

Schedule of Accreditation



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Website	https://www.enfermedical.ie
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Standard Version	2022
Date of award of accreditation	15/12/2021
Scope Classification	Microbiology and virology
Scope Classification	Haematology
Scope Classification	Chemical pathology
Services available to the public ¹	No

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	Unit T, M7 Business Park, Newhall, Naas, Kildare

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 transferase (ALT)	Serum/Plasma	Tris buffer without P5P	Abbott Alinity-c / LIS Interface	CE	EMSPC073
			Tris buffer without P5P	Abbott Alinity-c / LIS Interface	CE	EMSPC073
	Albumin		Bromocresol Purple	Abbott Alinity-c / LIS Interface	CE	EMSPC073
	Amylase		Enzymatic/Colorimetric	Abbott Alinity-c / LIS Interface	CE	EMSPC073
	Apolipoprotein B (ApoB)	Serum	Immunoturbidimetric Assay	Abbott Alinity-c	CE	EMSPC073
	Aspartate Transferase (AST)	Serum/Plasma	Tris buffer without P5P	Abbott Alinity-c / LIS Interface	CE	EMSPC073
	Bicarbonate (CO ₂)		PEP Carboxylase	Abbott Alinity-c / LIS Interface	CE	EMSPC073

Bilirubin Total		Diazonium Ion	Abbott Alinity-c / LIS Interface	CE	EMSPC073
C- Reactive protein high sensitivity (CRP-HS)		Immunoturbidimetric	Abbott Alinity-c / LIS Interface	CE	EMSPC073
Calcium		Arsenazo	Abbott Alinity-c / LIS Interface	CE	EMSPC073
Chloride		ISE indirect	Abbott Alinity-c / LIS Interface	CE	EMSPC073
Creatine Kinase		NAC (N-acetyl-L-cysteine)	Abbott Alinity-c / LIS Interface	CE	EMSPC073
Creatinine Enzymatic		Enzymatic	Abbott Alinity-c / LIS Interface	CE	EMSPC073
eGFR		Calculated	Abbott Alinity-c/LIS Interface	CE	EMSPC073
Gamma Glutamyl Transferase (GGT)		L-gamma glutamyl-3-carboxy-4-nitroanilide substrate	Abbott Alinity-c / LIS Interface	CE	EMSPC073
Globulin		Calculated	Abbott Alinity-c / LIS Interface	CE	EMSPC073
Glucose	Plasma	Enzymatic (Hexokinase/G-6-PDH)	Abbott Alinity-c / LIS Interface	CE	EMSPC073
High Density Lipoprotein (HDL)	Serum/Plasma	Accelerator Selective Detergent	Abbott Alinity-c / LIS Interface	CE	EMSPC073
Homeostatic assay Homa IR (calculated)	Serum	Calculated	Abbott Alinity-c/LIS Interface	CE	EMSPC073
Lactate-Dehydrogenase (LDH)	Serum/Plasma	L to P IFCC	Abbott Alinity-c / LIS Interface	CE	EMSPC073
Lipoprotein (a) (Lp (a))	Serum	Immunoturbidimetric Assay	Abbott Alinity-c	CE	EMSPC073
Lithium	Serum/Plasma	Colorimetric	Abbott Alinity-c / LIS Interface	CE	EMSPC073
Low Density Lipoprotein (LDL)		Calculated	Abbott Alinity-c / LIS Interface	CE	EMSPC073

