


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

|   |   |  |
|---|---|--|
| <br><b>8440</b><br>Accredited to<br>ISO 15189:2012 | <b>Barts Health NHS Trust as the host of NHS East and South East London Pathology Partnership</b> |  |
|   | Issue No: 006 Issue date: 14 October 2021   |  |
|   | Queen Elizabeth Hospital<br>Stadium Road<br>Woolwich<br>SE18 4QH                                  | Contact: Heather Dolphin<br>Tel: +44 (0)794 793 092<br>E-Mail: heather.dolphin@nhs.net<br>Website: www.lewishamandgreenwich.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 |
|--|--|---|---------------|
| <b>Address</b><br>Queen Elizabeth Hospital<br>Stadium Road<br>Woolwich<br>SE18 4QH | <b>Local contact</b><br>Kathleen kidd<br>Tel: +44 (0) 208 333 3000 ext. 8478<br>E mail: kathleenkidd@nhs.net | Routine Histopathology<br>Special Stains<br>Immunohistochemistry<br>Immunology<br>Clinical Biochemistry<br>Haematology<br>Blood transfusion | QEH           |
| University Hospital<br>Lewisham<br>High Street<br>Lewisham<br>London<br>SE13 6LH   | Kathleen Kidd<br>Tel: +44 (0) 208 333 3000 ext. 8478<br>E mail:Kathleenkidd@nhs.net                          | Clinical Biochemistry<br>Haematology<br>Blood transfusion   | UHL           |



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

| Location details   | Activity  | Location code |
|--|---|---------------|
| Blood Sciences Laboratory<br>Queen Elizabeth Hospital<br>Stadium Road<br>Woolwich<br>SE18 4QH                                  | Blood storage (stock/issue)<br>Fridge managed by laboratory         | QEH           |
| Ward 21 Haematology/Oncology<br>Queen Elizabeth Hospital<br>Stadium Road<br>Woolwich<br>SE18 4QH                               | Blood storage only<br>Fridge managed by laboratory                  | QEH           |
| Theatres<br>Queen Elizabeth Hospital<br>Stadium Road<br>Woolwich<br>SE18 4QH   | Blood storage only<br>Fridge managed by laboratory                  | QEH           |
| Blood issue room<br>Rapid response laboratory<br>University Hospital Lewisham<br>High Street<br>Lewisham<br>London<br>SE13 6LH | Blood product storage (Stock/issue)<br>Fridge managed by laboratory | UHL           |
| Main TheatrePaediatric<br>University Hospital Lewisham<br>High Street<br>Lewisham<br>London<br>SE13 6LH                        | Blood storage<br>Fridge managed by laboratory                       | UHL           |



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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 |
|---|--|--|---------------|
| <p>HUMAN BODY TISSUE</p> <p>Tissue samples (including breast; gastrointestinal; skin; urological; bronchial/lung/thoracic; endocrine including thyroid, parathyroid, adrenal; lymphoreticular including lymph nodes, spleen, and bone marrow trephines [processing only for bone marrow trephines]; liver; bone and soft tissues; , gynaecological; and head and neck)</p> <p>Formalin Fixed Tissue</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE)</p> | <p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p> | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Supported by:</p> <p>Specimen dissection:<br/>Cut-up Manual - Routine<br/>Specimens categorised according to the RCPATH as, SOP CHQ-DP-008 &amp; SOP CHQ-DP-009, CHQ-RP-00013 &amp; CHQ DP 0010<br/>'A' specimens<br/>'B' specimens<br/>'C' specimens<br/>'D' specimens</p> <p>Decalcification using acid decalcifiers (Decalcifier 1 and 2)<br/>SOP CHQ-DP-0010</p> <p>Processing using Sakura TissueTek VIPs ;<br/>VIP5 : SOP CHQ-MP-0026<br/>VIP6 : SOP CHQ-MP-0065</p> <p>Embedding using : Tissue tek Embedding Centre SOP CHQ-MP-005</p> <p>Microtomy: Using rotary Microtomes, Shandon Finesse, Leica (SOP CHQ-MP-006, CHQ-MF-0024)</p> <p>Macroscopic and Microscopic examination: Documented in-house procedures for staining for staining and reading</p> | <p>QEH</p>    |



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| <p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides</p> | <p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p><b>Demonstration Of:</b></p> <p>Basophilic and eosinophilic structures</p> <p>Acid Mucopolysaccharides</p> <p>Acid and Neutral Mucopolysaccharides</p> <p>Amyloid</p> <p>Elastic fibres and connective tissue</p> <p>Bile pigments</p> <p>Fungi including Pneumocystis jiroveci (carinii)</p> <p>Mucin; Cryptococcus</p> <p>Helicobacter/Microorganisms</p> <p>Gram +ve &amp; -ve microorganisms</p> <p>Connective tissue and fibrin</p> | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Haematoxylin and Eosin staining SOP CHQ-SP-001 in conjunction with manufacturer's instructions for Leica Autostainer</p> <p>Special Tinctorial Histochemical Staining:</p> <p>Alcian Blue (SOP CHQ-SP-003)</p> <p>Alcian Blue/Periodic Acid Schiff (SOP CHQ-SP-002)</p> <p>Congo Red (SOP CHQ-SP-005)</p> <p>Elastic/Haematoxylin Van Gieson (EVG/HVG) (SOP CHQ-SP-007, CHQ-SP-014)</p> <p>Fouchet van Gieson (SOP CHQ-SP-008)</p> <p>Grocott Hexamine Silver (SOP-CHQ-SP-013)</p> <p>Mucicarmine (SOP CHQ-SP-0020)</p> <p>Giemsa (SOP CHQ-SP-009)</p> <p>Gram (SOP CHQ-SP-0011)</p> <p>Martius Yellow, Brilliant Crystal Scarlet, Soluble Blue (MSB) (SOP CHQ-SP-0019)</p> | <p>QEH</p>    |



