

Schedule of Accreditation



Organisation Name	Regional Hospital Mullingar
Trading As	
INAB Reg No	195MT
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Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	10/06/2008
Scope Classification	Blood Transfusion Science
Scope Classification	Haematology
Scope Classification	Immunology
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	Mullingar, Westmeath, N37 YX99

Scope of Accreditation

Head Office

Blood Transfusion Science

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1020 Transfusion science - .01 Blood grouping including ABO, Rh(D) and other antigens by manual methods	Blood Grouping4	Red Blood Cells & Plasma in EDTA	Manual/Biorad Gel Card	CE Marked	N/A	LP-M/BTL/4
			Manual/Tube	CE Marked	N/A	LP-M/BTL/4
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods	Blood Grouping 4	Red Blood Cells & Plasma	Automated (IH-500)/Gel Card	CE Marked	N/A	LP-M/BTL/4
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screen 4	Plasma	Automated (IH-500)/Gel Card	CE Marked	N/A	LP-M/BTL/4
	Antibody Screen4	EDTA Plasma	Manual/ Biorad Gel Card	CE Marked	N/A	LP-M/BTL/4

1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification 4	Plasma	Automated (IH- 500)/Gel Card	CE Marked	N/A	LP-M/BTL/5
	Antibody Identification4	EDTA Plasma	Manual/ Biorad Gel Card	CE Marked	N/A	LP-M/BTL/5
1020 Transfusion science - .05 Cross match compatible donor units	Crossmatching	N/A	Electronic Issue	Based on standard method	N/A	LP-M/BTL/23
	Crossmatching 4	Plasma	Automated (IH- 500)/Gel Card	CE Marked	N/A	LP-M/BTL/21 LP-M/BTL/22
	Crossmatching4	EDTA Plasma	Manual/ Biorad Gel Card	CE Marked	N/A	LP-M/BTL/21 LP-M/BTL/22
1020 Transfusion science - .06 Red cell phenotyping	Red Cell Phenotyping 4	Red Blood Cells	Automated (IH- 500)/Gel Card	CE Marked	N/A	LP-M/BTL/6
	Red Cell Phenotyping4	Red Blood Cells in EDTA	Manual/ Biorad Gel Card	CE Marked	N/A	LP-M/BTL/6
1020 Transfusion science - .08 Antibody titration	Antibody Titration 4	Plasma	Automated (IH- 500)/Gel Card	CE Marked	N/A	LP-M/BTL/8
1020 Transfusion science - .09 Direct antiglobulin test	Direct Antiglobulin Test 4	Red Blood Cells	Automated (IH- 500)/Gel Card	CE Marked	N/A	LP-M/BTL/7
	Direct Antiglobulin Test4	Red Blood Cells in EDTA	Manual/ Biorad Gel Card	CE Marked	N/A	LP-M/BTL/7
1020 Transfusion science - .99 Miscellaneous tests	Kleihauer Test 4		Acid elution Guest Medical Kleihauer kit	CE Marked	N/A	LP-M/BTL/9
<i>The hospital blood bank has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (S.I. 360/2005 and S.I. 547/2006)</i>						

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	24 hour calcium **1,2,3,4	Urine	Calculation	Atellica Data Manager	Based on standard method	LP-M/B/9
	24 hour chloride **1,2,3,4		Calculation	Atellica Data Manager	Based on standard method	LP-M/B/23
	24 hour creatinine **1,2,3,4		Calculation	Atellica Data Manager	Based on standard method	LP-M/B/54
	24 hour potassium **1,2,3,4		Calculation	Atellica Data Manager	Based on standard method	LP-M/B/23
	24 hour sodium **1,2,3,4		Calculation	Atellica Data Manager	Based on standard method	LP-M/B/23
	Adjusted calcium (aCa) **1,2,3,4	Serum Lithium heparin plasma	Calculation	Atellica Data Manager	Based on standard method	LP-M/B/9
	Alanine aminotransferase (ALT) **1,2,3,4		Modified IFCC	Atellic CH 7 U/L to 3300 U/L	CE	LP-M/B/4
	Alkaline phosphatase (ALP) **1,2,3,4		IFCC Standardisation	Atellic CH 10 U/L to 2300 U/L	CE	LP-M/B/3
	Ammonia **1,2,3,4	EDTA plasma	Enzymatic	Atellica CH 10 µmol/L to 1493 µmol/L	CE	LP-M/B/5
	Amylase **1,2,3,4	Serum Lithium heparin	Ethylidene Blocked-pNPG7	Atellica CH 20 U/L to 4500 U/L	CE	LP-M/B/6

