

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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



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ISO 15189:2012

### NHS Borders

Issue No: 008 Issue date: 19 July 2021

NHS Borders Area Laboratory  
Borders General Hospital  
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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	
<b>Address</b> NHS Borders Area Laboratory Newstead Melrose TD6 9DA United Kingdom	<b>Local contact</b> As above	Microbiology Serology Virology Blood Sciences <ul style="list-style-type: none"><li>Blood Transfusion</li><li>Haematology</li><li>Clinical Biochemistry</li></ul>	A

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

Location details	Activity	Location code
Sexual Health Clinic Galashiels Health Centre Currie Road Galashiels TD1 2UA	Microbiology	B



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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 and TISSUES	<u>Clinical Biochemistry examinations to assist in clinical investigations</u>	In House documented procedure & manufacturer's instructions using the following equipment	
Blood	General Biochemistry  Albumin (1) Acetaminophen Alkaline Phosphatase ALT Ammonia Amylase AST Direct Bilirubin Total Bilirubin Calcium CO2 Total Cholesterol HDL Cholesterol Creatine Kinase Creatinine CRP Digoxin Ethanol Gamma Glutamyltransferase Glucose Immunoglobulin A Immunoglobulin G Immunoglobulin M Iron Lactic Acid Lactate Dehydrogenase Lithium Magnesium Phosphorus Phenytoin Total Protein Salicylate Theophylline Transferrin Triglycerides	Abbott Architect Plus ci8200 and Manufacturer's operating instructions.  Detected by Photometry  BSAUTO_Architect c8000 Assays  BSAUTO_Architect Operating Procedure	A



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HUMAN BODY FLUIDS and TISSUES	<u>Clinical Biochemistry examinations to assist in clinical investigations</u> (cont'd)	In House documented procedure & manufacturer's instructions using the following equipment	A
Blood	Urea Nitrogen Urate2 Valproate	Abbott Architect Plus ci8200 and Manufacturer's operating instructions. Detected by Photometry	
Serum/plasma	Gentamicin Vancomycin	Detected by Spectrophotometry	
Blood and Urine	Chloride Potassium Sodium	Detected by Potentiometry	
Urine /CSF	Microprotein		
Blood	Endocrine/Tumour Marker/Haematinics/Cardiac Marker CA125 Carcinoembryonic Antigen Troponin I PTH Cortisol Estradiol Ferritin FSH LH Progesterone Prolactin PSA Free T3 Free T4 Testosterone TSH Vitamin B12 Folate hCG	Detected by Immunoassay  BSAUTO_Architect Immunoassay Assays  BSAUTO_Architect Operating Procedure	
Blood		Abbott Architect ci8200 By CMIA	
Blood	Hcg (tumour marker) 25-OH Vitamin D	SOP-BSAUTO Architect Immunoassay Assays	



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Clinical Biochemistry examinations to assist in clinical investigations</u> (cont'd)	In House documented procedure & manufacturer's instructions using the following equipment	
Blood	Viral Serology: <ul style="list-style-type: none"> <li>Hepatitis B surface antigen and core</li> <li>Hepatitis C antibody</li> <li>HIV antibody/antigen combo</li> <li>Rubella IgG antibody</li> <li>Syphilis antibody</li> </ul>	Abbott Architect i2000SR and Abbott test kits using Manufacturer's operating instructions. QA for Abbott Architect under Virology Assays 1434 SOPs  Hepatitis B antibody 6558 Hepatitis B core Antibody 65615 Hepatitis B surface antigen" 65590 Hepatitis C 65591 HIV 65592 Rubella 65593 Syphilis 65589	A
Whole blood	HbA1C	TOSOH Bioscience G11 HPLC Analyser HPLC Reversed phase partition and cation exchange chromatography SOP;- BSAUTO_TOSOH G11 Glycohaemoglobin Analyser Operation	A
Blood	Coeliac (Anti Tissue Transglutaminase screen)	Stratec Biomedical Gemini Automated ELISA SOPs MANCHEM_Coeliac	
Faeces	Intrinsic Factor (Anti intrinsic factor)- Faecal Calprotectin-faeces	MANCHEM_Intrinsic Factor  MANCHEM_Faecal Calprotectin	
Faeces	Quantitative Faecal haemoglobin	Kyowa Medex Co HM-JACKarc QFIT (Quantitative Faecal Immunochemical Testing) by latex agglutination  SOP MANCHEM QFIT HM JACKarc	



