


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

| | | |
|--|---|--|
|  <p>UKAS MEDICAL</p> <p>8833</p> <p>Accredited to ISO 15189:2022</p> | <p>Northern Lincolnshire and Goole NHS Foundation Trust</p> <p>Issue No: 014 Issue date: 19 June 2025</p> | |
| | <p>Path Links NHS Pathology Service Diana Princess of Wales Hospital Scartho Road Grimsby DN33 2BA</p> | <p>Contact: James Maclean Tel: +44 (0)1536 493368 E-Mail: James.maclean@nhs.net</p> |
| <p>Testing performed by the Organisation at the locations specified below</p> | | |

Locations covered by the organisation and their relevant activities

Laboratory locations:

| Location details | Activity | Location code |
|---|--|---------------|
| <p>Address Pathology Diana Princess of Wales Scartho Road Grimsby DN33 2BA</p> <p>Local contact See above</p> | <ul style="list-style-type: none"> • Routine Haematology • Blood Transfusion • Biochemistry • Andrology • Phlebotomy • Blood Fridges • Blood issue/electronic issue • Serology | A |
| <p>Pathology Scunthorpe General Hospital Cliff Gardens Scunthorpe DN15 7BH</p> <p>See above</p> | <ul style="list-style-type: none"> • Routine Haematology • Blood Transfusion • Biochemistry • Immunology • Microbiology • Serology • Molecular • Phlebotomy • Blood fridges • Blood issue/electronic issue | B |
| <p>Pathology Lincoln County Hospital Greetwell Road Lincoln LN2 5QY</p> <p>See above</p> | <ul style="list-style-type: none"> • Routine Haematology • Blood transfusion • Biochemistry • Histology • Non gynae cytology • Phlebotomy • Blood Fridges • Blood issue/electronic issue | C |



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| <p>Address Pathology Boston Pilgrim Hospital Sibsey Road Boston PE21 9QS</p> <p>Local contact See above</p> | <ul style="list-style-type: none"> • Routine haematology • Blood transfusion • Biochemistry • Andrology • Microbiology • Phlebotomy • Blood fridges • Blood issue/electronic issue • Molecular | D |
| <p>Pathology Grantham and District General hospital Manthorpe Road Grantham NG21 8DG</p> <p>See above</p> | <ul style="list-style-type: none"> • Routine Haematology • Blood Transfusion • Biochemistry • Phlebotomy • Blood Fridges • Blood issue/electronic issue | E |
| Phlebotomy and blood fridges only : | | |
| <p>Goole and district Hospital Woodland Avenue Goole DN14 6RX</p> <p>See above</p> | <ul style="list-style-type: none"> • Phlebotomy • Blood fridges- Laboratory | F |
| <p>Louth County Hospital High Holme Road Louth LN11 0EU</p> <p>See above</p> | <ul style="list-style-type: none"> • Phlebotomy • Blood Fridges- Laboratory | G |
| <p>HMT St Hughs Peaks Lane Grimsby DN32 9RP</p> <p>See above</p> | <ul style="list-style-type: none"> • Blood fridges | H |
| <p>Lincoln BMI Nettleham Road Lincoln LN2 1QU</p> <p>See above</p> | <ul style="list-style-type: none"> • Blood fridges- Maternity and main theatres | I |
| <p>Diana Princess of Wales Scarcho Road Grimsby DN33 2BA</p> <p>See above</p> | <ul style="list-style-type: none"> • Blood fridges- main theatres | J |



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DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---------------------------|---|---|---|
| HUMAN BODY FLUIDS | <u>Haematological examination activities for the purposes of clinical diagnosis:</u> | Documented in house methods and manufacturers instructions for | |
| Venous Blood: Citrated | <p>Blood Coagulation</p> <p>Routine</p> <ul style="list-style-type: none"> • Prothrombin time <ul style="list-style-type: none"> ○ INR • Activated Partial Thromboplastin Time • Fibrinogen estimation <ul style="list-style-type: none"> ○ Clauss ○ <p>D-Dimers</p> <p>Special Coagulation</p> <ul style="list-style-type: none"> • APTT-SP • APTT-2 • APTT mixing studies • APCR • FVIII • FIX • FXI • FXII • Free protein S • Protein C • Von Williebrand Factor <ul style="list-style-type: none"> ○ Antigen ○ Activity • AntiThrombin III | <p>ACL TOPS 550(ABCD) ACL TOP 350 (E)</p> <p>Turbidimetric method Clot detection by optical rate of change of absorbance end point being the maximum rate of change</p> <p>SOP;- INT SOP 82</p> <p>Latex method SOP;- INT SOP 82</p> <p>SOPs;- INT INS 169 and 37 Turbidimetric method Clot detection by optical rate of change of absorbance end point being the maximum rate of change</p> <p>Chromogenic end point</p> | <p>A B C D E</p> <p>C</p> <p>C</p> <p>C</p> |