	plasma Urine				
Asparate aminotransferase (AST) **1,2,3,4	Serum Lithium heparin plasma	Modified IFCC	Atellica CH 8 U/L to 6000 U/L	CE	LP-M/B/7
Calcium (Ca) **1,2,3,4		Arsenazo - Colorimetric	Atellica CH 0.25 mmol/L to 8.00 mmol/L	CE	LP-M/B/9
	Urine	Arsenazo - Colorimetric	Atellica CH 0.25 mmol/L to 40.00 mmol/L	CE	LP-M/B/9
Chloride (Cl) **1,2,3,4	Serum Lithium heparin plasma	Indirect Integrated Multisensor Technology (IMT)	Atellica CH 50 mmol/L to 200 mmol/L	CE	LP-M/B/23
	Urine	Indirect Integrated Multisensor Technology (IMT)	Atellica CH 20 mmol/L to 660 mmol/L	CE	LP-M/B/23
Cholesterol **1,2,3,4	Serum	Colorimetric	Atellica CH 0.65 mmol/L to 32 mmol/L	CE	LP-M/B/11
Creatine kinase (CK) **1,2,3,4	Serum Lithium heparin plasma	Enzymatic	Atellica CH 15 U/L to 7800 U/L	CE	LP-M/B/12
Creatinine **1,2,3,4	Serum	Enzymatic	Atellica CH 9 µmol/L to 13,260 µmol/L	CE	LP-M/B/54
	Serum Lithium heparin plasma	Kinetic Jaffe	Atellica CH 13 µmol/L to 5304 µmol/L	CE	LP-M/B/14
	Urine	Enzymatic	Atellica CH 0.088 mmol/L to 108 mmol/L	CE	LP-M/B/54
Creatinine Clearance **1,2,3,4	Serum Urine	Calculation	Atellica Data Manager	Based on standard method	LP-M/B/54
Direct bilirubin (Dbili) **1,2,3,4	Serum	Vandate oxidation	Atellica CH 2 µmol/L to 385 µmol/L	CE	LP-M/B/16

Estimated glomerular filtration rate (eGFR) **1,2,3,4		Calculation	Atellica Data Manager	Based on standard method	LP-M/B/54
Gamma glutamyltransferase (GGT) **1,2,3,4	Serum Lithium heparin plasma	Modified IFCC	Atellica CH 7 U/L to 3600 U/L	CE	LP-M/B/20
Glucose **1,2,3,4	Fluoroxalate plasma CSF	Hexokinase	Atellica CH 0.2mmol/L to 116.6 mmol/L	CE	LP-M/B/21
High density lipoprotein cholesterol (HDL) **1,2,3,4	Serum	Elimination/catalase	Atellica CH 0.52 mmol/L to 6.68 mmol/L	CE	LP-M/B/22
High sensitive troponin I **1,2,3,4		3-site sandwich immunoassay	Atellica IM 2.51 ng/L to 25,000 ng/L	CE	LP-M/CC/18
Lactate **1,2,3,4	Fluoroxalate plasma CSF	Lactate oxidase to pyruvate and hydrogen peroxidase	Atellica CH 0.07 mmol/L to 12.21 mmol/L	CE	LP-M/B/24
Lactate dehydrogenase (LDH) **1,2,3,4	Serum	Lactate/NAD	Atellica CH 14 U/L to 750 U/L	CE	LP-M/B/25
Low density lipoprotein cholesterol (LDL) **1,2,3,4		Elimination/catalase	Atellica CH 0.13 mmol/L to 25.9 mmol/L	CE	LP-M/B/26
Magnesium (Mg) **1,2,3,4	Serum Lithium heparin plasma	Xylidyl blue	Atellica CH 0.21 mmol/L to 4.11 mmol/L	CE	LP-M/B/29
Non-HDL cholesterol **1,2,3,4	Serum	Calculation	Atellica Data Manager	Based on standard method	LP-M/B/11
N-terminal pro-brain natriuretic peptide (NT-proBNP) **1,2,3,4	EDTA plasma	2-site sandwich immunoassay	Atellica IM 35 pg/L to 350,000 pg/L	CE	LP-M/CC/7
Osmolality **1,3,4	Serum Urine	Freezing point depression	OsmoPro 0 - 2000 mOsm/kg H2O	CE marked	LP-M/CC/21
Phosphorous **1,2,3,4	Serum Lithium heparin plasma	Phosphomolybdate	Atellica CH 0.10mmol/L to 12.92 mmol/L	CE	LP-M/B/32

