

Schedule of Accreditation



Organisation Name	Blackrock Clinic Ltd
Trading As	
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Website	http://www.laboratory.blackrock-clinic.ie
Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	17/02/2009
Scope Classification	Microbiology and virology
Scope Classification	Blood Transfusion Science
Scope Classification	Haematology
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	Blackrock Clinic Laboratory	Rock Road, Blackrock, Dublin, Ireland, A94E4X7

Scope of Accreditation

Blackrock Clinic Laboratory

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 grouping (ABO & RhD) Typing	Whole blood	Grifols DG Gel Card Technology Column agglutination technology	CE./Based on standard method	N/A	LM-BT-0017 LP-BT-0047 EXT-BT-0077
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods			Grifols DG Gel Card Automated System Column agglutination technology	CE/ Based on standard method	N/A	LM-BT-0017 LP-BT-0047 EXT-BT-0077
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening	Plasma	Grifols Manual and Automated Gel Card Systems Column agglutination technology	CE/Based on standard method	N/A	LM-BT-0017 LP-BT-0047 EXT-BT-0077
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		Grifols Manual and Automated Gel Card Systems	CE/ based on standard method	N/A	LM-BT-0019 LP-BT-0047 EXT-BT-0077

			Column agglutination technology			
1020 Transfusion science - .05 Cross match compatible donor units	Crossmatch testing		Grifols Manual and Automated Gel Card Systems Electronic issue	CE/ based on standard method	N/A	LM-BT-0010 EXT-BT-0055 LP-BT-0047 EXT-BT-0077
1020 Transfusion science - .06 Red cell phenotyping	Antigen Typing	Red Blood Cells	Grifols Manual and Automated Gel Card Systems	CE/ based on standard method	N/A	LM-BT-0018 LP-BT-0047 EXT-BT-0077
1020 Transfusion science - .09 Direct antiglobulin test	Direct antiglobulin test (DAT)		Automated Method using Eflexis Grifols DG Gel Card System Manual Method using Grifols DG Gel Card System	CE/ based on standard method	N/A	LM-BT-0021 LP-BT-0047 EXT-BT-0077
<i>a. 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>						

Chemical Pathology

Category: B

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 - .05 CO-oximetry	COHb	Whole Blood	Co-oximetry	RAPIDpoint 500	CE	LP-POC-0007
	MetHb		Co-oximetry	RAPIDpoint 500	CE	LP-POC-0007
	O2Hb		Co-oximetry	RAPIDpoint 500	CE	LP-POC-0007
	Total Haemoglobin		Co-oximetry	RAPIDpoint 500	CE	LP-POC-0007
1061 Clinical Chemistry - .06 Blood pH and gas tensions	pCO2	Whole Blood	Potentiometric	RAPIDpoint 500	CE	LP-POC-0007
	pH		Potentiometric	RAPIDpoint 500	CE	LP-POC-0007
	pO2		Amperometric	RAPIDpoint 500	CE	LP-POC-0007
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Chloride	Whole Blood	Potentiometric	RAPIDpoint 500	CE	LP-POC-0007
	Glucose		Amperometric	RAPIDpoint 500	CE	LP-POC-0007
	Ionised Calcium		Potentiometric	RAPIDpoint 500	CE	LP-POC-0007
	Lactate		Amperometric	RAPIDpoint 500	CE	LP-POC-0007
	Potassium		Potentiometric	RAPIDpoint 500	CE	LP-POC-0007
	Sodium		Potentiometric	RAPIDpoint 500	CE	LP-POC-0007
1061 Clinical Chemistry - .65 Pregnancy tests – qualitative	HCG	Urine	CIA	Siemens Clinitek Status	CE	LM-POC-0004
1061 Clinical Chemistry - .76 Simple side tests for	Glucose	Whole Blood	Electrochemical	Abbott Freestyle Pro Meter	CE	LM-POC-0013

biochemical and immunological analytes						
	Ketones		Electrochemical	Abbott Freestyle Pro Meter	CE	LM-POC-0013

b
The hospital pathology laboratory is accredited for the provision of Point of Care testing in accordance with ISO 15189:2012 and ISO 22870:2016, for the tests identified in category B.

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.

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	Full Blood Count with automated differential leucocyte count	EDTA Blood	Automated Electrical Impedance VCS technology Calculations	Beckman Coulter Unicel DxH 800	CE	LM-HAEM-0025 LP-HAEM-0013
1030 Haematology - .02 Visual examination of blood films	Blood Film Examination and differential leucocyte count		Microscopy	Microscope	Standard Method	LM-HAEM-0017 LM-HAEM-0018 LP-HAEM-0004
1030 Haematology - .03 Erythrocyte sedimentation rate	Erythrocyte Sedimentation Rate (ESR)	Sodium Citrate/EDTA	Sedimentation	Westegren (Manual)	CE based on standard method	LM-HAEM-0011
1030 Haematology - .05 Automated differential leucocyte counts	Full Blood Count with automated differential leucocyte count	EDTA Blood	Automated Electrical Impedance VCS technology Calculations	Beckman Coulter Unicel DxH 800	CE	LM-HAEM-0025 LP-HAEM-0013
1030 Haematology - .09 Examination of malarial parasites	Examination for Malarial Parasites		Staining/ Microscopy/ Calculation/ Chromatographic Kit	Microscope	CE	LM-HAEM-0010 LM-HAEM-0012
1030 Haematology - .41 General haemostasis related tests	D Dimer	Sodium Citrate	Enzyme Linked Fluorescence	Mini Vidas	CE	LM-HAEM-0022 LP-HAEM-0011
1030 Haematology - .57 Screening test for infectious mononucleosis	Infectious Mononucleosis Screen	EDTA Blood Plasma	Manual Immunoassay	Clearview IM II Kit	CE	LM-HAEM-0016