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| <p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides</p> | <p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p><b>Demonstration Of: (cont'd)</b></p> <p>Melanin, Argentaffin cells and Lipofuchsin</p> <p>Connective tissue</p> <p>Neutral Mucopolysaccharides, glycogen and fungus</p> <p>Haemosiderin and ferric iron</p> <p>Reticulin fibres</p> <p>Copper-associated protein and Hepatitis B-affected cells</p> <p>Mast cells</p> <p>Tubercle bacilli</p> <p>Melanin bleach</p> <p>Leprosy bacilli</p> | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Special Tinctorial Histochemical Staining Cont'd.:</p> <p>Masson Fontana (SOP CHQ-SP-0016)</p> <p>Masson's Trichrome (SOP CHQ-SP-0017)</p> <p>Periodic Acid Schiff (PAS) &amp; Diastase PAS (D/PAS) (SOP CHQ-SP-0023)</p> <p>Perl's Prussian Blue (SOP CHQ-SP-0024)</p> <p>Reticulin- Gordon &amp; Sweets (SOP CHQ-SP-0010)</p> <p>Shikata's Orcein (SOP CHQ-SP-0022)</p> <p>Toluidine Blue (SOP CHQ-SP-0028)</p> <p>Ziehl Neelsen (ZN) (SOP CHQ-SP-0021)</p> <p>Mallory Melanin Bleach (SOP CHQ-SP-0015)</p> <p>Wade-Fite (SOP CHQ-SP-0029)</p> | <p>QEH</p>    |



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| <p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd)</p> | <p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Immunohistochemistry to detect the following:</p> <p>Embryonic cell in normal tissues and germ cell tumours</p> <p>Cytokeratins (acidic, basic)</p> <p>HGPIN, prostate adenocarcinoma</p> <p>T lymphocytes, follicular lymphoma, basal cell carcinoma</p> <p>Epithelial cell types</p> <p>Pancreaticobiliary adenocarcinomas</p> <p>Ovarian tumours</p> <p>Smooth muscle</p> <p>Myoepithelial cells, smooth muscle cells</p> <p>Mesothelial cells</p> <p>Glandular cells</p> <p>T cells</p> <p>Mature T cells, T cell lymphomas</p> | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Ventana Benchmark stainer SOP (CHQ-IP-0015) in conjunction with manufacturers instructions<br/>Incorporating the following antibodies:</p> <p>Alpha Fetoprotein</p> <p>AE1/AE3</p> <p>AMACR (Racemase)</p> <p>Bcl2 oncoprotein</p> <p>Ber Ep4</p> <p>CA 19.9</p> <p>CA 125</p> <p>Caldesmon</p> <p>Calponin</p> <p>Calretinin</p> <p>CAM 5.2</p> <p>CD3</p> <p>CD5</p> | <p>QEH</p>    |



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| <p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd)</p> | <p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Immunohistochemistry to detect the following: (cont'd)</p> <p>Mature B cells, CALLA</p> <p>Granulocytes, Reed-Sternberg cells</p> <p>B cells</p> <p>Reed-Sternberg cells, plasma cells, ALCL</p> <p>Endothelial cells</p> <p>Haematopoetic cells, vascular endothelium</p> <p>Natural killer cells, neuroendocrine tissues</p> <p>Macrophages, monocytes, myeloid cells</p> <p>B cells</p> <p>Ewing Sarcoma, atypical fibroxanthoma</p> <p>Mast cells, GIST</p> <p>Plasma cells</p> <p>Intestinal epithelial cells, colorectal + other adenocarcinomas</p> | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Ventana Benchmark stainer SOP (CHQ-IP-0015) in conjunction with manufacturers instructions<br/>Incorporating the following antibodies:</p> <p>CD10</p> <p>CD15</p> <p>CD20</p> <p>CD30</p> <p>CD31</p> <p>CD34</p> <p>CD56</p> <p>CD68</p> <p>CD79alpha</p> <p>CD99</p> <p>CD117/CKIT</p> <p>CD138</p> <p>CDX2</p> | <p>QEH</p>    |



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| <p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd)</p> | <p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Immunohistochemistry to detect the following: (cont'd)</p> <p>CEA glycoproteins</p> <p>Tissues of neuroendocrine origin</p> <p>CytoMeglo Virus</p> <p>Mantle cell lymphoma</p> <p>Basal cells, filamentous keratins from glandular to stratified squamous</p> <p>Epithelial tissue from glandular to stratified squamous</p> <p>Stratified squamous epithelium, basal cells, mesotheliomas</p> <p>Normal and neoplastic epithelia</p> <p>Carcinomas of simple epithelium</p> <p>Epithelial and carcinoma cells</p> <p>Adenocarcinomas, columnar epithelial cells</p> <p>Striated and smooth muscle cells</p> | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Ventana Benchmark stainer SOP (CHQ-IP-0015) in conjunction with manufacturers instructions<br/>Incorporating the following antibodies:</p> <p>CEA</p> <p>Chromogranin</p> <p>CMV</p> <p>Cyclin D1</p> <p>Cytokeratin (HMWCK/34βE12)</p> <p>Cytokeratin (MNF116)</p> <p>Cytokeratin 5/6</p> <p>Cytokeratin 7</p> <p>Cytokeratin 8/18</p> <p>Cytokeratin 19</p> <p>Cytokeratin 20</p> <p>Desmin</p> | <p>QEH</p>    |





