



# Scope of Accreditation

## Mercy University Hospital

### Blood Transfusion Science

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1020 Transfusion science - .01 Blood grouping including ABO, Rh(D) and other antigens by manual methods	ABO & Rh(D) typing	Whole Blood	Autovue Innova and Diamed Micro Typing Systems Autovue Innova and Diamed Micro Typing Systems	Automatic, Column Agglutination test, Tube		LP-BB-101 ABO and RhD grouping combined with reverse ABO grouping by Diamed Micro typing Systems LP-BB-200, Procedure for performing ABO/RhD groups, Kell types, antibody screens and compatibility tests on the Autovue Innova LP-BB-116, ABO and RhD grouping by tube technique
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screen	Plasma	Autovue Innova and Diamed Micro Typing Systemss	Automatic, Column Agglutination test, Tube		LP-BB-103, Antibody Screening using the Diamed Micro Typing Systems LP-BB-200, Procedure for performing ABO/RhD groups, Kell types, antibody screens and compatibility tests on the Autovue Innova
1020 Transfusion science - .04 Identification of	Antibody Identification		Diamed Micro Typing Systems	Column Agglutination test,		LP-BB-104, Antibody

blood group antibodies						investigation
1020 Transfusion science - .05 Cross match compatible donor units	Compatibility Testing (IAT)	Plasma Serum	Diamed Micro Typing Systems	Column Agglutination test,		LP-BB-110, Compatibility Testing, LP-BB-117, Transfusion Reaction Investigation
1020 Transfusion science - .06 Red cell phenotyping	Red cell phenotyping	Red cells	Diamed Micro Typing Systems	Column Agglutination test, Tube		LP-BB-109, Antigen typing of donor units and patient samples
1020 Transfusion science - .99 Miscellaneous tests	Direct Coombs Test		Diamed Micro Typing Systems	Column Agglutination test		LP-BB-115, performing a DCT and investigation of a positive DCT

*Note: Mercy University Hospital, Blood Transfusion Department, Grenville Plc, Cork has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (S.I. No 360 of 2005 and S.I. No 547 of 2006).*

Chemical Pathology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Technique	Equipment/Range of Measurement	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1061 Clinical Chemistry - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies	Adjusted Calcium <sup>**1,2,3,4</sup>	Serum/ Lithium Heparin	Architect C8000	CE	0.5 – 6mmol/L	LP-BIO-103 Procedure for analysing samples on the Architect and reporting Biochemistry tests in the event of LIS downtime.
	Alanine aminotransferase (ALT) <sup>**1,2,3,4</sup>		Architect C8000	NADH (without P-5'-P)	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Architect c8000	
	Alkaline Phosphatase (ALP) <sup>**1,2,3,4</sup>		Architect C8000	Para-nitro phenylphosphate	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Architect c8000	
	Amylase <sup>**1,2,3,4</sup>		Architect C8000	CNPG3 substrate	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Architect c8000	
	Aspartate Amino Transferase (AST) <sup>**1,2,3,4</sup>		Architect C8000	NADH (without P-5'-P)	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Architect c8000	
	Bilirubin Total			Architect C8000	Diazonium salt	LP-BIO-101

**1,2,3,4			Procedure for c8000 chemistries LP-BIO-102 Operation and maintenance of the Architect c8000
Calcium **1,2,3,4	Architect C8000	Arsenazo III	LP-BIO-101 Procedure for c8000 chemistries LP-BIO-102 Operation and maintenance of the Architect c8000
Carbamazepine **1,2,3,4	Architect C8000	Enzyme immunoassay	LP-BIO-101 Procedure for c8000 chemistries LP-BIO-102 Operation and maintenance of the Architect c8000
Chloride **1,2,3,4	Architect C8000	Ion selective electrode diluted (indirect)	LP-BIO-101 Procedure for c8000 chemistries LP-BIO-102 Operation and maintenance of the Architect c8000
Cholesterol **1,2,3,4	Architect C8000	Enzymatic	LP-BIO-101 Procedure for c8000 chemistries LP-BIO-102 Operation and maintenance of the Architect c8000
Creatine Kinase (CK) **1,2,3,4	Architect C8000	NAC (N-acetyl-L-cysteine)	LP-BIO-101 Procedure for c8000 chemistries LP-BIO-102 Operation and maintenance of the Architect c8000
Creatinine	Architect C8000	Kinetic alkaline picrate	LP-BIO-101

