



National Maternity Hospital



Title: List of Flexible Scope of Accreditation Changes	Document Number: RF-CS-LM-121
	Revision Number: 8
Author: Laura Kennedy	Date Effective From: 12/05/2022
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Registration Number: 240MT; October 2020 to May 2022

Note: This must be read in conjunction with the scope of accreditation for the National Maternity Hospital

INAB Class No. (Ref. P9)	Test/Assay Name	Specimen Type	Technique	Equipment	Range of Measurement	Description of Change	Associated Document	Date added to List of Flexible Scope (QO/Deputy)	Change Control No.
1061 Clinical Chemistry - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies	Protein: Creatinine Ratio **1,2,3,4	Urine	Calculation	Beckman Coulter AU680 Chemistry Analyser	Beckman Coulter AU680 Chemistry Analyser	Calculation of Protein: Creatinine Ratio from Urinary Protein and Urinary Creatinine (INAB accredited tests).	PP-CS-BIO-1 Routine Operation of the AU680 Clinical Chemistry Analyser / PP-CS-BIO-42 Management of Reported Calculations in Biochemistry	15/10/2020	FS-8
1061 Clinical Chemistry - .20 Hormones	sFlt-1: PIGF ratio **1,2,3,4	Serum	Electrochemiluminescence immunoassay / Calculation	Roche Cobas e601	Roche Cobas e601	Addition of new test	PP-CS-BIO-38 Operation of the Roche Cobas e601, PP-CS-BIO-42 Management of Reported Calculations in Biochemistry	01/02/2021	FS-9
1061 Clinical Chemistry - .32 Maternal markers for foetal wellbeing	Free β HCG, PAPP-A **1,2,3,4	Serum	Electrochemiluminescence immunoassay	Roche Cobas e601	Roche Cobas e601	Addition of new tests	PP-CS-BIO-38 Operation of the Roche Cobas e601	04/03/2021	FS-10
1030 Haematology -	Haematocrit **1,2,3,4	Whole blood	Hydro Dynamic Focusing (DC Detection), flow	Sysmex XN-2000	Sysmex XN-2000	Upgrade Analyser	PP-CS-HAE-42 Operation of	07/03/2022	FS-6

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.01 Blood counts			cytometry				Sysmex FBC Analyser		
	Haemoglobin **1,2,3,4	Whole blood	SLS-haemoglobin method.	Sysmex XN-2000	Sysmex XN-2000	Upgrade Analyser	PP-CS-HAE-42 Operation of Sysmex FBC Analyser	07/03/2022	FS-6
	MCH **1,2,3,4	Whole blood	Hydro Dynamic Focusing (DC Detection), flow cytometry	Sysmex XN-2000	Sysmex XN-2000	Upgrade Analyser	PP-CS-HAE-42 Operation of Sysmex FBC Analyser	07/03/2022	FS-6
	MCHC **1,2,3,4	Whole blood	Hydro Dynamic Focusing (DC Detection), flow cytometry	Sysmex XN-2000	Sysmex XN-2000	Upgrade Analyser	PP-CS-HAE-42 Operation of Sysmex FBC Analyser	07/03/2022	FS-6
	MCV **1,2,3,4	Whole blood	Hydro Dynamic Focusing (DC Detection), flow cytometry	Sysmex XN-2000	Sysmex XN-2000	Upgrade Analyser	PP-CS-HAE-42 Operation of Sysmex FBC Analyser	07/03/2022	FS-6
	Platelet Count **1,2,3,4	Whole blood	Hydro Dynamic Focusing (DC Detection), flow cytometry. Impedance / Optical	Sysmex XN-2000	Sysmex XN-2000	Upgrade Analyser	PP-CS-HAE-42 Operation of Sysmex FBC Analyser	07/03/2022	FS-6
	White Cell count **1,2,3,4	Whole blood	Hydro Dynamic Focusing (DC Detection), flow cytometry	Sysmex XN-2000	Sysmex XN-2000	Upgrade Analyser	PP-CS-HAE-42 Operation of Sysmex FBC Analyser	07/03/2022	FS-6
1030 Haematology - .05 Automated differential leucocyte counts	Basophil count **1,2,3,4	Whole blood	Hydro Dynamic Focusing (DC Detection), flow cytometry	Sysmex XN-2000	Sysmex XN-2000	Upgrade Analyser	PP-CS-HAE-42 Operation of Sysmex FBC Analyser	07/03/2022	FS-6
	Eosinophil count **1,2,3,4	Whole blood	Hydro Dynamic Focusing (DC Detection), flow cytometry	Sysmex XN-2000	Sysmex XN-2000	Upgrade Analyser	PP-CS-HAE-42 Operation of Sysmex FBC Analyser	07/03/2022	FS-6
	Lymphocyte count	Whole blood	Hydro Dynamic Focusing (DC Detection), flow	Sysmex XN-2000	Sysmex XN-2000	Upgrade Analyser	PP-CS-HAE-42 Operation of	07/03/2022	FS-6

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	**1,2,3,4		cytometry				Sysmex FBC Analyser		
	Monocyte count **1,2,3,4	Whole blood	Hydro Dynamic Focusing (DC Detection), flow cytometry	Sysmex XN-2000	Sysmex XN-2000	Upgrade Analyser	PP-CS-HAE-42 Operation of Sysmex FBC Analyser	07/03/2022	FS-6
	Neutrophil count **1,2,3,4	Whole blood	Hydro Dynamic Focusing (DC Detection), flow cytometry	Sysmex XN-2000	Sysmex XN-2000	Upgrade Analyser	PP-CS-HAE-42 Operation of Sysmex FBC Analyser	07/03/2022	FS-6
	n-RBC's **1,2,3,4	Whole blood	Hydro Dynamic Focusing (DC Detection), flow cytometry	Sysmex XN-2000	Sysmex XN-2000	Upgrade Analyser	PP-CS-HAE-42 Operation of Sysmex FBC Analyser	07/03/2022	FS-6
1030 Haematology - .06 Automated reticulocyte counts	Reticulocyte count **1,2,3,4	Whole blood	Hydro Dynamic Focusing (DC Detection), flow cytometry	Sysmex XN-2000	Sysmex XN-2000	Upgrade Analyser	PP-CS-HAE-42 Operation of Sysmex FBC Analyser	07/03/2022	FS-6
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Gentamicin **1,2,3,4	Plasma	Homogenous enzyme immunoassay	Beckman Coulter AU680 Chemistry Analyser	Beckman Coulter AU680 Chemistry Analyser	Change of reagent and sample type	PP-CS-BIO-1 Routine Operation of the AU680 Clinical Chemistry	12/05/2022	FS-11