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| HUMAN BODY TISSUE (cont'd)   | <u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd) | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:        | QEH           |
| Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd) | Immunohistochemistry to detect the following: (cont'd)  | Ventana Benchmark stainer SOP (CHQ-IP-0015) in conjunction with manufacturers instructions<br>Incorporating the following antibodies: |               |
|  | Lymphatic vessels   | D2-40   |               |
|  | Gastrointestinal stromal tumour   | DOG-1   |               |
|  | Normal ductal epithelial cells, ductal carcinoma  | E-Cadherin  |               |
|  | Normal and neoplastic epithelium  | EMA   |               |
|  | Endothelial cell  | Factor XIIIa  |               |
|  | Thyroid tumours   | Galectin 3  |               |
|  | Mammary gland carcinomas  | GATA-3  |               |
|  | Mammary gland carcinomas  | GCDFP-15  |               |
|  | Mammary gland carcinomas  | Mammaglobin   |               |
|  | Placental trophoblasts  | HCG   |               |
|  | Hep B virus   | Hep B surface antigen   |               |
|  | Kaposi's sarcoma  | HHV-8   |               |
|  | Melanoma, melanocyte differentiation  | HMB45   |               |
|  | Sex cord stromal tumours  | Inhibin   |               |
|  | Proliferating Cells   | Ki 67   |               |



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| HUMAN BODY TISSUE (cont'd)   | <u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd) | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:        | QEH           |
| Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd) | Immunohistochemistry to detect the following: (cont'd)  | Ventana Benchmark stainer SOP (CHQ-IP-0015) in conjunction with manufacturers instructions<br>Incorporating the following antibodies: |               |
|  | B cells, T cells, monocytes, macrophages  | LCA   |               |
|  | Melanoma marker   | Melan-A   |               |
|  | Adenocarcinoma  | MOC-31  |               |
|  | Rhabdomyosarcoma  | MyoD1   |               |
|  | Alveolar cells, lung adenocarcinoma   | Napsin A  |               |
|  | Nuclei of cells expressing oestrogen  | Oestrogen Receptors   |               |
|  | High grade dysplasia of cervix  | p16   |               |
|  | Dysplasia in Barrett's oesophagus   | p53   |               |
|  | Gestational trophoblastic disease   | p57   |               |
|  | Prostate basal cells, myoepithelial cells   | p63   |               |
|  | Prostatic glandular epithelium  | PAP   |               |
|  | Ovarian tumour, renal cell carcinoma  | PAX-8   |               |
|  | Neurones, melanocytes, neuroendocrine cells   | PGP 9.5   |               |



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| HUMAN BODY TISSUE (cont'd)   | <u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd) | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:        | QEH           |
| Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd) | Immunohistochemistry to detect the following: (cont'd)  | Ventana Benchmark stainer SOP (CHQ-IP-0015) in conjunction with manufacturers instructions<br>Incorporating the following antibodies: |               |
|  | Germ cell tumours   | PLAP  |               |
|  | Pneumocystis jiroveci (carinii)   | Pneumocystis jiroveci (carinii)   |               |
|  | Nuclei of cells expressing Progesterone   | Progesterone Receptors  |               |
|  | Prostate secretory and ductal epithelium  | PSA   |               |
|  | Renal cell carcinoma  | RCC   |               |
|  | Schwann cells, nerve processes, neural and melanocytic neoplasms                                | S100  |               |
|  | Smooth muscle cells, myoepithelial cells  | Smooth Muscle Actin (SMA)   |               |
|  | Smooth muscle cells, myoepithelial cells  | Smooth Muscle Myosin (SMMS-1)   |               |
|  | Melanocytes   | SOX-10  |               |
|  | Neuroendocrine cells  | Synaptophysin   |               |
|  | Thyroid epithelial cells  | Thyroglobulin   |               |
|  | Thyroid and lung epithelial cells   | TTF1  |               |
|  | Gastrointestinal epithelium   | Villin  |               |



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| <p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd)</p> | <p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Immunohistochemistry to detect the following: (cont'd)</p> <p>Mesothelial cells, serous carcinoma</p> <p>Mismatch Repair Genes in Hereditary Nonpolyposis Colonic Cancer (HNPCC)</p> <p>lung squamous cell carcinomas</p> <p>skin basal cell carcinomas</p> <p>breast and prostate carcinoma</p> | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Ventana Benchmark stainer SOP (CHQ-IP-0015) in conjunction with manufacturers instructions<br/>Incorporating the following antibodies:</p> <p>WT-1</p> <p>MMR Panel (MSH2, MSH6, MLH1, PMS2)</p> <p>P40</p> <p>CK14</p> <p>Androgen receptor</p> | <p>QEH</p>    |



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| HUMAN TISSUES AND BIOLOGICAL FLUIDS | <u>Biochemistry examination activities for the purpose of clinical diagnosis</u> | In house documented methods incorporating manufacturers' instructions as required  |                                   |
| Serum unless otherwise stated       |  | Roche Cobas c8000 -with Roche ISE, c702 for spectrophotometric and e801 for immunoassays in conjunction with manufacturer's instructions and SOP BB-AP-042 (QEH) & SOP BB-AP-052 BB-AP-046 & BB-AP-073 BB-AP-079 (UHL) and the following principles: | QEH UHL (Unless otherwise stated) |
|                                     | ACE  | Kinetic method using third party reagents Buhlmann as an open channel using SOP BB-AP-065  | QEH                               |
|                                     | Albumin  | Colorimetric detection methods   |                                   |
|                                     | Ammonia  | Enzymatic detection, BB-AP-078   |                                   |
| Fluid                               | Fluid amylase  | Enzymatic detection  | QEH                               |
| Serum                               | Bicarbonate  | Colorimetric detection methods   |                                   |
|                                     | Bile Acid  | Colorimetric method BB-AP-006 Bile acid as an open channel   | QEH                               |
| Serum unless otherwise stated       |  | Roche Cobas c8000 -with Roche ISE, c702 for spectrophotometric and e801 for immunoassays in conjunction with manufacturer's instructions and SOP BB-AP-042 (QEH) & SOP BB-AP-052 BB-AP-046 & BB-AP-073 BB-AP-079 and the following principles:       |                                   |



