

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



9308

Accredited to
ISO 15189:2012

University Hospitals of Derby and Burton NHS Foundation Trust operating as Derbyshire Pathology

Issue No: 016 Issue date: 01 April 2025

Royal Derby Hospital
Uttoxeter Road
Derby
Derbyshire
DE22 3NE

Contact: Mariska Faint-Uffen
Tel: +44 (0) 1332 789316
Website: www.derbyhospitals.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 Department of Pathology Royal Derby Hospital Uttoxeter Road Derby Derbyshire DE22 3NE Local contact: Contact: Mariska Faint-Uffen Tel: +44 (0) 1332 789316 | <ul style="list-style-type: none">• Haematology• Blood Transfusion• Chemistry• Immunology• Cellular Pathology• Microbiology | A |
| Address Fertility Unit, Level 1 Royal Derby Hospital Uttoxeter Road Derby Derbyshire DE22 3NE Local contact: Contact: Mariska Faint-Uffen Tel: +44 (0) 1332 789316 | <ul style="list-style-type: none">• Andrology | B |
| Address Combined Day Unit Royal Derby Hospital Uttoxeter Road Derby Derbyshire DE22NE Local contact: Contact: Mariska Faint-Uffen Tel: +44 (0) 1332 789316 | | C |
| Address Microbiology Department Chesterfield Royal Hospital Calow S44 5BL Local contact: Contact: Mariska Faint-Uffen Tel: +44 (0) 1332 789316 | <ul style="list-style-type: none">• Microbiology | D |
| Address Blood Sciences Department Chesterfield Royal Hospital Calow S44 5BL Local contact: Contact: Mariska Faint-Uffen Tel: +44 (0) 1332 789316 | <ul style="list-style-type: none">• Haematology• Blood Transfusion• Chemistry | E |



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Site activities performed away from the locations listed above:

| Location details | Activity |
|--|--|
| Royal Derby Hospital Uttoxeter Road Derby Derbyshire DE22 3NE Local Contact: Contact: Mariska Faint-Uffen Tel: +44 (0) 1332 789316 | Phlebotomy |
| Florence Nightingale Community Hospital London Road Derby Derbyshire DE1 2QY Local Contact: Contact: Mariska Faint-Uffen Tel: +44 (0) 1332 789316 | Phlebotomy |
| Blood Bank satellite issue fridge - Fridge room, level 5 Royal Derby Hospital DE22 3NE Local Contact: Contact: Mariska Faint-Uffen Tel: +44 (0) 1332 789316 | Blood Issue Fridge No testing occurs on this site, blood storage only |
| Blood satellite issue fridge - General theatre, level 2 Royal Derby Hospital DE22 3NE Local Contact: Contact: Mariska Faint-Uffen Tel: +44 (0) 1332 789316 | Blood Issue Fridge No testing occurs on this site, blood storage only |
| Local Contact: Contact: Mariska Faint-Uffen Tel: +44 (0) 1332 789316 | Blood Issue Fridge No testing occurs on this site, blood storage only |
| Blood satellite fridge - Gynae theatre M&G, level 2 Royal Derby Hospital DE22 3NE Local Contact: Contact: Mariska Faint-Uffen Tel: +44 (0) 1332 789316 | Blood Issue Fridge No testing occurs on this site, blood storage only |
| Blood satellite fridge - Combined Day unit, level 1 Royal Derby Hospital DE22 3NE Local Contact: Contact: Mariska Faint-Uffen Tel: +44 (0) 1332 789316 | Blood Issue Fridge No testing occurs on this site, blood storage only |
| Mortuary, Level 0 Royal Derby Hospital DE22 3NE Local Contact: Contact: Mariska Faint-Uffen Tel: +44 (0) 1332 789316 | Body storage facilities |
| Blood issue fridge W9G9163 Theatre Phase 1 Main Theatres Chesterfield Royal Hospital S44 5BL Local contact: Contact: Mariska Faint-Uffen Tel: +44 (0) 1332 789316 | Blood storage & issue only Fridge managed by Blood transfusion |



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| Location details | Activity |
|--|---|
| Blood Issue Fridge W9F8652 Theatres Phase 2 Obs & Gynae theatres Chesterfield Royal Hospital S44 5BL | Blood storage & issue only Fridge managed by Blood transfusion |
| Blood Product Issue fridge Trinity Ward Chesterfield Royal Hospital S44 5BL | Anti-D Immunoglobulin storage and issue Fridge managed by Blood Transfusion |
| Blood component issue fridge NGS Macmillan Unit Chesterfield Royal Hospital S44 5BL | Red blood cells and platelet storage and issue Fridge managed by Blood Transfusion |
| Ward areas, The Den, Antenatal Clinic Suite 9, NGS Macmillan Unit Chesterfield Royal Hospital S44 5BL | Phlebotomy |
| OPD/ward areas Chesterfield Royal Hospital | Sweat collection for diagnostic purposes using Wescor Macroduct iontophoretic sweat collection system |



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DETAIL OF ACCREDITATION

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|---------------------------|---|---|---------------|
| HUMAN BODY FLUIDS | <u>Andrological examination activities for the purposes of clinical diagnosis</u> | | |
| Semen | <u>Post vasectomy</u> Detection of sperm Sperm concentration | Based on 2016 Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons) Manual method using large volume chambers/ manual microscopy and documented in-house procedure SOP FERTSOP11 | B |
| Semen | <u>Fertility testing</u> Volume pH Sperm morphology including TZI scoring Sperm concentration Sperm motility | Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method using documented in-house procedure SOP FERTSOP48 Volume/weight Colorimetric strips Stained slides (Papanicolau) microscopy (Bright field) Microscopy (Phase contrast) Microscopy (Phase contrast) | |



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| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis: | In house documented procedures based on standard methods and incorporating Roche cobas 6000 manufacturers' instructions as relevant: AUTOCHSOP232 Use of Roche Cobas 6000 analysers AUTOCHSOP259 Roche Cobas MPA 8100 user guide Roche Cobas e601 Module using Immunoassay: | A |
| Serum/Plasma | AlphaFetoProtein (AFP) | | |
| Serum/Plasma | Anti-Mullerian Hormone | | |
| Serum/Plasma | CA12-5 | | |
| Serum/Plasma | CA15-3 | | |
| Serum/Plasma | CA19-9 | | |
| Serum/Plasma | CEA | | |
| Serum/Plasma | C-Peptide | | |
| Serum/Plasma | Free PSA | | |
| Serum/Plasma | Total HCG | | |
| Serum/Plasma | Insulin | | |
| Serum/Plasma | Thyroglobulin | | |
| Serum/Plasma | Thyroglobulin antibodies | | |



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| Serum/Plasma | Alpha-1-antitrypsin | | |
| Serum/Plasma | Amikacin | | |
| Plasma | Ammonia | | |
| Serum/Plasma | Carbamazepine | | |
| Serum/Plasma | Complement C3 | | |
| Serum/Plasma | Complement C4 | | |
| Serum/Plasma | Ethanol | | |
| Serum/Plasma | Haptoglobin | | |
| Serum/Plasma | IgA | | |
| Serum/Plasma | Lactate dehydrogenase | | |



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| Serum/Plasma | Methotrexate | | |
| Serum/Plasma | Phenobarbitone | | |
| Serum/Plasma | Phenytoin | | |
| Serum/Plasma | Rheumatoid factor | | |
| Serum/Plasma | Teicoplanin | Thermo Scientific Quantitative Micoparticle system (QMS), AUTOCHSOP249 | |
| Serum/Plasma | Theophylline | | |
| Serum/Plasma | Thyroid peroxidase antibodies | AUTOCHSOP213 | |
| Serum/Plasma | Tobramycin | | |
| Serum/Plasma | Valproate | | |



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| Serum, Plasma, Urine | Sodium, Potassium, Chloride | Roche Cobas c702 Module using Indirect ISE Line 1, 2, 3 | A |
| Serum, plasma | Albumin | Roche Cobas c702 Module using photometry Line 1, 2, 3 | A |
| Urine | Albumin | Line 2, 3 | |
| Serum, plasma | ALP | Line 1, 2, 3 | |
| | ALT | | |
| | Aspartate Aminotransferase | | |
| Serum, plasma | Amylase | | |
| Serum, plasma | Bicarbonate | | |
| Serum, plasma | Bilirubin total | | |
| | Bilirubin conjugated | | |
| Serum, plasma, urine | Calcium | | |
| Serum, plasma | Creatinine Kinase | | |
| | C-Reactive Protein | | |
| | Creatinine (enzymatic) | | |



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| Urine | Creatinine (Jaffe) | | |
| CSF | Glucose and total protein | | |
| Serum, plasma, urine | Glucose | | |
| Serum, plasma | Gentamicin | | |
| | Gamma-GT | | |
| | HDL Cholesterol | | |
| | IgA | Line 2, 3 | |
| | IgG | | |
| | IgM | | |
| Serum, plasma | Iron | Line 1, 2 ,3 | |
| Plasma | Lactate | | |
| Serum, plasma | Magnesium | | |
| | Paracetamol | Cambridge Life Sciences kit, AUTOCHSOP196 | |
| Serum, plasma, urine | Phosphate | | |
| Serum, plasma | Salicylate | | |
| | Total cholesterol | | |



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| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis: (cont'd) | In house documented procedures based on standard methods and incorporating Roche cobas 6000 manufacturers' instructions as relevant: | A |
| Serum, plasma, urine | Total protein | AUTOCHSOP232 Use of Roche Cobas 6000 analysers | |
| | Transferrin | AUTOCHSOP259 Roche Cobas MPA 8100 user guide | |
| | Triglyceride | Roche Cobas c702 Module using photometry | |
| | Urea | Line 2, 3 | |
| | Urate | Line 1, 2, 3 | |
| Serum, plasma | Vancomycin | Roche Cobas c502 module using photometry | |
| Plasma | Ammonia | Line 1 | |
| Serum, plasma | Bile acid | DIALAB kit, AUTOCHSOP159 | |
| | Ethanol | | |
| | Lactate dehydrogenase | | |
| | Lithium | Roche Cobas e801 Module using Immunoassay | |
| | Cortisol | Line 1, 2, 3 | |
| | Digoxin | | |
| | Oestradiol | Line 2, 3 | |