			Calculated	Abbott Alinity-c/LIS Interface	CE	EMSPC073
	Magnesium		Enzymatic	Abbott Alinity-c / LIS Interface	CE	EMSPC073
	Non-HDL Cholesterol		Calculated	Abbott Alinity-c / LIS Interface	CE	EMSPC073
	N-Terminal Pro B-Type Natriuretic Peptide (NT-proBNP)	Serum	Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	Phosphorous	Serum/Plasma	Phosphomolybdate enzymatic	Abbott Alinity-c / LIS Interface	CE	EMSPC073
	Potassium		ISE indirect	Abbott Alinity-c / LIS Interface	CE	EMSPC073
	Sodium		ISE indirect	Abbott Alinity-c / LIS Interface	CE	EMSPC073
	Total Cholesterol		Enzymatic	Abbott Alinity-c / LIS Interface	CE	EMSPC073
	Total Protein		Biuret reaction, end point	Abbott Alinity-c / LIS Interface	CE	EMSPC073
	Triglycerides		Glycerol Phosphate Oxidase	Abbott Alinity-c / LIS Interface	CE	EMSPC073
	Urea		Urease, kinetic	Abbott Alinity-c / LIS Interface	CE	EMSPC073
	Uric acid		Uricase	Abbott Alinity-c / LIS Interface	CE	EMSPC073
	Urine Microalbumin	Urine (MSU)	Immunoturbidimetric Assay	Abbott Alinity-c	CE	EMSPC073
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Adjusted Calcium	Serum/Plasma	Calculated	Abbott Alinity-c / LIS Interface	CE	EMSPC073
	Alkaline phosphatase (ALP)		P-NPP	Abbott Alinity-c / LIS Interface	CE	EMSPC073
	IgE (Total)	Serum	Immunoturbidimetric Assay	Abbott Alinity-c	CE	EMSPC073
1061 Clinical Chemistry - .20 Hormones	Anti-Mullerian hormone (AMH)		Simultaneous one-step	Beckman Coulter Access 2	CE	EMSPC076

		immunoenzymatic (sandwich) assay			
	Cortisol	Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	Estradiol (E2)	Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i / LIS Interface	CE	EMSPC073
	Follicle stimulating hormone (FSH)	Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i / LIS Interface	CE	EMSPC073
	Free T3 (FT3)	Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i / LIS Interface	CE	EMSPC073
	Free T4 (FT4)	Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i / LIS Interface	CE	EMSPC073
	FT3/FT4 Ratio	Calculated	Abbott Alinity-i/LIS Interface	CE	EMSPC073
	Human chorionic gonadotropin (β HCG)	Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i / LIS Interface	CE	EMSPC073
	Insulin	Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	Intact Parathyroid Hormone (iPTH)	Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	Luteinizing hormone (LH)	Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i / LIS Interface	CE	EMSPC073
	Progesterone	Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i / LIS Interface	CE	EMSPC073
	Prolactin	Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i / LIS Interface	CE	EMSPC073

	Sex Hormone Binding Globulin (SHBG)		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	Testosterone		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i / LIS Interface	CE	EMSPC073
	Thyroid Peroxidase Antibodies (TPO)		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	Thyroid Stimulating Hormone (TSH)		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i / LIS Interface	CE	EMSPC073
	Total Prostate Specific antigen (TPSA)	Serum/Capillary	Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	Total T3	Serum	Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	Total T4		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
1061 Clinical Chemistry - .40 Iron studies	Ferritin	Serum/Plasma	Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i / LIS Interface	CE	EMSPC073
	Iron		Ferene	Abbott Alinity-c / LIS Interface	CE	EMSPC073
	Transferrin		Immunoturbidimetric	Abbott Alinity-c / LIS Interface	CE	EMSPC073
	Transferrin saturation		Calculated	Abbott Alinity-c / LIS Interface	CE	EMSPC073
	Unsaturated Iron-binding capacity (UIBC)		Ferene	Abbott Alinity-c / LIS Interface	CE	EMSPC073
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Active B12	Serum	Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073

	Folate		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i / LIS Interface	CE	EMSPC073
	Vitamin B		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i / LIS Interface	CE	EMSPC073
1061 Clinical Chemistry - .47 Vitamin assays	Vitamin D - 25(OH)		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i / LIS Interface	CE	EMSPC073
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Alpha Fetoprotein (AFP)		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	CA 15-3		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	Cancer Antigen 19-9 (CA19-9)		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	Cancer Antigen 125 (CA 125)		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
	Carcinoembryonic Antigen		Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073
1061 Clinical Chemistry - .61 Hb A1c	Glycated Haemoglobin test (HbA1c)	Whole Blood EDTA	Enzymatic using IFCC units	Abbott Alinity-c / LIS Interface	CE	EMSPC073
1061 Clinical Chemistry - .85 Anti-thyroglobulin antibodies	Anti Thyroglobulin Antibody	Serum	Chemiluminescent Microparticle Immunoassay	Abbott Alinity-i	CE	EMSPC073