**1,2,3,4					Procedure for c8000 chemistries LP-BIO-102 Operation and maintenance of the Architect c8000
Digoxin **1,2,3,4			Architect C8000	Particle enhanced turbidimetric inhibition immunoassay (PETINIA)	LP-BIO-101 Procedure for c8000 chemistries LP-BIO-102 Operation and maintenance of the Architect c8000
Faecal CalProtectin **1,2,3,4		Architect C8000	CE	20-1922 µg/gram	LP-BIO-316 Procedure for calprotectin
Gamma Glutamyl Transferase (GGT) **1,2,3,4			Architect C8000	L-gamma-glutamyl-3-carboxy-4-nitroanilide substrate	LP-BIO-101 Procedure for c8000 chemistries LP-BIO-102 Operation and maintenance of the Architect c8000
Glucose **1,2,3,4	CSF/Fluoride oxalate		Architect C8000	Hexokinase/G-6-PDH	LP-BIO-101 Procedure for c8000 chemistries LP-BIO-102 Operation and maintenance of the Architect c8000
High density Lipoprotein (HDL) **1,2,3,4	Serum/ Lithium Heparin		Architect C8000	Accelerator selective detergent	LP-BIO-101 Procedure for c8000 chemistries LP-BIO-102 Operation and maintenance of the Architect c8000
Lactate Dehydrogenase (LDH) **1,2,3,4			Architect C8000	IFCC recommended forward reaction lactate→pyruvate	LP-BIO-101 Procedure for c8000 chemistries LP-BIO-102 Operation and maintenance of the Architect

					tect c8000
Lithium **1,2,3,4	Serum		Architect C8000	Colormetric	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi tect c8000
Magnesium **1,2,3,4	Serum/ Lithium Heparin		Architect C8000	Enzymatic	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi tect c8000
Osmolality **1,2,3,4	Serum/Urine		Advanced Instruments Model 3320 Osmometer	Freezing Point Depression	LP-BIO-17 Procedure for the Operation and Maintenance of the Advanced Micro- Osmometer Model 3320
Phenytoin **1,2,3,4	Serum/ Lithium Heparin		Architect C8000	Enzyme immunoassay	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi tect c8000
Phosphate- inorganic **1,2,3,4			Architect C8000	Phosphomolybdate	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi tect c8000
Potassium **1,2,3,4			Architect C8000	Iron selective electrode, diluted (indirect)	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi tect c8000

PSA **1,2,3,4		Architect C8000	CE	0.008 – 100ng/ml	LP-BIO-104 Procedure for Outlining the Analytical Details of i2000SR Assays
Sodium **1,2,3,4	Serum/ Lithium Heparin		Architect C8000	Ion selective electrode diluted (indirect)	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi tect c8000
Theophylline **1,2,3,4			Architect C8000	Enzyme immunoassay	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi tect c8000
Triglyceride **1,2,3,4			Architect C8000	Glycerol phosphate oxidase	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi tect c8000
Troponin I hs **1,2,3,4		EDTA plasma		Abbott Architect I2000	Chemiluminescent Microparticle immunoassay
Urea **1,2,3,4	Serum/ Lithium Heparin		Architect C8000	Urease	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi



					tect c8000
Uric acid **1,2,3,4			Architect C8000	Uricase	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi tect c8000
Urinary amylase **1,2,3,4	Urine		Architect C8000	CNPG3 substrate	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi tect c8000
Urinary calcium **1,2,3,4			Architect C8000	Arsenazo III	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi tect c8000
Urinary creatine **1,2,3,4			Architect C8000	Kinetic alkaline Picrate	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi tect c8000
Urinary phosphate **1,2,3,4			Architect C8000	Phosphomolybdate	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi tect c8000
Urinary potassium **1,2,3,4			Architect C8000	Ion selective electrode diluted (indirect)	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi

						tect c8000
	Urinary sodium **1,2,3,4			Architect C8000	Ion selective electrode diluted (indirect)	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi tect c8000
	Urinary urea **1,2,3,4			Architect C8000	Urease	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi tect c8000
	Urinary uric acid **1,2,3,4			Architect C8000	Uricase	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi tect c8000
	Valproate **1,2,3,4	Serum/ Lithium Heparin		Architect C8000	Particle enhanced turbidimetric inhibition immunoassay (PETINIA)	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi tect c8000
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	AFP **1,2,3,4	Blood/ Serum		Abbott Architect	Chemiluminescent microparticle immunoassay	P-BIO-104 Procedure for Outlining the Analytical Details of i2000SR Assays  LP-BIO-105 Procedure for the Operation and Maintenance of the Architect i2000SR
	Albumin **1,2,3,4	Serum/ Lithium Heparin		Architect C8000	Bromocressol purple	LP-BIO-101 Procedure for c8000 chemistries

					LP-BIO-102 Operation and maintenance of the Architect c8000
BHCG **1,2,3,4	Blood/Serum		Abbott Architect	Chemiluminescent microparticle immunoassay	LP-BIO-104 Procedure for Outlining the Analytical Details of i2000SR Assays  LP-BIO-105 Procedure for the Operation and Maintenance of the Architect i2000SR
BNP (Brain natriuretic peptide) **1,2,3,4	EDTA plasma		Abbott Architect	Chemiluminescent microparticle immunoassay	P-BIO-104 Procedure for Outlining the Analytical Details of i2000SR Assays  LP-BIO-105 Procedure for the Operation and Maintenance of the Architect i2000SR
CA125 **1,2,3,4	Blood/Serum		Abbott Architect	Chemiluminescent microparticle immunoassay	P-BIO-104 Procedure for Outlining the Analytical Details of i2000SR Assays  LP-BIO-105 Procedure for the Operation and Maintenance of the Architect i2000SR
CA19.9 **1,2,3,4			Abbott Architect	Chemiluminescent microparticle immunoassay	P-BIO-104 Procedure for Outlining the Analytical Details of i2000SR Assays  LP-BIO-105 Procedure for the Operation and Maintenance of the Architect i2000SR

