

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames TW18 3HR

 7896 Accredited to ISO 15189:2012	North Tees & Hartlepool NHS Foundation Trust	
	Issue No: 011	Issue date: 30 January 2025
	Department of Blood Sciences University Hospital of North Tees Hardwick Stockton-on-Tees TS19 8PE	Contact: Ann Wallis, Pathology Quality Manager Tel: +44 (0)1642 850850 Ext 55239 E-Mail: ann.wallis1@nhs.net Website: www.nth.nhs.uk
Testing performed by the Organisation at the locations specified below		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
Address University Hospital of North Tees Hardwick Stockton-on-Tees TS19 8PE Local contacts Ann Wallis	Haematology & Blood Transfusion Blood issue Clinical Biochemistry Documented in-house methods to meet the requirements of the Sickle cell and Thalassaemia (SCT) screening programme as defined in the laboratory QA evidence requirements: <ul style="list-style-type: none">Review of Family Origin Questionnaire and Full Blood Count screenSubsequent testing at a laboratory accredited to ISO 15189 for detection of haemoglobin variants via HPLC	A
Address University Hospital of Hartlepool Holdforth Road Hartlepool TS24 9AH Local contacts Ann Wallis	Haematology Blood Issue	B

Site activities performed away from the locations listed above:

Location details	Activity	Location code
Address Blood Fridge Main Theatre – first floor tower block University Hospital of North Tees Hardwick Stockton-on-Tees TS19 8PE	Products only; no testing occurs at this site	A



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DETAIL OF ACCREDITATION

Assessment Manager: JR2



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house procedures with manufacturer's instructions (cont'd)	
Venous whole blood (EDTA)	Erythrocyte sedimentation rate	Beckman Coulter ALIFAX photometric assay with reference to NTH_HAEM_83	A
	Coagulation screen including:	Stago STA-R Max 3 Analyser Clot formation/Chromogenic/Immunoturbidometric using procedures below: NTH_Haem_112	
Venous Blood: Citrated	Prothrombin Time/Ratio	NTH_Haem_112	A
	Activated Partial Prothrombin Time/Ratio	NTH_Haem_112	
	Warfarin monitoring (INR)	NTH_Haem_133	
Venous blood: Citrated	Clauss Fibrinogen	NTH_Haem_112	A
	Mixing Studies	NTH_Haem_117	
	Thrombin	NTH_Haem_130	
Venous blood; Citrated	D Dimer	NTH_Haem_116	A
	Anti Xa	NTH_Haem_111	
	Thrombophilia Screen including:		A
	ATIII	NTH_Haem_142	
	Protein C	NTH_Haem_141	
	Protein S	NTH_Haem_132	



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house procedures with manufacturer's instructions (cont'd)	
Venous blood: Citrated	Factor V Leiden	Cepheid GeneExpert cartridge Polymerase Chain Reaction (PCR) method. With reference to NTH_HAEM_81	A
Venous blood: Citrated	Factor II Gene mutation	Cepheid GeneExpert cartridge PCR method. With reference to NTH_HAEM_81	A
Venous blood plasma	Kleihaur fetal red cell detection	Guest Medical Fetal Red Cell detection kit (Elution HD) with reference to NTH_BT_014	A
Venous whole blood (EDTA)	Epstein-Barr Virus (EBV) antibodies - Infectious Mononucleosis Screen	Manual Chromogenic test using IM Clearview II kit with reference to NTH_HAEM_69	A
Venous whole blood (EDTA)	Malaria Parasite screen and identification of species: <i>Plasmodium falciparum</i> , <i>P ovale</i> , <i>P malariae</i> <i>P vivax</i>	Manual chromogenic test using Carestart Rapid Malarial Screening kit with reference to NTH_HAEM_61	A
Venous whole blood (EDTA), serum, plasma	Sickle cell solubility for the presence of Haemoglobin S	Streck Sickledex Kit qualitative solubility test with reference to NTH_Haem_9	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house procedures with manufacturer's instructions (cont'd)	
Venous blood: EDTA unless otherwise stated	Group and Screen ABO and RhD Blood Group	Automated: Grifols Eflexis Analyser - column agglutination NTH_BT_73 NTH_BT_74	A
	Red cell antibody screen: Rh blood group antibodies: anti-Cw anti-C anti-c anti-D anti-E anti-e	Manual: Grifols DG - Gel column agglutination NTH_BT_04	A
	Kell System blood group antibodies: anti-K anti-k anti-Kpa	Automated: Grifols Eflexis Analyser - column agglutination NTH_BT_10	A
	Kidd blood group antibodies: anti-JKa anti-JKb	Manual: Grifols DG - Gel column agglutination NTH_BT_10	