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	Haematocrit (HCT)**1,2,3,4	EDTA Whole Blood	Measured as a function of the numeric integration of FBC	0.1 to 75.0 L/L / Sysmex XN / LIS Interface	CE	EMSPH021
	Mean Cell Haemoglobin Concentration (MCHC)**1,2,3,4		Calculated parameter	N/A / Sysmex XN / LIS Interface	CE	EMSPH021
	Mean Cell Volume (MCV)**1,2,3,4		Calculated parameter	N/A / Sysmex XN / LIS Interface	CE	EMSPH021
	Haemoglobin (Hb)**1,2,3,4		Sodium Lauryl Sulphate (SLS) Haemoglobin method	0.1g/dL to 26.0 g/dL / Sysmex XN / LIS Interface	CE	EMSPH021
	Mean Cell Haemoglobin (MCH)**1,2,3,4		Calculated parameter	N/A / Sysmex XN / LIS Interface	CE	EMSPH021
	Platelet Count (PLT)**1,2,3,4		Impedance technology	2 x 10 ⁹ /L to 5000 X10 ⁹ /L / Sysmex XN / LIS Interface	CE	EMSPH021
	Red Cell count (RBC)**1,2,3,4		Impedance technology	0.01 x 10 ¹² /L to 8.6 X10 ¹² /L / Sysmex XN / LIS Interface	CE	EMSPH021
	Red Cell Distribution Width - CV%**1,2,3,4		Calculated parameter	Calculated parameter / Sysmex XN / LIS Interface	CE	EMSPH021
	Red Cell Distribution Width - SD**1,2,3,4		Calculated parameter	Calculated parameter / Sysmex XN	CE	EMSPH021

1030 Haematology - .02 Visual examination of blood films	Blood Film examination		Staining / Microscopy	N/A	Based on standard method	EMSPH081
1030 Haematology - .03 Erythrocyte sedimentation rate	Erythrocyte sedimentation rate (ESR)**1,3,4		Westergren sedimentation method / RR Mechatronics Starrsed RS ESR analyser / Manual Westergren sedimentation method, Starstedt S-Sedivette	0-140mm	CE	EMSPH096
1030 Haematology - .05 Automated differential leucocyte counts	Basophil Count**1,2,3,4		Flourescence Flow Cytometry	0.03x10 ⁹ /L to 440x10 ⁹ /L / Sysmex XN / LIS Interface	CE	EMSPH021
	Eosinophil Count**1,2,3,4		Flourescence Flow Cytometry	0.03x10 ⁹ /L to 440x10 ⁹ /L / Sysmex XN / LIS Interface	CE	EMSPH021
	Lymphocyte Count**1,2,3,4		Flourescence Flow Cytometry	0.03x10 ⁹ /L to 440x10 ⁹ /L / Sysmex XN / LIS Interface	CE	EMSPH021
	Monocyte Count**1,2,3,4		Flourescence Flow Cytometry	0.03x10 ⁹ /L to 440x10 ⁹ /L / Sysmex XN / LIS Interface	CE	EMSPH021
	Neutrophil Count**1,2,3,4		Flourescence Flow Cytometry	0.03x10 ⁹ /L to 440x10 ⁹ /L / Sysmex XN / LIS Interface	CE	EMSPH021
	White Cell Count (WBC)**1,2,3,4		Flourescence Flow Cytometry	0.03x10 ⁹ /L to 440x10 ⁹ /L / Sysmex XN / LIS Interface	CE	EMSPH021
1030 Haematology - .06 Automated reticulocyte counts	Reticulocyte Count**1,2,3,4		Flourescence Flow Cytometry	1x 10 ⁹ /L to 720x 10 ⁹ /L / Sysmex XN / LIS Interface	CE	EMSPH021
1030 Haematology - .41 General haemostasis related tests	APTT - activated partial thromboplastin time**1,2,4	Citratd Plasma	Photo-optical detection, ACL TOP 550 CTS	16-400 seconds	CE	EMSPH100
	D-Dimer**1,2,4		Latex immunoassay, ACL TOP 550 CTS	215-128000ng/mL	CE	EMSPH100

	Fibrinogen C**1,2,4		Photo-optical detection, ACL TOP 550 CTS	35-1000mg/dL	CE	EMSPH100
	INR - International normalised ratio**1,2,4		Photo-optical detection, ACL TOP 550 CTS	0.67 - 26	CE	EMSPH100
	PT - Prothrombin time**1,2,4		Photo-optical detection, ACL TOP 550 CTS	8-320 seconds	CE	EMSPH100
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious mononucleosis (IM)	Plasma	Lateral flow POC Immunoassay, Clearview IM II	N/A	CE	EMSPH105