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| HUMAN BODY FLUIDS (cont'd) | <p>Biochemistry examination activities for the purpose of clinical diagnosis: (cont'd)</p> <p>Ferritin</p> <p>Follicle stimulating hormone</p> <p>Free T3</p> <p>Free T4</p> <p>Free beta HCG</p> <p>Luteinising hormone</p> <p>NT Pro BNP</p> <p>Prolactin</p> <p>Macroprolactin</p> <p>Progesterone</p> <p>Parathyroid hormone</p> <p>Folate</p> <p>Sex hormone binding globulin</p> <p>Testosterone</p> <p>Total PSA</p> <p>Troponin T</p> <p>Thyroid stimulating hormone</p> | <p>In house documented procedures based on standard methods and incorporating Roche cobas 6000 manufacturers' instructions as relevant:</p> <p>AUTOCHSOP232 Use of Roche Cobas 6000 analysers</p> <p>AUTOCHSOP259 Roche Cobas MPA 8100 user guide</p> <p>Roche Cobas e801 Module using Immunoassay</p> <p>Line 1, 2, 3</p> <p>Line 2, 3</p> <p>AUTOCHSOP101</p> <p>Line 1, 2, 3</p> <p>Line 2, 3</p> <p>Line 1, 2, 3</p> | A |



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| | Vitamin B12 | Line 2, 3 | |
| | Vitamin D | Line 3 | |
| | | Chromsystems HPLC-ECD: SPCHEMSOP46 - HPLC | A |
| Urine | Metadrenaline, Normetadrenaline and 3-methoxytyramine | SPCHEMSOP3 | |
| Urine | 5-Hydroxy indole acetic acid (5HIAA) | SPCHEMSOP1 Chromsystems HPLC-UV: SPCHEMSOP46 - HPLC | |
| Blood | Vitamin B1 | SPCHEMSOP37 | |



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| Serum/ Plasma | Protein Electrophoresis: monoclonal protein | SPCHEMSOP13 | |
| Serum/ Plasma | Immunofixation: monoclonal protein typing | SPCHEMSOP14 | |
| Serum/Plasma | Alkaline Phosphatase Isoenzymes | SPCHEMSOP16 | |
| Serum | Alpha 1 antitrypsin phenotyping | SPCHEMSOP54 Binding Site: Optilite Immunoassay SPCHEMSOP31 | |
| Serum/Plasma | Free Kappa and Lambda Light Chains | SPCHEMSOP30 | |
| Serum/Plasma | Beta-2-microglobulin | SPCHEMSOP29 | |



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| HUMAN BODY TISSUES AND FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd): | In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant: | |
| Sweat | Conductivity | Wescor Macroduct® Sweat Collection System , conductivity measurement POCSOP3 | |
| Serum/Plasma | IgA anti-tTg antibody IgG anti-tTg antibody | ThermoPhadia ImmunoCap 250: Immunoassay SPCHEMSOP35 – TGA PATHEXT177 - Phadia Immunocap IDM User Manual PATHEXT178 - Phadia Immunocap Information Data Manager SPCHEMSOP20 - USE OF THE PHADIA IMMUNOCAP 250 ANALYSER CHIAUTH8-Authorisation guidelines for coeliac serology SPCHEMSOP52-Use of the Phadia 250 for measuring IgG Tissue Transglutaminase antibodies | |



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| HUMAN BODY TISSUES AND FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd): | In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant: | A |
| Serum and Urine | Osmolality | Advanced Instruments 3320 and - Advanced Instruments OSMO1 Osmometry - Freezing point depression AUTOCHSOP97 AUTOCHSOP242 - Chemistry Calculators PATHEXT1125 - Osmometer 3320 User Guide & Service Manual | A |
| CSF | CSF Xanthochromia | UVIKON/Northstar BIO UV SpectrophotometerSPCHEMSOP9 SPCHEMSOP26 – Spectrophotometer CRHSPE-LP-SPE043 | A, E |
| Serum, Plasma, Urine | Osmolality | Advanced Instruments Osmometer using freezing point depression: CRHCHE-LP-RCH029 | E E |



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| Serum | Cryoglobulins | Hydrasys using hydra gel and electrophoresis CRHSPE-LP-SPE035 | E |
| Serum/Urine | Paraproteins Quantification: | Sebia Hydrasys 2 Scan using hydra gel and electrophoresis and immunofixation Sebia Capillarys 2 using capillary zone electrophoresis: | E |
| | IgG IgA IgM Kappa Lambda | CRHSPE-LP-SPE030/031 | E |
| | | ABSciex API5000Tandem Mass spectrometer LCMSMS SPCHEMSOP32 – API5000 | A |
| Serum/Plasma | androstenedione | SPCHEMSOP42 | |
| Serum/Plasma | testosterone | SPCHEMSOP42 | |
| Blood | Cyclosporin | SPCHEMSOP28 | |
| Blood | Sirolimus | SPCHEMSOP28 | |
| Blood | Tacrolimus | SPCHEMSOP28 | |
| Serum/plasma | 17 OH- progesterone | SPCHEMSOP42 | |
| Serum/Plasma | DHEAS | SPCHEMSOP42 | |



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| Blood | Carboxy-haemoglobin | Werfen Gem5000 Blood gas analyser, spectrophotometric analysis POCSOP7 POCUG1 | A |
| Serum/Plasma & Urine | Calculated Tests: eGFR Adjusted Calcium AKI Standard urine test reporting per 24hrs AST: ALT ratio Albumin excretion ratio Calcium excretion index Calcium creatinine ratio Low density lipoprotein Creatinine clearance Free androgen index Globulin Kappa/Lambda Ratio Macroprolactin % recovery Macroprolactin – monomeric Non-HDL Cholesterol Normalised Carbamazepine Normalised Phenytoin Transferrin saturation Urine protein: creatinine | CHIAUTH44 | A |
| Serum/ Plasma and Urine | Calculated Tests: eGFR Adjusted Calcium 24 hr Urine Anionic gap | Tests calculated from output of various methodologies from Roche Cobas Systems: DOC47 | E |
| Serum/Plasma and Urine | Amylase/Creatinine clearance ratio Calcium excretion index Calcium creatinine ratio LDL | CRHCHE-LP-RCH048 | E |



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| HUMAN BODY TISSUES AND FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd): | | |
| Serum/Plasma and Urine (cont'd) | Creatinine clearance Free androgen index FIB4 Non HDL- Cholesterol Transferrin Saturation Urine protein: Creatinine Globulins AKI | CRHCHE-LP-RCH048 | E |
| | Quantitative determination of: | Roche Cobas c702 Module: Immunoturbidometric | E |
| Serum (unless otherwise stated) | Alpha 1 antitrypsin Phenobarbitone Complement C3 & C4 Caeruloplasmin CRP | CRHRMO-LP-RMO059 CRHRMO-LP-RMO030 CRHSPE-LP-SPE033 CRHRMO-LP-RMO058 CRHRMO-LP-RMO014 CRHSPE-LP-SPE027 | |
| Serum & Plasma | IgA IgG IgM Haptoglobin Phenytoin Theophylline Albumin | CRHSPE-LP-SPE034 CRHRMO-LP-RMO031 CRHRMO-LP-RMO036 CRHRMO-LP-RMO028 | |
| Urine | Quantitative determination of: | Roche Cobas c702 Module: Spectrophotometry | E |
| Serum, Plasma | Albumin | CRHRMO-LP-RMO001 | |
| Serum, Plasma | Alkaline Phosphatase | CRHRMO-LP-RMO002 | |
| Serum, Plasma | Alanine Transferase | CRHRMO-LP-RMO003 | |
| Serum, Plasma, Urine | Amylase | CRHRMO-LP-RMO005 | |
| Serum, Plasma | Aspartate transferase | CRHRMO-LP-RMO006 | |
| Serum, Plasma | Bicarbonate | CRHRMO-LP-RMO007 | |
| Serum, Plasma | Bilirubin Total | CRHRMO-LP-RMO008 | |
| Serum, Plasma | Creatinine (enzyme assay) | CRHRMO-LP-RMO013 | |
| Urine | Creatinine (Jaffe assay) | CRHRMO-LP-RMO013 | |
| CSF, Urine, Serum & Plasma | Total Protein | CRHRMO-LP-RMO037 CRHRMO-LP-RMO038 | |



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| HUMAN BODY TISSUES AND FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd): | | |
| | Quantitative determination of: (cont'd) | Roche Cobas c702 Module: Spectrophotometry | E |
| Serum, Plasma, Urine | Calcium | CRHRMO-LP-RMO009 | |
| Serum, Plasma | Direct Bilirubin | CRHRMO-LP-RMO017 | |
| Serum, Plasma | Total Cholesterol | CRHRMO-LP-RMO011 | |
| Serum, Plasma | Creatine Kinase | CRHRMO-LP-RMO012 | |
| Serum, Plasma, CSF | Glucose | CRHRMO-LP-RMO015 | |
| | | CRHRMO-LP-RMO020 | |
| Plasma, CSF | Lactate | CRHRMO-LP-RMO24 | |
| Serum, Plasma | Triglycerides | CRHRMO-LP-RMO038 | |
| Serum, Plasma | GGT | CRHRMO-LP-RMO018 | |
| Serum, Plasma | Iron | CRHRMO-LP-RMO022 | |
| Serum, Plasma, CSF | Lactate dehydrogenase | CRHRMO-LP-RMO025 | |
| Serum, Plasma | Magnesium | CRHRMO-LP-RMO027 | |
| Plasma | Ammonia | CRHRMO-LP-RMO004 | |
| Serum, Plasma | Paracetamol | CRHRMO-LP-RMO029 | |
| Serum, Plasma | Phosphate | CRHRMO-LP-RMO032 | |
| Serum | Salicylate | CRHRMO-LP-RMO034 | |
| Serum, Plasma | Transferrin | CRHRMO-LP-RMO043 | |
| Serum, Plasma, Urine | Urate | CRHRMO-LP-RMO040 | |
| Serum, Plasma, Urine | Urea | CRHRMO-LP-RMO039 | |
| | Quantitative determination of: | Roche Cobas e801 Module: Using Chemiluminescence Immunoassay: | E |
| Serum, Plasma | Vitamin B12 | CRHSPE-LP-SPE017 | |
| Serum | Pro BNP | CRHSPE-LP-SPE025 | |
| Serum, Plasma | CA 125 | CRHSPE-LP-SPE021 | |
| Serum, Plasma | CEA | CRHSPE-LP-SPE022 | |
| Serum, Plasma | Cortisol | CRHSPE-LP-SPE014 | |
| Serum | Digoxin | CRHSPE-LP-SPE016 | |
| Serum, Plasma | Ferritin | CRHSPE-LP-SPE018 | |
| Serum, Plasma | FSH | CRHSPE-LP-SPE008 | |
| Serum, Plasma | Free thyroxine (FT4) | CRHSPE-LP-SPE005 | |
| Serum, Plasma | Free tri-iodothyronine | CRHSPE-LP-SPE006 | |
| Serum, Plasma | HCG | CRHSPE-LP-SPE024 | |
| Serum, Plasma | LH | CRHSPE-LP-SPE007 | |
| Serum | Oestradiol | CRHSPE-LP-SPE009 | |