					Maintenance of the Architect i2000SR
CEA **1,2,3,4			Abbott Architect	Chemiluminescent microparticle immunoassay	LP-BIO-104 Procedure for Outlining the Analytical Details of i2000SR Assays  LP-BIO-105 Procedure for the Operation and Maintenance of the Architect i2000SR
Cortisol **1,2,3,4			Abbott Architect	Chemiluminescent microparticle immunoassay	P-BIO-104 Procedure for Outlining the Analytical Details of i2000SR Assays  LP-BIO-105 Procedure for the Operation and Maintenance of the Architect i2000SR
CRP **1,2,3,4	Serum/ Lithium Heparin		Architect C8000	Turbidimetric/immunoturbidimetric	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Architect c8000
FSH **1,2,3,4	Blood/Serum		Abbott Architect	Chemiluminescent microparticle immunoassay	LP-BIO-104 Procedure for Outlining the Analytical Details of i2000SR Assays  LP-BIO-105 Procedure for the Operation and Maintenance of the Architect i2000SR
FT4 **1,2,3,4			Abbott Architect	Chemiluminescent microparticle immunoassay	LP-BIO-104 Procedure for Outlining the

					Analytical Details of i2000SR Assays LP-BIO-105 Procedure for the Operation and Maintenance of the Architect i2000SR
IgA **1,2,3,4	Serum/ Lithium Heparin		Architect C8000	Immunoturbidimetric	LP-BIO-101 Procedure for c8000 chemistries LP-BIO-102 Operation and maintenance of the Architect c8000
IgG **1,2,3,4			Architect C8000	Immunoturbidimetric	LP-BIO-101 Procedure for c8000 chemistries LP-BIO-102 Operation and maintenance of the Architect c8000
IgM **1,2,3,4			Architect C8000	Immunoturbidimetric	LP-BIO-101 Procedure for c8000 chemistries LP-BIO-102 Operation and maintenance of the Architect c8000
Protein-total **1,2,3,4			Architect C8000	Biuret	LP-BIO-101 Procedure for c8000 chemistries LP-BIO-102 Operation and maintenance of the Architect c8000
Total PSA	Blood/ Serum		Abbott Architect	Chemiluminescent microparticle immunoassay	P-BIO-104 Procedure for Outlining the Analytical Details of i2000SR Assays LP-BIO-105

						Procedure for the Operation and Maintenance of the Architect i2000SR
	Troponin **1,2,3,4			Abbott Architect	Chemiluminescent microparticle immunoassay	P-BIO-104 Procedure for Outlining the Analytical Details of i2000SR Assays  LP-BIO-105 Procedure for the Operation and Maintenance of the Architect i2000SR
	TSH **1,2,3,4			Abbott Architect	Chemiluminescent microparticle immunoassay	P-BIO-104 Procedure for Outlining the Analytical Details of i2000SR Assays  LP-BIO-105 Procedure for the Operation and Maintenance of the Architect i2000SR
	Urinary CSF/protein **1,2,3,4	Urine/CSF		Architect C8000	Benzethonium chloride	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Architect c8000
	Urinary microalbumin **1,2,3,4	Urine		Architect C8000	Turbidimetric/immunoturbidimetric	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Architect c8000
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Paracetamol **1,2,3,4	Serum/Li-Heparin Plasma		Abbott Architect C8000	Enzymatic	LP-BIO-101 PROCEDURE FOR THE OUTLINING THE

						ANALYTICAL DETAILS OF c8000 CHEMISTRIES  LP-BIO-102 PROCEDURE FOR OPERATION AND MAINTENANCE OF THE c8000
	Salicylate **1,2,3,4	Serum/ Lithium Heparin		Architect C8000	Enzymatic/ Colormetric	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi tect c8000
1061 Clinical Chemistry - .20 Hormones	LH **1,2,3,4	Blood/ Serum		Abbott Architect	Chemiluminescent microparticle immunoassay	LP-BIO-104 Procedure for Outlining the Analytical Details of i2000SR Assays  LP-BIO-105 Procedure for the Operation and Maintenance of the Architect i2000SR
1061 Clinical Chemistry - .47 Vitamin assays	Vitamin D **1,2,3,4	Serum		Abbott Architect I2000	Chemiluminescent Microparticle immunoassay	LP-BIO-104 Procedure for Outlining the Analytical Details of i2000SR Assays  LP-BIO-105 Procedure for the Operation and Maintenance of the Architect i2000SR
1061 Clinical Chemistry - .71 Faecal Immunochemical test	Faecal Occult Blood **1,2,3,4	Faeces		Abbott Architect I2000	Actim Faecal Blood Kit	LP-BIO-306 PROCEDURE FOR OCCULT BLOOD
1061 Clinical Chemistry - .81 Qualitative investigation of immunoglobulins G,	Qualitative investigation of immunoglobulins G, A, D M and in body fluids	Serum/Urine		Agarose Gel EasyFix G26 Interlab	N/A	LP-BIO-300 Procedure for Electrophoresis