1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Potassium (K) **1,2,3,4	Serum	Direct ISE	iSmart Pro 30 0.5 mmol/L to 20.2 mmol/L	CE	LP-M/B/56	
		Serum Lithium heparin plasma	Indirect Integrated Multisensor Technology (IMT)	Atellica CH 1 mmol/L to 10 mmol/L	CE	LP-M/B/23	
		Urine	Indirect Integrated Multisensor Technology (IMT)	Atellica CH 2 mmol/L to 600 mmol/L	CE	LP-M/B/23	
	Remnant cholesterol **1,2,3,4	Serum	Calculation	Atellica Data Manager	Based on standard method	LP-M/B/11	
	Sodium (Na) **1,2,3,4		Direct ISE	iSmart Pro 30 20 mmol/L to 250 mmol/L	CE	LP-M/B/56	
		Serum Lithium heparin plasma	Indirect Integrated Multisensor Technology (IMT)	Atellica CH 50 mmol/L to 200 mmol/L	CE	LP-M/B/23	
		Urine	Indirect Integrated Multisensor Technology (IMT)	Atellica CH 10 mmol/L to 600 mmol/L	CE	LP-M/B/23	
	Total bilirubin (TBili) **1,2,3,4	Serum Lithium heparin plasma	Vandate oxidation	Atellica CH 3 µmol/L to 1,197 µmol/L	CE	LP-M/B/8	
	Total cholesterol: HDL	Serum	Calculation	Atellica Data Manager	Based on standard method	LP-M/B/11	
	Triglyceride **1,2,3,4		GPO	Atellica CH 0.11 mmol/L to 12.43 mmol/L	CE	LP-M/B/34	
	Urea **1,2,3,4	Serum Lithium heparin plasma	Urease with GLDH	Atellica CH 1.8 mmol/L to 107.1 mmol/L	CE	LP-M/B/40	
	Uric acid (UA) **1,2,3,4		Uricase/Peroxidase	Atellica CH 30 µmol/L to 5990 µmol/L	CE	LP-M/B/37	
		24 hour protein **1,2,3,4	Urine	Calculation	Atellica Data Manager	Based on standard method	LP-M/B/38

