


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL 7896</p> <p>Accredited to ISO 15189:2012</p>	<h3>North Tees &amp; Hartlepool NHS Foundation Trust</h3> <p>Issue No: 007    Issue date: 08 April 2022</p>	
	<p>Department of Blood Sciences University Hospital of North Tees Hardwick Stockton-on-Tees TS19 8PE</p>	<p>Contact: Joanne Wintrip, Pathology Quality Manager Tel: +44 (0)1642 617617 E-Mail: Joanne.Wintrip1@nhs.net Website: www.nth.nhs.uk</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

Location details	Activity	Location code
<p><b>Address</b> University Hospital of North Tees Hardwick Stockton-on-Tees TS19 8PE</p> <p><b>Local contacts</b> Joanne Wintrip</p>	<p>Haematology &amp; Blood Transfusion Blood issue Clinical Biochemistry</p>	A
<p><b>Address</b> University Hospital of Hartlepool Holdforth Road Hartlepool TS24 9AH</p> <p><b>Local contacts</b> Joanne Wintrip</p>	<p>Haematology Blood Issue</p>	B

#### Site activities performed away from the locations listed above:

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



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	<u>Haematological examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures with manufacturer's instructions	
Venous whole blood: EDTA	Full Blood Count (FBC) Including:-  Haemoglobin White Blood Count Platelet Count Red Blood Count Haematocrit MCV MCH MCHC RDW Hypochromic RBC % Neutrophil count Lymphocyte count Monocyte count Eosinophil count Basophil count Large unstained cells Reticulocytes	Beckmann Coulter DxH800 analyser with specific reference to SOP: NTH_Haem_072 Using Flow Cytometry, impedance and spectrophotometry, laser light scatter, calculated parameters.	A, B
Venous whole blood: EDTA	Thick and thin Blood Film for detection of abnormalities and for intra-erythrocytic parasites	Giemsa staining and light microscopy with reference to: NTH_Haem_014  Modified Wrights stain using Beckman Coulter SMS Automated slide stainer with reference to NTH_HAEM_084	A  A
Human Bone marrow	Bone Marrow Film for the detection of abnormalities	Modified Wrights stain using Beckman Coulter SMS Automated slide stainer with reference to NTH_HAEM_084	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examination activities for the purpose of clinical diagnosis</u> (cont'd)	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_0903	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_133	A
	Activated Partial Prothrombin Time/Ratio		
	Warfarin monitoring (INR)		
Venous blood: Citrated	Clauss Fibrinogen	NTH_Haem_117	A
	Mixing Studies	NTH_Haem_130	
	Thrombin		
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	
	Lupus Anticoagulant Screen	NTH_Haem_131	



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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_081	A
Venous blood: Citrated	Factor II Gene mutation	Cepheid GeneExpert cartridge PCR method. With reference to NTH_HAEM_081	A
Venous Blood: Citrated	Heparin Induced Thrombocytopenia (HIT) screen	Biorad Heparin/PF4 Test kit with reference to NTH_HAEM_079	A
Venous blood: Citrated	Lupus Anticoagulant	Instrumentation Laboratory ACL TOP 500 Turbidimetric method Clot detection by optical rate of change of absorbance end point being the maximum rate of change with reference to SOP: NTH_Haem_044	A
Venous blood plasma	Kleihaur fetal red cell detection	Source Bioscience Fetal Red Cell detection kti (Elution HD) with reference to NTH_BT_014	A
Venous blood: Citrated	Anti Factor Xa	Instrumentation Laboratory ACL TOP 500 Turbidimetric method Clot detection by optical rate of change of absorbance end point being the maximum rate of change with reference to SOP: NTH_Haem_018	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_069	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 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 Biorad optimal T kit with reference to NTH_HAEM_061	A
Venous whole blood (EDTA)	Thick and thin Blood films for identification of intra-erythrocytic parasites	Giemsa staining and light microscopy with reference to: NTH_Haem_014	A
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
		Manual: Grifols DG - Gel column agglutination NTH_BT_04	A
	Red cell antibody screen: Rh blood group antibodies: anti-Cw anti-C anti-c anti-D anti-E anti-e	Automated: Grifols Eflexis Analyser - column agglutination NTH_BT_10	A
	Kell System blood group antibodies: anti-K anti-k anti-Kpa	Manual: Grifols DG - Gel column agglutination NTH_BT_10	
	Kidd blood group antibodies: anti-JKa anti-JKb		



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HUMAN BODY FLUIDS (cont'd)  Venous blood: EDTA unless otherwise stated	<u>Haematological examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house procedures with manufacturer's instructions (cont'd)	
	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	A
		Manual: Grifols DG – Gel column agglutination NTH_BT_75	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</u> (cont'd)	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 DxI800 or Beckman AU5800 analysers with random access colorimetry, turbidimetry or chemiluminescence technology.	A
	Quantitative determination of:		
Serum / plasma	AFP	NTH_B_068 (DxI800)	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 & Urine	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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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	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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Serum/Plasma	Quantitative determination of:-  Vitamin D	NTH_B_117 (AU5800)	A
Serum/plasma	NT proBNP	In house documented procedure in conjunction with manufacturers instructions using Roche cobas e411 random access colorimetry or turbidimetry or chemiluminescence technology  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 Unicam Helios Alpha 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 <sub>2</sub> , pCO <sub>2</sub> , 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			