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| HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd) | <u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd) | In house documented methods incorporating manufacturers' instructions as required | QEH/UHL (Unless otherwise stated) |
| Serum/blood                                  | CSF glucose   | Enzymatic detection   |                                   |
|  | CK  | Enzymatic detection   |                                   |
|  | Fructosamine  | Colorimetric detection  |                                   |
|  | CSF protein   | Turbidimetric detection   |                                   |
|  | Bilirubin Total   | Colorimetric detection  |                                   |
| Serum/urine                                  | Calcium   | Colorimetric detection  |                                   |
| Serum  | Adjusted Calcium  | Calculation   |                                   |
|  | Iron  | Colorimetric detection methods  |                                   |
|  | Magnesium   | Colorimetric detection methods  |                                   |
|  | Total Protein   | Colorimetric detection methods  |                                   |
|  | Globulin  | Calculation   |                                   |
|  | Alkaline Phosphatase  | enzymatic detection methods   |                                   |
| Serum/urine                                  | Amylase   | Enzymatic detection methods   |                                   |
| Serum  | Cholesterol   | Enzymatic detection methods   |                                   |
| Blood, Urine                                 | Creatine Kinase   | Colorimetric detection methods  |                                   |
| CSF  | Lactate   | Enzymatic detection methods   | QEH                               |
| Serum  | Glucose (Fasting, random)   | Enzymatic detection methods   |                                   |



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| HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd) | <u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd) | In house documented methods incorporating manufacturers' instructions as required  | QEH/UHL (Unless otherwise stated) |
| Serum unless otherwise stated                |   | Roche Cobas c8000 -with Roche ISE, c702 for spectrophotometric and e801 for immunoassays in conjunction with manufacturer's instructions and SOP BB-AP-042 (QEH) & SOP BB-AP-052 BB-AP-046 & BB-AP-073 BB-AP-079 and the following principles: |                                   |
|  | Ethanol   | Enzymatic detection methods  |                                   |
|  | Gamma GT  | Enzymatic colorimetric   |                                   |
| Urine  | Protein:creatinine ratio  | Calculation  |                                   |
| Urine  | Albumin:creatinine ratio  | Calculation  | QEH                               |
| Urine  | Microalbumin  | Immuno-turbidimetric detection methods   | QEH                               |
|  | Rheumatoid Factor   | Immuno-turbidimetric detection methods   | QEH                               |
|  | Direct Bilirubin  | Wako Vandate oxidation method colorimetric SOP BB-AP-074 Direct Bilirubin on Cobas 8000 as an open channel   |                                   |
|  | Ferritin  | sandwich immunoassay detection   |                                   |
|  | Troponin T  | sandwich immunoassay detection   |                                   |
|  | Vitamin D   | competitive immunoassay detection  |                                   |
|  | HDL Cholesterol   | Enzymatic colorimetric detection methods   |                                   |



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| HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd)<br><br>Serum unless otherwise stated | <u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u> | In house documented methods incorporating manufacturers' instructions as required<br><br>Roche Cobas c8000 -with Roche ISE, c702 for spectrophotometric and e801 for immunoassays in conjunction with manufacturer's instructions and SOP BB-AP-042 (QEH) & SOP BB-AP-052 BB-AP-046 & BB-AP-073 BB-AP-079 (UHL) and the following principles: | QEH/UHL (Unless otherwise stated) |
|   | Non HDL Cholesterol   | Calculation   |                                   |
|   | LDL Cholesterol   | Calculation   |                                   |
| CSF   | Lactate   | Enzymatic detection methods   | QEH                               |
| Serum   | Lactate   | Enzymatic colorimetric detection methods  |                                   |
|   | Triglycerides   | Enzymatic colorimetric detection methods  |                                   |
| Serum/Urine   | Uric acid   | Enzymatic colorimetric detection methods  |                                   |
| Blood   | Lactate Dehydrogenase   | rate enzymatic detection  |                                   |
| Fluid   | Lactate Dehydrogenase   | rate enzymatic detection  | QEH                               |
| Blood/urine   | Potassium   | ion selective electrode (indirect) detection  |                                   |
|   | Sodium  | ion selective electrode (indirect) detection  |                                   |
| Urine   | Protein   | Turbidimetry detection  |                                   |
| Blood/Urine   | Urea  | Kinetic enzymatic   |                                   |
|   | Phosphate   | UV Photometric  |                                   |
|   | Alpha Fetoprotein   | Sandwich immunoassay detection  | QEH                               |





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| Serum unless otherwise stated                |   | Roche Cobas c8000 -with Roche ISE, c702 for spectrophotometric and e801 for immunoassays in conjunction with manufacturer's instructions and SOP BB-AP-042 (QEH) & SOP BB-AP-052 BB-AP-046 & BB-AP-073 BB-AP-079 and the following principles: |                                   |
|  | NT-Pro-BNP (natriuretic peptide)  | Sandwich immunoassay detection   | QEH                               |
|  | CA125   | Sandwich immunoassay detection   | QEH                               |
|  | CA 15-3   | Sandwich immunoassay detection   | QEH                               |
|  | CA 19-9   | Sandwich immunoassay detection   | QEH                               |
|  | Follicle Stimulating Hormone  | Sandwich immunoassay detection   | QEH                               |
|  | BhCG  | Sandwich immunoassay detection   |                                   |
|  | Leutinsing Hormone  | Sandwich immunoassay detection   | QEH                               |
|  | Prolactin   | Sandwich immunoassay detection   | QEH                               |
|  | Total Prostate Specific Antigen   | Sandwich immunoassay detection   | QEH                               |
|  | Parathyroid Hormone   | Sandwich immunoassay detection   | QEH                               |



