


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 8115 Accredited to ISO 15189:2012	Northampton General Hospital NHS Trust	
	Issue No: 010 Issue date: 24 April 2024	
	Pathology Department Northampton General Hospital Cliftonville Northampton Northamptonshire NN1 5BD	Contact: Josephine Evans Tel: +44 (0)1604 523809 E-Mail: ben.briggs1@nhs.net Josephine.evans7@nhs.net Website: http://www.northamptongeneral.nhs.uk/OurServices/ Clinical/Pathology/Pathology.aspx
Testing performed by the Organisation at the locations specified below		

Additional site activity performed away from the laboratory

Location details	Activity
Main Theatre Northampton General Hospital	Storage and issue of blood and blood products
Manfield Theatre Northampton General Hospital	Storage and issue of blood and blood products
Strutridge Theatre Northampton General Hospital	Storage and issue of blood and blood products
Cynthia Spencer Hospice Northampton	Issue of blood and blood products
Three Shires Hospital Northampton	Storage and issue of blood and blood products
Danetre Hospital Daventry	Storage and issue of blood and blood products



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purposes of clinical diagnosis</u>	Documented in house methods and manufacturer's instructions for
Serum / Plasma	Quantitation of: ALT AST Ammonia Amylase ALP Alpha-1-antitrypsin (AAT) ACE Bicarbonate Bile Acids C3 / C4 complement Caeruloplasmin Calcium Cholesterol CK Creatinine CRP Direct Bilirubin Ethanol Gamma GT Glucose Immunoglobulin G Immunoglobulin A Immunoglobulin M Iron Lactate LDH Magnesium Phosphate Rheumatoid Factor (RF) Total Bilirubin Total Protein Transferrin Triglyceride Urate Urea	Roche Cobas c702 using photometric analysis BIO-49,50,54,64



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturer's instructions for
Urine	Quantitation of: Amylase Calcium Creatinine Microalbumin Phosphate Protein Urate Urea	Roche Cobas c702 using photometric analysis BIO-49,50,54
CSF	Glucose Lactate Protein Quantitation of:	Roche Cobas ISE module using potentiometric analysis
Serum / Plasma	Chloride Potassium Sodium	BS-B-161, 162, 171, 177
Urine	Chloride Potassium Sodium	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturer's instructions for
Serum / Plasma	Therapeutic Drug Monitoring Carbamazepine Gentamicin Lithium Paracetamol Phenytoin Salicylate Theophylline Valproate Vancomycin (Roche Cobas c702 using photometric analysis BIO-49,50,54,64
Serum / Plasma	Immunoassay Investigations Quantitation of: AFP Anti-Throglobulin antibody Anti-TSH Receptor antibody NTPro-BNP CA125 CA153 CA199 CEA Cortisol Digoxin Ferritin FSH Free T3 Free T4 Folate GH HCG IGF-1 LH Macroprolactin Oestradiol	Roche Cobas e801 using Electrochemical luminescence (ECL) BIO-49,50,54,64



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturer's instructions for
Serum / Plasma	Immunoassay Investigations (cont'd) Quantitation of: P1NP Progesterone Prolactin PSA PTH SHBG Testosterone Thyroglobulin Thyroid antibodies (ATPO) Troponin T TSH Vitamin B12 Vitamin D	Roche Cobas e801 using Electrochemical luminescence (ECL) BIO-49,50,54,64
Whole Blood	Diabetic Monitoring Tests: HbA1C	Roche Cobas c513 using photometric analysis BIO-50,65
Serum, Plasma, Urine	Osmolality	Osmo1 single-sample micro-osmometer SOP BIO-52



