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263
	Ceruloplasmin ¹²³⁴		Immunoturbidimetric	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	C-Reactive Protein ¹²³⁴	Plasma/Serum	Immunoturbidimetric	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Free Kappa Light Chains ¹²	Serum	Nephelometric	BNII Nephelometer	CE Marked Assay	PPG-CUH-PAT-269
	Free Kappa Light Chains ¹²⁴		Nephelometric	BNII Nephelometer	CE Marked Assay	PPG-CUH-PAT-269
	Free Lambda Light Chains ¹²⁴		Nephelometric	BNII Nephelometer	CE Marked Assay	PPG-CUH-PAT-269
	Haptoglobin ¹²³⁴		Immunoturbidimetric	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Insulin-like Growth Factor 1 ¹²³⁴		Immunoassay	IDS-isys	CE Marked Assay	PPG-CUH-PAT-265
	Procalcitonin**1,2,3,4		Immunoassay	Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263
Troponin I (hs) ¹²³⁴ -		CMIA	Abbott ARCHITECT®	CE Marked Assay	PPG-CUH-PAT-263	

	please delete this scope edit; there is no change			i2000SR/i4000 SR System		
1061 Clinical Chemistry - .03 Proteins, qualitative and semiquantitative analysis	Bence-Jones Protein ¹²	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-223
	Protein Electrophoresis ¹²³⁴		Electrophoresis	Sebia Capillarys III	CE Marked Assay	PPG-CUH-PAT-1403
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Carbamazepine ¹²³⁴		Enzymatic	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Cyclosporin ¹²³⁴	Whole Blood	CMIA	Architect i 1000 System	CE Marked Assay	PPG-CUH-PAT-263
	Digoxin ¹²³⁴	Serum	Enzymatic	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Lithium ¹²³⁴		Colorimetric	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Methotrexate ¹²³⁴		CMIA	Architect i 1000 System	CE Marked Assay	PPG-CUH-PAT-263
	Paracetamol ¹²³⁴		Enzymatic	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Phenobarbitone ¹²³⁴		Enzymatic	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Phenytoin ¹²³⁴		Enzymatic	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Tacrolimus ¹²³⁴	Whole Blood	CMIA	Architect i 1000 System	CE Marked Assay	PPG-CUH-PAT-263
	Theophylline ¹²³⁴	Serum	Enzymatic	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Valproate ¹²³⁴		Enzymatic	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
1061 Clinical Chemistry - .14 Alcohol for non-legal purposes	Alcohol ¹²³⁴	Serum/Urine	Enzymatic	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Salicylate (Serum) ¹²³⁴	Serum	Enzymatic	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420

1061 Clinical Chemistry - .20 Hormones	Cortisol ¹²³⁴		CMIA	Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263
	Follicle-stimulating hormone (FSH) ¹²³⁴		CMIA	Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263
	Free T3 ¹²³⁴		CMIA	Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263
	Free T4 ¹²³⁴		CMIA	Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263
	Growth Hormone ¹²³⁴		CMIA	IDS-isys	CE Marked Assay	PPG-CUH-PAT-265
	Luteinizing hormone (LH) ¹²³⁴		CMIA	Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263
	Oestradiol ¹²³⁴		CMIA	Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263
	Parathyroid hormone (PTH) ¹²³⁴	EDTA-Plasma	CMIA	Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263
	Progesterone ¹²³⁴	Serum	CMIA	Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263
	Prolactin ¹²³⁴		CMIA	Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263
Sex Hormone-Binding Globulin ¹²³⁴	CMIA		Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263	
Testosterone ¹²³⁴	CMIA		Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263	
Thyroid-stimulating hormone (TSH) ¹²³⁴	CMIA		Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263	
1061 Clinical Chemistry - .40 Iron studies	Iron ¹²³⁴		Ferrazine	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Transferrin ¹²³⁴		Immunoturbid- imetric	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420