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| HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd) | <u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd) | In house documented methods incorporating manufacturers' instructions as required  | QEH/UHL (Unless otherwise stated) |
| Serum unless otherwise stated                |   | Roche Cobas c8000 -with Roche ISE, c702 for spectrophotometric and e801 for immunoassays in conjunction with manufacturer's instructions and SOP BB-AP-042 (QEH) & SOP BB-AP-052 BB-AP-046 & BB-AP-073 BB-AP-079 and the following principles: |                                   |
|  | Sex Hormone Binding Globulin  | Sandwich immunoassay detection   | QEH                               |
|  | Thyroid Stimulating Hormone   | Sandwich immunoassay detection   |                                   |
|  | Carcinoembryonic Antigen  | Sandwich immunoassay detection   | QEH                               |
|  | Cortisol  | Competitive Immunoassay detection  |                                   |
|  | Free T3   | Competitive Immunoassay detection  |                                   |
|  | Free T4   | Competitive Immunoassay detection  |                                   |
|  | Progesterone  | Competitive Immunoassay detection  |                                   |
|  | Testosterone  | Competitive Immunoassay detection  | QEH                               |
|  | Oestradiol  | Competitive Immunoassay detection  | QEH                               |
|  | Anti-TPO (Thyroid Peroxidase)   | Competitive Immunoassay detection  | QEH                               |



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| HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd) | <u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd) | In house documented methods incorporating manufacturers' instructions as required  | QEH/UHL (Unless otherwise stated) |
| Serum unless otherwise stated                |   | Roche Cobas c8000 -with Roche ISE, c702 for spectrophotometric and e801 for immunoassays in conjunction with manufacturer's instructions and SOP BB-AP-042 (QEH) & SOP BB-AP-052 BB-AP-046 & BB-AP-073 BB-AP-079 and the following principles: |                                   |
|  | Digoxin   | competitive Immunoassay detection  |                                   |
|  | Lithium   | colorimetric detection   |                                   |
|  | Paracetamol   | enzymatic detection  |                                   |
|  | Salicylate  | enzymatic detection  |                                   |
|  | Phenytoin   | KIMS detection   | QEH                               |
|  | Theophylline  | KIMS detection   |                                   |
|  | Carbamazepine   | KIMS detection   | QEH                               |
|  | Valproate   | enzymatic immunoassay detection  | QEH                               |
|  | Gentamicin  | enzymatic immunoassay detection  |                                   |
|  | Vancomycin  | enzymatic immunoassay detection  |                                   |
|  | Amikacin  | KIMS detection, BB-AP-077 Amikacin run on Roche Cobas 8000   | UHL                               |
| Blood, arterial and Venous                   | Actual Base Excess (blood gas)  | Radiometer ABL90 Plus, calculated with manufacturer's instructions using SOP PC-P-051  |                                   |



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| HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd) | <u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd) | In house documented methods incorporating manufacturers' instructions as required                                      | QEH/UHL (Unless otherwise stated) |
| Blood, arterial and Venous                   | Standard Bicarbonate (blood gas)  | Radiometer ABL90 Plus, calculated with manufacturer's instructions using SOP PC-P-051                                  |                                   |
|  | Calcium (Blood gas)   | Potentiometry Radiometer ABL90 Plus, calculated with manufacturer's instructions using SOP PC-P-051                    |                                   |
|  | Oxygen saturation (blood gas)   | Radiometer ABL90 Plus calculated with manufacturer's instructions using SOP PC-P-051 and Using Ion selective electrode |                                   |
|  | Glucose (Blood gas)   | Amperometry  |                                   |
|  | Haematocrit (Blood gas)   | Calculated method  |                                   |
|  | Lactate (Blood gas)   | Amperometry  |                                   |
|  | Methaemoglobin  | spectrophotometry  |                                   |
|  | Oxyhaemoglobin (Blood gas)  | spectrophotometry  |                                   |
|  | Oxygen saturation (Blood gas)   | spectrophotometry  |                                   |
|  | Chloride (Blood gas)  | Potentiometry  |                                   |
|  | Potassium (blood gas)   | Using Ion selective electrode, Potentiometry   |                                   |
|  | Sodium (blood gas)  | Using Ion selective electrode, potentiometry   |                                   |
|  | pH (blood gas)  | Using Ion selective electrode, potentiometry   |                                   |
|  | pCO <sub>2</sub> (blood gas)  | potentiometry  |                                   |



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| HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd) | <u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u> | In house documented methods incorporating manufacturers' instructions as required                                    | QEH/UHL (Unless otherwise stated) |
| Blood, arterial and Venous                   | pO <sub>2</sub>   | Radiometer ABL90 Plus, with manufacturer's instructions using SOP PC-P-051 spectrophotometry                         |                                   |
|  | Total Haemoglobin (blood gas)   | Spectrophotometry, Radiometer ABL90 Plus, with manufacturer's instructions using SOP PC-P-051                        |                                   |
| Blood  | Carboxyhaemoglobin (blood gas)  | Spectrophotometric Radiometer ABL90 Plus with manufacturer's instructions and SOP PC-P-051                           |                                   |
| Faeces                                       | Calprotectin  | Immunoassay, using chemiluminescent technology – Werfen instrument – AcuStar Manual extraction – pre-analytical      | QEH                               |
| Blood  | HbA1c   | Biorad D100 HPLC with manufacturer's instructions using SOP BB-MP-049  | QEH                               |
|  | Ketones   | Electrode strips, Abbott Freestyle Optimum H ketone meter with manufacturer's instructions using SOP PC-P-009        | QEH                               |
| Blood/Urine                                  | Osmolality  | Advanced micro osmometer 3300 freezing point depression using BB-AP-002  |                                   |
| Blood  | Macroprolactin  | PEG precipitation and Cobas 8000 with manufacturer's instructions using SOP BB-MP-014                                | QEH                               |
| Urine  | Myoglobin   | Multi-sticks dipstick. Seimens Clinitek Urinalysis with manufacturer's instructions using SOP BB-MP-010 and PC-P-028 | QEH                               |