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturer's instructions for
CSF	Xanthochromia testing: Bilirubin Oxyhaemoglobin	Northstar Scientific UVIKON XS scanning spectrophotometer using spectrophotometric analysis assisted with data interpretation software BIO-65
Serum	Protein Electrophoresis Immunotyping	SEBIA Capillarys 3 Octa CZE system using capillary zone electrophoresis and immunotyping BIO5,6
Serum	Serum Free Light Chains Beta-2-Microglobulin	BindingSite Optility Protein Analyser BIO-77
Sweat	Sweat Chloride Sweat Weight	Sherwood Scientific Chloride Meter using potentiometry BIO-3
Whole Blood	<u>Haematological examination activities for the purposes of clinical diagnosis</u> Full Blood Count Haemoglobin g/L White cell count 10 ⁹ /L Platelet count 10 ⁹ /L Haematocrit % Red cell count 10 ¹² /L Mean corpuscular volume fl Mean corpuscular haemoglobin pg Mean corpuscular haemoglobin concentration g/L Neutrophil count 10 ⁹ /L Lymphocyte count 10 ⁹ /L Monocyte count 10 ⁹ /L Eosinophil count 10 ⁹ /L Basophil count 10 ⁹ /L Nucleated red cells 10 ⁹ /L Reticulocyte count 10 ⁹ /L	Documented in house methods and manufacturer's instructions for Sysmex XN9001 using impedance and flow cytometry HAE-17,
Whole Blood	Erythrocyte Sedimentation Rate (ESR)	Sysmex Interrliner using Westergren method HAE-48



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HUMAN BODY FLUIDS (cont'd)	<u>Routine coagulation examination activities for the purposes of clinical diagnosis</u>	Documented in house methods and manufacturer's instructions for
Citrated Plasma	Routine Coagulation testing for Prothrombin Time (PT) Activated Partial Thromboplastin Time (APTT) Fibrinogen (Clauss) Thrombin Time (TT) D Dimer Factor Assay analysis: FII FV FVII FVIII FIX FX FXI FXII Anti-Xa Acquired Thrombophilia (Lupus) Screen DRVVT screen / confirm Actin FSL Inherited Thrombophilia Screen Protein C ATIII Free Protein S	Systemex CN6000 using clotting, chromogenic and immunoassay and PCR using Hain genoXtract and fluorocycler HAE- 2,10,11,22,24,25,30 SOP HAE 30, 12, SOP HAE 24, 10 SOP HAE 22, 2 SOP HAE-25, 2



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HUMAN BODY FLUIDS (cont'd)	<u>Routine Haematological examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturer's instructions for
Whole Blood	Blood film assessment for detection of abnormal cell types, morphology and numbers including malaria	Sysmex SP 5 staining analysers and microscopes HAE-18,27
	Detection of Epstein Barr (Glandular Fever)	Clearview Infectious Mononucleosis (IM) kit, immunoassay HAE-32
		Documented in-house methods to meet the requirements of the Sickle cell and Thalassaemia screening programme as defined in the laboratory QA evidence requirements
Whole Blood	Screening for haemoglobin variants	Capillary zone electrophoresis on Sebia Capillarys HAE-34
Whole Blood	Screening for HbA2, HbA, HbF	Alkaline Electrophoresis using Sebia Hydrays HAE-36
Whole Blood	Identification of haemoglobin variants: HbF, HbS, HbC, HbD, Hb E	Acid Electrophoresis using Sebia Hydrays HAE-36
	<u>Blood Transfusion examination activities for the purpose of clinical diagnosis</u>	
Whole Blood	Blood Grouping <ul style="list-style-type: none"> • A B O • Rhesus D status 	Automated using Grifols Erytra by column agglutination BLD-3,33 Manual using Grifols column agglutination and tube techniques BLD19,22,33,53