1061 Clinical Chemistry - .47 Vitamin assays	Vitamin D ¹²³⁴		CMIA	Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-206
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Alphafetaprotein ¹²³⁴		CMIA	Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263
	Ca125 ¹²³⁴		CMIA	Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263
	Ca15-3 ¹²³⁴		CMIA	Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263
	Ca19-9 ¹²³⁴		CMIA	Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263
	Carcinoembryonic Antigen (CEA) ¹²³⁴		CMIA	Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263
	Human chorionic gondadotropin ¹²³⁴		CMIA	Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263
	PSA (Total) ¹²³⁴		CMIA	Abbott ARCHITECT® i2000SR/i4000 SR System	CE Marked Assay	PPG-CUH-PAT-263
1061 Clinical Chemistry - .80 Quantitative investigation of immunoglobulins G, A, M and in body fluids	IgA ¹²³⁴		Immunoturbidimetric	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	IgG ¹²³⁴		Immunoturbidimetric	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	IgM ¹²³⁴		Immunoturbidimetric	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
1061 Clinical Chemistry - .86 C3 and C4	Complement C3 ¹²³⁴		Immunoturbidimetric	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
	Complement C4 ¹²³⁴		Immunoturbidimetric	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
1061 Clinical Chemistry - .99 Miscellaneous tests	%Iron Saturation		Calculated Parameter	n/a	Based on Standard Method	INS-CUH-PAT-126
	24 Hour Urinary Amylase	Urine	Calculated Parameter	n/a	Based on Standard Method	INS-CUH-PAT-126

24 Hour Urinary Magnesium		Calculated Parameter	n/a	Based on Standard Method	INS-CUH-PAT-126
24 Hour Urinary Phosphate		Calculated Parameter	n/a	Based on Standard Method	INS-CUH-PAT-126
24 Urinary Urea		Calculated Parameter	n/a	Based on Standard Method	INS-CUH-PAT-126
24hr Urinary Calcium		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
24hr Urinary Chloride		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
24HR Urinary Creatinine		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
24hr Urinary Microalbumin		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
24hr Urinary Potassium		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
24hr Urinary Protein		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
24hr Urinary Sodium		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
24hr Urinary Urate		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
Adjusted Calcium	Serum	Calculated Parameter	n/a	Based on Standard Method	INS-CUH-PAT-126
Amy:Creat Clearance Ratio	Urine	Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
Androgen Index	Serum	Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
Ca:Creat Clearance Ration	Urine/Serum	Calculated Parameter	n/a	Annals of Clinical Biochemistry 2004; 41:441-458	INS-CUH-PAT-126
Calcium Excretion		Calculated Parameter	n/a	Annals of Clinical Biochemistry 2004; 41:441-458	INS-CUH-PAT-126
Corrected Calcium	Serum	Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
Creatinine Clearance	Urine/Serum	Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
CSF Glucose ¹²⁴	CSF	Enzymatic	AU General	CE Marked Assay	PPG-CUH-PAT-1420

			Chemistry Analyser		
CSF Lactate ¹²⁴		Enzymatic	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
CSF Total Protein ¹²⁴		Pyrogallol Red	AU General Chemistry Analyser	CE Marked Assay	PPG-CUH-PAT-1420
eGFR Female	Serum	Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
Estimated GFR		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
Kappa: Lambda Ratio		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
LDL Calculation		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
Microalbumin Creatinine Ratio	Urine	Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
Ur.Protein /Creat. ratio		Calculated Parameter	n/a	Based on standard method	INS-CUH-PAT-126
UTP:Creat Ratio		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