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| HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd) | <u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd) | In house documented methods incorporating manufacturers' instructions as required  | QEH/UHL (Unless otherwise stated) |
| Faeces                                       | Faecal Immunichemical testing   | Latex Immune-agglutination method using nephlaometry-Instrumenr OCsensor iO MAST   |                                   |
| CSF  | Xanthochromia   | Scanning spectrophotometric Perkin Elmer Spectrophotometer with manufacturer's instructions using SOP BB-MP-017                    | QEH                               |
| Urine  | Catecholamines  | Thermo Fisher U3000, HPLC, BB-MP-038 HPLC Method for Urine Catecholamines  | QEH                               |
| Urine  | 5 Hrydroxy indole acetic acid (5HIAA)   | Thermo Fisher U3000, HPLC, BB-MP-038 HPLC. BB-MP-041 Urine 5-hydroxy-indole acetic acid (5HIAA) by HPLC                            | QEH                               |
| Sweat  | Sweat Chloride  | Wescor Macroduct Collection system<br>Wescor 3100 Sweat Check<br>Sweat conductivity analyser,<br>Corning 925 Chloride analyser     | UHL                               |
| Faeces                                       | Haemoglobin concentration   | Faecal Immunochemical Test based on Latex immune-agglutination method, using 22ephelometry– Instrument OC sensor iO MAST-BB-MP-059 | QEH                               |



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| HUMAN BODY FLUIDS         | <u>Haematological examination activities for the purpose of clinical diagnosis</u>   | In house documented methods incorporating manufacturers' instructions where relevant  | QEH/UHL (Unless otherwise stated) |
| Whole Blood (EDTA)        | Full blood count (FBC):<br><br>Platelets<br>Red blood cells<br>Haematocrit<br>MCV<br>MCH<br>MCHC<br>RDW<br>White cell count<br>neutrophils<br>Lymphocytes<br>Monocytes<br>Eosinophils<br>Basophils<br>Reticulocytes<br>Nucleated Red Cells<br>Haemoglobin Hb | Sysmex XN 2000 (XN10) SOP BH-AP-045<br>Sysmex XN 9000 (XN10/20) SOP BH-AP-007<br>Sheath flow detection Sysmex XN 2000/9000 (XN10/20)<br><br>Sysmex XN 2000/ 9000 (XN10 & XN20) using SLS haemoglobin method-photometric method with manufacturer's instructions using SOP BH-AP-007/045 |                                   |
| Blood                     | Blood Film examination-<br>Detection of normal and abnormal morphologies and white blood cell differential   | Romanowski staining Haematek 2000 and Light microscopy using SOP BH-AP-014  |                                   |
| Bone marrow               | Examination of bone marrow: in order to identify or exclude Morphological and Cytological abnormalities for the purpose of diagnosis   | Light microscopy using SOP BH-SP-013<br>MGG and Iron stain using SOP BH-SP-024  |                                   |



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| HUMAN BODY FLUIDS (cont'd) | <u>Haematological examination activities for the purpose of clinical diagnosis</u> (cont'd)  | In house documented methods incorporating manufacturers' instructions where relevant                                | QEH/UHL (Unless otherwise stated) |
| Plasma- citrate            | Erythrocyte Sedimentation Rate (automated)   | Westergren reference method using StaRRsed ST Analyser SOP BH-AP-042  | UHL                               |
|                            | <u>Coagulation screen</u>  | Werfen ACL350/550/750 with manufacturers instructions using SOP BH-CP-003,007,012, ,022, ,025, photo optical method |                                   |
|                            | Prothrombin time (PT)  |   |                                   |
|                            | INR  |   |                                   |
|                            | Activated Partial Thromboplastin Time (APTT)   |   |                                   |
|                            | Thrombin time  |   |                                   |
|                            | Fibrinogen<br>Anti Xa Assay<br>D-Dimer   | I latex immunoassay using SOP BH-CP-011   |                                   |
|                            | Glandular fever/infectious mononucleosis (IM)<br>Heterophile antibodies  | Clearview IM ELISA test kit using SOP BH-AP-018   |                                   |
|                            | Malarial Parasite identification<br>Detection of Malarial antigens of:<br><i>P. falciparum</i><br>Pan-detection for <i>P. malariae</i><br><i>P. ovale</i><br><i>P. vivax</i> | ICT method pLDH/HRP-2 combination antibody test SOP BH-AP- 016  |                                   |





