

# Schedule of Accreditation



Organisation Name	Enfer Medical Ltd
Trading As	
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Accreditation Standard	EN ISO 15189
Standard Version	2012
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 <sup>1</sup>	No

<sup>1</sup> 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 - .71 Faecal Immunochemical test	Faecal Immunochemical test (FIT) using the OC Sensor Pledia	Faeces	Latex Agglutination	OC Sensor Pledia	CE	EMSPC050

# 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)	EDTA Whole Blood	Measured as a function of the numeric integration of FBC	0.1 to 75.0 L/L / Sysmex XN	CE	EMSPH021
	Mean Cell Haemoglobin Concentration (MCHC)		Calculated parameter	N/A / Sysmex XN	CE	EMSPH021
	Mean Cell Volume (MCV)		Calculated parameter	N/A / Sysmex XN	CE	EMSPH021
	Haemoglobin (Hb)		Sodium Lauryl Sulphate (SLS) Haemoglobin method	0.1g/dL to 26.0 g/dL / Sysmex XN	CE	EMSPH021
	Mean Cell Haemoglobin (MCH)		Calculated parameter	N/A / Sysmex XN	CE	EMSPH021
	Platelet Count (PLT)		Impedence technology	$2 \times 10^9/L$ to 5000 $\times 10^9/L$ / Sysmex XN	CE	EMSPH021
	Red Cell count (RBC)		Impedence technology	$0.01 \times 10^{12}/L$ to $8.6 \times 10^{12}/L$ / Sysmex XN	CE	EMSPH021
	Red Cell Distribution Width - CV%		Calculated parameter	Calculated parameter / Sysmex XN	CE	EMSPH021
	Red Cell Distribution Width - SD		Calculated parameter	Calculated parameter / Sysmex XN	CE	EMSPH021
1030 Haematology - .05 Automated differential leucocyte counts	Basophil Count		Flourescence Flow Cytometry	$0.03 \times 10^9/L$ to $440 \times 10^9/L$ / Sysmex XN	CE	EMSPH021

	Eosinophil Count		Flourescence Flow Cytometry	0.03x10 <sup>9</sup> /L to 440x10 <sup>9</sup> /L / Sysmex XN	CE	EMSPH021
	Lymphocyte Count		Flourescence Flow Cytometry	0.03x10 <sup>9</sup> /L to 440x10 <sup>9</sup> /L / Sysmex XN	CE	EMSPH021
	Monocyte Count		Flourescence Flow Cytometry	0.03x10 <sup>9</sup> /L to 440x10 <sup>9</sup> /L / Sysmex XN	CE	EMSPH021
	Neutrophil Count		Flourescence Flow Cytometry	0.03x10 <sup>9</sup> /L to 440x10 <sup>9</sup> /L / Sysmex XN	CE	EMSPH021
	White Cell Count (WBC)		Flourescence Flow Cytometry	0.03x10 <sup>9</sup> /L to 440x10 <sup>9</sup> /L / Sysmex XN	CE	EMSPH021
1030 Haematology - .06 Automated reticulocyte counts	Reticulocyte Count		Flourescence Flow Cytometry	1x 10 <sup>9</sup> /L to 720x 10 <sup>9</sup> /L / Sysmex XN	CE	EMSPH021

## 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
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay,	(1-3)-beta-D-Glucan (BDG)	Serum	Associates of Cape Cod/EIA	CE	Qualitative	EMSPM061
	Aspergillus Galactomannan Antigen	Serum/Bronchoalveolar lavage (BAL)	Dynex Agility/Manual, Enzyme immunoassay (EIA)	CE	Qualitative	EMSPM065
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Altona RNA RealStar SARS-CoV-2 RT-PCR	Nose & throat swabs	Chemagic 360	CE Marked	Qualitative	EMSPM001
	Chlamydia trachomatis	Genital Swab/Urine	Panther - Nucleic Acid Amplification Test (NAAT)	CE	Qualitative	EMSPM006
	Chlamydia trachomatis/Neisseria gonorrhoeae Combo	Genital Swab/Pharyngeal Swab/Rectal Swab/Urine	Panther - Nucleic Acid Amplification Test (NAAT)	CE	Qualitative	EMSPM005
	Neisseria gonorrhoeae	Genital Swab/Urine	Panther - Nucleic Acid Amplification Test (NAAT)	CE	Qualitative	EMSPM007
	Pneumocystis jirovecii	Bronchoalveolar lavage	Altona RealStar®	CE	Qualitative	EMSPM064

	PCR	(BAL) and Non directed bronchoalveolar lavage (NBL)	PJP/PCR			
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)	Serum/Plasma/Capillary	Biorad/Manual	CE	Qualitative	EMSPM070
	Treponema Pallidum Haemagglutination (TPHA)	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 A IgG Antibody	Serum	Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA)	CE	Qualitative	EMSPM022
	Hepatitis B Surface Antigen	Serum/Plasma/Capillary	Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA)	CE	Qualitative	EMSPM016
	Hepatitis B Core Antibody		Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA)	CE	Qualitative	EMSPM019
	Hepatitis B Surface Antibody		Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA)	CE	2.00 mIU/mL to 1000.00 mIU/mL	EMSPM018
	Hepatitis B Surface Antigen (Confirmatory)	Serum/Plasma	Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA)	CE	Qualitative	EMSPM017

	Hepatitis C IgG Antibody	Serum/Plasma/Capillary	Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA)	CE	Qualitative	EMSPM020
	Human Immunodeficiency Virus HIV Ag/Ab Combo		Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA)	CE	Qualitative	EMSPM013
	Rubella IgG Antibody	Serum/Plasma	Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA)	CE	0.5 to 500.0 IU/mL	EMSPM047
	Syphilis TP	Serum/Plasma/Capillary	Alinity i - Chemiluminescent Microparticle Immunoassay (CMIA)	CE	Qualitative	EMSPM023