A, M and in body fluids	**1,2,3,4					
1061 Clinical Chemistry - .99 Miscellaneous tests	eGFR **1,2,3,4	Serum		Abbott Architect	Calculated	LP-BIO-101 Procedure For Outlining the Analytical Details of c8000 Chemistries
	Ferritin **1,2,3,4	Blood/Serum		Abbott Architect	Chemiluminescent microparticle immunoassay	LP-BIO-104 Procedure for Outlining the Analytical Details of i2000SR Assays  LP-BIO-105 Procedure for the Operation and Maintenance of the Architect i2000SR
	Folate **1,2,3,4			Abbott Architect	Chemiluminescent microparticle immunoassay	LP-BIO-104 Procedure for Outlining the Analytical Details of i2000SR Assays  LP-BIO-105 Procedure for the Operation and Maintenance of the Architect i2000SR
	Iron **1,2,3,4	Serum/ Lithium Heparin		Architect C8000	FERENE without a protein removal step	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi tect c8000
	Transferrin **1,2,3,4	Serum/ Lithium Heparin		Architect C8000	Immunoturbidimetric	LP-BIO-101 Procedure for c8000 chemistries  LP-BIO-102 Operation and maintenance of the Archi tect c8000
	Vitamin B12 **1,2,3,4	Blood/ Serum		Abbott Architect	Chemiluminescent microparticle immunoassay	P-BIO-104 Procedure for Outlining the Analytical



						Details of i2000SR Assays  LP-BIO-105 Procedure for the Operation and Maintenance of the Architect i2000SR
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*The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratories approved and documented procedures.*

*Note 1 - Range may be extended for the test*

*Note 2 – New parameters / tests may be added*

*Note 3 – New matrices may be added*

*Note 4 – Changes to equipment / kits where the underlying methodology does not change*

*For further details please refer to the laboratories 'Master list of Flexible scope changes', available directly from the laboratory.*

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	Haemaglobin **1,2,3,4	Blood	Flow Cytometry	Advia 2120i	Flow Cytometry	LP-HAE-106- Authorisation of FBC and retic results
	Haematocrit **1,2,3,4		Calculated parameter	Advia 2120i	Calculated parameter	LP-HAE-106- Authorisation of FBC and retic results
	MCH **1,2,3,4		Calculated parameter	Advia 2120i	Calculated parameter	LP-HAE-106- Authorisation of FBC and retic results
	MCHC **1,2,3,4		Flow Cytometry	Advia 2120i	Calculated parameter	LP-HAE-106- Authorisation of FBC and retic results
	Mean Cell Volume **1,2,3,4		Flow Cytometry	Advia 2120i	Flow Cytometry	LP-HAE-106- Authorisation of FBC and retic results
	Platelet Count **1,2,3,4		Flow Cytometry	Advia 2120i	Flow Cytometry	LP-HAE-106- Authorisation of FBC and retic results
	Red Cell Count **1,2,3,4		Flow Cytometry	Advia 2120i	Flow Cytometry	LP-HAE-103- Advia 2120i operation, maintenance and trouble shooting
	White cell count **1,2,3,4		Flow Cytometry	Advia 2120i	Flow Cytometry	LP-HAE-106- Authorisation of FBC and retic results
1030 Haematology - .02 Visual examination of blood films	Manual Differentiation, red cell morphology and Platelet morphology **1,2,3,4		Staining/microscopy	Manual	Staining/microscopy	LP-HAE-122 Examination of blood films. LP- HAE-120 making blood films procedure
1030 Haematology - .03 Erthrocyte sedimentation rate	ESR (Automated) **1,2,3,4		Sedimentation of red cells	Alifax Test-1	Sedimentation of red cells	LP-HAE-143 Operation and Maintenance of the Alifax Test- 1 ESR analyzer and Westergren ESR method
1030 Haematology - .05 Automated differential leucocyte counts	Basophil Count **1,2,3,4		Flow Cytometry	Advia 2120i	Flow Cytometry	LP-HAE-106- Authorisation of FBC and retic results