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| HUMAN BODY FLUIDS (cont'd) | <u>Haematology examination activities for the purpose of clinical diagnosis:</u> (cont'd) | Documented In-house methods using: | |
| Venous whole blood: EDTA | FBC <ul style="list-style-type: none"> Haemoglobin estimation Red cell and platelet counts Haematocrit Differential white cell count Reticulocyte MCV MCH MCHC | Sysmex XN 10 series Haematology Analysers SOP:INT-SOP-141 Colorimetric Laser light scatter Calculated parameter from Haemoglobin and RBC Laser and light scatter and light absorbance Laser light scatter and absorbance Calculated parameters Calculated parameters Calculated parameters | A B C D E |
| Blood | ESR | Visual detection of sedimentation interface by automated photometric detection using Vacuette SRS100/II Greiner SOP: INT-SOP-114 | A B C D E |
| Blood | Identification of normal and abnormal morphologies including WBC differential count | Staining by SP 10 SOP: INT SOP 60 staining by Romanowsky examined by microscopy SOP;-INT SOP 122 microscopy | A B C D E |
| Whole Blood | Malaria Parasite detection <ul style="list-style-type: none"> P.Falciparum Non-falciparum Speciation <ul style="list-style-type: none"> P.Falciparum P.Ovale P.Malariae P.Vivax P.Knowlesi | Antigen testing with CareStart kit by Immunochromatographic interface SOP: INT-SOP-64 And Thick film –Field Stain Thin Film – Giemsa Stain Examined by microscopy SOP: INT SOP 64 | A B C D E |



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| HUMAN BODY FLUIDS (cont'd) | <u>Haematology examination activities for the purpose of clinical diagnosis:</u> (cont'd) | Documented In-house methods using: | |
| Whole Blood | Plasmodium Falciparum parasitaemia | Thin Film – Giemsa Stain. Enumeration by microscopy SOP;-INT SOP 64 | A B C D E |
| Venous whole blood :EDTA | Infectious Mononucleosis screen (EBV) antibody | Clearview II Card Qualitative Immunoassay agglutination interpreted by visual inspection. SOP: INT SOP 48 | A B C D E |
| | Glucose 6 dehydrogenase (G6PD) detection | Qualitative Fluorescence detection- Trinity Biotech SOP ; - INT SOP 107 | B |
| | | Documented in-house methods to meet the requirements of the Sickle Cell and Thalassaemia Screening Programme as defined in the July 2018 'NHS Sickle Cell and Thalassaemia Screening Programme as defined in the laboratory quality assurance evidence requirements | |
| Venous whole blood :EDTA | Haemoglobin analysis by detection of haemoglobin variants: HbA, HbA2,HbF, HbS, HbC, HbD, HbE | Capillarys3 Tera - Sebia capillary Zone electrophoresis (CZE) SOP: INT SOP 165 | B |
| | Haemoglobinopathy screening (Antenatal and non-antenatal) | | |
| Venous whole blood :EDTA | Haemoglobin S | Detection of decreased sickle cell solubility of Haemoglobin S with Streck SickleDEX SOP: INT SOP 61 | B |
| Whole blood | HbA1c | Capillarys3 Tera - Sebia capillary Zone electrophoresis (CZE) SOP: INT SOP 165 | A B D E |