Category: B

Medical pathology field - Test	Test/assay	Specimen Type	Technique	Equipment/Range of Measurement	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1061 Clinical Chemistry - .05 CO-oximetry	COHb	Whole Blood taken into Heparinised Blood Gas Syringe /Capillary	Siemens RP500 /CO-Oximetry	CE Marked Assay	0 - 100%	PPG-CUH-PAT-5006
	Hb		Siemens RP500 /CO-Oximetry	CE Marked Assay	5 - 20.63 g/dl	PPG-CUH-PAT-5006
	HHb		Siemens RP500 /CO-Oximetry	CE Marked Assay	0 - 100%	PPG-CUH-PAT-5006
	MetHb		Siemens RP500 /CO-Oximetry	CE Marked Assay	0 - 100%	PPG-CUH-PAT-5006
	O2 Saturation (Blood Gas)		Siemens RP500 /CO-Oximetry	CE Marked Assay	0 - 100%	PPG-CUH-PAT-5006
	O ² Hb		Siemens RP500 /CO-Oximetry	CE Marked Assay	0 - 100%	PPG-CUH-PAT-5006
	SO ²		Siemens RP500 /CO-Oximetry	CE Marked Assay	0 - 100%	PPG-CUH-PAT-5006
1061 Clinical Chemistry - .06 Blood pH and gas tensions	H+		Siemens RP500, Siemens RL1240 /Potentiometry	CE Marked Assay	196.663 - 20.543 nmol/L	PPG-CUH-PAT-5006
	pCO2		Siemens RP500, Siemens RL1240 /Potentiometry	CE Marked Assay	2.277 - 19.157 kPa	PPG-CUH-PAT-5006
	pH		Siemens RP500, Siemens RL1240 /Potentiometry	CE Marked Assay	6.709 - 7.688 pH units	PPG-CUH-PAT-5006
	pO2		Siemens RP500, Siemens RL1240 /Amperometry	CE Marked Assay	6.977 - 60.743 kPa	PPG-CUH-PAT-5006
1061 Clinical Chemistry - .07 Other analytes	Chloride		Siemens RP500 /Direct ISE	CE Marked Assay	72 - 125 mmol/L	PPG-CUH-PAT-5006

performed on a blood gas analyser						
	Glucose		Siemens RP500 /Amperometry	CE Marked Assay	1.47 - 35.8 mmol/L	PPG-CUH-PAT-5006
	Ionized Calcium		Siemens RP500 /Potentiometry	CE Marked Assay	0.537 - 2.883 mmol/L	PPG-CUH-PAT-5006
	Lactate		Siemens RP500 /Amperometry	CE Marked Assay	0.553 - 17.14 mmol/L	PPG-CUH-PAT-5006
	Neonatal Bilirubin		Siemens RP500 /Potentiometry	CE Marked Assay	34 - 403.7 umol/L	PPG-CUH-PAT-5006
	Potassium		Siemens RP500/Direct ISE	CE Marked Assay	1.496 - 11.163 mmol/L	PPG-CUH-PAT-5006
	Sodium		Siemens RP500 /Direct ISE	CE Marked Assay	111.93 - 164.3 mmol/L	PPG-CUH-PAT-5006

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	Technique	Range of Measurement/Equipment	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1030 Haematology - .01 Blood counts	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	Starrsed 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	Examination for malaria parasites ¹²³⁴	Whole Blood in EDTA	May Grunwald and Giemsa manual	Manual and Binax NOW Malaria Ag Screen	CE Marked Assay	PPG-CUH-PAT-477 PPG-CUH-