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| HUMAN BODY TISSUES AND FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd): | | |
| | Quantitative determination of: (cont'd) | Roche Cobas e801 Module: Using Chemiluminescence Immunoassay: | E |
| Plasma | Parathyroid hormone | CRHSPE-LP-SPE015 | |
| Serum | Progesterone | CRHSPE-LP-SPE013 | |
| Serum | Prolactin/Macroprolactin | CRHSPE-LP-SPE010 | |
| Serum, Plasma | Total PSA | CRHSPE-LP-SPE012 | |
| Serum, Plasma | Folate | CRHSPE-LP-SPE019 | |
| Serum | SHBG | CRHRMO-LP-RMO63 | |
| Serum | Testosterone | CRHSPE-LP-SPE011 | |
| Serum, Plasma | Thyroid peroxisomal antibody | CRHSPE-LP-SPE023 | |
| Serum, Plasma | TSH | CRHSPE-LP-SPE004 | |
| Serum, Plasma | Troponin T | CRHSPE-LP-SPE020 | |
| Serum | Vitamin D | CRHSPE-LP-SPE052 | |
| Serum | Lithium | CRHRMO-LP-RMO64 | |
| Serum, plasma | Procalcitonin | BSC-CP-SOP-8 | |
| | Quantitative determination of: | Roche Cobas c702 Module: Microparticle agglutination | E |
| Serum | Carbamazepine | CRHRMO-LP-RMO010 | |
| | | Roche Cobas c702 Module : Using Indirect ISE: | E |
| Serum, Plasma, Urine | Sodium | CRHRMO-LP-RMO033 | |
| | Potassium | CRHRMO-LP-RMO035 | |
| | Chloride | CRHRMO-LP-RMO068 | |
| | Quantitative determination of: | Roche Cobas c702 Module: Enzymatic Colorimetric analysis | E |
| Serum, Plasma | HDL Cholesterol | CRHRMO-LP-RMO021 | |
| | Quantitative determination of: | Roche Cobas c702 Module: Enzyme immunoassay | E |
| Serum | Gentamicin | CRHRMO-LP-RMO019 | |
| Serum | Vancomycin | CRHRMO-LP-RMO062 | |
| Serum | Valproate | CRHRMO-LP-RMO041 | |



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| HUMAN BODY TISSUES AND FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd): | | |
| Urine | Urine drugs of abuse screen to include: Barbiturates Amphetamine Benzodiazepine Buprenorphine Cocaine Methamphetamine Methadone Phencyclidine THC Cannabis Tricyclic antidepressants Opiates Bicarbonate | Abbott/Alere Dipstix analysis by chromatographic assay: CRHRMO-LP-RMO044 | E |



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| HUMAN BODY TISSUES AND FLUIDS (cont'd) | Histopathology <u>examination activities for the purpose of clinical diagnosis:</u> | Macroscopic and Microscopic examination supported by: | |
| Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis | <u>Tissue Dissection</u> - HISDSOPs 1-68 HISDSOP1-10, 12-21, 23-39,41-42, 44-47, 49, 51-55, 58, 62-65, 67-69, 71-73, HGENSOP58 - 59 <u>Decalcification</u> – HISRSOP20 | A |
| Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples. | | Macroscopic and Microscopic examination supported by: <u>Tissue Processing</u> Leica- ASP6025 Thermo- AS, ET HISDSOP23, HISRSOP50, HISRSOP43 HISDSOP40, HISDSOP56 | A |
| Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples. | | Specimen X-Ray Daax BioVision Path Vision Faxitron HISROP21 <u>Embedding</u> Thermo Histostar HRLSOP1 CPMANHIST 08 <u>Microtomy</u> Leica RM2235 Leica RM2255 Thermo-cryotome AS 620E HRLSOP4, HRLSOP5, HRLSOP7 | |



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| HUMAN BODY TISSUES AND FLUIDS (cont'd) | Histopathology <u>examination activities for the purpose of clinical diagnosis:</u> (cont'd) | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis: All stains are undertaken manually; however, some stains are performed on an automated special stains platform (Benchmark Special stains): HSSSOP43, HSSSOP45. Automated stains are highlighted below. | A |
| | Routine staining for identification of basophilic and eosinophilic structures | <u>Frozen section</u> H+E staining- HSSSOP13 <u>Routine FFPE Automated</u> - Sakura Tissue-Tek Prisma with Film coverslipper - HRLSOP41 Haematoxylin & Eosin Stain – SOP HRLSOP9 and HRLSOP12 | |
| Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples. | Acid Mucins | Alcian Blue Method (pH2.5) for Acid Mucin – SOP HSSSOP1 | |
| | Glycogen, Neutral & Acid Mucins | Alcian Blue Periodic Acid Schiff's diastase – SOP HSSSOP46 Diastase Periodic Acid Schiff's- HSSSOP6 (Automated). | |
| | Amyloid | Congo Red – SOP HSSSOP5 | |
| | Elastic Fibres, Collagen and muscle, connective tissue | Elastin Van Gieson - HSSSOP7 HVG - HSSSOP15 | |
| | Microrganisms and parasites: Campylobacter | Giemsa - HSSSOP9 | |
| | Gram | Gram - HSSSOP10 | |
| | Pnumocystis /Fungi | Grocott - HSSSOP12 (Automated) | |
| | Leprosy | Wade Fite - HSSSOP33 | |
| | TB | Ziehl Neelsen - HSSSOP35 | |
| | Collagen/fibrin | MSB - HSSSOP19 | |



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| HUMAN BODY TISSUES AND FLUIDS (cont'd) | Histopathology <u>examination activities for the purpose of clinical diagnosis:</u> (cont'd) | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis: All stains are undertaken manually; however, some stains are performed on an automated special stains platform (Benchmark Special stains): HSSSOP43, HSSSOP45. Automated stains are highlighted below. | A |
| Fixed and fresh tissue, excisional resection specimens and incisional biopsies and surgical including Non-gynae samples (cont'd) | Melanin and argentaffin granules | Masson Fontana- HSSSOP16 | |
| | Ferric Iron | Perls - HSSSOP24 (Automated). | |
| | Reticulin fibres | Retic - HSSSOP27 (Automated). | |
| | Fibrin and muscle | Masson Trichrome - HSSSOP17 (Automated). | |
| | Neutral fats | Oil Red O - HSSSOP20 | |
| | Hepatitis B surface antigen | Shikata's Orcein - HSSSOP29 | |
| FFPE tissue on slides and tissue curls | Detection of EGFR mutations | RT-PCR on Cobas z480, HMOLSOP1 and HMOLSOP2 | |
| | Fibrin and muscle | Masson Trichrome - HSSSOP17 (Automated). | |
| | Neutral fats | Oil Red O - HSSSOP20 | |
| | Hepatitis B surface antigen | Shikata's Orcein - HSSSOP29 | |
| FFPE tissue on slides and tissue curls | Detection of EGFR mutations | RT-PCR on Cobas z480, HMOLSOP1 and HMOLSOP2 | |



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| <p>HUMAN BODY TISSUES AND FLUIDS (cont'd)</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples</p> | <p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis:</u></p> <p>Normal/neoplastic tissue of epithelial origin</p> <p>Non-neoplastic, neoplastic liver disease, tumours of the testis and ovary such as yolk sac tumour</p> <p>ALK-positive anaplastic large cell lymphoma</p> <p>Androgen Receptor – member of the superfamily of ligand responsive transcription regulators.</p> <p>Desmoid tumors, colorectal cancer and colon adenoma.</p> <p>Follicular lymphomas and diffuse lymphoproliferative diseases.</p> <p>Diffuse large B-cell lymphomas, follicular lymphomas and Burkitt lymphomas/ leukaemia</p> <p>Adenocarcinoma V malignant mesothelioma and BBC v SCC of Skin</p> | <p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment:</p> <p>Dako OMNIS (Serial number 1810002125)* Dako OMNIS (Serial number 1810003023)** Ventana Benchmark Ultra^ SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20, HIHCSOP27, HIHCSOP32 HIHCSOP41, HIHCSOP42, HIHCSOP43, HIHCSOP45</p> <p>AE1/AE3*- Reacts with the 65-67, 64, 59, 58, 56.5, 56, 54, 52, 50, 48 and 40 kDa cytokeratins.</p> <p>AFP- Alpha-1-fetoprotein (AFP)*</p> <p>ALK1**</p> <p>AR^</p> <p>B-CATENIN*</p> <p>BCL2*</p> <p>BCL6*</p> <p>BEREP4**</p> | <p>A</p> |