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house procedures with manufacturer's instructions (cont'd)	
Venous blood: EDTA unless otherwise stated	Kidd blood group antibodies: anti-JKa anti-JKb	Automated: Grifols Eflexis Analyser - column agglutination NTH_BT_10	A
	Duffy blood group antibodies: anti-Fya anti Fyb	Manual: Grifols DG - Gel column agglutination NTH_BT_10	A
	Lutheran blood group antibodies: anti-Lua anti-Lub		
	MNS blood group antibodies: anti-M anti-N anti-S anti-s		
	Prophylactic Anti D screen	Automated: Grifols Eflexis Analyser - column agglutination NTH_BT_75 Manual: Grifols DG – Gel column agglutination NTH_BT_75	A A
	Serological Crossmatch	Manual: Grifols DG-Gel Column agglutination NTH_BT_06	A
	Direct Antiglobulin Test	Manual: Grifols DG-Gel Column agglutination NTH_BT_22	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house procedures with manufacturer's instructions (cont'd)	
	Red Cell Phenotyping – Rh	Manual: Grifols DG-Gel Column agglutination NTH_BT_11	A
	Neonate Blood Grouping	Manual: Grifols DG-Gel Column agglutination NTH_BT_08	A
	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures in conjunction with manufacturer's instructions using Beckman Dxl800 or Beckman AU5800 analysers with random access colorimetry, turbidimetry or chemiluminescence technology.	A
Serum / plasma	Quantitative determination of: AFP	NTH_B_068 (Dxl800)	A
Serum/Plasma/Urine	Albumin	NTH_B_067 (AU5800)	A
Urine	Albumin creatinine ratio	NTH_B_004 (AU5800)	A
Serum/Plasma	Alcohol/Ethanol	NTH_B_077 (AU5800)	A
Serum/Plasma	ALP	NTH_B_018 (AU5800)	A
Serum/Plasma	ALT	NTH_B_017 (AU5800)	A
Serum/Plasma	Ammonia	NTH_B_069 (AU5800)	A
Serum/Plasma	Bicarbonate	NTH_B_133 (AU5800)	A
Serum/Plasma	Amylase	NTH_B_039 (AU5800)	A
Serum/Plasma	AST	NTH_B_125 (AU5800)	A
Serum/Plasma	Bile acids	NTH_B_111 (AU5800)	A
Serum/Plasma	Direct bilirubin	NTH_B_050 (AU5800)	A



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd) Quantitative determination of:-	Documented in-house procedures in conjunction with manufacturer's instructions using Beckman AU5800 or DxI800 analysers with random access colorimetry, turbidimetry or chemiluminescence technology. (cont'd)	
Serum/Plasma	Bilirubin	NTH_B_050 (AU5800)	A
Serum/Plasma/Urine	Calcium	NTH_B_072 (AU5800)	A
Serum/Plasma	Adjusted Calcium	NTH_B_072 (AU5800)	A
Serum/Plasma	CA125	NTH_B_073 (DxI800)	A
Serum/Plasma	Carbamazepine	NTH_B_037 (AU58000)	A
Serum/Plasma	CEA	NTH_B_020 (DxI800)	A
Serum/Plasma/Urine	Chloride	NTH_B_074 (AU5800)	A
Serum/Plasma	Cholesterol (including HDL, non HDL and LDL)	NTH_B_023 (AU5800)	A
Serum/Plasma	CK	NTH_B_045 (AU5800)	A
Serum/Plasma	Cortisol	NTH_B_024 (DxI800)	A
Serum/Plasma/Urine	Creatinine	NTH_B_048 (AU5800)	A
Serum/Plasma	CRP	NTH_B_035 (AU5800)	A
Serum/Plasma	Digoxin	NTH_B_058 (AU5800)	A
Serum/Plasma	Estradiol	NTH_B_005 (DxI800)	A
Serum/Plasma	Ferritin	NTH_B_040 (DxI800)	A
Serum/Plasma	Folate	NTH_B_036 (DxI800)	A