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Clinical Biochemistry examinations to assist in clinical investigations</u> (cont'd)	In House documented procedure & manufacturer's instructions using the following equipment	
Blood/Urine	Osmolality	The Advanced Micro Osmometer 3320 by Freezing point depression  SOP: MANCHEM_ Osmometer	
Whole Blood	Blood gases <ul style="list-style-type: none"> <li>• pH</li> <li>• pO<sub>2</sub></li> <li>• pCO<sub>2</sub></li> <li>• Bicarbonate</li> <li>• Base Excess</li> <li>• Carboxyhaemoglobin</li> <li>• Oxygen Saturation</li> </ul>	Radiometer ABL 820/825 By Potentiometry, amperometry.  SOP: CSR ABL Blood Gas Analyser	
Blood	Proteins <ul style="list-style-type: none"> <li>• monoclonal bands/immunotyping</li> </ul>	Sebia Minicap Electrophoresis electrical charge for detection of abnormal bands SOPs: MANCHEM_Minicap Urine MANCHEM_Minicap Serum and Urine IT	
Urine	<ul style="list-style-type: none"> <li>• Bence Jones Protein</li> </ul>	MANCHEM_Minicap Protein 6	



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HUMAN BODY FLUIDS and TISSUES	<u>Blood Transfusion examinations to assist in clinical investigations</u>	In House documented procedure & manufacturer's instructions using the following equipment	A
Venous Blood	Blood Grouping	BioRad IH500 analyser and associated testing protocols – fully automated Diamed cassette technology. Electronic detection of interface SOP: Routine Use of IH500	
	<ul style="list-style-type: none"> <li>• A B O</li> <li>• Rhesus: C, c, D, E, e,</li> <li>• K</li> <li>• A B O</li> <li>• Rhesus:-C<sup>w</sup>, C, c, D, E, e,</li> <li>• K</li> <li>• Fya, Fyb</li> <li>• Jka, Jkb</li> <li>• Kpa</li> <li>• Lea, Leb</li> <li>• Lua</li> <li>• M, N, S, s</li> </ul>	Rh-subgroup and K phenotyping cards  Manual procedures by Diamed cassette technology and by manual tube methods- macroscopic detection of interface SOP MTS002-Manual Testing by Card MTS 001 Manual Testing by Tube	
	Antibody Detection	3 and 11 cell panels processing panels on BioRad IH500 and manual procedures by Diamed cassette technology tube technology-red cell agglutination, macroscopic visual detection SOP;-Routine Use of IH500 SOP MTS002-Manual Testing by Card MTS 001 Manual Testing by Tube	



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u> (cont'd)	In House documented procedure & manufacturer's instructions using the following equipment	
Venuous Blood	Compatibility testing of patients plasma with donor cells	Manual procedures by Diamed cassette technology and by tube technology-red cell agglutination, macroscopic visual detection SIS001 Selection, Issue and Return of red cell concentrates	
	Electronic Issue	Electronic Issue of compatible units SOP:SIS 007	
	Direct Anti-Human Globulin	BioRad IH500analyser and associated testing protocols – fully automated Diamed cassette technology. Routine Use of IH500 Manual procedures by Diamed cassette technology. MTS001-2 Manual Testing by Card	A
Venuous Blood	Detection of foetal cells and calculation of foetal bleed.	Manual tube techniques MTS001-1 Manual Testing by Tube  Acid Elution by Source Bioscience SOP : ANS003-Kleihauer Testing	A



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<p><u>Haematology examinations to assist in clinical investigations</u></p> <p>Coagulation</p> <ul style="list-style-type: none"> <li>• D-Dimer</li> <li>• APTT</li> <li>• APTR</li> <li>• Fibrinogen (Claus)</li> <li>• INR</li> <li>• PT</li> </ul> <p>ESR</p>	<p>In House documented procedure &amp; manufacturer's instructions using the following</p> <p>Instrumentation Laboratory ACL TOP 350 coagulation analyser. Coagulometric (turbidimetric) clot detection SOP;- BSAUTO_ACL TOP350</p> <p>Alifax Roller 20-PN. Capillary Micro-photometer for the Erythro-Sedimentation Rate (ESR). SOP; BS_AUTO_Alifax Roller 20-PN</p>	
Venous whole blood	<p>Reporting of normal and abnormal morphologies including WBC differential count</p> <p>Malaria Parasite antigen detection</p> <ul style="list-style-type: none"> <li>• P.Falciparum</li> <li>• Non falciparum common antigens               <ul style="list-style-type: none"> <li>• P.Vivax</li> <li>• P.Ovale</li> <li>• P.Malariae</li> <li>• P.Knowlesi</li> </ul> </li> </ul>	<p>May Grunwald Giemsa stain – examined by microscopy</p> <p>Antigen testing with kit by Binax Now kit</p> <p>SOP BS_MAN Malaria Parasite Screen (Slide Test)</p>	A