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| <p>HUMAN BODY TISSUES AND FLUIDS (cont'd)</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)</p> | <p>Immuno-histochemistry examination activities for the purpose of clinical diagnosis: (cont'd)</p> <p>Germ cell tumours, choriocarcinoma, granulosa cell tumour, hydatiform mole and seminoma</p> <p>Serous ovarian carcinoma and mesothelioma</p> <p>Gastrointestinal and pancreatic cancers</p> <p>Identification of thyroid medullary carcinoma and thyroid C cells</p> <p>Primarily for identification of mesothelial cells and malignant mesothelioma of the epithelial type. Other tumours such as granulosa cell tumour also express calretinin.</p> <p>Identification of tumors of epithelial origin and non-small cell lung cancer and in distinguishing carcinomas from other malignant tumors of non-epithelial origin.</p> | <p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment:</p> <p>Dako OMNIS (Serial number 1810002125)* Dako OMNIS (Serial number 1810003023)** Ventana Benchmark Ultra^ SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20, HIHCSOP27, HIHCSOP32 HIHCSOP41, HIHCSOP42, HIHCSOP43, HIHCSOP45</p> <p>B-HCG*</p> <p>CA125*</p> <p>CA19.9*</p> <p>Calcitonin*</p> <p>Calretinin*</p> <p>CAM5.2*</p> | A |



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| <p>HUMAN BODY TISSUES AND FLUIDS (cont'd)</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)</p> | <p>Immuno-histochemistry examination activities for the purpose of clinical diagnosis: (cont'd)</p> <p>Identification of thymoma, precursor T-lymphoblastic leukaemia/lymphoma and Langerhans' cell histiocytosis.</p> <p>Identification of T cells and their neoplasms such as T- and/or NK-cell lymphomas and mycosis fungoides.</p> <p>Identification of thymocytes, T-helper cells and related tumour's such as peripheral T-cell lymphoma (unspecified), anaplastic large cell lymphoma and mycosis fungoides.</p> <p>Identification of B-and T-cell malignancies including B-cell chronic lymphoid leukaemia/ small lymphocytic lymphoma, mantle cell lymphoma and T-cell lymphoma and leukaemia.</p> <p>Identification of cytotoxic / suppressor T cells and their neoplastic counterparts.</p> | <p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment: Dako OMNIS (Serial number 1810002125)* Dako OMNIS (Serial number 1810003023)** Ventana Benchmark Ultra^ SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20. HIHCSOP27, HIHCSOP32 HIHCSOP41, HIHCSOP42, HIHCSOP43, HIHCSOP45</p> <p>CD1 A*</p> <p>CD3**</p> <p>CD4*</p> <p>CD5*</p> <p>CD8*</p> | A |



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| <p>HUMAN BODY TISSUES AND FLUIDS (cont'd)</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples</p> | <p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis:</u> (cont'd)</p> <p>Identification of Burkitt lymphoma/leukaemia, follicular lymphoma (except grade III), precursor B-cell lymphoblastic leukaemia/lymphoma and renal cell carcinoma of the clear cell type.</p> <p>Identification of mononuclear Hodgkin cells and Reed-Sternberg cells in Hodgkin lymphoma.</p> <p>Identification of the B-cell lineage and different types of B-cell lymphoma.</p> <p>Identification of follicular dendritic cells, mature B cells and structural alterations in the meshwork of follicular dendritic cells.</p> <p>Normal B lymphocytes and malignant lymphomas. Mantle cell lymphoma is generally negative for CD23.</p> | <p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment: Dako OMNIS (Serial number 1810002125)* Dako OMNIS (Serial number 1810003023)** Ventana Benchmark Ultra^ SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20, HIHCSOP27, HIHCSOP32 HIHCSOP41, HIHCSOP42, HIHCSOP43, HIHCSOP45</p> <p>CD10*</p> <p>CD15**</p> <p>CD20*</p> <p>CD21**</p> <p>CD23**</p> | A |



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| <p>HUMAN BODY TISSUES AND FLUIDS (cont'd)</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)</p> | <p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis:</u> (cont'd)</p> <p>Reed-Sternberg cells in Hodgkin lymphoma and anaplastic large cell lymphoma</p> <p>Endothelial cells, and benign and malignant vascular disorders.</p> <p>Vascular and lymphatic vessels and tumours of vascular origin</p> <p>Low-grade B-cell lymphoma, peripheral T-cell lymphoma and myeloid disorders</p> <p>Natural killer (NK) cells, NK-like T cells, neural/neuroendocrine tissues and their neoplasms</p> <p>Hodgkin lymphoma (lymphocyte-predominant subtype), T-cell large granular lymphocyte disorder, oligodendroglioma and neuroendocrine tumour</p> <p>Macrophages, other members of the mononuclear phagocyte lineage, and neoplasm of myeloid and macrophage/monocyte origin</p> | <p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment: Dako OMNIS (Serial number 1810002125)* Dako OMNIS (Serial number 1810003023)** Ventana Benchmark Ultra^ SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20. HIHCSOP27, HIHCSOP32 HIHCSOP41, HIHCSOP42, HIHCSOP43, HIHCSOP45</p> <p>CD30**</p> <p>CD31*</p> <p>CD34*</p> <p>CD43*</p> <p>CD56*</p> <p>CD57*</p> <p>CD68*</p> | A |



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| <p>HUMAN BODY TISSUES AND FLUIDS (cont'd)</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)</p> | <p>Immuno-histochemistry examination activities for the purpose of clinical diagnosis: (cont'd)</p> <p>B cells during all stages of differentiation and of B-cell neoplasm</p> <p>Glioblastomas and ependymomas of the CNS, certain islet cell tumours of the pancreas, Ewing's sarcoma, granulosa cell tumour and primitive peripheral neuroectodermal tumours</p> <p>Mesenchymal tumours of the gastrointestinal tract.</p> <p>Plasma cells and multiple myeloma, and for sub classification of diffuse large B-cell lymphoma</p> <p>Adenocarcinoma and carcinoids of the gastrointestinal tract</p> <p>Various tumours such as lung adenocarcinoma, meningioma and medullary carcinoma of the thyroid.</p> | <p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment: Dako OMNIS (Serial number 1810002125)* Dako OMNIS (Serial number 1810003023)** Ventana Benchmark Ultra^ SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20, HIHCSOP27, HIHCSOP32 HIHCSOP41, HIHCSOP42, HIHCSOP43, HIHCSOP45</p> <p>CD79a*</p> <p>CD99*</p> <p>CD117**</p> <p>CD138*</p> <p>CDX2*</p> <p>CEA (Mono) and CEA (Poly)*</p> | A |



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| <p>HUMAN BODY TISSUES AND FLUIDS (cont'd)</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)</p> | <p>Immuno-histochemistry examination activities for the purpose of clinical diagnosis: (cont'd)</p> <p>Neuroendocrine cells and tumours with neuroendocrine differentiation.</p> <p>Distinguishing stratifying epithelial cell types from simple epithelial cell types.</p> <p>Epithelial tumours with cytokeration 19 expression</p> <p>Normal GI epithelia and urothelium Gastrointestinal tumours, mucinous ovarian tumours and Merkel cell carcinoma.</p> <p>Prostatic adenocarcinoma and prostatic intraepithelial neoplasia (PIN) or its benign mimics such as atypical hyperplasia.</p> <p>Cytokeratin 5 in normal and neoplastic tissues.</p> <p>Squamous epithelium and neoplasms</p> <p>Classification of NSCLC</p> | <p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment: Dako OMNIS (Serial number 1810002125)* Dako OMNIS (Serial number 1810003023)** Ventana Benchmark Ultra^ SOPS- HHC SOP16, HHC SOP34 HHC SOP20. HHC SOP27, HHC SOP32 HHC SOP41, HHC SOP42, HHC SOP43, HHC SOP45</p> <p>Chromogranin A*</p> <p>CK14*</p> <p>CK19*</p> <p>CK20*</p> <p>CK34Be12*</p> <p>CK5*</p> <p>CK5/6*</p> <p>CK5/6 + P40 Dual Stain * **</p> | <p>A</p> |



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| <p>HUMAN BODY TISSUES AND FLUIDS (cont'd)</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)</p> | <p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis:</u> (cont'd)</p> <p>Glandular and transitional epithelia and neoplasia of type</p> <p>Epithelial Cell Tumours</p> <p>C-myc oncogene</p> <p>Mantle cell lymphoma.</p> <p>Smooth and striated muscle cells and reactive mesothelial cells, tumours leiomyoma and rhabdomyo-sarcoma.</p> <p>Plasma membrane of gastrointestinal stromal tumors (GISTs)</p> <p>Lymphatic marker</p> <p>Epstein-Barr virus-infected cells</p> <p>Ductal carcinoma of the breast. E-cadherin also stains normal breast duct and various tumours such as oesophageal adenocarcinoma and squamous carcinoma, and transitional cell carcinoma of the bladder.</p> | <p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment: Dako OMNIS (Serial number 1810002125)* Dako OMNIS (Serial number 1810003023)** Ventana Benchmark Ultra^ SOPS- HHC SOP16, HHC SOP34 HHC SOP20. HHC SOP27, HHC SOP32 HHC SOP41, HHC SOP42, HHC SOP43, HHC SOP45</p> <p>CK7*</p> <p>CK8/18*</p> <p>C-MYC*</p> <p>Cyclin D1*</p> <p>Desmin*</p> <p>DOG-1*</p> <p>D2-40 * **</p> <p>EBV**</p> <p>E-Cadherin*</p> | A |



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United Kingdom Accreditation Service

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

University Hospitals of Derby and Burton NHS Foundation Trust operating as Derbyshire Pathology

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| <p>HUMAN BODY TISSUES AND FLUIDS (cont'd)</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)</p> | <p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis:</u> (cont'd)</p> <p>Tumours of epithelial origin in a wide variety of tissues light chains</p> <p>Expression of ER containing cells, e.g. Normal and neoplastic breast cells</p> <p>Vascular tumours and benign haemangioma variants and haemangioendotheliomas</p> <p>Breast carcinoma and metastatic tumours</p> <p>Human Herpes Virus Type 8</p> <p>Hepatocellular tumours.</p> <p>Melanomas and other tumors demonstrating melanoma/melanocytic differentiation</p> <p>HER2 antigen</p> | <p>Microscopic examination supported by <u>automated</u> staining with positive stain controls:</p> <p>Automated equipment: Dako OMNIS (Serial number 1810002125)* Dako OMNIS (Serial number 1810003023)** Ventana Benchmark Ultra^ SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20. HIHCSOP27, HIHCSOP32 HIHCSOP41, HIHCSOP42, HIHCSOP43, HIHCSOP45</p> <p>EMA*</p> <p>Estrogen Receptor^</p> <p>Factor 8 (FVIII)*</p> <p>GCDFF-15*</p> <p>HHV-8^</p> <p>Hepatocyte*</p> <p>HMB45*</p> <p>HER2^</p> | A |