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| HUMAN BODY FLUIDS (cont'd) | <u>Haematological examination activities for the purpose of clinical diagnosis</u> (cont'd)   | In house documented methods incorporating manufacturers' instructions where relevant  | QEH/UHL (Unless otherwise stated) |
| Blood films                | Malarial Parasite identification<br>Detection of:<br><br><i>P. falciparum</i><br><i>P. malariae</i><br><i>P. ovale</i><br><i>P. vivax</i><br><i>P. Knowlesi</i> | Manual interpretation of blood films<br>Using microscope and SOP BH-AP- 016   |                                   |
| Blood (EDTA)               | Detection of HbS solubility<br><br>Abnormal Haemoglobin studies detection of presence and separation of Hb,<br>Hb C<br>Hb D<br>Hb E<br>HbF<br>Hb Lepore<br>Hb O | Sickle cell screen using Itano's solution an Microgen S-Test kit using SOP BH-SP-011 with manufacturer's instructions<br><br>HPLC using SOP BH-SP-018 |                                   |
|                            | Abnormal Haemoglobin studies detection of presence and separation of Hb,<br>Hb C<br>Hb D<br>Hb E<br>HbF<br>Hb Lepore<br>Hb O                                    | Sebia Hydrasys 2 scan using gel electrophoresis with manufacturers instructions using SOP BH-SP-016,017   | QEH                               |



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| HUMAN BODY FLUIDS (cont'd) | <u>Haematological examination activities for the purpose of clinical diagnosis</u> (cont'd)  | In house documented methods incorporating manufacturers' instructions where relevant                          | QEH/UHL (unless otherwise stated) |
| Blood<br>Plasma:citrate    | Lupus screening<br>Factor assays:<br><br>Factor II<br>Factor V<br>Factor VII<br>Factor VIII<br>Factor IX<br>Factor X<br>Factor XI<br>Factor XII<br>Protein C<br>Protein S<br>Anti-thrombin iii | Werfen ACL 750 with manufacturer's instructions using SOP BH-CP-003, 007, 012,014,015,022,024,025,026,027,031 | QEH                               |
|                            | Mutation Detection for Factor V Leiden/ Prothrombin gene (G20210A)   | Chromogenic method<br><br>Chromogenic method<br><br>PCR technique using GeneXpert and SOP BH-CP-033           | QEH                               |
|                            | CD4/CD8 Immunophenotyping  | Beckman Coulter Aquios by flow cytometry BH-AP-033  | QEH                               |



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| <p>HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd)</p> <p>Blood: EDTA</p> | <p><u>Blood Transfusion examination activities for the purpose of clinical diagnosis:</u></p> <p>Blood Group A,B,O and AB detected, Antibody detection</p> <ul style="list-style-type: none"> <li>• A B O</li> <li>• Rhesus: anti-C<sup>w</sup>, anti-C, anti-c, anti-D, anti-E, anti-e,</li> <li>• Kell system: anti-K, anti-k, anti-Kp<sup>a</sup>,</li> <li>• Kidd: anti-Jk<sup>a</sup>, anti-Jk<sup>b</sup>,</li> <li>• Duffy: anti-Fy<sup>a</sup>, anti-Fy<sup>b</sup>,</li> <li>• Lutheran: anti-Lu<sup>a</sup>,</li> <li>• MNS: anti-M, anti-N, anti-S, anti-S,</li> <li>• Lewis: anti-Le<sup>a</sup>, anti-Le<sup>b</sup>,</li> </ul> <p>P<sub>1</sub>: anti-P:-</p> <p>Antibody identification of the following:</p> <ul style="list-style-type: none"> <li>• Rhesus: anti-C<sup>w</sup>, anti-C, anti-c, anti-D, anti-E, anti-e,</li> <li>• Kell system: anti-K, anti-k, anti-Kp<sup>a</sup>,</li> <li>• Kidd: anti-Jk<sup>a</sup>, anti-Jk<sup>b</sup>,</li> <li>• Duffy: anti-Fy<sup>a</sup>, anti-Fy<sup>b</sup>,</li> <li>• Lutheran: anti-Lu<sup>a</sup>,</li> <li>• MNS: anti-M, anti-N, anti-S, anti-S,</li> <li>• Lewis: anti-Le<sup>a</sup>, anti-Le<sup>b</sup>,</li> </ul> <p>P<sub>1</sub>: anti-P:-</p> | <p>In house documented methods incorporating manufacturers' instructions as required</p> <p>Gel techniques using Grifols: DG Gel Coombs card, DG Gel Neutral card, Serascan Diana 3/3P, DG Gel Sol.<br/>SOPs required: QE-BTAUT008, QE-BT-AUT009, QE-BT-MAN002, QE-BT-MAN003</p> <p>Gel techniques using Grifols: DG Gel Coombs card, DG Gel Neutral card, DG Gel Sol, Identisera Diana, NHSBT ID Panel Cells in CellMedia.<br/>SOPs required: QE-BTAUT008, QE-BT-AUT009, QE-BT-MAN002, QE-BT-MAN003.</p> | <p>QEH/UHL (unless stated otherwise)</p> |



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| HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd)                                | <u>Blood Transfusion examination activities for the purpose of clinical diagnosis:</u> (cont'd) | In house documented methods incorporating manufacturers' instructions as required   | QEH/UHL (unless stated otherwise) |
| Red blood cells in EDTA   | Direct Anti-globulin Test Automated / Manual: Monospecific and Polyspecific)                    | Gel techniques using Grifols: DG Gel Coombs card, DG Gel DC Scan card, DG Gel Sol. SOPs required: QE-BTAUT008, QE-BT-MAN004, QE-BT-MAN005.  |                                   |
|   | Transfusion reaction investigation  | Grifols Manual Gel Card technology SOP QE-BT-ISS011   |                                   |
|   | Electronic Issue Crossmatch   | WinPath. SOPs required: QE-BT-ISS007, QE-BT-ISS008, QE-BT-ISS009, QE-BT-ISS010, QE-BT-ISS012, QE-BT-ISS 0202, QE-BT-ISS021, QE-BT-ISS029, QE-BT-ISS030, QE-BT-ISS031, QE-BT-ISS032, QE-BT-ISS035, QE-BT-ANT002, QE-BT-ANT005. |                                   |
| <b>Donor red blood cells, patient red blood cells and/or plasma in EDTA</b> | IAT manual Crossmatch   | Manual gel technique using Grifols: DG Gel Coombs card, GD Gel Sol, NHSBT OR1r, NHSBT Weak Anti-D<br>SOP required:QE-MAN005   |                                   |
| Whole blood in EDTA   | Foetal Maternal Haemorrhage Estimation (Kleihauer Test)   | Manual techniques using BioScience: PBSS Ph 7.0, Fixol fixative, fetal red cell detection Kit.<br>SOP required: QE-BT-ANT004  | QEH/UHL unless otherwise stated   |