parasites			staining and Kits	CareStart Ag Screen		PAT-478 PPG-CUH-PAT-1981	
	Malaria**3,4	Whole blood EDTA	PCR	Alethia PCR bench top analyser	CE Marked Assay	PPG-CUH-PAT-1980	
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 KitHYDRASYS System Tosoh G8	CE Marked Assay	PPG-CUH-PAT-458 PPG-CUH-PAT-457 PPG-CUH-PAT-453	
			High Performance Liquid Chromatography HPLC				
			Acid elution	Manual			Based on a standard method
1030 Haematology - .31 Tests for foetal Hb (Kleihauer)	Foetal cells (Acid Elution) ¹²³⁴						
1030 Haematology - .36 Screening tests for G6Pd	G6PD screen ¹²³⁴ G6PD assay ¹²³⁴		Fluorescence spot test Ultraviolet, kinetic determination of G6PDH	UV Lamp Spectrophotometer CAMSPEC-M550	CE Marked Assay	PPG-CUH-PAT-454 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-425 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
	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-425 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
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 Intracellular Markers ¹²³⁴ cyCD3, cyCD79a, cyIgM, TdT, MPO, Kappa, Lambda ¹²³⁴ CD4 Assay ¹²³⁴ CD3/8/45/4 ¹²³⁴	Whole Blood in EDTA or Bone Marrow in EDTA/RPMI	Flow Cytometry	FACS Lyse Wash Assistant (LWA) FACS Calibur, FACS Lyric, FACS Duet	CE Marked Assay	PPG-CUH-PAT-491 PPG-CUH-PAT-492 PPG-CUH-PAT-493 PPG-CUH-PAT-499 PPG-CUH-PAT-494 PPG-CUH-PAT-497 PPG-CUH-PAT-500 PPG-CUH-PAT-1973
	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		Flow Cytometry	FACS Duet, FACS Lyric, FACS Calibur	CE Marked Assay	PPG-CUH-PAT-491 PPG-CUH-PAT-492 PPG-CUH-PAT-497

	CD3/8/45/4 ¹²³⁴					PPG-CUH-PAT-498 PPG-CUH-PAT-499 PPG-CUH-PAT-500 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	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	CE Marked Assay	PPG-CUH-PAT-451 PPG-CUH-PAT-452
	Intrinsic factor antibody ¹²³⁴	Serum sample	Chemiluminescent immunoassay	DxI 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

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
	Embedding	Paraffin infiltrated	Embedding Centre & Cold Plate Manual	Based on standard method	Qualitative test	PPG-CUH-PAT-569 PPG-CUH-PAT-655
	H & E Staining	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 Bondmax	Based on standard method	Qualitative test	PPG-CUH-PAT-951
	Nerve biopsy	Nerve	Manual Cryostat Microtome	Based on standard method	Qualitative test	PPG-CUH-PAT-952

			Stainer Fluorescent Microscope Electron Microscope Bondmax			
	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	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 Bondmax	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
	Immunohistochemistry**24 Detection Kit: 1. Optiview 2. Ultraview 3. Ultraview Red Alkaline hosphatase 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
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	
Non-gynae cytology Immunohistochemistry: ICC on Cell Blocks and cytocentrifuged samples.	Human Tissue	Immunohistochemistry Antibodies ¹²³⁴ AE1-3 , AFP, ALK NSCLC , Alk1, AMACR/P504S,	CE	Qualitative test	PPG-CUH-PAT-665	

			<p>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, CD45RO/UCHL-1, 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, 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 , MDM2,, MNF 116, MOC31 Mum 1, MPO , Myogenin, Napsin, NSE, OCT2, OCT4 P16, P40, P40/TTF1, P57, P53 , P63, P63/CK5/6, Parvovirus, PAX5, PAX8, PD1, PD- L1, Perforin</p>		
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			PCP, PLAP, PR, Prostein / P501S, PSA, PSAP RCC , SMA, Synapto, S100 , TDT, Thyroglobulin, TTF-1 , WT1 Vimentin , SOX 10, SOX 11, Uroplakin, 34βE12			
	<p>Special Stains: Artisan: AFB/ZN, Alcian Blue/PAS, Congo Red , Elastic stain, Grocott's Methenamine Silver , Perl's Masson's Trichrome, PAS , PASD (Diastase), Reticulin,</p> <p>Manual Methods: H & E Biebrich Scarlet Congo Red Rapid Giemsa MSB Masson Fontana Masson Trichrome PAM Toluidine Blue Von Kossa Elastic Van Gieson Gallyas Gram HVG LFB-H&E LFB-Cresyl violet Oil Red O PAS/DPAS Solochrome cyanine Gomori trichrome stain</p>	Glass slides – tissue sections & smears	Automated Artisan	Based on standard method	Qualitative test	PPG-CUH-PAT-622 PPG-CUH-PAT-989
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	Stained glass slides – Tissue sections	H&E - Special Stains - ICC	Based on standard method	Qualitative test	PPG-CUH-PAT-602