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Serum/Plasma	FSH	NTH_B_022 (DxI800)	A
Serum/Plasma	FT3	NTH_B_049 (DxI800)	A
Serum/Plasma	FT4	NTH_B_025 (DxI800)	A
Serum/Plasma	GGT	NTH_B_047 (AU5800)	A
Serum/Plasma	Gentamicin	NTH_B_060 (AU5800)	A
Serum/Plasma & CSF	Glucose	NTH_B_051 (AU5800)	A
Serum/Plasma	HCG	NTH_B_026 (DxI800)	A
Serum/plasma	Iron	NTH_B_080 (AU5800)	A
Serum/Plasma	Lipase	NTH_B_132 (AU5800)	A
Serum/Plasma	LDH	NTH_B_082 (AU5800)	A
Serum/Plasma	LH	NTH_B_027 (DxI800)	A
Serum/Plasma	Lithium	NTH_B_083 (AU5800)	A
Serum/Plasma & CSF	Lactate	NTH_B_081 (AU5800)	A
Serum/Plasma/Urine	Magnesium	NTH_B_054 (AU5800)	A
Serum/Plasma	Paracetamol	NTH_B_055 (AU5800)	A
Serum/plasma	Phenytoin	NTH_B_091 (AU5800)	A
Serum/Plasma/Urine	Phosphate	NTH_B_092 (AU5800)	A
Serum/Plasma &	Potassium	NTH_B_057 (AU5800)	A
Serum/Plasma	Progesterone	NTH_B_028 (DxI800)	A



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Serum/Plasma	Prolactin	NTH_B_034 (DxI800)	A
CSF, Urine only	Protein	NTH_B_044 (AU5800)	A
Urine	Protein/Creatinine ratio	NTH_B_044 (AU5800)	A
Serum/plasma	PSA	NTH_B_029 (DxI800)	A
Plasma	Red cell folate	NTH_B_036 (DxI800)	A
Serum/Plasma	Salicylate	NTH_B_094 (AU5800)	A
Serum/Plasma	SHBG	NTH_B_107 (DxI800)	A
Serum/Plasma/Urine	Sodium	NTH_B_095 (AU5800)	A
Serum/plasma	Testosterone	NTH_B_033 (DxI800)	A
Serum/Plasma	Theophylline	NTH_B_065 (AU5800)	A
Serum/Plasma	Total Protein	NTH_B_038 (AU5800)	A
Serum/Plasma	Triglyceride	NTH_B_041 (AU5800)	A
Serum/Plasma	Troponin I	NTH_B_105 (DxI800)	A
Serum/plasma	TSH	NTH_B_031 (DxI800)	A
Serum/Plasma/Urine	Urea	NTH_B_097 (AU1800)	A
Serum/Plasma/Urine	Urate	NTH_B_043 (AU5800)	A
Serum/Plasma	Valproate	NTH_B_062 (AU5800)	A
Serum/Plasma	Vancomycin	NTH_B_059 (AU5800)	A
Serum/Plasma	Vitamin B12	NTH_B_042 (DxI800)	A



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	Quantitative determination of:-		
Serum/Plasma	Vitamin D	NTH_B_117 (AU5800)	A
		In house documented procedure in conjunction with manufacturers instructions using Roche cobas e411 random access colorimetry or turbidimetry or chemiluminescence technology	
Serum/plasma	NT proBNP	NTH_B_085	A
Serum/Plasma	CA153	SOP NTH_B_109	A
Serum/Plasma	CA199	SOP NTH_B_114	A
CSF	Xanthochromia	In house documented procedure in conjunction with manufacturers instructions NTH_B_076 using Uvikon XS spectrophotometry / NorthStar scientific spectrophotometry	A
Whole blood	COHB	In house documented procedure in conjunction with manufacturers instructions NTH_B_070 using Cobas b123 automated POC technology	A
Whole blood	Gas (pO ₂ , pCO ₂ , Na, K, Cl, pH, MethB)	NTH_B_070	A
Whole blood, plasma	Ionised calcium	NTH_B_070	A



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Serum/Plasma/Urine	Quantitative determination of:- Osmolality	In house documented procedure in conjunction with manufacturers instructions NTH_B_001 using Advanced Osmometer 3320 using freezing point depression	A
END			