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| <p>HUMAN BODY TISSUES AND FLUIDS (cont'd)</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)</p> | <p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd):</p> <p>IgG4 related sclerosing disease has been recognized as a systematic disease entity characterised by an elevated serum igG4 level.</p> <p>Ovarian sex cord and stromal tumours</p> <p>Plasma cells and lymphoid cells containing kappa light chains</p> <p>Proliferating cells in normal and neoplastic tissues</p> <p>Plasma cells and lymphoid cells containing lambda light chains</p> <p>Tumours of lymphoid origin</p> <p>Macrophages, Langerhans' cell histiocytic and squamous cell carcinoma of the skin.</p> <p>Mismatch repair gene associated with HNPCC</p> <p>Mismatch repair gene MSH6 associated with HNPCC</p> | <p>Microscopic examination supported by <u>automated</u> staining with positive stain controls (cont'd):</p> <p>Automated equipment: Dako OMNIS (Serial number 1810002125)* Dako OMNIS (Serial number 1810003023)** Ventana Benchmark Ultra^ SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20. HIHCSOP27, HIHCSOP32 HIHCSOP41, HIHCSOP42, HIHCSOP43, HIHCSOP45</p> <p>IgG4^</p> <p>Inhibin*</p> <p>Kappa**</p> <p>KI67**</p> <p>Lambda**</p> <p>Leucocyte Common Antigen**</p> <p>Mac387**</p> <p>MSH2^</p> <p>MSH6^</p> | <p>A</p> |



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| <p>HUMAN BODY TISSUES AND FLUIDS (cont'd):</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)</p> | <p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd):</p> <p>Melanocytes and Melanomas.</p> <p>Type II pneumocytes and in most lung adenocarcinomas and some renal cell carcinomas</p> <p><u>Classification of NSCLC</u></p> <p>Normal and neoplastic cells of epithelial origin.</p> <p>Sub classification of lymphoid malignancies</p> <p>Myoglobin Demonstrated inskeletal and cardiac muscle but not in smooth muscle.</p> <p>Differentiation of prostatic cancers</p> <p>Normal and neoplastic cells of neuronal and neuroendocrine origin</p> <p>Germ cell tumours</p> <p>Tumor suppressor protein</p> <p>Viral capsid protien of HIV-1</p> | <p>Microscopic examination supported by <u>automated</u> staining with positive stain controls (cont'd):</p> <p>Automated equipment: Dako OMNIS (Serial number 1810002125)* Dako OMNIS (Serial number 1810003023)** Ventana Benchmark Ultra^ SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20. HIHCSOP27, HIHCSOP32 HIHCSOP41, HIHCSOP42, HIHCSOP43, HIHCSOP45</p> <p>Melan A**</p> <p>Napsin A**</p> <p>Napsin A + TTF1 Dual Stain * **</p> <p>MNF116**</p> <p>MUM1**</p> <p>Myoglobin**</p> <p>NKX3.1^</p> <p>NSE**</p> <p>OCT3/4**</p> <p>P16**</p> <p>P24**</p> | <p>A</p> |



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| <p>HUMAN BODY TISSUES AND FLUIDS (cont'd)</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)</p> | <p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis (cont'd):</u></p> <p>P40 protein. P40 is selectively expressed in lung SCC</p> <p>For identification of wild-type and mutant-type p53 protein and accumulation in human neoplasia</p> <p>Basal epithelial cells</p> <p>Cytokeratins</p> <p>Protien of the paired box (PAX) family of transcription factors</p> <p>PD-L1 testing in NSCLC</p> <p>Malignant germ cell tumours</p> <p>Mismatch repair gene marker</p> <p>Progesterone receptor levels in breast cancer tissue</p> <p>Tumours of prostatic origin prostate adenocarcinoma.</p> <p>Renal cell carcinoma vs. non-renal cell tumours</p> | <p>Microscopic examination supported by <u>automated</u> staining with positive stain controls (cont'd):</p> <p>Automated equipment: Dako OMNIS (Serial number 1810002125)* Dako OMNIS (Serial number 1810003023)** Ventana Benchmark Ultra^ SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20. HIHCSOP27, HIHCSOP32 HIHCSOP41, HIHCSOP42, HIHCSOP43, HIHCSOP45</p> <p>P40**</p> <p>P53**</p> <p>P63**</p> <p>PanCK**</p> <p>PAX8^</p> <p>PD-L1 (SP263) ^</p> <p>PLAP**</p> <p>PMS2^</p> <p>Progesterone Receptor^</p> <p>Prostate Specific Antigen (PSA) & Racemase (AMACAR)**</p> <p>Renal Cell Carcinoma**</p> | <p>A</p> |



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| <p>HUMAN BODY TISSUES AND FLUIDS (cont'd)</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)</p> | <p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis (cont'd):</u></p> <p>Malignant melanoma, chondroblastoma, schwannoma</p> <p>Smooth muscle cells, myofibroblasts, and myoepithelial cells and their tumours</p> <p>For identification of myoepithelial cells and smooth muscle neoplasm.</p> <p>Melanoma Marker</p> <p>Neuroendocrine neoplasms and tumours with neuroendocrine differentiation.</p> <p>Non Small cell lung cancer (NSCLC)</p> <p>Precursor B- and T-cell lymphoblastic lymphoma/ leukemia, and for identification of thymoma.</p> <p>Differentiation of mesothelioma from adenocarcinoma: Identification of vascular tumours</p> <p>Tumours of thyroid origin</p> | <p>Microscopic examination supported by <u>automated</u> staining with positive stain controls (cont'd):</p> <p>Automated equipment: Dako OMNIS (Serial number 1810002125)* Dako OMNIS (Serial number 1810003023)** Ventana Benchmark Ultra^ SOPS- HIHC SOP16, HIHC SOP34 HIHC SOP20, HIHC SOP27, HIHC SOP32 HIHC SOP41, HIHC SOP42, HIHC SOP43, HIHC SOP45</p> <p>S100**</p> <p>SMA**</p> <p>SMM-HC**</p> <p>SOX10 * **</p> <p>Synaptophysin **</p> <p>ROS1^</p> <p>TdT**</p> <p>Thrombomodulin**</p> <p>Thyroglobulin**</p> | <p>A</p> |



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| <p>HUMAN BODY TISSUES AND FLUIDS (cont'd)</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens including Non-gynae samples (cont'd)</p> | <p><u>Immuno-histochemistry examination activities for the purpose of clinical diagnosis (cont'd):</u></p> <p>Primary vs. metastatic tumours in the lung and thyroid</p> <p>Cells of mesenchymal origin in normal and neoplastic tissues</p> <p>Wilms's tumour, malignant mesotheliomas</p> | <p>Microscopic examination supported by <u>automated</u> staining with positive stain controls (cont'd):</p> <p>Automated equipment: Dako OMNIS (Serial number 1810002125)* Dako OMNIS (Serial number 1810003023)** Ventana Benchmark Ultra^ SOPS- HIHCSOP16, HIHCSOP34 HIHCSOP20, HIHCSOP27, HIHCSOP32 HIHCSOP41, HIHCSOP42, HIHCSOP43, HIHCSOP45</p> <p>TTF1**</p> <p>Vimentin**</p> <p>WT1**</p> | A |



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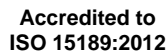
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| <p>HUMAN BODY TISSUES AND FLUIDS (cont'd)</p> <p>Liquid Based Cytology (LBC) suspension of cervical/vaginal cells</p> <p>Samples collected from the cervix and stored in Liquid Based Cytology Collection Fluid</p> | <p>Cytopathology <u>examination activities for the purpose of clinical diagnosis:</u></p> <p>Preparation and screening for detection or exclusion of pathological abnormalities</p> <p>Detection of high-risk HPV mRNA</p> | <p>Sample preparation using the Hologic Thinprep Liquid Based Cytology method in conjunction with manufacturer's instructions using:</p> <p>Gynaecological cytology - Hologic T5000 Processor Papanicolaou Staining and coverslipping using: Sakura Tissue-Tek Prisma Stainer and Film coverslipper Screening by light microscopy (qualitative analysis). CSRSOP46, CSRSOP49, CSRSOP50, CSRSOP51, and CCSOP9</p> <p>HOLOGIC –TOMCAT pre-analytics instrument, CSRSOP53 and HOLOGIC – PANTHER Molecular analyser: SOP CCSOP33 HPV Hologic Panther – Aptima HPV Assay.</p> | <p>A</p> <p>A</p> |



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| HUMAN BODY FLUIDS (cont'd) | Haematology examination activities for the purpose of clinical diagnosis (cont'd) | In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant: | A, E |
| | | In house documented procedures based on standard methods and incorporating Sysmex CS5100 and Sysmex CS2500 manufacturers' instructions as relevant: | A |
| Plasma | APTT | COAGSOP5 | |
| Plasma | Fibrinogen | COAGSOP7 | |
| | | In house documented procedures based on standard methods and incorporating Sysmex CS5100 manufacturers' instructions as relevant: | A |
| Plasma | Prothrombin & International normalised ratio (INR) | COAGSOP4 | |
| | | Immunoassay: Sysmex CS5100i automated clotting assays, light transmission | E |
| Plasma | Routine Coagulation testing for: Prothrombin Time (PT) INR Activated Partial Thromboplastin Time (APTT) Fibrinogen | BSC-COAG-SOP-020 | |
| Plasma | D-Dimers | COAGSOP6 | A |
| | | In house documented manual procedures based on visual end point tilt tube method: Clifton Water Bath | |
| Plasma | Manual Clotting Tests PT & APTT | COAGSOP36 | A |