	Eosinophil Count **1,2,3,4	Flow Cytometry	Advia 2120i	Flow Cytometry	LP-HAE-106- Authorisation of FBC and retic results
	Lymphocyte Count **1,2,3,4	Flow Cytometry	Advia 2120i	Flow Cytometry	LP-HAE-103- Advia 2120i operation, maintenance and trouble shooting
	Monocyte Count **1,2,3,4	Flow Cytometry	Advia 2120i	Flow Cytometry	LP-HAE-106- Authorisation of FBC and retic results
	Neutrophil Count **1,2,3,4	Flow Cytometry	Advia 2120i	Flow Cytometry	LP-HAE-106- Authorisation of FBC and retic results
1030 Haematology - .06 Automated reticulocyte counts	Retic count **1,2,3,4	Flow Cytometry	Advia 2120i	Flow Cytometry	LP-HAE-106- Authorisation of FBC and retic results
1030 Haematology - .09 Examination of malarial parasites	Malaria Screen **1,2,3,4	Blood Film	Blood Film Examination	Blood Film	LP-HAE-171 Procedure for Malaria Testing
		Immunoassay	Optimal-IT test kit	Immunoassay	LP-HAE-171 Procedure for Malaria Testing
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Sickle Screen **1,2,3,4	Haemoglobin Solubility test	Clin-tech sickle test	Haemoglobin Solubility test	LP-HAE-176 Sickle Cell Procedure
1030 Haematology - .40 Limited haemostasis related tests	Lupus anticoagulant	Chromogenic analysis	Sysmex CA2100i	CE	LP-HAE-162 Lupus Anticoagulant Procedure and AFSL procedure
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time (APTT) **1,2,3,4	Clotting assay	Sysmex CA2100i	Clotting assay	LP-Hae-159 Performing Routine Tests on the Sysmex CS2100i Coagulation Analyser
	D-Dimer **1,2,3,4	Immunoturbidimetric assay	Sysmex CA2100i	Immunoturbidimetric assay	LP-Hae-159 Performing Routine Tests on the Sysmex CS2100i Coagulation Analyser
	Fibrinogen (Clauss) **1,2,3,4	Clotting assay	Sysmex CA2100i	Clotting assay	LP-Hae-159 Performing Routine Tests on the Sysmex CS2100i Coagulation Analyser
	International Normalised Ratio (INR) **1,2,3,4	Ratio calculation	Sysmex CA2100i	Ratio calculation	LP-Hae-159 Performing Routine Tests on the Sysmex

					CS2100i Coagulation Analyser	
	Protein C activity **1,2,3,4		Chromogenic analysis	Sysmex CA2100i	Chromogenic analysis	LP-Hae-160 Procedure for PC, AT3 and Free Protein S
	Prothrombin Time (PT) **1,2,3,4		Clotting assay	Sysmex CA2100i	Clotting assay	LP-Hae-159 Performing Routine Tests on the Sysmex CS2100i Coagulation Analyser
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious Mononucleosis (Monospot) **1,2,3,4		Immunoassay		Immunoassay	LP-HAE-147 Clearview infectious mononucleosis test
1030 Haematology - .80 Molecular genetic studies	Detection of Factor V Leiden & Prothrombin Variant		PCR Amplification	GeneXpert	PCR	LP-HAE-172 Factor V Leiden and Prothrombin Variant on GeneXpert
1030 Haematology - .99 Miscellaneous tests	Antithrombin **1,2,3,4		Chromogenic analysis	Sysmex CA2100i	Chromogenic analysis	LP-Hae-160 Procedure for PC, AT3 and Free Protein S
	APCR (FV Leiden Screen)		Clotting assay	Sysmex CA2100i	Clotting assay	LP-Hae-161 Procedure for APCR
	Free Protein S **1,2,3,4		Immunoassay	Sysmex CA2100i	Immunoassay	LP-Hae-160 Procedure for PC, AT3 and Free Protein S
	Rheumatoid Factor **1,2,3,4		Immunoassay	Rheumajet RF kit	Immunoassay	LP-HAE-155 Rheumatoid Factor Test Procedure

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*Note 2 – New parameters / tests may be added*

*Note 3 – New matrices may be added*

*Note 4 – Changes to equipment / kits where the underlying methodology does not change*