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 specimens using Gram Stain **3,4	High vaginal swab	Microscope/Manual	CE Marked	Positive / Negative	EMSPM109
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	Automated culture of specimens for general bacteria ** 3,4	Urine, Eye swabs, ear swabs, nasal swabs, mouth swabs, superficial wound swabs, deep wound swabs, throat swabs, high vaginal swabs, MRSA screening swabs (nasal & groin), CPE screening swabs (rectal), VRE screening swab (rectal).	WASP (Walk away specimen processor)	CE marked	Growth / no growth	EMSPM082, EMSPM098, EMSPM118, EMSPM119, EMSPM121, EMSPM116, EMSPM106, EMSPM122, EMSPM120, EMSPM107, EMSPM086, EMSPM124 and EMSPM123
	Culture of specimens for General Bacteria **3,4	Urine, Eye swabs, ear swabs, nasal swabs, mouth swabs, superficial wound swabs, deep wound swabs, throat swabs, high vaginal swabs	Manual	CE marked	Growth/ no growth	EMSPM082, EMSPM098, EMSPM118, EMSPM119, EMSPM121, EMSPM116, EMSPM106,

						EMSPM122, EMSPM120 and EMSPM107
	Culture screening swabs for CPE ** 3,4	Rectal Swab	Manual inoculation on CPE Chromogenic agar	CE marked	Growth/ no growth	EMSPM082 and EMSPM124
	Culture screening swabs for MRSA ** 3,4	Nasal, Throat, Groin swabs	Manual inoculation on MRSA Chromogenic agar	CE marked	Growth/ no growth	EMSPM082, EMSPM086
	Culture screening swabs for VRE ** 3,4	Rectal Swabs	Manual inoculation on VRE Chromogenic agar	CE marked	Growth/ no growth	EMSPM082, EMSPM123
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi	Automated Culture of specimens for yeast and fungi ** 3,4	Urine, Eye swabs, ear swabs, nasal swabs, mouth swabs, superficial wound swabs, deep wound swabs, throat swabs, high vaginal swabs, MRSA screening swabs (nasal & groin), CPE screening swabs (rectal), VRE screening swab (rectal).	WASP (Walk away specimen processor)	CE marked	Growth / no growth	EMSPM082, EMSPM098, EMSPM118, EMSPM119, EMSPM121, EMSPM116, EMSPM106, EMSPM122, EMSPM120, EMSPM107, EMSPM086, EMSPM124 and EMSPM123
	Culture of specimens for yeast and fungi ** 3,4	Urine, Eye swabs, ear swabs, nasal swabs, mouth swabs, superficial wound swabs, deep wound swabs, throat swabs, high vaginal swabs	Manual	CE marked	Growth/ no growth	EMSPM082 , EMSPM098, EMSPM118, EMSPM119, EMSPM121, EMSPM116, EMSPM106, EMSPM122, EMSPM120 and EMSPM107
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .02 Particle agglutination	Pastorex Staph Plus Test ** 3,4	Bacterial Isolate	Manual/Particle agglutination	CE Marked	Positive / Negative	EMSPM090

	Streptococcal Grouping ** 3,4		Manual/Particle agglutination	CE Marked	Qualitative agglutination or non-agglutination	EMSPM090
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay,	(1-3)-beta-D-Glucan (BDG) **2,3,4	Serum	Associates of Cape Cod/EIA	CE	Qualitative	EMSPM061
	Aspergillus Galactomannan Antigen **2,3,4	Serum/Bronchoalveolar lavage (BAL)	Dynex Agility/Manual, Enzyme immunoassay (EIA)	CE	Qualitative	EMSPM065
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods,	Detection of CPE resistance genes: OXA-48, KPC, NDM, VIM, IMP-1 ** 3,4	Bacterial Isolate	Manual / lateral flow	CE Marked	Positive / Negative	EMSPM090
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	16S and/or 18S rRNA gene detection **2,3,4	Bodily fluids, Tissue	SelectNA plus/ Bio-Rad CFX	CE marked	Detected/ Not Detected	EMSPG102, EMSPG113
	Altona RNA RealStar SARS-CoV-2 RT-PCR **2,3,4	Nose & throat swabs	Chemagic 360	CE Marked	Qualitative	EMSPM001
	Chlamydia trachomatis **2,3,4	Genital Swab/Urine	Panther - Nucleic Acid Amplification Test (NAAT) / LIS Interface	CE	Qualitative	EMSPM006
	Chlamydia trachomatis/Neisseria gonorrhoeae Combo **2,3,4	Genital Swab/Pharyngeal Swab/Rectal Swab/Urine	Panther - Nucleic Acid Amplification Test (NAAT) / LIS Interface	CE	Qualitative	EMSPM005
	Euroimmun EURORealtime	Nose & throat swabs	Chemagic 360	CE Marked	Qualitative	EMSPM002