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| HUMAN BODY FLUIDS (cont'd) | Haematology examination activities for the purpose of clinical diagnosis (cont'd) | In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant: | |
| Blood | Factor VIII inhibitor | Sysmex CS2500 Photometric Bethesda Method – COAGSOP37 | A |
| Plasma | Factor assays Factor II Factor V Factor VII Factor VIII Factor IX Factor X Factor XI Factor XII | Sysmex CS2500 Photometric COAGSOP10 COAGSOP15 | A |
| Plasma | Lupus screen | COAGSOP14 | |
| Plasma | Thrombin time | COAGSOP18 | |
| Plasma | Protein S | COAGSOP13 | |
| Plasma | VWF activity | COAGSOP16 | |
| Plasma | VWF antigen | COAGSOP17 | |
| Plasma | Antithrombin | COAGSOP11 | |
| Plasma | Activated protein C Resistance (APC-R) | COAGSOP8 | |
| Plasma | Anti-Xa activity, Rivaroxaban and Apixaban | COAGSOP39 | |
| Plasma | Protein C | COAGSOP12 | |
| Blood | Detection of: Prothrombin 20210A | Hain GenoXtract and Fluorocycler PCR, COAGSOP21 | |
| | Factor V Leiden | Hain GenoXtract and Fluorocycler PCR, COAGSOP21 | |



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| HUMAN BODY FLUIDS (cont'd) | Haematology examination activities for the purpose of clinical diagnosis (cont'd): | In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant: | A, E |
| Blood | Erythrocyte Sedimentation Rate (ESR) | StaRRsed InteRRlinar ESR machine, Westergren sedimentation. BSC-HAEM-SOP-3 | E |
| Bone Marrow | Examination of bone marrow: in order to identify or exclude Morphological and Cytological abnormalities for the purpose of diagnosis | Manual slide preparation and interpretation. AUTOHASOP15 - Processing Bone Marrow Requests AUTOHASOP16 – Procedure for staining of bone marrow slides SPHAEMSOP63 – Reporting bone marrow aspirates and trephines | A |
| Blood | Blood Film: Detection of normal and abnormal morphologies and white blood cell differential | Manual slide preparation and interpretation. AUTOHASOP30 - Examination and Reporting Blood of Blood Films | A |
| | Pre-caterisation of cells | Sysmex DI-60 Digital Morphology Analyser for automated blood film morphology AUTOHASOP65, AUTOHASOP43. | A |
| | | Manual preparation of slide or Sysmex SP-10 (May-Grunwald and Giemsa) Hematek 3000-Modified Wrights stain | E |
| Blood | Red cell, white cell and platelet morphology and white cell differential | BSC-HAEM-SOP-6, 7, 20 | |



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| Blood | Glandular fever: heterophile antibodies to Epstein Barr Virus | Accusay mono Immunoassay AUTOHASOP10 | A |
| | | Monogen Manual assay with latex reagent | E |
| Plasma | IM Heterophile antibody | BSC-HEAM-SOP-21 | |
| Blood | Haemoglobin A1C (HbA1C) | Bio-Rad D100 HPLC system SPHAEMACSOP16 SPHAEMACSOP17 | A |
| | | Documented in-house methods to meet the requirements of the Sick cell and Thalassaemia screening programme, as defined in the laboratory QA evidence requirements. | A, E |
| Blood | Haemo-globinopathy: Quantitation of HbA2, HbF, HbS Identification/ Quantitation of other Variant Hb | Biorad Variant II: SPHAEMHBESOP1 - Haemoglobinopathies Introduction SPHAEMHBESOP5 -Biorad Variant II run procedure | A |
| Blood | Sickle Solubility test | Microgen Bioproducts S-Test Turbidity SPHAEMSOP28 | A |
| Blood | CD4 count / Immune Monitoring CD3 % & Absolute CD3/4 % & Absolute CD3/8 % & Absolute CD19 % & Absolute | Beckman Coulter Navios: Flow cytometry SPHAEMSOP55 - Navios Processing of samples for CD4 counts | A |
| Urine | Haemosiderin | Manual Colorimetric stain assay SPHAEMSOP27 AUTOHASOP17 – Iron Stain | A |



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| HUMAN BODY FLUIDS (cont'd) | Haematology examination activities for the purpose of clinical diagnosis (cont'd): | In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant: | |
| Plasma | Detection of Malarial antigens of: <i>P. falciparum</i> Pan-detection for <i>P. malariae</i> , <i>P. ovale</i> & <i>P. vivax</i> | CareStart™ Malaria HRP2/pLDH Combo Immunoassay AUTOHASOP34 | A |
| Blood | Detection of Plasmodium falciparum, Plasmodium vivax, Plasmodium ovale, Plasmodium malariae, Plasmodium knowlesi | Manual staining of thick and thin films using Fields stain AUTOHASOP9. | A |
| | Blood Transfusion examination activities for the purpose of clinical diagnosis: | Documented in-house procedures based on manufacturer's instructions for BioRad analysers, IH1000: | A |
| Whole blood (EDTA) | Automated blood grouping by antigen detection: <ul style="list-style-type: none"> ABO blood groups Rh blood group antigens: C,c,D,E,e K (K1) blood group antigens | Automated antibody screening using 3 cells containing the following antigens: D,C,E,c,e,Cw,K,k,Kpa,Kpb,Fya,Fyb,Jka,Jkb,Lea,Leb,P1,M,N,S,s,Lu,Lub, Xga: BBSOP92 BBSOP97 BBSOP15 BBSOP6 | A |
| | Automated antibody Identification for the following antigens: D,C,E,c,e,Cw,K,k,Kpa,Kpb, Fya,Fy, JkaJkb,Lea,Leb,P1,M,N,S, s,Lua,Lub, Xga | BBSOP4 Automated (IAT) identification of red cell antibodies. | A |



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| HUMAN BODY FLUIDS (cont'd): | <u>Blood Transfusion</u> <u>examination activities for the purpose of clinical diagnosis (cont'd)</u> | | |
| Whole Blood | Blood Group by detection and identification of antigens: A D Positive A D Negative AB D Positive AB D Negative B D Positive B D Negative O Positive O Negative | Automated BioRad analysers, IH1000, ABO/D forward and reverse grouping, Manual using Biorad cards, screening on IgG cards by Gel column agglutination and centrifugation CRHBLB-LP-BLB018 IH1000 CRHBLB-LP-BLB003 Manual Biorad cards/ | E |
| Whole Blood | Antibody Screen by detection of antibodies to: Rh which includes anti-C, D, E, c, e, C ^w K, k, Kp ^a , Kp ^b , Fy ^a , Fy ^b , Jk ^a , Jk ^b Le ^a , Le ^b S, s, M, N P ₁ Lu ^a , Lu ^b X ^{ga} | Automated BioRad analysers, IH1000 BSC-BB-SOP-138 BSC-BB-SOP-136 | E |
| Plasma | Red Cell antibody identification: anti-C, D, E, c, e, C ^w K, Kp ^a Fy ^a , Fy ^b , Jk ^a , Jk ^b Le ^a , Le ^b S, s, M, N P ₁ Lu ^a , Anti-A1 | BSC-BB-SOP-106 | E |



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| HUMAN BODY FLUIDS (cont'd): | Blood Transfusion examination activities for the purpose of clinical diagnosis (cont'd) Antibody Screen by detection of antibodies to: Rh which includes anti-C, D, E, C ^w Kp ^a Red Cell antibody identification: anti-C, D, E, c, e, Kell (K1) | Manual using Biorad cards, screening on IgG cards by Gel column agglutination and centrifugation BSC-BB-SOP-138 BSC-BB-SOP-136 Manual using Biorad cards, screening on IgG cards by Gel column agglutination and centrifugation BSC-BB-SOP-138 BSC-BB-SOP-136 | |
| Red Cells | Direct Antiglobulin Test (DAT) | IH1000 automated or manually read Diamed ID Microtyping cards: Coombs direct antiglobulin test. BBSOP19 | A |
| Red Cells | Direct Antiglobulin Test (DAT) | DAT card using LISS/Monospecific IgG gel column technology and centrifugation BSC-BB-SOP-147 | E |



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| HUMAN BODY FLUIDS (cont'd) | Blood Transfusion examination activities for the purpose of clinical diagnosis: (cont'd) Red cell phenotyping: <ul style="list-style-type: none"> • Biorad Diaclon Anti-M (monoclonal) • Lorne Anti-Fya (monoclonal) • Lorne Anti-Fyb (polyclonal) • Lorne Anti-Jka (polyclonal) • Lorne Anti-Jkb (monoclonal) • Lorne Anti-S (polyclonal) • Lorne Anti-s (monoclonal) | Documented in-house procedures based on manufacturer's instructions for BioRad analysers, IH1000: BBSOP56 | A |
| Whole blood (EDTA) | Manual blood grouping by antigen detection: <ul style="list-style-type: none"> • ABO blood groups • Rhesus blood group antigens: C,c,D,E,e K (K1) blood group antigens | ABO/D Forward + Reverse Group, K and Rh Phenotype by Gel column agglutination and centrifugation. BBSOP14 BBSOP43 BBSOP6 | A |
| Whole Blood | Blood Group by detection and identification of antigens: <ul style="list-style-type: none"> A D Positive A D Negative AB D Positive AB D Negative B D Positive B D Negative O Positive O Negative Manual antibody screening and identification using cells containing the following antigens: D,C,E,c,e,Cw,K,k,Kpa,Kpb, Fya,Fyb,Jka,Jkb,Lea,Leb,P 1,M,N,S,s,Lua Lub, Xga | Automated BioRad analysers, IH1000 ABO/D forward and reverse grouping, Manual using and Biorad cards, screening on IgG cards by Gel column agglutination and centrifugation CRHBLB-LP-BLB018 IH1000 CRHBLB-LP-BLB003 Manual Biorad cards/tubes BioRad -Gel column agglutination and centrifugation technology: BBSOP4 | E A |



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| HUMAN BODY FLUIDS (cont'd) | <p>Blood Transfusion examination activities for the purpose of clinical diagnosis:</p> <p>Compatibility Testing: Serological Crossmatch - serological compatibility testing between donor red cell antigens and patient plasma.</p> <p>Detection and Estimation of Foetal Maternal Haemorrhage</p> <p>Acid Elution & confirmation of FMH >2mL</p> | <p>Documented in-house procedures based on manufacturer's instructions for BioRad analysers, IH1000:</p> <p>Documented in-house procedures based on BioRad manufacturer's instructions for column technology and centrifugation. BBSOP18</p> <p>Clin-Tech Kleihauer Method BBSOP7</p> <p>Navios Flow Cytometer SPHAEMSOP19</p> | A |
| Maternal whole blood | Detection of fetal cells in maternal whole blood | Manual microscopy using Kleihauer Betke staining for foetal cells BSC-BB-SOP-28 | E |