	Albumin **1,2,3,4	Serum Lithium heparin plasma	BCG Dye binding	Atellica CH 10 g/L to 120 g/L	CE	LP-M/B/2
	Albumin Creatinine Ratio (ACR) **1,2,3,4	Urine	Calculation	Atellica Data Manager	Based on standard method	LP-M/B/28 LP-M/B/54
	C-reactive protein (CRP) **1,2,3,4	Serum Lithium heparin plasma	Latex-enhanced immunoturbidimetric assay	Atellica CH 4 mg/L to 912 mg/L	CE	LP-M/B/15
	Globulin **1,2,3,4		Calculation	Atellica Data Manager	Based on standard method	LP-M/B/36
	Protein Creatinine Ratio (PCR) **1,2,3,4	Urine	Calculation	Atellica Data Manager	Based on standard method	LP-M/B/28 LP-M/B/38
	Total protein (TP) **1,2,3,4	Serum Lithium heparin plasma	Biuret	Atellica CH 20 g/L to 240 g/L	CE	LP-M/B/36
	Urinary albumin **1,2,3,4	Urine	PEG- enhanced immunoturbidimetric	Atellica CH 3 mg/L to 3,800 mg/L	CE	LP-M/B/28
	Urinary/CSF Protein **1,2,3,4	Urine CSF	Pyrogallol red- molybdate	Atellica CH 0.06 g/L to 25 g/L	CE	LP-M/B/38
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Carbamazepine **1,2,3,4	Serum	PETINIA	Atellica CH 0.4 mg/L to 40 mg/L	CE	LP-M/B/10
	Digoxin **1,2,3,4		Latex-enhanced immunoturbidimetric assay	Atellica CH 0.14 µg/L to 10.0 µg/L	CE	LP-M/E/3
	Gentamicin **1,2,3,4		PETINIA	Atellica CH 0.5 mg/L to 24 mg/L	CE	LP-M/B/19
	Lithium **1,2,3,4		Colorimetric endpoint chemistry	Atellica CH 0.1 mmol/L to 6.0 mmol/L	CE	LP-M/CC/6
	Phenobarbitone **1,2,3,4		PETINIA	Atellica CH 3.0 mg/L to 160 mg/L	CE	LP-M/B/30
	Phenytoin **1,2,3,4		PETINIA	Atellica CH 2.0 mg/L to 80 mg/L	CE	LP-M/B/31

	Theophylline **1,2,3,4		PETINIA	Atellica CH 2.0 mg/L to 80 mg/L	CE	LP-M/B/35
	Valproate **1,2,3,4		PETINIA	Atellica CH 3.0 mg/L to 300 mg/L	CE	LP-M/B/41
	Vancomycin **1,2,3,4		PETINIA	Atellica CH 3.0 mg/L to 100 mg/L	CE	LP-M/CC/15
1061 Clinical Chemistry - .14 Alcohol for non-legal purposes	Alcohol **1,2,3,4	Fluoroxalate plasma	Enzymatic reaction	Atellica CH 3 mg/dL to 900 mg/dL	CE	LP-M/B/17
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Paracetamol (Acetaminophen) **1,2,3,4	Serum	Colorimetric: acyl amidohydrolase	Atellica CH 2 mg/L to 600 mg/L	CE	LP-M/B/1
	Salicylate **1,2,3,4		Colorimetric	Atellica CH 3 mg/L to 1000 mg/L	CE	LP-M/CC/13
1061 Clinical Chemistry - .20 Hormones	Cortisol **1,2,3,4	Serum	Competitive immunoassay	Atellica IM 13.8 mmol/L to 4138.5 mmol/L	CE	LP-M/E/2
	Follicle stimulating hormone (FSH) **1,2,3,4		2-site sandwich immunoassay	Atellica IM 0.3 IU/L to 400 IU/L	CE	LP-M/E/8
	Free thyroxine (FT4) **1,2,3,4		Competitive immunoassay	Atellica IM 1.3 pmol/L to 154.8 pmol/L	CE	LP-M/E/21
	Free triiodothyronine (FT3) **1,2,3,4		Competitive immunoassay	Atellica IM 0.31 pmol/L to 30.8 pmol/L	CE	LP-M/E/12
	Intact parathyroid hormone (PTH) **1,2,3,4	EDTA plasma	2-site sandwich immunoassay	Atellica IM 0.5 pmol/L to 1060 pmol/L	CE	LP-M/CC/9
	Luteinising hormone (LH) **1,2,3,4	Serum	2-site sandwich immunoassay	Atellica IM 0.07 IU/L to 400 IU/L	CE	LP-M/E/10
	Oestradiol **1,2,3,4		Competitive immunoassay	Atellica IM 43.6 pmol/L to 55,050 pmol/L	CE	LP-M/E/24