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Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .02 Microscopic examination for parasites	Cryptosporidium **1,2,3,4	Urine	N/A	CE	Pos/Neg	LP-MIC-244 Investigation of Cryptosporidium Species
	Mycobacterium Culture **1,2,3,4	Mycobacterium Cultures	Manual Method using Staining Method	Culture/Sensitivity	N/A	LP-MIC-221
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			Manual Method using Staining Method	Culture/Sensitivity	N/A	LP-MIC-221
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	Abscesses, post-op, wounds and deep seated infections **1,2,3,4	Bacterial Cultures	Manual	Culture/Sensitivity	N/A	LP-MIC-231 LP-MIC-290 LP-MIC-291
	CSF Culture **1,2,3,4	CSF	Manual	Microscope Culture/Sensitivity	N/A	LP-MIC-233 LP-MIC-290 LP-MIC-291
	Ear, Nose, Throat, related specimens **1,2,3,4	Bacterial Cultures	Manual	Culture/Sensitivity	N/A	LP-MIC-231 LP-MIC-290 LP-MIC-291
	Eye Swab **1,2,3,4	Eye Swab	Manual	Culture/Sensitivity	N/A	LP-MIC-231 LP-MIC-290 LP-MIC-291
	Faeces Culture **1,2,3,4	Faeces	Manual	Culture/Sensitivity	N/A	LP-MIC-241 LP-MIC-290 LP-MIC-291
	Fluid Culture **1,2,3,4	Bacterial Cultures	Manual	Culture/Sensitivity	N/A	LP-MIC-231 LP-MIC-290 LP-MIC-291
	MRSA Culture **1,2,3,4		Manual	Bacterial Cultures	N/A	LP-MIC-232 LP-MIC-290 LP-MIC-291
	Respiratory Cultures **1,2,3,4	Respiratory Cultures	Manual	Culture/Sensitivity	N/A	LP-MIC-222 LP-MIC-221
	Superficial wounds and intravascular cannulae **1,2,3,4	Bacterial Cultures	Manual	Culture/Sensitivity	N/A	LP-MIC-231 LP-MIC-290 LP-MIC-291
	Tissues, biopsies, bone and prosthetic devices **1,2,3,4		Manual	Culture/Sensitivity	N/A	LP-MIC-231 LP-MIC-290 LP-MIC-291
	Urine culture **1,2,3,4	Urine	Manual	Microscope Culture/Sensitivity	N/A	LP-MIC-250 LP-MIC-290 LP-MIC-291
1013 Culture of organisms in liquid or	Abscesses, post-op, wounds and deep	Bacterial Cultures	Manual	Culture/Sensitivity	N/A	LP-MIC-231 LP-MIC-290 LP-MIC-291

agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi	seated infections **1,2,3,4					
	CSF Culture **1,2,3,4	CSF	Manual	Microscope Culture/Sensitivity	N/A	LP-MIC-233 LP-MIC-290 LP-MIC-291
	Ear, Nose, Throat, related specimens **1,2,3,4	Bacterial Cultures	Manual	Culture/Sensitivity	N/A	LP-MIC-231 LP-MIC-290 LP-MIC-291
	Eye Swab **1,2,3,4	Eye Swab	Manual	Culture/Sensitivity	N/A	LP-MIC-231 LP-MIC-290 LP-MIC-291
	Faeces Culture **1,2,3,4	Faeces	Manual	Culture/Sensitivity	N/A	LP-MIC-241 LP-MIC-290 LP-MIC-291
	Fluid Culture **1,2,3,4	Bacterial Cultures	Manual	Culture/Sensitivity	N/A	LP-MIC-231 LP-MIC-290 LP-MIC-291
	MRSA Culture **1,2,3,4		Manual	Bacterial Cultures	N/A	LP-MIC-232 LP-MIC-290 LP-MIC-291
	Respiratory Cultures **1,2,3,4	Respiratory Cultures	Manual	Culture/Sensitivity	N/A	LP-MIC-222 LP-MIC-221
	Superficial wounds and intravascular cannulae **1,2,3,4	Bacterial Cultures	Manual	Culture/Sensitivity	N/A	LP-MIC-231 LP-MIC-290 LP-MIC-291
	Tissues, biopsies, bone and prosthetic devices **1,2,3,4		Manual	Culture/Sensitivity	N/A	LP-MIC-231 LP-MIC-290 LP-MIC-291
	Urine culture **1,2,3,4	Urine	Manual	Culture/Sensitivity	N/A	LP-MIC-250 LP-MIC-290 LP-MIC-291
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .03 Culture of mycobacteria	Abscesses, post-op, wounds and deep seated infections	Bacterial Cultures	Manual	Culture/Sensitivity	N/A	LP-MIC-231 LP-MIC-290 LP-MIC-291
	CSF Culture **1,2,3,4	CSF	Manual	Microscope Culture/Sensitivity	N/A	LP-MIC-233 LP-MIC-290 LP-MIC-291
	Ear, Nose, Throat, related specimens **1,2,3,4	Bacterial Cultures	Manual	Culture/Sensitivity	N/A	LP-MIC-231 LP-MIC-290 LP-MIC-291
	Eye Swab **1,2,3,4	Eye Swab	Manual	Culture/Sensitivity	N/A	LP-MIC-231 LP-MIC-290 LP-MIC-291
	Fluid Culture **1,2,3,4	Bacterial Cultures	Manual	Culture/Sensitivity	N/A	LP-MIC-231 LP-MIC-290 LP-MIC-291
	MRSA Culture **1,2,3,4		Manual	Bacterial Cultures	N/A	LP-MIC-232 LP-MIC-290 LP-MIC-291
	Respiratory Cultures **1,2,3,4	Respiratory Cultures	Manual	Culture/Sensitivity	N/A	LP-MIC-222 LP-MIC-221
	Superficial wounds and intravascular cannulae **1,2,3,4	Bacterial Cultures	Manual	Culture/Sensitivity	N/A	LP-MIC-231 LP-MIC-290 LP-MIC-291
	Tissues, biopsies, bone and prosthetic devices **1,2,3,4		Manual	Culture/Sensitivity	N/A	LP-MIC-231 LP-MIC-290 LP-MIC-291
	Urine culture	Urine	Manual	Culture/Sensitivity	N/A	LP-MIC-250 LP-MIC-290 LP-MIC-291
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques -	Antistreptolysin-O-Titre(ASOT)	Serum	Kit	CE	Pos/Neg	LP-MIC-261 Determination of Antistreptolysin-O-Titre(ASOT)