	EQA participation is presented)					
1051 Histopathology - .04 Histological interpretation- medical renal pathology	Renal Pathology: Neoplastic Non-neoplastic		H&E - Special Stains - ICC	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 , 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, CD45RO/UCHL-1, CD56, CD57, CD68, CD79a, CD99 CD117/C-KIT, CD138, CDX2, CEA Poly , Chromogranin A, CK 5/6, CK7 , CK19 , CK20, C- MYC,, CMV, CMYC, CYCLIN D1 , D2-40 / Podoplanin, DESMIN , Dog- 1 EBER/EBV, EMA, E-Cad, ER, ERG, FOX-L2, GATA 3, Glycophorin A, Glypican-3, Granzyme B HEPAR 1,	Human Tissue	Immunostaining Ventana Ultra	CE	Qualitative test	PPG-CUH-PAT-669 PPG-CUH-PAT-580 PPG-CUH-PAT-926

	<p>HCG, HER2, HER2 DDISH , H Pylori , HMB45 Inhibin, IgG4 , Ki-67, Ki-67/Melan-A, Lysozyme, Mel A, Mel tri-cocktail , MDM2, MLH1 MMR/MSH6, MMR/PMS2, MNF 116, MOC31 Mum 1, MPO, MSH2 , Myogenin, Napsin, NKX3.1, NSE, OCT2, OCT4 P16, P40, P40/TTF1, P57, P53 , P63, P63/CK5/6, PAX5, PAX8, Parvovirus, PD1, PD-L1, Perforin PCP, PLAP, PR, PRAME, Prostein / P501S, PSA, PSAP RCC ,Sara CoV-2, SMA, Synapto, S100 , TDT, Thyroglobulin, TTF-1 , Uroplakin II, WT1 Vimentin , SOX 10, SOX 11, 34βE12</p> <p>*****Note re flexible scope: In addition BCL-2 (raw material improvement change) and Inhibin (Clone change). Negative control slides were removed for ER, PR, and HER-2 for each case (replaced with a single control for each run instead)</p>					
	<p>Immunohistochemistry Neuropathology Markers**24: Alpha-synuclein,, ATRX, B-Amyoid, A4), Brachyury, B-APP, C5b-9, FUS , GFAP , H3K27M, HIV (P24), HSV 1, IDH1, INI1 , MAP2 , MHC1, MBP, Measles, Myosin (fast), Myosin (slow) Myosin (neonatal) , Nestin, NeuN, NF (52/2F11), Olig 2, PHH3, Pre-albumin/ Transthyretin, P62, SV40, Tau-AT8, Tau (RD3), Tau</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>

	(RD4), TDP-Phosphorylated, Toxoplasma, Dystrophin1 , 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 ***** Note re flexible scope: New antibodies to Toxoplasma, MAP2 and H3K27M were optimised in 2021.					
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.	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		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: Poly-FITC, 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)	Human Tissue	Direct Immuno- fluorescence, Fluorescent microscope	Standard Method	Qualitative method	PPG-CUH-PAT-687
			Indirect Immuno- fluorescenece			
				Direct Immuno- fluorescence, Fluorescent microscope Indirect Immuno- fluorescenece	Standard Method	Qualitative method
	Paraneoplastic screen	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 Cytocentrifugation Direct Smear Thin Prep 2000 Statspin 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-564
	Non-gynae cytology: Staining PAP and Giemsa Special Stains ICC		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