	Progesterone **1,2,3,4
	Prolactin **1,2,3,4
	Testosterone **1,2,3,4
	Thyroid stimulating hormone (TSH) **1,2,3,4
	Total human chorionic gonadotropin (ThCG) **1,2,3,4
1061 Clinical Chemistry - .40 Iron studies	Ferritin **1,2,3,4
	Iron **1,2,3,4
	Transferrin **1,2,3,4
	Transferrin saturation (Tsat) **1,2,3,4
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate **1,2,3,4
	Vitamin B12 **1,2,3,4
1061 Clinical Chemistry - .47 Vitamin assays	Vitamin D **1,2,3,4
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Prostate specific antigen (PSA) **1,2,3,4

Competitive immunoassay	Atellica IM 0.67 nmol/L to 1908 nmol/L	CE	LP-M/E/13
2-site sandwich immunoassay	Atellica IM 6.36 mIU/L to 21,200 mIU/L	CE	LP-M/E/14
Competitive immunoassay	Atellica IM 0.15 nmol/L to 104.1 nmol/L	CE	LP-M/E/22
3rd generation immunoassay	Atellica IM 0.008 mIU/L to 750 mIU/L	CE	LP-M/E/16
2-site sandwich immunoassay	Atellica IM 2 IU/L to 200,000 IU/L	CE	LP-M/E/15
2-site sandwich immunoassay	Atellica IM 0.5 µg/L to 1650 µg/L	CE	LP-M/E/5
Ferrozine	Atellica CH 0.4 µmol/L to 358 µmol/L	CE	LP-M/B/18
PEG- enhanced immunoturbidimetric	Atellica CH 0.01 g/L to 44.0 g/L	CE	LP-M/B/57
Calculation	Atellica Data Manager	Based on standard method	LP-M/B/18 LP-M/B/57
Competitive immunoassay	Atellica IM 0.35 µg/L to 48 µg/L	CE	LP-M/E/6
Competitive immunoassay	Atellica IM 45 ng/L to 20,000 ng/L	CE	LP-M/E/17
Competitive immunoassay	Atellica IM 10.5 nmol/L to 750 nmol/L	CE	LP-M/CC/8
2-site sandwich immunoassay	Atellica IM 0.01 µg/L to 10,000 µg/L	CE	LP-M/E/11

1061 Clinical Chemistry - .61 Hb A1c	HbA1c **1,2,3,4	Blood in EDTA	HPLC	Arkray ADAMS A1c HA-8180V 20 mmol/mol to 151 mmol/mol	CE	LP-M/CC/12
1061 Clinical Chemistry - .83 Rheumatoid factor – quantitative assays	Rheumatoid factor (RF) **1,2,3,4	Serum	Latex-enhanced immunoturbidimetric assay	Atellica CH 3.5 IU/mL to 900 IU/mL	CE	LP-M/B/47