.02 Particle agglutination						
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods,	Adenovirus	Faeces	GeneXpert PCR (amplification)	CE	Pos/Neg	LP-MIC-242 Rotavirus/Adenovirus antigen detection in Faeces
	C Difficile **1,2,3,4		Kit	CE	Pos/Neg	LP-MIC-243 Investigation of C Difficile in Faeces
	Rotavirus		GeneXpert PCR (amplification)	CE	Pos/Neg	LP-MIC-242 Rotavirus/Adenovirus antigen detection in Faeces
	Urinary legionella Antigen	Urine	Sofia Reader	CE	Pos/Neg	LP-MIC-265 Operation of Quidel Sofia FIA analyser
	Urinary Pneumococcal Antigen		Sofia Reader	CE	Pos/Neg	LP-MIC-265 Operation of Quidel Sofia FIA analyser
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	CPE	Swab/Culture	GeneXpert PCR (amplification)	CE	N/A	LP-MIC-224 Operation of the Cepheid GeneXpert Instrument System, LP-MIC-232 Investigation of Multi Drug Resistant Organisms
	Blood Culture using the FilmArray Meningitis/Encephalitis Panel (ME)	Blood Culture	FilmArray system multiplex PCR system	CE	N/A	LP-MIC-300 Operation of FilmArray
	CSF using the FilmArray Meningitis/Encephalitis Panel (ME)	CSF	Multiplex PCR	FilmArray system	N/A	LP-MIC-300 Operation of FilmArray
	Detection of Influenza A, Pandemic (H1N1) 2009 and Influenza B	Nasopharyngeal Specimens	PCR Amplification	GeneXpert	N/A	LP-MIC-224 Operation of the Cepheid GeneXpert Instrument System
	Detection of M. Tuberculosis	Sputum	PCR Amplification	GeneXpert	CE	LP-MIC-224 Operation of the Cepheid GeneXpert Instrument System
	Detection of M.tuberculosis		PCR Amplification	GeneXpert	N/A	LP-MIC-224 Operation of the Cepheid GeneXpert Instrument System
	Detection of Norovirus	Faeces	PCR Amplification	GeneXpert	N/A	LP-MIC-224 Operation of the Cepheid GeneXpert Instrument System
	RSV	Nasal Throat Swabs	PCR Amplification	GeneXpert	N/A	LP-MIC-224 Operation of the Cepheid GeneXpert Instrument System
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to	Antimicrobial resistance using disc diffusion **1,2,3,4	Urine Culture, Mycobacterium Culture, Respiratory	Manual	MIC Discs	N/A	LP-MIC-271 LP-MIC-272

<p>general bacteria (rapidly growing aerobes) - .01 Anaerobes</p>		<p>Cultures, Tissues, biopsies, bone and prosthetic devices, Abscesses, post-op, wounds and deep seated infections, Eye Swab, Superficial wounds and intravascular cannulae, Ear, Nose, Throat, related specimens, Fluid Culture, MRSA Culture, CSF Culture, Genital tract and associated Culture, Faeces Culture</p>				
	<p>Antimicrobial Susceptibility Testing **1,2,3,4</p>	<p>Urine Culture, Respiratory Cultures, Tissues, biopsies, bone and prosthetic devices, Abscesses, post-op, wounds and deep seated infections, Eye Swab, Superficial wounds and intravascular cannulae, Ear, Nose, Throat, related specimens, Fluid Culture, MRSA Culture, CSF Culture, Genital tract and associated Culture, Faeces Culture</p>	<p>Automated</p>	<p>Vitek</p>	<p>N/A</p>	<p>LP-MIC-273</p>
	<p>Minimum inhibitory concentration using MIC strips **1,2,3,4</p>	<p>Urine Culture, Mycobacterium Culture, Respiratory Cultures, Tissues, biopsies, bone and prosthetic devices, Abscesses, post-op, wounds and deep seated infections, Eye Swab, Superficial wounds and intravascular cannulae, Ear, Nose, Throat, related</p>	<p>Mlc Strips</p>	<p>Culture/Sensitivity</p>	<p>N/A</p>	<p>LP-MIC-272</p>