Head Office

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 (IUCD) Semen Blood Cultures	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

		Bone Marrow CSF CSF Shunts Peritoneal Dialysis Fluid				
			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
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
			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	Microscopic examination of Mycobacteria ^{**2,3,4}	Brocheoalveolar Lavage /Bronchial washings, Blood or bone	Light/ Fluorescent microscope	Based on standard method	Qualitative test	PPG-CUH-PAT-766

staining with dyes as required - .04 Microscopic examination for mycobacteria		marrow, CSF, body fluids, aspirates, pus, Gastric lavage fluid, Laryngeal swabs / Other swabs, Skin / tissue biopsy / post-mortem specimens, Sputum, Urine				
		Sputum, Brocheoalveolar 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 growth - .01 Culture of general bacteria	Culture of General Bacteria 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	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-721

		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				
	Microscopic examination of General bacteriology ¹²³⁴		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-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 Brochoealveolar 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	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

		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 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 **2,3,4	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 test	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.NV**2,3,4	Isolate	Immunochromatography	Ce Marked assay	Qualitative test	PPG-CUH-PAT-843
	Detection of Respiratory Syncytial Virus (RSV) Antigen <small>1234</small>	Nasopharyngeal Aspirate	Immunochromatographic Kit	CE marked assay	Qualitative test	PPG-CUH-PAT-832

	Detection of Rotavirus and Adenovirus Antigens in Faecal Samples ¹²³⁴	Faeces	Immunochromographic Kit	CE marked assay	Qualitative test	PPG-CUH-PAT-726
	Legionella Urinary Antigen ¹²³⁴	Urine	Immunochromographic Kit	CE marked assay	Qualitative test	PPG-CUH-PAT-832
	TBCheck MPT64 ^{**2,3,4}	bacteria grown in liquid medium	MPT64 kit cartridge Immunochromatographic method	CE marked assay	Qualitative test	PPG-CUH-PAT-1956
	Urinary Pneumococcal Antigen ¹²³⁴	Urine	Immunochromographic 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)	Nose and/or Throat swabs in VTM, UTM or equivalent	GenMark ePlex® system	CE marked	n/a	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 ^{**2,3,4}	CSF	FilmArray v2.0	Ce Marked assay	Qualitative test	PPG-CUH-PAT-3047
	Biofire® FilmArray® Respiratory panel ^{**2,3,4}	Nose and/or Throat swabs in VTM, UTM or equivalent	Film Array Biofire Film Array Torch	Ce Marked assay	Qualitative test	PPG-CUH-PAT-3047
	Cepheid GeneXpert® system MTB/RIF Ultra ^{**2,3,4}	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 ^{**2,3,4}	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 ^{**2,3,4}	Rectal swab or Isolate	Cepheid GeneXpert® DX system Real time PCR platform	CE marked assay	Qualitative test	PPG-CUH-PAT-718
	Investigation of Specimens for Mycobacterium	Liquid culture medium Isolates from culture medium	Hain GenoType system	CE marked assay	Qualitative test	PPG-CUH-PAT-772

Molecular Identification **2,3,4					
Real Time PCR for Chlamydia trachomatis**2,3,4	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**2,3,4	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 **2,3,4	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**2,3,4		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**2,3,4		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*2,3,4		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**2,3,4	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**2,3,4	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	Identification of	Liquid culture medium	Biochemical	Based on standard	Qualitative test	PPG-CUH-PAT-761

cultured bacteria and fungi using non-nucleic acid based techniques - .03 Identification of fungi by microscopic morphology	Cultured Fungi ¹²³⁴	Isolates from culture medium	Characterisation kits	method		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 growing aerobes) - .01 Anaerobes	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
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .02 Mycobacteria	Mycobacteria**2,3,4		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	Yeasts ¹²³⁴		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

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	Serum	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 Chemi-luminescent 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

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>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>						