	SARS-CoV-2 RNA **2,3,4					
	Neisseria gonorrhoeae **2,3,4	Genital Swab/Urine	Panther - Nucleic Acid Amplification Test (NAAT) / LIS Interface	CE	Qualitative	EMSPM007
	Pneumocystis jirovecii PCR **2,3,4	Bronchoalveolar lavage (BAL) and Non directed bronchoalveolar lavage (NBL)	Altona RealStar® PJP/PCR	CE	Qualitative	EMSPM064
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .05 Nucleotide sequencing & analysis	16S and/or 18S rRNA amplicon sequencing	Bodily fluids, Tissue	Bio-Rad CFX / SeqStudio	In house developed	Bacterial and/or Fungal Genus/species	EMSPG110
	Metagenomic pathogen detection		SelectNA plus / Bio-Rad CFX / MiSeq	In house developed	Bacterial species	EMSPG069
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	Identification of Cultured Bacteria **4	Bacterial Isolate	Biomerieux Vitek 2 XL	CE Marked	N/A	EMSPM084
	Identification of yeast **4	Yeast Isolate	Biomerieux Vitek 2 XL	CE Marked	N/A	EMSPM084
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy	Rapid method for microorganism identification from microbial cultures **4	Bacterial and fungal Isolates	Vitek Prime MS/Matrix-assisted laser desorption/ionization	CE Marked	N/A	EMSPM085
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	Antimicrobial susceptibility testing (automated) **4	Bacterial Isolate	Biomerieux Vitek 2 XL / MIC	CE Marked	S/I/R	EMSPM084

	Antimicrobial susceptibility testing (disc diffusion and MIC) ** 2,4		Calipers/Manual/Zone Measurements	CE Marked	S/I/R	EMSPM091
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .05 Other categories of organism (as specified)	Identification of ESBL/AMPC organisms ** 2,4		Manual/ Zone Measurements	CE Marked	ESBL/ AMPC/ ESBL + AMPC/ Negative	EMSPM090
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .01 Particle agglutination, using CE marked commercial systems	Rapid Plasma Reagin Test (RPR) **2,3,4	Serum/Plasma/Capillary	Biorad/Manual	CE	Qualitative	EMSPM070
	Treponema Pallidum Haemagglutination (TPHA) **2,3,4	Serum/Plasma	Manual, Partial agglutination	CE	Qualitative	EMSPM071
1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .07 Chemiluminescent microparticle immunoassay, using CE marked commercial systems	Hepatitis B Surface Antigen **2,3,4	Serum/Plasma/Capillary	Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA) / LIS Interface	CE	Qualitative	EMSPM016
	Hepatitis B Core Antibody **2,3,4		Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA) / LIS Interface	CE	Qualitative	EMSPM019
	Hepatitis B Surface Antibody **2,3,4		Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA) / LIS Interface	CE	2.00 mIU/mL to 1000.00 mIU/mL	EMSPM018

	Hepatitis B Surface Antigen (Confirmatory) **2,3,4	Serum/Plasma	Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA) / LIS Interface	CE	Qualitative	EMSPM017
	Hepatitis C IgG Antibody **2,3,4	Serum/Plasma/Capillary	Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA) / LIS Interface	CE	Qualitative	EMSPM020
	Human Immunodeficiency Virus HIV Ag/Ab Combo **2,3,4		Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA) / LIS Interface	CE	Qualitative	EMSPM013
	Rubella IgG Antibody **2,3,4	Serum/Plasma	Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA) / LIS Interface	CE	0.5 to 500.0 IU/mL	EMSPM047
	Syphilis TP **2,3,4	Serum/Plasma/Capillary	Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA) / LIS Interface	CE	Qualitative	EMSPM023
1029 Miscellaneous - .99 Miscellaneous tests	Urine microscopy Automated **4	Urine (MSU, CSU)	Sedimax Pro Contrast/Automated urine sediment analyser	CE marked	WCC, RCC 1000 per ul YEA, EPI, CRY, PAT	EMSPM083

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.