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

Note 1 - Range may be extended for the test

Note 2 – New parameters / tests may be added

Note 3 – New matrices may be added

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

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

Category: A

Medical pathology field - Test	Test/Assay	Specimen Type	Technique	Range of Measurement/Equipment	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1030 Haematology - .01 Blood counts	Full Blood Count (FBC) including White Cell Count (WBC), Red Cell Count (RBC), Platelet Count (PLT), Haemoglobin (Hb), Haematocrit (Hct), Mean Cell Volume (MCV), Mean Cell Haemoglobin (MCH), Mean Cell Haemoglobin Concentration (MCHC), Red cell Distribution Width (RDW) 4	Whole Blood in EDTA	Flow Cytometry Colourimetry Calculation	Advia 2120i RBC: 0.0 to 7.0 x10 ¹² /L Hb: 0.0 to 22.5 g/dL Plt: 5 to 3500 x10 ⁹ /L WBC: 0.02 to 400 x10 ⁹ /L	CE Marked	LP-M/H/13
1030 Haematology - .02 Visual examination of blood films	Blood Film Examination		Microscopy	Wescor Stainer Microscope	CE Marked	LP-M/H/4
1030 Haematology - .03 Erythrocyte sedimentation rate	Erythrocyte sedimentation rate (ESR) **3, 4	Blood in EDTA	Capillary photometric-kinetic technology	2 mm/hour to 120 mm/hour Alifax Roller 20	CE	LP-M/H/3
	Erythrocyte Sedimentation Rate (ESR) 3,4	Whole Blood in EDTA	Sedimentation Photometry	Vesmatic Cube 0 to 120 mm/hr	CE Marked	LP-M/H/3
1030 Haematology - .05 Automated differential leucocyte counts	Automated Leucocyte Differential Count including Neutrophils (Neut),		Flow Cytometry	Advia 2120i	CE Marked	LP-M/H/13

	Lymphocytes (Lymph), Monocytes (Mono), Eosinophils (Eos), Basophils (Bas), Large unstained cells (LUC) 4					
1030 Haematology - .06 Automated reticulocyte counts	Automated Reticulocyte Count (Retic) 4		Flow Cytometry Colourimetry	Advia 2120i 0.2 to 24.5 %	CE Marked	LP-M/H/13
1030 Haematology - .09 Examination of malarial parasites	Malaria Testing 4		Immunochromatography Microscopy	CareUS Malaria Rapydtest Kit Microscope	CE Marked	LP-M/H/5
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Sickle Cell Screen 4		Haemoglobin Solubility	Clintech Sickle Cell Kit	CE Marked	LP-M/H/6
1030 Haematology - .40 Limited haemostasis related tests	Activated Partial Thromboplastin Time (APTT)/ Activated Partial Thromboplastin Time Ratio (APTT _r) 4	Citratd Plasma	Coagulation	Stago Star 20 to 140 s	CE Marked	LP-M/C/1
	D-dimer 4		Coagulation	Stago Star 220 to 20,000 ng/mL	CE Marked	LP-M/C/1
	Fibrinogen 4		Coagulation	Stago Star 0.6 to 12 g/L	CE Marked	LP-M/C/1
	Prothrombin Time (PT)/International Normalised Ratio (INR) 4		Coagulation	Stago Star 10 to 90 s	CE Marked	LP-M/C/1
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious Mononucleosis Screen (IM) 4	Whole Blood in EDTA Serum Plasma in EDTA	Immunoassay	Clearview IM II Kit	CE Marked	LP-M/H/2

Immunology

Category: A

Medical pathology field - Test	Test/Assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. Ref & SOP
1040 Immunology - .01 Quantitative investigation of immunoglobulins G,A,M and D in body fluids	Alpha-1 antitrypsin (AAT)1,2,3,4	Serum	Atellica Neph/ Nephelometry	CE Marked	0.16 to 5.2 g/L	LP-M/I/28
	Caeruloplasmin 1,2,3,4		Atellica Neph/ Nephelometry	CE Marked	7 to 220 mg/L	LP-M/I/28
	Haptoglobin 1,2,3,4		Atellica Neph/ Nephelometry	CE Marked	2.6 to 8.3 g/L	LP-M/I/28
	Immunoglobulins including IgG, IgA, IgM 1,2,3,4		Atellica Neph/ Nephelometry	CE Marked	IgG: 1.4 to 49 g/L IgA: 0.25 to 8.0 g/L IgAs: 0.06 to 2.0 g/L IgM: 0.2 to 6.4 g/L	LP-M/I/28
1040 Immunology - .02 Qualitative investigation of immunoglobulins G,A,M and D in body fluids	Immunofixation 1,2,3,4	Serum Urine	Sebia Hydrasys/Immunofixation Electrophoresis	CE Marked	N/A	LP-M/I/3
	Immunotyping 1,2,3,4	Serum	Sebia MiniCap/ Capillary Zone Electrophoresis	CE Marked	N/A	LP-M/I/27
	Serum Protein Electrophoresis (SPE) 1,2,3,4		Sebia Hydrasys/Electrophoresis Sebia MiniCap/ Capillary Zone Electrophoresis	CE Marked	N/A	LP-M/I/2 LP-M/I/27
	Urine Protein Electrophoresis (UPE)1,2,3,4	Urine	Sebia Hydrasys/Electrophoresis	CE Marked	N/A	LP-M/I/2
1040 Immunology - .03 Total IgE	Total IgE 1,2,3,4	Serum	Phadia 250/Enzyme Immunoassay	CE Marked	0 to 5000 kU/L	LP-M/I/29 LP-M/I/30