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturer's instructions for
Whole Blood	Antibody Screening <ul style="list-style-type: none"> • Rh- C,D,E,c,e, • Duffy- Fya, Fyb • Kidd- Jka, Jkb • MNS: M,N,S,s • Lewis- Le(a), Le(b) • Kell- K,k • P: P1 • D negative 4 cells screen 	Automated using Grifols Erytra by column agglutination BLD-3 Manual using Grifols column agglutination, indirect antiglobulin test BLD-19,53 BLD-46 Grifols Serascan 4 cell screen, NBS 3 cell antibody screen in Cellmedia and NBS rr 4 cells screen in Cellmedia
Whole Blood	Antibody Identification <ul style="list-style-type: none"> • Rh- C,D,E,c,e, • Duffy- Fya, Fyb • Kidd- Jka, Jkb • MNS: M,N,S,s • Lewis- Le(a), Le(b) • Kell- K,k • P: P1 	Automated using Grifols Erytra by column agglutination BLD-3 Manual using Grifols column agglutination, indirect antiglobulin test BLD19,55 Cells used are Grifols Identisera 11 cell panel and 4 cell extension panel in Cellmedia, Grifols Identisera P 11 cell panel and 4 cell extension panel in Cellmedia, and NBS 10 cell panel in Cellmedia.
EDTA	Direct antiglobulin test	Automated using Grifols Erytra by column agglutination BLD-3,43 Manual using Grifols column agglutination, indirect antiglobulin test, direct antiglobulin test BLD-43



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturer's instructions for
EDTA Whole Blood	Foetal Maternal Haemorrhage	Manual method by acid elution BLD-40 Alkali Denaturation Test BLD-57
EDTA Whole Blood	Red Cell Phenotyping <ul style="list-style-type: none"> • Rh C,c,E,e,Cw • Lewis Le(a), Le(b) • Duffy Fy(a), Fy(b) • Kidd Jk(a) Jk(b) • MNS MNSs • Kell, Kpa • Anti-A1 	Manual using Grifols column agglutination, indirect antiglobulin test or immediate spin BLD-15,17
	Cross Matching	Manual using Grifols column BLD-19, 47 and Manual using immediate spin



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<p>HUMAN BODY FLUIDS AND TISSUES</p> <p>Swabs Fluids Aspirates Tissues Pus/Exudates Tips/Lines Nails Hair Skin IUCD coils Respiratory samples Urine Faeces</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis</u></p> <p>General isolation of micro-organisms of clinical significance</p>	<p>In house documented methods based on related UK Standards for Microbiology Investigations (UK SMIs):</p> <p>Manual inoculation followed by culture</p> <p>MIC-51 MIC-6 MIC-175</p>
<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Whole Blood</p> <p>Urine</p> <p>Urine</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>General isolation of micro-organisms of clinical significance</p> <p>Quantification of white and red blood cells, bacteria and epithelial cells</p> <p>Isolation, identification and antibiotic susceptibility testing of microorganisms of clinical significance</p>	<p>In house documented methods based on related UK Standards for Microbiology Investigations (UK SMIs):</p> <p>Automated culture using BD BacTec FX</p> <p>MIC-45 MIC-77</p> <p>Automated urine analysis using Roche Cobas u701 MIC-7</p> <p>Mast UriSystem MIC-7</p>



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HUMAN BODY FLUIDS AND TISSUES	<u>Microbiology examination activities for the purpose of clinical diagnosis</u>	In house documented methods based on related UK Standards for Microbiology Investigations (UK SMIs):
Cultures isolated in house from the above	Identification of microorganisms of clinical significance	Manual and/or automated biochemical methods using: Automated Matrix-assisted laser desorption/ionisation (MALDI-TOF) MIC-53 MIC-81 MIC-99
Cultures isolated in house from the above	Antimicrobial susceptibility testing of clinically significant bacteria	Manual disc diffusion and/or automated methods using EUCAST methodology MIC-65
Cultures isolated in house from the above	Antimicrobial susceptibility testing of clinical significance	Automated BD Phoenix MIC-99, MIC-76
Urine	Detection of: Legionella Antigen Pneumoniae antigen	Fluorescent Immunoassay using SD Biosensor Standard F analyser MIC-3
Genital swabs	Detection of Bacterial vaginosis and Trichomonas vaginalis	Gram stained microscopy examination by automated slide stainer (Aerospray) MIC-34, MIC-76



