Schedule of Accreditation

Organisation Name	Saolta University Health Care Group Galway University Hospital Haematology
Trading As	
INAB Reg No	239MT
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Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	15/09/2009
Scope Classification	Haematology

Services available to the public[1]

[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	Haematology Laboratory, Newcastle Road, Galway, H91 YR71

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	Basophil Count	Blood	Fluorescence Flow Cytometry	Sysmex XN10 / XN20	CE	FBC/SOP/022
	Eosinophil Count		Fluorescence Flow Cytometry	Sysmex XN10 / XN20	CE	FBC/SOP/022
	Haematocrit		Cumulative Pulse Measurement	Sysmex XN10 / XN20	CE	FBC/SOP/022
	Haemoglobin		Photometric (SLS)	Sysmex XN10 / XN20	CE	FBC/SOP/022
	Lymphocyte Count		Fluorescence Flow Cytometry	Sysmex XN10 / XN20	CE	FBC/SOP/022
	MCH		Calculated	Sysmex XN10 / XN20	CE	FBC/SOP/022
	MCHC		Calculated	Sysmex XN10 / XN20	CE	FBC/SOP/022
	Mean Cell Volume		Calculated	Sysmex XN10 / XN20	CE	FBC/SOP/022
	Monocyte Count		Fluorescence Flow Cytometry	Sysmex XN10 / XN20	CE	FBC/SOP/022
	Neutrophil Count		Fluorescence Flow Cytometry	Sysmex XN10 / XN20	CE	FBC/SOP/022
	NRBC		Fluorescence Flow Cytometry	Sysmex XN10 / XN20	CE	FBC/SOP/022

	Platelet Count	Fluorescence Flow Cytometry	Sysmex XN20	CE	FBC/SOP/022
		Impedance	Sysmex XN10 / XN20	CE	FBC/SOP/022
		Optical	Sysmex XN10 / XN20	CE	FBC/SOP/022
	RDW	Derived from Histogram	Sysmex XN10 / XN20	CE	FBC/SOP/022
	Red Cell Count	Impedance	Sysmex XN10 / XN20	CE	FBC/SOP/022
	White Cell Count	Fluorescence Flow Cytometry	Sysmex XN10 / XN20	CE	FBC/SOP/022
1030 Haematology - .02 Visual examination of blood films	Blood Films. Includes Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Red Cell Morphology.	Staining/Microscopy	Sysmex SP50 / Microscopes	CE	FBC/SOP/021
		Staining/Microscopy	Sysmex SP50 / Microscopes	CE	FBC/SOP/021
1030 Haematology - .03 Erthrocyte sedimentation rate	ESR	Photo optical based on Westergren method	Starrsed Interliner	CE	ESR/SOP/005
		Photo optical based on Westergren method	Starrsed Inversa	CE	ESR/SOP/005
1030 Haematology - .05 Automated differential leucocyte counts	Basophil Count	Fluorescence Flow Cytometry	Sysmex XN10 / XN20	CE	FBC/SOP/022
	Eosinophil Count	Fluorescence Flow Cytometry	Sysmex XN10 / XN20	CE	FBC/SOP/022
	Lymphocyte Count	Fluorescence Flow Cytometry	Sysmex XN10 / XN20	CE	FBC/SOP/022
	Monocyte Count	Fluorescence Flow Cytometry	Sysmex XN10 / XN20	CE	FBC/SOP/022
	Neutrophil Count	Fluorescence Flow Cytometry	Sysmex XN10 / XN20	CE	FBC/SOP/022
1030 Haematology - .06 Automated reticulocyte counts	Reticulocytes	Fluorescence Flow Cytometry	Sysmex XN10 / XN20	CE	FBC/SOP/022
1030 Haematology - .09 Examination of malarial parasites	Blood Film Examination	Staining / Microscopy	Manual	Based on standard method	SHaem/SOP/004 Malaria Screening