1040 Immunology - .04 Allergen - specific IgE	Specific IgE 1,2,3,4	Phadia 250/Enzyme Immunoassay	CE Marked	0.1 to 100 kAU/L	LP-M/I/29 LP-M/I/30
1040 Immunology - .06 Investigation of complement	Complement C3 (C3) 1,2,3,4	Atellica Neph/ Nephelometry	CE Marked	0.12 to 4.1 g/L	LP-M/I/28
	Complement C4 (C4) 1,2,3,4	Atellica Neph/ Nephelometry	CE Marked	0.06 to 1.9 g/L	LP-M/I/28
1040 Immunology - .12 Detection of autoantibodies in body fluids and biopsy material	Anti dsDNA antibodies 1,2,3,4	INOVA Quanta-Lyser & Fluorescent Microscope/Indirect Immunofluorescence	CE Marked	N/A	LP-M/I/37 LP-M/I/20 LP-M/I/21
	Anti Liver/Kidney/ Microsomal antibodies (LKM) 1, 2, 3, 4	INOVA Quanta-Lyser & Fluorescent Microscope/Indirect Immunofluorescence	CE Marked	N/A	LP-M/I/37 LP-M/I/20 LP-M/I/26
	Anti thyroid peroxidase antibodies (TPO) 1,2,3,4	Phadia 250/Enzyme Immunoassay	CE Marked	33.4 to 3340 U/mL	LP-M/I/24 LP-M/I/29
	Anti Tissue transglutaminase antibodies IgA (TTG IgA) 1,2,3,4	Phadia 250/Enzyme Immunoassay	CE Marked	0.1 to 128 U/mL	LP-M/I/32 LP-M/I/29
	Anti-nuclear antibodies (ANA) 1,2,3,4	INOVA Quanta-Lyser & Fluorescent Microscope/Indirect Immunofluorescence	CE Marked	N/A	LP-M/I/37 LP-M/I/20 LP-M/I/26
	Endomysial antibodies IgA 1,2,3,4	INOVA Quanta-Lyser & Fluorescent Microscope/Indirect Immunofluorescence	CE Marked	N/A	LP-M/I/37 LP-M/I/22
	Endomysial antibodies IgG **1,2,3,4	INOVA Quanta-Lyser & Fluorescent Microscope/Indirect Immunofluorescence	CE Marked	N/A	LP-M/I/37 LP-M/I/22
	Gastric parietal cell antibodies (GPC) 1,2,3,4	INOVA Quanta-Lyser & Fluorescent Microscope/Indirect Immunofluorescence	CE Marked	N/A	LP-M/I/37 LP-M/I/20 LP-M/I/26

	Mitochondrial antibodies 1,2,3,4		INOVA Quanta-Lyser & Fluorescent Microscope/Indirect Immunofluorescence	CE Marked	N/A	LP-M/I/37 LP-M/I/20 LP-M/I/26
	Smooth muscle antibodies (SMA) 1,2,3,4		INOVA Quanta-Lyser & Fluorescent Microscope/Indirect Immunofluorescence	CE Marked	N/A	LP-M/I/37 LP-M/I/20 LP-M/I/26
1040 Immunology - .14 b2-microglobulin	B2-microglobulin (B2M) 1,2,3,4		Atellica Neph/ Nephelometry	CE Marked	0.7 to 23 mg/L	LP-M/I/28