		specimens, Fluid Culture, MRSA Culture, CSF Culture, Genital tract and associated Culture, Faeces Culture				
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts	Antimicrobial resistance using disc diffusion **1,2,3,4		Manual	MIC Discs	N/A	LP-MIC-271 LP-MIC-272
	Antimicrobial Susceptibility Testing **1,2,3,4	Urine Culture, Respiratory Cultures, Tissues, biopsies, bone and prosthetic devices, Abscesses, post-op, wounds and deep seated infections, Eye Swab, Superficial wounds and intravascular cannulae, Ear, Nose, Throat, related specimens, Fluid Culture, MRSA Culture, CSF Culture, Genital tract and associated Culture, Faeces Culture	Automated	Vitek	N/A	LP-MIC-273
	Minimum inhibitory concentration using MIC strips **1,2,3,4	Urine Culture, Mycobacterium Culture, Respiratory Cultures, Tissues, biopsies, bone and prosthetic devices, Abscesses, post-op, wounds and deep seated infections, Eye Swab, Superficial wounds and intravascular cannulae, Ear, Nose, Throat, related specimens, Fluid Culture, MRSA Culture, CSF Culture, Genital tract and associated Culture, Faeces Culture	Mic Strips	Culture/Sensitivity	N/A	LP-MIC-272

1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .05 Other categories of organism (as specified )	Antimicrobial resistance using disc diffusion **1,2,3,4		Manual	MIC Discs	N/A	LP-MIC-271 LP-MIC-272
	Antimicrobial Susceptibility Testing **1,2,3,4	Urine Culture, Respiratory Cultures, Tissues, biopsies, bone and prosthetic devices, Abscesses, post-op, wounds and deep seated infections, Eye Swab, Superficial wounds and intravascular cannulae, Ear, Nose, Throat, related specimens, Fluid Culture, MRSA Culture, CSF Culture, Genital tract and associated Culture, Faeces Culture	Automated	Vitek	N/A	LP-MIC-273
	Minimum inhibitory concentration using MIC strips **1,2,3,4	Urine Culture, Mycobacterium Culture, Respiratory Cultures, Tissues, biopsies, bone and prosthetic devices, Abscesses, post-op, wounds and deep seated infections, Eye Swab, Superficial wounds and intravascular cannulae, Ear, Nose, Throat, related specimens, Fluid Culture, MRSA Culture, CSF Culture, Genital tract and associated Culture, Faeces Culture	Mic Strips	Culture/Sensitivity	N/A	LP-MIC-272
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .02 Enzyme immunoassay, using CE	Hep A IgM using Abbott Architect **1,2,3,4	Blood/ Serum	Abbott Architect	Chemiluminescent microparticle immunoassay	N/A	LP-MIC-100 Operation of the Abbott Architect i1000 SR

marked commercial systems						
	Hepatitis B sAg using Abbott Architect **1,2,3,4		Abbott Architect	Chemiluminescent microparticle immunoassay	N/A	LP-MIC-100 Operation of the Abbott Architect i1000 SR
	Hepatitis BsAg Antibody using Abbott Architect **1,2,3,4		Abbott Architect	Chemiluminescent microparticle immunoassay	N/A	LP-MIC-100 Operation of the Abbott Architect i1000 SR
	Hepatitis C Antibody using Abbott Architect **1,2,3,4		Abbott Architect	Chemiluminescent microparticle immunoassay	N/A	LP-MIC-100 Operation of the Abbott Architect i1000 SR
	HIV Ag/Ab using Abbott Architect **1,2,3,4		Abbott Architect	Chemiluminescent microparticle immunoassay	N/A	LP-MIC-100 Operation of the Abbott Architect i1000 SR
	Rubella IgG using Abbott Architect **1,2,3,4		Abbott Architect	Chemiluminescent microparticle immunoassay	N/A	LP-MIC-100 Operation of the Abbott Architect i1000 SR
1029 Miscellaneous - .99 Miscellaneous tests	Gentamycin **1,2,3,4		Abbott Architect	Chemiluminescent microparticle immunoassay	N/A	LP-MIC-100 Operation of the Abbott Architect i1000 SR
	Pregnancy tests – qualitative **1,2,3,4	Urine	Kit	QuickVue & SureStep Kit	N/A	LP-MIC-301 Procedure for performing Pregnancy Test
	Vancomycin **1,2,3,4	Blood/ Serum	Abbott Architect	Chemiluminescent microparticle immunoassay	N/A	LP-MIC-100 Operation of the Abbott Architect i1000 SR

*The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratories approved and documented procedures.*

*Note 1 - Range may be extended for the test*

*Note 2 – New parameters / tests may be added*

*Note 3 – New matrices may be added*

*Note 4 – Changes to equipment / kits where the underlying methodology does not change*

*For further details please refer to the laboratories 'Master list of Flexible scope changes', available directly from the laboratory.*