	CareStart Malaria		Immuno-chromatographic Test	CareStart Malaria Kit	CE	SHaem/SOP/004
1030 Haematology - .20 Bone marrow examination	Bone Marrow Examination	Bone Marrow	Staining / Microscopy	Manual	Based on standard method	SHaem/SOP/005 Bone Marrow
1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia	Sickle Screen (Sickledex)	Blood	Qualitative Solubility Test	Manual	CE Method	SHaem/SOP/015 Sickledex Screen
1030 Haematology - .31 Tests for foetal Hb (Kleihauer)	Kleihauer Betke Guest Medical		Acid Elution	Semi quantative / Manual	CE Method	Shaem/SOP/001
	Kleihaur Test		Semi-Quantitative Acid Elution/Microscopy	Manual	CE Method	SHaem/SOP/001 Kleihaur Betke Test
1030 Haematology - .36 Screening tests for G6Pd	Glucose 6 Phosphate Dehydrogenase (G6PD) Screen		Qualitative Visual Flourescence	Manual	CE Method	SHaem/SOP/002 G6PD Assay
1030 Haematology - .40 Limited haemostasis related tests	Activated Protein C Resistance		Photo-Optical Technology Ratio 1-5	Sysmex CS2100i	CE Method	SCoag/SOP/022 Thrombophilia Screen Sysmex
	Anti-Factor Xa Level (LMWH)		Chromogenic	Sysmex CS50100	S Coag-SOP-030	
	Antithrombin		Photo-Optical Technology 0-130%	Sysmex CS2100i	CE Method	SCoag/SOP/022 Thrombophilia Screen Sysmex
	FII Coagulation Factor Assay		Photo-Optical Technology 6-150%	Sysmex CS2100i	CE Method	SCoag/SOP/023 Factor Assays Intrinsic and Extrinsic - Sysmex
	FIX Coagulation Factor Assay		Photo-Optical Technology 2.5-132%	Sysmex CS2100i	CE Method	SCoag/SOP/023 Factor Assays Intrinsic and Extrinsic - Sysmex
	Free Protein S		Photo-Optical Technology 0-165%	Sysmex CS2100i	CE Method	SCoag/SOP/022 Thrombophilia Screen Sysmex
	FV Coagulation Factor Assay		Photo-Optical Technology 6-136%	Sysmex CS2100i	CE Method	SCoag/SOP/023 Factor Assays Intrinsic and Extrinsic - Sysmex
	FVII Coagulation		Photo-Optical Technology	Sysmex CS2100i	CE Method	SCoag/SOP/023

	Factor Assay		6-145%			Factor Assays Intrinsic and Extrinsic - Sysmex
	FVIII Chromogenic		Chromogenic	Sysmex CS2100i	CE Method	Scoag/SOP/032
	FVIII Coagulation Factor Assay		Photo-Optical Technology 2.5-123%	Sysmex CS2100i	CE Method	SCoag/SOP/023 Factor Assays Intrinsic and Extrinsic - Sysmex
	FX Coagulation Factor Assay		Photo-Optical Technology 6 -145%	Sysmex CS2100i	CE Method	SCoag/SOP/023 Factor Assays Intrinsic and Extrinsic - Sysmex
	FXI Coagulation Factor Assay		Photo-Optical Technology 5.5 -133%	Sysmex CS2100i	CE Method	SCoag/SOP/023 Factor Assays Intrinsic and Extrinsic - Sysmex
	FXII Coagulation Factor Assay		Photo-Optical Technology 6 -144%	Sysmex CS2100i	CE Method	SCoag/SOP/023 Factor Assays Intrinsic and Extrinsic - Sysmex
	Lupus Anticoagulant		Photo-Optical Technology Interpretative Pos/Neg	Sysmex CS2100i	CE Method	SCoag/SOP/026 Lupus Anticoagulant Assay Sysmex
	Protein C		Photo-Optical Technology 0-150%	Sysmex CS2100i	CE Method	SCoag/SOP/022 Thrombophilia Screen Sysmex
	Von Willebrand Factor Antigen		Photo-Optical Technology 10-150%	Sysmex CS2100i	CE Method	SCoag/SOP/028 Von Willebrand Factor Antigen Assay Sysmex
	Von Willebrand Ristocetin Cofactor (RiCof) Assay		Coagulation technique	11 IU/ml - 150 IU/ml depending on Lot number of calibrator / Sysmex CS2100i	CE Method	SCoag/SOP/029 Sysmex VW Ristocetin Cofactor (RiCof) Assay
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time (APTT)	Blood	Photo-Optical Technology	Sysmex CS5100	CE Method	RCoag/SOP/026 Sysmex Activated Partial Thromboplastin Time (APTT) Assay
	D-Dimer	Blood	Photo-Optical Technology	Sysmex CS5100	CE Method	RCoag/SOP/027 Sysmex D-Dimer
	Derived Fibrinogen		Derived Calculation from PT	Sysmex CS5100	CE Method	RCoag/SOP/025 Sysmex Prothrombin

