

Schedule of Accreditation



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Trading As	
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Accreditation Standard	EN ISO 15189
Standard Version	2022
Date of award of accreditation	15/12/2021
Scope Classification	Microbiology and Virology
Scope Classification	Haematology
Services available to the public ¹	No

¹ Refer to document on interpreting INAB Scopes of Accreditation

Sites from which accredited services are delivered
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(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

Haematology

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 2000 / Sysmex XN 9100 / LIS Interface	CE	EMSPH021
	Mean Cell Haemoglobin Concentration (MCHC)**1,2,3,4		Calculated parameter	N/A / Sysmex XN 2000 / Sysmex XN 9100 / LIS Interface	CE	EMSPH021
	Mean Cell Volume (MCV)**1,2,3,4		Calculated parameter	N/A / Sysmex XN 2000 / Sysmex XN 9100 / 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 2000 / Sysmex XN 9100 / LIS Interface	CE	EMSPH021

	Mean Cell Haemoglobin (MCH)**1,2,3,4
	Platelet Count (PLT)**1,2,3,4
	Red Cell count (RBC)**1,2,3,4
	Red Cell Distribution Width - CV%**1,2,3,4
	Red Cell Distribution Width - SD**1,2,3,4
1030 Haematology - .02 Visual examination of blood films	Blood Film examination
	Blood Film Examination
1030 Haematology - .03 Erythrocyte sedimentation rate	Erythrocyte sedimentation rate (ESR)**1,3,4

Calculated parameter	N/A / Sysmex XN 2000 / Sysmex XN 9100 / LIS Interface	CE	EMSPH021
Impedence technology	2 x 10 ⁹ /L to 5000 X10 ⁹ /L / Sysmex XN 2000 / Sysmex XN 9100 / LIS Interface	CE	EMSPH021
Impedence technology	0.01 x 10 ¹² /L to 8.6 X10 ¹² /L / Sysmex XN 2000 / Sysmex XN 9100 / LIS Interface	CE	EMSPH021
Calculated parameter	LIS Interface	CE	EMSPH021
Calculated parameter	Calculated parameter / Sysmex XN 2000 / Sysmex XN 9100	CE	EMSPH021
Staining / Microscopy	N/A	Based on standard method	EMSPH081
Automated digital morphology	SP-50 Blood Film Stainer Sysmex DI-60	CE	EMSPH081
Non-westergren Method/ ALIFAX	0-140 mm	CE	EMSPH115
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 2000 / Sysmex XN 9100 / LIS Interface	CE	EMSPH021
	Eosinophil Count**1,2,3,4		Flourescence Flow Cytometry	0.03x10 ⁹ /L to 440x10 ⁹ /L / Sysmex XN 2000 / Sysmex XN 9100 / LIS Interface	CE	EMSPH021
	Lymphocyte Count**1,2,3,4		Flourescence Flow Cytometry	0.03x10 ⁹ /L to 440x10 ⁹ /L / Sysmex XN 2000 / Sysmex XN 9100 / LIS Interface	CE	EMSPH021
	Monocyte Count**1,2,3,4		Flourescence Flow Cytometry	0.03x10 ⁹ /L to 440x10 ⁹ /L / Sysmex XN 2000 / Sysmex XN 9100 / LIS Interface	CE	EMSPH021
	Neutrophil Count**1,2,3,4		Flourescence Flow Cytometry	0.03x10 ⁹ /L to 440x10 ⁹ /L / Sysmex XN 2000 / Sysmex XN 9100 / 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 2000 / Sysmex XN 9100 / 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 2000 / Sysmex XN 9100 / 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

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 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	Manual	CE marked	Growth/ no growth	EMSPM082 , EMSPM098, EMSPM118, EMSPM119, EMSPM121,

		swabs, throat swabs, high vaginal swabs				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	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

marked commercial systems						
	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 SARS-CoV-2 RNA **2,3,4	Nose & throat swabs	Chemagic 360	CE Marked	Qualitative	EMSPM002
	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	Identification of Cultured Bacteria **4	Bacterial Isolate	Biomerieux Vitek 2 XL	CE Marked	N/A	EMSPM084

Biochemical methods , CE marked commercial systems						
	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,	Rapid Plasma Reagin Test (RPR) **2,3,4	Serum/Plasma/Capillary	Biorad/Manual	CE	Qualitative	EMSPM070

using CE marked commercial systems						
	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		Alinity i - Chemiluminescent	CE	Qualitative	EMSPM013

	Virus HIV Ag/Ab Combo **2,3,4		Microparticle Immunoassay (CMIA) / LIS Interface			
	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.