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

### Barts Health NHS Trust as the host of NHS East and South East London Pathology Partnership

Issue No: 006 Issue date: 14 October 2021

Testing performed by the Organisation at the locations specified

| Materials/Products tested                    | Type of test/Properties measured/Range of measurement   | Standard specifications/ Equipment/Techniques used                                  | Location Code |
|--|---|---|---------------|
| HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd) | <u>Immunology examination activities for the purpose of clinical diagnosis</u>  | In house documented methods incorporating manufacturers' instructions as required   | QEH           |
| Serum  | RAST (specific IgE)<br><br>Avocado<br>Almond<br>Alternaria alternate<br>Apple<br>Aspergillus fumigatus<br>Banana<br>Blue Mussel<br>Brazil nut<br>Cacao<br>Cashew<br>Cat dander<br>Cheese<br>Coconut<br>Cod<br>Dog dander<br>Egg white<br>Egg yolk<br>Gluten<br>Hazel nut<br>House dust mite<br>Kiwi<br>Latex<br>Milk<br>Mixed fish (cod, shrimp, blue mussel, salmon, tuna)<br>Mixed food (egg white, milk, cod, wheat, peanut, soya)<br>Mixed grass<br>Mixed nuts (peanut, hazelnut, brazil nut, almond, coconut)<br>Mixed trees<br>Orange<br>Peanut<br>Pistachio<br>Salmon<br>Sesame seed<br>Shrimp<br>Silver birch<br>Soya | Phadia Immucap 250 with manufacturer's instructions using SOP BB-IP-009 Immucap 250 |               |



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| HUMAN TISSUES AND BIOLOGICAL FLUIDS (cont'd) | <u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)   | In house documented methods incorporating manufacturers' instructions as required       | QEH           |
| Serum (cont'd)                               | RAST (specific IgE) (cont'd)  | Phadia Immucap 250 with manufacturer's instructions using SOP BB-IP-009 Immucap 250     |               |
|  | Strawberry<br>Timothy grass<br>Tomato<br>Tuna<br>Walnut<br>Wheat  |   |               |
| Serum  | Total IgE   | EIA Phadia Immucap 250 with manufacturer's instructions using SOP BB-IP-009 Immucap 250 |               |
|  | Cyclic citrullinated protein (CCP)  |   |               |
|  | Tissue transglutaminase antibody (Ttg)  |   |               |
|  | Cardiolipin Abs   |   |               |
|  | Double stranded DNA   |   |               |
|  | Extractable Nuclear Antigen (ENA)   |   |               |
|  | Anti Neutrophil Cytoplasmic Antibody (ANCA), includes: <ul style="list-style-type: none"> <li>• MPO antibody</li> <li>• PR3 antibody</li> </ul> |   |               |
|  | GBM Antibodies- Glomerular Basement membrane antibodies   |   |               |
|  | CTD Connective Tissue Disease   |   |               |
|  | Aspergillus Antibody  |   |               |



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| Serum  | Autoantibody screen:<br><br>Anti-nuclear antibodies (ANA)<br>Anti-mitochondrial antibodies (AMA)<br>Anti-smooth muscle antibodies (ASMA)<br>Anti-liver kidney microsomal antibodies (ALKM)<br>Anti-gastric parietal cell antibodies (AGPCA)<br><br>Anti-Neutrophil cytoplasmic Antibody (ANCA) screen (includes P-ANCA & C-ANCA)<br><br>Antinuclear antibody (Hep2 screen) | Helmed automated indirect Immunofluorescence with manufacturer's instructions using SOP BB-IP-020 automated IFA                            |               |
| Serum/Urine                                  | Abnormal/normal serum/urine proteins quantitation of paraprotein bands.  | Gel electrophoresis Sepia Hydrasys with manufacturer's instructions using SOP BB-PP-3 using gel Electrophoresis and immunofixation BB-PP-4 |               |
| Serum/Urine                                  | Identification of abnormal protein bands   | SOP BB-PP-4 using Immunofixation   |               |
| Serum  | Abnormal/normal serum/urine proteins, quantitation of paraprotein bands  | Capillary zone electrophoresis Sebia CZE BB-PP-8   |               |
| Serum  | IgA  | Beckman Immage Nephelometry with manufacturer's instructions using SOP BB-PP-6   |               |
|  | IgG  |  |               |
|  | IgM  |  |               |



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| Serum  | C3  | Beckman Immage Nephelometry with manufacturer's instructions using SOP BB-PP-6    |               |
|  | C4  |   |               |
|  | A1 Antitrypsin  |   |               |
|  | Haptoglobin   |   |               |
|  | Ceruloplasmin   |   |               |
|  | Transferrin   |   |               |
| Serum  | B2 Microglobulin  | Beckman Immage Nephelometry with manufacturer's instructions using SOP BB-PP-6    |               |
| Serum/Urine                                  | Free light Chains   | Binding site Spa Plus nephelometry BB-PP-7  |               |
| Blood  | Cryoglobulins   | visual technique using SOP BB-PP-5  |               |
| END  |   |   |               |