						Time/ Derived Fibrinogen Assay
	Fibrinogen (Clauss)		Photo-Optical Technology	Sysmex CS5100	CE Method	RCoag/SOP/028 Sysmex Clauss Fibrinogen
	International Normalised Ratio (INR)		Ratio Calculation	Sysmex CS5100	CE Method	RCoag/SOP/025 Sysmex Prothrombin Time/ Derived Fibrinogen Assay
	Prothrombin Time (PT)		Photo-Optical Technology	Sysmex CS5100	CE Method	RCoag/SOP/025 Sysmex Prothrombin Time/ Derived Fibrinogen Assay
	Thrombin Time		Coagulation technique	15-27 seconds / Sysmex CS2100i	CE Method	Rcoag/SOP/031 Sysmex Thrombin Time
1030 Haematology - .45 Tests of platelet function	Platelet Aggregation Studies	Blood	Optical Impedance	Platelet Aggregation Profiler	Based on standard method	SCoag/SOP/002 Platelet Aggregation
1030 Haematology - .55 Iron studies	Ferritin	Blood	Electrochemiluminescence	Cobas e801	CE	Haematinics/SOP/011
1030 Haematology - .58 Vitamin B12 and folate (serum and red cell)	Serum Folate		Electrochemiluminescence	Cobas e801	CE	Haematinics/SOP/010
	Vitamin B12		Electrochemiluminescence	Cobas e801	CE	Haematinics/SOP/009
1030 Haematology - .62 Plasma viscosity	Plasma Viscosity (Automated)		Capillary Viscometer	Benson Viscometer	CE	SHaem/SOP/032
1030 Haematology - .70 Immunophenotyping	Acute Leukaemia Panel	Bone Marrow Aspirate in RPMI-Heparin or Peripheral blood in EDTA	Flow Cytometry	BD Facscanto II + BD Lyric	In-House	Shaem/SOP/053
	Chronic Leukaemia Panel T and B Cell	Bone Marrow Aspirate in RPMI-Heparin or EDTA. Peripheral blood in EDTA. Lymph Node / FNA	Flow Cytometry	BD Facscanto II + BD Lyric	In-House	Shaem/SOP/053
	CSF Immunophenotyping Screen	CSF in RPMI-Heparin or Transfix	Flow Cytometry	BD Facscanto II	In House	Shaem/SOP/057

	MRD for CLL	Bone Marrow Aspirate in RPMI-Heparin or EDTA.	Flow Cytometry	BD Facscanto II	In-House	Shaem/SOP/056
	MRD for Myeloma		Flow Cytometry	BD Lyric	CE	Shaem/SOP/059
	PNH	Peripheral Blood	Flow Cytometry	BD Facscanto II + BD Lyric	In-House	Shaem/SOP/055
	RCD II	Duodenal biopsy in PRMI without heparin	Flow Cytometry	BD Facscanto II + BD Lyric	In-House	Shaem/SOP/058
	Stem Cell	Pripheral Blood Harvest/ Frozen Harvest	Flow Cytometry	IVDR kit + BD Lyric /BD Facscanto II	CE	Shaem/SOP/054