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| HUMAN BODY FLUIDS (cont'd) | <u>Blood Transfusion examinations to assist in clinical investigations</u> | Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods: | |
| Venous Blood | Blood Grouping <ul style="list-style-type: none"> • A B O • Rhesus: C, c, D, E, e, • K • Jka, Jkb • Ss • MN • Fya, Fyb | BioRad IH500 analyser and associated testing protocols – fully automated cassette technology including Rh-subgroup and K phenotyping cards SOP: INT-SOP-93 And Jka/Jkb phenotyping cards INT SOP 35 | A B C D E (E Manual only) |
| Plasma/EDTA | Red cell Antibody Screening and identification : Rh- D, C, E, c, e, f and cw Kell K, k, kpa, kpb Duffy Fya and Fyb Kidd Jka and Jkb Lewis Lea and Leb MNS S, s, M, N Lutheran Lua and Lub Antibody Detection Direct Anti-Human Globulin (DAGT) | BioRad and Manual tube methods using Biovue technology serological methods INT-INS-117 BioRad 3 cell panels, 11 cell panels BioRad DAGT cards Auto BioRad SOP: INT-SOP-93 Manual gel technology SOP:-INT-SOP-35 | A B C D E (E Manual only) |
| | Blood Grouping/Phenotype <ul style="list-style-type: none"> • Fya, Fyb • S, s • M | Manual procedures by BioRad gel technology -red cell agglutination, macroscopic visual detection SOP: INT-SOP-35 | |
| | Blood Grouping <ul style="list-style-type: none"> • ABO RhD | Manual tube procedures- red cell agglutination, macroscopic visual detection SOP;- INT-SOP-35 | |



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| HUMAN BODY FLUIDS (cont'd) | <u>Blood Transfusion examinations to assist in clinical investigations:</u> (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods: | |
| Venous Blood | Compatibility testing of patient's plasma with donor cells | Fully automated BioRad cassette technology and manual procedures SOP: INT-SOP-93 SOP: INT-SOP-35 Electronic Issue SOP;-INT SOP21 | A B C D E (E Manual only) |
| Venous Blood | Estimation of Foetal cells | Kleihauer by Acid Elution using Source BioScience kit and Haematoxylin counterstain SOP : INT SOP 28 | B D |
| Venous Blood | FMH | Beckman Coulter Navios Flow Cytometer | B |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum/Heparinised plasma (unless otherwise stated)</p> | <p><u>Biochemical examination activities for the purposes of clinical diagnosis:</u></p> <p>Quantitative determination of:</p> <p>17 Beta Oestradiol 25 Hydroxy Vitamin D ACTH Alpha fetoprotein Anti-CCP B HCG</p> <p>CA125 CA 153 CA 19-9 CEA Cortisol DHAS Digoxin Ferritin</p> <p>Folate</p> <p>Free T3</p> | <p>Documented in house methods and manufacturers instructions for</p> <p>Using Roche Cobas 8000 e602 (C D E) and e801 (A B) module SOP INT-SOP-110 and INT-INS-246</p> <p>Electrochemiluminescence assay:</p> | <p>A D A D E D A B A B C D E A A A A A B C A B C D A A B C D A B C D E A B C D E A</p> |



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| HUMAN BODY FLUIDS (cont'd) | <u>Biochemical examination activities for the purposes of clinical diagnosis:</u> (cont'd) | Documented in house methods and manufacturers instructions for | |
| Serum/Heparinised plasma (unless otherwise stated) (cont'd) | Quantitative determination of: (cont'd) | Using Roche Cobas 8000 e602 module and e801 (A) c702 (All) SOP INT-INS 110 and INT-INS-246 | |
| Serum/Plasma/Ascitic Fluid/ PD fluid (C D)/ Pleural Fl. (B C D E), Urine | Alcohol | Photometric assays: | A B C D E |
| | Albumin | | A B C D E |
| | Alkaline Phosphatase | | A B C D E |
| | Alpha-1-Antitrypsin | | B |
| | ALT | | A B C D E |
| Serum/Plasma/Ascitic Fluid/ Pleural fluid (B C D E), Urine | Amylase | | A B C D E |
| | AST | | A C D |
| | Beta 2 Microglobulin | | B |
| | Bicarbonate | | A B C D E |
| | Bile Acids | | A |
| | Bilirubin | | A B C D E |
| Serum | Ammonia | | A B C D |
| | C3 | | B |
| | C4 | | B |
| | Caeruloplasmin | | B |
| Serum, Plasma, Urine | Calcium | | A B C D E |