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| HUMAN BODY FLUIDS (cont'd) | Immunology examination activities for the purpose of clinical diagnosis: | In house documented procedures based on standard methods and incorporating Dynex DS2 immunoassay manufacturers' instructions as relevant IMMSOP48 | A |
| Serum/Plasma | Anti-Cardiolipin abs IgG | IMMSOP34 | |
| | Anti-ds-DNA antibodies | IMMSOP35 | |
| | Anti-ENA antibodies | IMMSOP37 | |
| | Anti-Jo-1 antibodies | IMMSOP36 | |
| | Anti-RNP antibodies | IMMSOP36 | |
| | Anti-Sm antibodies | IMMSOP36 | |
| | Anti-SS-A antibodies (Ro) | IMMSOP36 | |
| | Anti-SS-B antibodies (La) | IMMSOP36 | |
| | Glomerular basement membrane antibodies | IMMSOP33 | |
| | Intrinsic factor antibody | IMMSOP38 | |
| | Myeloperoxidase antibodies | IMMSOP39 | |
| | Proteinase 3 | IMMSOP40 | |
| | SCL-70 antibody | IMMSOP36 | |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd): | In house documented procedures based on standard methods and incorporating ThermoPhadia ImmunoCap 250: PATHEXT177 - Phadia Immunocap IDM User Manual PATHEXT178 - Phadia Immunocap Information Data Manager SPCHEMSOP20 - USE OF THE PHADIA IMMUNOCAP 250 ANALYSER | |
| Serum/Plasma | Specific IgE testing: Almond Apple Aspergillus F Banana Bee venom Birch Brazil nut Cashew Cat Celery Cheddar Cheese Coconut Cod Crab Dog Egg Fish mix Food mix Hazel Horse House Dust Mite Total IgE Kiwi Latex Milk (Cows) Mould mix Nut mix Peanut Pecan Penicillin g Penicillin v Pistachio Salmon Sesame Seed Shrimp | SPCHEMSOP18 | A |



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| HUMAN BODY FLUIDS (cont'd) | Immunology examination activities for the purpose of clinical diagnosis (cont'd): | In house documented procedures based on standard methods and incorporating manufacturers' instructions for ThermoPhadia ImmunoCap 250: PATHEXT177 - Phadia Immunocap IDM User Manual PATHEXT178 - Phadia Immunocap Information Data Manager SPCHEMSOP20 - USE OF THE PHADIA IMMUNOCAP 250 ANALYSER | A |
| Serum/Plasma (cont'd) | Specific IgE testing: Soya Strawberry Timothy Grass Tomato Tree mix Tuna Wheat Weed mix Walnut Wasp | SPCHEMSOP18 | |
| Serum/Plasma | Anti-cyclic citrullinated peptide antibodies | IMMSOP46 | |
| | Anti-nuclear antibodies (IgG) | ASP1200 Automated slide processor, Immunofluorescence: IMMSOP51 IMMSOP47 IMMSOP1 IMMSOP42 | |
| | | Manual, Indirect Immunofluorescence: IMMSOP1 | |
| | Anti-nuclear cytoplasmic antibody Screen | IMMSOP16 | |
| | Crithidia Immuno-fluorescence | IMMSOP18 | |
| | Endomysial antibody – IgA Endomysial antibody - IgG | IMMSOP11 | |
| | Intercellular/skin antibodies - IgG | IMMSOP10 | |



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| HUMAN BODY FLUIDS (cont'd): | Immunology examination activities for the purpose of clinical diagnosis (cont'd): | In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant | A |
| Serum | Liver/Kidney microsomal antibodies. | IMMSOP43 | |
| Serum/Plasma | Mitochondrial antibodies – IgG | IMMSOP43 | |
| | Smooth muscle antibodies - IgG | IMMSOP43 | |
| | Parietal cell antibodies | IMMSOP49 | |



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| HUMAN BODY FLUIDS (cont'd) | <u>Microbiology examination activities for the purpose of clinical diagnosis</u> | In-house documented procedures following current UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions | A, D |
| Material from swabs from wounds, skin, lines, eyes, ears, throats, ulcers and nose. Line Tips | General isolation and characterisation of micro-organisms of clinical significance. | <u>Manual</u> culture using SOP's: MICNEWSOP20 - Processing diagnostic swabs. | A |
| Cellular and fluid material contained on swabs, catheter tips and IUCDs Aspirates Fluids Genital samples Pus Samples from sterile sites Semen Tissues Urine | Isolation of microorganisms of clinical significance | Manual inoculation, incubation and culture using: CRHMIC-LP-GB030, GB033 CRHMIC-LP-GEN02, GB004 CBM06,GB013,GB034 CRHMIC-LP-UR001 GB003,GB014, GB002, GB015, GB002, GB016, | D |
| Material from swabs from Nose, Groin, Throat, Axilla, Perineum and Wounds. | Isolation of MRSA and MSSA | MICSCRSOP3 – MRSA screen. MICSCRSOP10 – Investigation of swabs for Staphylococcus aureus | A |
| Swabs , Fluids, urines, tips and sputum | Isolation of MRSA | Manual culture on chromogenic agar/broths using SOP CRHMIC-LP-AST06 | D |
| Faeces | General isolation and characterisation of Salmonella, Shigella, Campylobacter, Ecoli O157, Vibrio and Yersinia. | MICENTSOP7 – Investigation and Identification of Enteric samples (excluding C.difficile). | A |



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| HUMAN BODY FLUIDS (cont'd) | Microbiology examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures following current UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions | A, D |
| Faeces | General isolation and characterisation of <i>Salmonella</i> , <i>Shigella</i> , <i>Campylobacter</i> & <i>E. coli</i> 0157 | Manual culture and using selective agar with SOPs CRHMIC-LP-EB004, GB004, EB003, EB011 | D |
| Faeces and bowel contents | Detection of <i>Clostridium difficile</i> GDH antigen and toxins A & B | Immunochromatographic assay using SOP CRHMIC-LP-EB010 in conjunction with manufacturers' instructions using C. difficile Quik Chek complete. | D |
| Faeces | Detection of <i>Helicobacter pylori</i> antigen | Immunochromatographic technique using SOP CRHMIC-LP-EB008 and Proflow H pylori kit | D |
| Sputum, Bronchial Washings, Nasopharyngeal Aspirates, Tracheal Aspirates, Cough Swabs and Endotracheal tubes | General isolation and characterisation of Respiratory Tract infections (excluding TB) for micro-organisms of clinical significance | MICCL3SOP7 - Culture of Respiratory Specimens (except Mycobacterium sp). | A |
| Respiratory specimens: Sputum, Bronchoalveolar lavage, Bronchial aspirate, brushings and washings, Cellular material contained on swabs, Endotracheal tube specimens, Nasopharyngeal aspirate, Pleural fluid | General isolation and characterisation of micro-organisms of clinical significance | Manual media culture using SOPs CRHMIC-LP-RB003, CBM06, CL302, GB034 | D |



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| HUMAN BODY FLUIDS (cont'd) | Microbiology examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures following current UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions | |
| Material from swabs from Rectum, Wound and Invasive Device Sites. Faeces, CSU and Sputum. (Patients transferred from other major hospitals only). | Carbapenemase Resistant Enterobacteriaceae (CRE) and Carbapenemase Resistant Organisms (CRO) | MICSCRSOP11 – Carbapenemase producing organism screening | A |
| Material from swabs: from vagina, vulva, vulvo-vaginal, rectal, urethral, mouth and endocervix. | General isolation and characterisation of micro-organisms of clinical significance. | <u>Manual</u> culture and microscopy (wet prep) using SOP: MICSCRSOP9 – Investigation of Genital Tract specimens MICSCRSOP12 – Investigation of mouth swabs for Candida spp. | A |
| CSF's, Ascitic, Peritoneal, Pleural, Pericardial, Amniotic, Joint/bursa and CAPD fluid. | Quantification of white and red blood cells and bacteria. Culture leading to general isolation and characterisation of micro-organisms of clinical significance. | <u>Manual</u> culture and microscopy (including Gram stain) using SOP: MICBBSOP1– Investigation and Identification of Body Bench Samples | A |
| Tissue, Biopsies, synovium, nodes, tissue swabs and bone. | | | |
| Pus, drain fluids, semen, breast milk, seroma, aspirate, washouts, fluid swabs and bile | | | |



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| HUMAN BODY FLUIDS (cont'd) | Microbiology examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures following current UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions | A, D |
| Aspirates Corneal scrapes Eye (specimens from) Fluids Tissues CSF Ascitic fluids | Detection and identification of: White blood cells Red blood cells Bacterial cells Yeast cells and fungal hyphae | Staining (inc. Gram) and microscopic examination using: | D |
| CSF / Ascitic | General isolation and characterisation of micro-organisms of clinical significance | Manual microscopy and manual inoculation and media culture using SOPs CRHMIC-LP-GB016, CBM06, GB034 | D |
| Urine - MSU, CSU, Nephrostomy, Supra pubic aspirate and Bag urine. | The quantification of white and red blood cells, bacteria and epithelial cells. Leading to general isolation and characterisation of micro-organisms of clinical significance. | <u>Manual</u> culture and <u>automated</u> microscopy using SOP: MICURSOP7 - Microbiological Investigation of Urine, in conjunction with the equipment manual using the Sysmex UF5000 automated urine microscopy analyser. | A |
| Urine | Quantification of white and red blood cells, bacteria and epithelial cells | Automated urinalysis, image capture and recognition using: SOP CRHMIC-LP-UR001, in conjunction with equipment manual using UF1000i, UR003 | D |
| Blood, CAPD, Joint Aspirates, Pleural Fluid & Pericardial Fluid | General isolation and characterisation of micro-organisms of clinical significance | BD Bactec FX blood culture fluorescent growth detection system, by detection of pH changes due to CO ₂ production. <u>Manual</u> culture and Microscopy using SOP: MICBCSOP11 – Blood Culture Procedures | A |