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods based on related UK Standards for Microbiology Investigations (UK SMIs):
Faeces	Detection of ova, cysts and parasites (OCP)	Direct microscopy and concentration using Parasep MIC-41
Faeces	Detection of: <i>Cryptosporidium</i> and <i>Giardia</i> antigens <i>H.pylori</i> IgG Rotavirus antigen	Automated enzyme linked immunosorbent assay (ELISA) using Triturus Instrument (Grifols) MIC-8
Respiratory samples Urine Blood	Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. <i>Mycobacterium</i> spp.) and routine respiratory culture of clinical significance	Manual culture and microscopy (screening by fluorescent microscopy using Auramine stain, and ZN light microscopy on automated detection) using BD Bactec MGIT 320 MIC-39, MIC-97, MIC-18, MIC-116
Joint Fluids	Detection of crystals for diagnosis of gout and pseudo gout: <ul style="list-style-type: none"> • Monosodium urate • Calcium pyrophosphate crystals 	Polarised light microscopy MIC-40
Anal swabs	Detection of <i>Enterobius vermicularis</i> larvae and ova	Direct microscopic examination MIC-41



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serological activities for the purpose of clinical diagnosis</u>	Documented in-house methods to meet the requirements of the Infectious Diseases in Pregnancy Screening Programme as defined in the laboratory QA evidence requirements' (targets marked *)
Blood serum samples	Detection of: Antistreptolysin Rubella IgG HIV-1 & HIV-2 Antibodies and HIV1 p24 Antigen* Hepatitis B surface Ag* Hepatitis B core Hepatitis B e Ab Hepatitis B e Ag Hepatitis B Ab Hepatitis A IgG and IgM Hepatitis C Ab Syphilis total Antibody* Syphilis TPLA*	Cobas 8000 BIO-49,BIO-54,MIC-32, MIC-52, MIC-55, MIC-57, MIC-35, MIC-11, MIC-80, MIC-59, MIC-56
Blood serum samples	Detection of: Treponema IgM	Automated ELISA using Chorus MIC-11
Faeces	Detection of rotavirus	Imunochromatographic assay using Coris BioConcept Rota-Strip ME001



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular activities for the purpose of clinical diagnosis</u>	
Nose and Throat Swabs (NSA), nasopharyngeal aspirates (NPA) in VTM	Multiplex Respiratory Panel: Influenza A (H1, H3) Adenovirus Parainfluenza (1-4) Human Metapneumovirus Rhinovirus Bordetella pertussis	Automated, multiplexed, flexible nucleic acid test using Verigene NanoSphere MIC-17
Nose and Throat Swabs (NSA) in VTM	Influenza A & B	Automated PCR using Roche Liat technology MIC-17
Nose and Throat Swabs (NSA) in VTM Faeces Faeces	RSV A/B Norovirus C. difficile	Automated PCR using Aries Luminex technology MIC-17
Faeces	Detection of genomic DNA from bacteria causing infectious gastroenteritis: Salmonella spp., Shigella spp. Enteroinvasive E.coli (EIEC), Campylobacter spp. (jejuni and coli) Shiga toxin-producing organisms (STEC, Shigella dysenteriae)	Automated DNA extraction, amplification & detection on the BD MAX platform MIC-4



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Plasma	Detection of: HIV Viral load Hepatitis C viral load Hepatitis B viral load	Realtime PCR using Cobas 6800 MIC-1
Genital swabs, urine, throat and rectal	Detection of: <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> DNA. Including confirmation testing Trichomonas vaginalis	Automated transcription-mediated amplification (TMA) using Hologic Panther MIC-26
Genital swabs	HSV 1 and 2	
END		