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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Haematology examinations to assist in clinical investigations</u> (cont'd)	In House documented procedure & manufacturer's instructions using the following	A
Bone Marrow	Malaria Parasite – <ul style="list-style-type: none"> <li>• P.Falciparum</li> <li>• P.Vivax</li> <li>• P.Ovale</li> <li>• P.Malariae</li> <li>• P.Knowlesi</li> </ul> Parasitaemia  Reporting of normal and abnormal morphologies	Thick film – 1:10 Giemsa pH7.2 stain Thin Film – Giemsa pH7.2 stain. Enumeration by microscopy SOP BS_MAN Parasite Screen (Microscopy)	
Venous whole blood :EDTA	Infectious Mononucleosis  HbS	May Grunwald Giemsa stain – examined by microscopy SOPs MANHAEM_Bone Marrow Reporting by Consultants  Perl's Prussian Blue staining – Examined by microscopy. SOP BSMAN_Demonstration of Stainable Iron  Clearview IM 11Card agglutination interpreted by visual inspection. SOP BS_MAN Glandular Fever Screening  Microgen Bioproducts Kit Sickle solubility test detected by visual detection of precipitation. SOP: BS-Man-Sickle Cell Screening	A



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>General Bacteriology Examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures based on PHE UK SMIs	
Swabs Blood Stool Sputum Skin Tissue Urine Line tips Fluids (joint, CSF, pleural, drain, peritoneal)	General isolation and characterisation of micro-organisms of clinical significance	Light Microscopy, Phase contrast Microbiological culture methods using commercially prepared media.  SOPS M-Methods Swabs and Fluids 65610  Stains and IDs 65609 CSF 65603 CPE Screen 1062 Line Tips 1064 Urines 65602	
Isolates	Identification	bioMerieux Vitek 2  SOPS M-Methods Swabs and Fluids 65610 CSF65603 Vitek card setup 13104 Vitek 65613	



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Isolates	Antimicrobial susceptibility testing and determination of minimum inhibitory concentration (MIC).	bioMerieux Vitek 2  MIC sensitivity profiles  SOPS Antibiotic Susceptibility Testing 65613 MIC gradient strip 65582 Interpretation using EUCAST criteria	
Swabs from nose, perineum and other wound sites	Isolation of MRSA	Manual culture on chromogenic agar using SOP: Swabs and fluids 65610	
Respiratory type samples	General isolation and characterisation of micro-organisms of clinical significance	Manual culture using SOP: Sputum 65601 ITU BALS 253 Cystic fibrosis 252	
Enteric samples	General isolation and characterisation of Salmonella, Shigella, Campylobacter, E.coli O157	Manual culture methods using selective media and SOP: Faeces 65607	
Enteric samples	Detection of ova, cysts and parasites (OCP)	Unstained and iodine stained direct microscopic examination and/or Formol-ether faecal concentration and microscopic examination using in-house procedure SOP: OCP ( Ova, Cysts and Parasites)	
	Detection of Cryptosporidium oocysts	Auramine phenol staining and incident-light fluorescence microscopic examination using in-house procedure: Cryptosporidia Auramine Staining 13095 by microscopy	



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>General Bacteriology Examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures based on PHE UK SMLs	A
Skin, Hair, Nail	ID of Fungi	Manual culture and microscopic and macroscopic detection using SOP: Mycology 65614	
Blood cultures	General isolation and characterisation of micro-organisms of clinical significance	BacTAlert and manual subculture Detection of growth in blood cultures using SOP: Blood Cultures 65594	
CSF & Ascitic fluids	Detection and quantification of white blood cells and bacteria	Manual microscopy using SOP: Cell counts 13070 CSF 65603	
Enteric samples	Detection of <i>Clostridioides difficile</i> GDH antigen and toxins A & B	Screening for <i>C. difficile</i> GDH and toxins A&B using Meridian Immunocard. SOP: <i>C.difficile</i> 65604	
Blood	Detection of Varicella Zoster Virus (VZV)	Stratec Biomedical Gemini Automated ELISA SOP VZV	
Faeces	IgG Helicobacter pylori stool antigen	SOP Helicobacter Pylori stool antigen HPSA	
Uro-Genital swabs Specimens from other sites e.g. rectal or throat	Genital Pathogens	Standard culture and identification Microscopy SOP GUM Clinic 65611	A A and B
Genital samples	<u>Molecular activities for clinical diagnosis</u> <ul style="list-style-type: none"><li>• Chlamydia trachomatis</li><li>• Neisseria gonorrhoeae</li></ul>	Roche COBAS® 4800 COBAS® 4800 CT/NG test kit for detecting both Chlamydia trachomatis and Neisseria gonorrhoeae Realtime PCR CTNG Chlamydia and Gonorrhoea 854	A



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