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| HUMAN BODY FLUIDS (cont'd) | Microbiology examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures following current UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions | A, D |
| Blood, CAPD, Joint Aspirates, Pleural Fluid & Pericardial Fluid (cont'd) | Identification of microorganisms of clinical significance | Identification of microorganisms of clinical significance by matrix assisted laser desorption ionization-time of flight mass spectrometry: Bruker/BD Microflex Biotyper (MALDI-TOF) Mass Spectrometry. MICMALDISOP1-MALDI-TOF MS Test Procedure | A |
| Blood | Detection of microbial growth and general isolation and characterisation of micro-organisms of clinical significance | Liquid media culture using SOP CRHMIC-LP-BC003 in conjunction with manufacturers' instructions for BD BACTEC FX automated system BC004, BC005 | D |
| Bacterial cultures (isolated in-house) | Identification and characterisation of micro-organisms | Manual and/or automated identification methods using : SOPs CRHMIC-LP-CBM15, CBM01, CBM16, CBM02, CBM05, CBM17 GB001, CBM03, CBM09, CBM13, CBM11, CBM06, AST11, UR001, AM001, CBM08, EB004, CBM12 with Automated methods using Vitek 2 | D |
| Bacterial cultures (isolated in-house) | Antimicrobial susceptibility testing and determination of minimum inhibitory concentration (MIC) | SOP CRHMIC-LP-AST10, 04, 11, 03, CBM01, BC004, UR001 by manual disk diffusion using BSAC guidelines and MIC determination using E-Tests and Vitek 2 | D |
| Skin, Hair and nail clippings | Isolation and identification of clinically significant dermatophyte fungi | Manual inoculation, media culture, and macroscopic & microscopic examination (stained & unstained) using: SOP CRHMIC-LP-MYC013 | D |
| Blood | All Malarial Parasites known to cause human disease | CRHMIC-LP-GB005 using light microscopy and Giemsa Stain | D |
| Blood | Malarial Parasites to include: Plasmodium falciparum Pan malarial antigen | Immunochromatographic assay using CRHMIC-LP-GB005 and Binax NOW malaria kit. | D |



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| HUMAN BODY FLUIDS (cont'd) | Microbiology examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures following current UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions | A, D |
| Sputum, Bronchial Washings, Nasopharyngeal Aspirates, Tracheal Aspirates, Pleural fluids, Lymph Nodes, Tissues, Fluids, Pus and CSF's | General isolation and characterisation of Mycobacterium (typical and atypical). | <u>Manual</u> microscopy for the detection of Acid Fast Bacilli (Mycobacterium) by Auramine-Phenol Stain and confirmation by Ziehl-Neelsen stain. MICCL3SOP15 – Investigation of specimens for Mycobacterium species. Automated culture using BD Bactec MGIT 960 system . Detection of pH changes due to the presence of CO ₂ . MICCL3SOP15 - Investigation of Specimens for Mycobacterium species. | A |
| Sputum, fluid, urine, tissue and swabs | Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. <i>Mycobacterium</i> spp.) | Liquid culture, auramine phenol staining and incident-light fluorescence microscopy and confirmation ZN staining using light microscopy using: CRHMIC-LP-RB005, CL302, EB009 in conjunction with BD TB MGIT, RB001 | D |
| Faeces, urine and Sellotape slides | Examination for the presence of parasites (ova, cysts, trophozoites and worms (OCP) of clinical significance. Detection of Schistosoma haematobium ova. Detection of Cryptosporidium oocysts | Light Microscopy using SOP MICENTSOP7 – Investigation and Identification of Enteric samples (excluding C.difficile) using unstained and iodine stained direct microscopic examination and/or Formol-ether faecal concentration (parasep system method). MICENTSOP8 – Investigation of faeces and other samples for parasites. Direct fluorescence microscopy using Auramine Phenol staining | A |
| Faeces, fluids, urine & perianal swabs, sellotape slide and suspected parasitic material | Examination for the presence of parasites (ova, cysts, trophozoites and worms) of clinical significance | Unstained and iodine stained direct microscopic examination and/or Formol-ether faecal concentration and microscopic examination using: SOPs CRHMIC-LP-EB005 | D |



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| HUMAN BODY FLUIDS (cont'd) | Microbiology examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures following current UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions | A, D |
| Faeces | Rotavirus detection | Rapid membrane test for the qualitative detection of rotavirus antigen in human stool using Immunocard STAT Rotavirus using SOP: MICENTSOP7 – Investigation and Identification of Enteric samples (excluding C.difficile). | A |
| Faeces | Detection of Cryptosporidium | Fluorescent microscopy method (auramine stain) and confirmation using Cold ZN incident-light microscopic examination | D |
| Urine - MSU, CSU, Nephrostomy, Sub Phrenic Aspirate and Bag urine. | detection of Legionella pneumophila antigen and Streptococcus pneumonia antigen. | Manual Immunochromatographic assay - Binax NOW Legionella pneumophila antigen and Streptococcus pneumonia antigen kits: MICURSOP8 – Urinary antigen detection for Legionella and Streptococcus pneumoniae | A |
| Urine | Detection of Legionella urinary antigen | Immunochromatographic assay using SOP CRHMIC-LP-SE044 and Alere Binax NOW for legionella Ag detection | D |
| Urine | Detection of S.pneumoniae urine antigen | Immunochromatographic assay using SOP CRHMIC-LP-SE053 and Alere Binax NOW for s.pneumoniae Ag detection | D |
| Faeces | Detection of Norovirus | Immunochromatographic assay SOP CRHMIC-LP-EB007 using Ridascreen Norovirus kit | D |
| Serum/plasma | HIV p24 antigen/antibody (HIV1/2) | Immunochromatographic detection method using the SOP: MICSERSOP7 - Determine HIV1/2 Ag/Ab | A |



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| HUMAN BODY FLUIDS (cont'd) | Microbiology examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures following current UK Standards for Microbiological Investigations (SMIs) and incorporating relevant manufacturers' instructions | A, D |
| | IgG and IgM antibody to Parvovirus B19 | In house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant: Automated EIA - Dynex DS2 : Using the microassay plates and Novalisa kit using: MICSERSOP12 – Qualitative Determination of IgG and IgM antibodies to Erythrovirus (Parvovirus) B19 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 *) | A |
| | Detection of Hepatitis B surface antigen.* Detection of Hepatitis B core Antibody. Detection of Hepatitis B antibody Detection of Hepatitis C antibody. Detection of Rubella IgG antibody. Detection of HIV Antibody/Antigen* Detection of Syphilis IgG/IgM* | Roche cobas 6000/8000 Immunoassay MICSERSOP4 - Procedure for Serology Testing (HBsAg, Hep B cAb, Hep B Ab HCV Ab, Syphilis and Rubella IgG). MICSERSOP28 - ROCHE HIV COMBI for the detection of HIV Antibody/Antigen. 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 *) | A |
| | | | |



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| Serum | Hepatitis A IgM Hepatitis B Surface Antibody Hepatitis B Core IgG and IgM Hepatitis B Surface antigen* Rubella IgG Hepatitis C antibody HIV 1 & 2 antibody and p24 antigen* Treponema IgG and IgM* | In-house procedures in conjunction with manufacturers instructions using Roche COBAS C8000 e801/e802 (testing performed in blood sciences) with reference to CRHMIC-LP-SE133 | D |
| Serum or plasma | Detection of Hepatitis A IgM. Detection of Varicella-Zoster IgG. Detection of Rubella IgM. Detection of CMV IgG, CMV IgM and CMV IgG Advitiy Detection of Measles IgG Detection of Mumps IgG | Biomerieux VIDAS automated ELISA & associated SPR's, using the SOP's: MICSERSOP8 – Hepatitis A IgM Detection. MICSERSOP24 - Varicella-Zoster IgG Detection MICSERSOP16 - Rubella IgM Detection MICSERSOP5, 29 and 36 CMV testing MICSERSOP41 Mumps IgG antibody detection MICSERSOP47 Measles IgG antibody detection MICSERSOP25 - Use of the Vidas in conjunction with the manufacturer's instructions for the VIDAS machine | A |
| | Anti-streptolysin (ASO) | Biokit rheumajet ASO latex slide test MICSERSOP3 – ASO Titre | A |
| | Aspergillus antibody | ThermoPhadia ImmunoCap 250 Immunoassay MICSERSOP39 and AUTOCHISOP233 | A |
| Genital, rectal and throat swab and urine | Chlamydia NAATs detection Gonorrhoea NAATs detection | Automated Roche Cobas 4800 extraction and amplification platform MICSERSOP30 – Cobas 4800 CT/NG test | A |



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| HUMAN BODY FLUIDS (cont'd) | Microbiology examination activities for the purpose of clinical diagnosis (cont'd) | In house documented methods incorporating manufacturer's instructions where relevant | A, D |
| Cervix/Urethral/Vagina swabs and urine | Detection of Chlamydia trachomatis and Neisseria gonorrhoea DNA NAAT esting | Strand Displacement Amplification (SDA) using SOP CRHMIC-LP-SE119 in conjunction with manufacturers instructions using BD VIPER | D |
| Throat swab in viral transport media | Molecular detection of Influenza A and B, RSV | PCR using ELITech Ingenius analyser and MICSERSOP51 | A |
| Nose/throat swabs, NPA samples | Molecular detection of Influenza A and B, RSV | RT PCR using Nanosphere and SOP CRHMIC-LP-GB031 | D |
| CSF | Molecular detection of HSV1, HSV2, VZV, Enterovirus | PCR using ELITech Ingenius analyser and MICSERSOP50 | A |
| | | RT PCR using BD Max and SOP CRHMIC-LP-GB035 in conjunction with manufacturer's instructions | D |
| Cervix / Urethral / Vaginal swabs and urine | Confirmation of Neisseria gonorrhoea DNA | | |
| Faeces | tcdB gene in C.difficile DNA | | |
| Faeces | Molecular detection of DNA of: Salmonella species Shigella/EIEC Campylobacter STEC | | |
| END | | | |