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
1011 Macroscopic examination and description	Macroscopic examination and description of specimens	Sputum, CSF, Faeces, Sterile fluids	Manual/ Macroscopic examination and description of specimens	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO- 0025 LM-MICRO-0026 LM-MICRO- 0032 LM-MICRO- 0081 LM-MICRO- 0031
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 General Bacteriology	All swabs BAL Respiratory Specimens CSF CAPD Fluids Faeces Colonic Aspirates Fluids Corneal Scrapings Tissues Biopsies Artificial devices Urine	Microscope/ Microscopic examination with or without fixation and staining with dyes for enumeration and description of bacteria	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0012
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	Microscopic examination for Parasites	Faeces Worms Sellotape slides Urine	Light Microscope	Microscopic examination with or without fixation and staining with dyes for enumeration and description of parasites	N/A	LM-MICRO-0070

1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .03 Microscopic examination for fungi	Microscopic examination for Fungi	Urine Liver and spleen aspirates Sputum Bile CSF Skin Hair Nail	Microscope/ Microscopic examination with or without fixation and staining with dyes for enumeration and description of fungi	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0008
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	Culture of general bacteria	Aqueous/Vitreous fluids Corneal Scrapings	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0029
		Artificial devices	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0045
		Aspirates	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0032 LM-MICRO-0022
		Axilla swab	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0038 LM-MICRO-0042 LM-MICRO-0040
		BAL	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0025

	defined periods. Visual observation of growth.			
CAPD Fluid	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0027
Cerebrospinal Fluid	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0026
Ear Swab	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0028
Eye swabs Conjunctival swabs	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0029
Faeces Colonic aspirates	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0031
Fluids	Manual/ Manual culture in agar based media with incubation of specimens at defined	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0032

	temperatures for defined periods. Visual observation of growth.			
High Vaginal Swabs Endocervical Swabs Cervical swabs Urethral swabs	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0058
Mouth Swabs	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0037
Nasal Swab Groin Swabs	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0038 LM-MICRO-0042 LM-MICRO-0040
Pharyngeal swabs	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0044
Pus	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0022
Rectal swabs	Manual/ Manual culture in agar based media with incubation of	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology

	specimens at defined temperatures for defined periods. Visual observation of growth.			LM-MICRO-0043 LM-MICRO-0087
Respiratory Specimens	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0025
Skin	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0040
Throat swab	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0044
Tips	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0036
Tissue	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0045
Urine Suprapubic Aspirate	Manual/ Manual culture in agar based media	Based on Standard Method	N/A	Public Health England (PHE) - UK standards

			with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.			for Microbiology LM-MICRO-0046
		Wound swabs	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0022 LM-MICRO-0040
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi	Culture of fungi	CSF	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0026
		Skin Hair Nail	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0033
		Sputum	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0025
		Urine	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0046

1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay,	Clostridium Difficile	Faeces	TechLab C.Diff Quik Chek Complete Kit/ Enzyme Immunoassay	CE	N/A	LM-MICRO-0081
	Legionella Pneumophilia Antigen	Urine	BINAX Legionella Urinary Antigen Kit/ Enzyme Immunoassay	CE	N/A	LM-MICRO-0073
	Streptococcus Pneumonia Urinary Antigen		BINAX Streptococcus pneumoniae Urinary Antigen Kit/ Enzyme Immunoassay	CE	N/A	LM-MICRO-0074
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods,	Detection of OXA-48, KPC, NDM, VIM and IMP Carbapenemases in bacterial culture	Bacterial Isolate	O.K.N.V.I RESIST-5 Kit CORIS BioConcept	CE	N/A	LM-MICRO-0093
	MRSA Confirmation Testing		PBP2a SA Culture Colony Test Alere Kit	CE/ Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0097
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Detection of Carbapenemases Using the Xpert® Carba-R Assay		Cepheid Gene Xpert/ RT-PCR	CE	N/A	LM-MICRO-0095
	Detection of toxin producing C. difficile using the Xpert® C. difficile BT Assay	Faeces	Cepheid Gene Xpert/ RT-PCR	CE	N/A	LM-MICRO-0081
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE	Identification of Organisms	Bacterial and Fungal Isolates	Identification using manual and automated systems/ Kits/tests and automated Vitek 2	Based on Standard Method	N/A	Public Health England (PHE) - UK standards for Microbiology LM-MICRO-0017 LP-MICRO-0021

marked commercial systems						LP-MICRO-0022 LP-MICRO-0026
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy			MALDI-TOF/ Mass Spectrometry	CE	N/A	LP-MICRO-0026
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes	E Test	Bacterial isolates	Based on Standard Method	CE	N/A	LM-MICRO-0003 Public Health England (PHE) - UK standards for Microbiology
	Manual Disc diffusion		Based on Standard Method	CE	N/A	LM-MICRO-0060 Public Health England (PHE) - UK standards for Microbiology