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| HUMAN BODY FLUIDS (cont'd) | <u>Biochemical examination activities for the purposes of clinical diagnosis:</u> (cont'd) | Documented in house methods and manufacturers instructions for | |
| Serum/Heparinised plasma (unless otherwise stated) (cont'd) | Quantitative determination of: (cont'd) | Using Roche Cobas 8000 e602 module and e801 (A) c702 (All) SOP INT-INS 110 and INT-INS-246 | |
| | Carbamazepine | Photometric assay: | A |
| | Cholesterol | | A B C D E |
| | CK | | A B C D E |
| | Conjugated Bilirubin | | A B C D E |
| | CRP | | A B C D E |
| Serum, Plasma, PD fluid (C D), Urine | Creatinine | | A B C D E |
| | Gamma GT | | A B C D E |
| Serum, plasma, Sodium Fluoride EDTA plasma, PD Ascitic Fluid, CSF (B C D), Fluid (C D), Pleural fl. (B C D E) EDTA Plasma | Gentamicin | | A B C D |
| | Glucose | | A B C D E |
| | Haptoglobin | | C |
| | HDL cholesterol | | A B C D E |
| | Homocysteine | | B |
| | IgA | | B |
| | IgG | | B |
| | IgM | | B |
| | Iron | | A B C D E |
| Sodium Fluoride EDTA, CSF (B C D) | Lactate | | A B C D E |
| Serum, Plasma, CSF (B C D), Pleural Fluid (B C D E) | LDH | | A B C D E |
| Serum | Lithium | | A D |
| Serum, Plasma, Urine (A) | Magnesium | | A B C D E |



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| HUMAN BODY FLUIDS (cont'd) | <u>Biochemical examination activities for the purposes of clinical diagnosis:</u> (cont'd) | Documented in house methods and manufacturers instructions for | |
| Serum/Heparinised plasma (unless otherwise stated) (cont'd) | Quantitative determination of: (cont'd) | Using Roche Cobas 8000 e602 module and e801 (A) c702 (All) SOP INT-INS 110 and INT-INS-246 | |
| Serum, Plasma, Urine | Paracetamol | Photometric assay: | A B C D E |
| | Phenytoin | | A D |
| | Phosphate | | A B C D E |
| | Salicylate | | A B C D E |
| | Theophylline | | A D |
| | Tobramycin | | B C D |
| | Total Protein | | A B C D E |
| Serum, Plasma, Ascitic Fluid, CSF (B C D) PD fluid (C D) Pleural FI (B C D E), Urine | Transferrin | | A B C D E |
| | Triglycerides | | A B C D E |
| Serum, Plasma,Urine | Urate | | A B C D E |
| Serum,Plasma,Urine, PD fluid (C D) | Urea | | A B C D E |
| | Vancomycin | | A B C D |
| | | Using Roche Cobas 8000 c702 SOP INT-INS 110 and INT-INS-271 Turbidimetric immunoassay | |
| Faeces | Faecal immuno elastase Calprotectin | Buhlmann fPELA turbo test Buhlmann fCAL turbo test | B B |
| Faeces | Faecal Haemoglobin measurement (FIT) | Using Roche Cobas 8000 c801 (A) and c702 (E) module FIT FOB Gold NG Wide homogenous latex based immunoassay | A E |



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| HUMAN BODY FLUIDS (cont'd) | <u>Biochemical examination activities for the purposes of clinical diagnosis:</u> (cont'd) | Documented in house methods and manufacturers instructions for | |
| Serum, Plasma, Urine | Chloride | Roche Cobas 8000 ISE module ISE principles INT-INS-250 AND INT-INS-246 | A B C D E |
| Serum/Plasma, Urine | Potassium | | A B C D E |
| Serum, plasma,Urine | Sodium | | A B C D E |
| CSF | Xanthochromia | Northstar (Uvikon) Spectrophotometer INT-SOP-126 | B C D |
| Serum, Plasma, Urine | Osmolality | Advance instruments Osmometer using Freezing point depression INT-SOP-26 | A B C D |
| Sweat | Chloride | Sherwood Scientific Chloride Meter (Macroduct Iontophoresis System) INT-INS-243 INT-SOP-84 | A B C D |
| Heparinised Blood | pH Glucose Sodium Potassium Ionised Calcium Lactate Haemoglobin Haematocrit Chloride Carboxyhaemoglobin Methaemoglobin pCO2 pO2 | Roche Cobas b123 Blood gas analyser using POCT-2: Sensor Sensor Spectrophotometry Sensor Co-oximetry Sensor | A B D |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunological examination activities for the purposes of clinical diagnosis:</u> | Documented in house methods and manufacturers instructions for | |
| Urine | Bence Jones protein | Electrophoresis and immunofixation using Helena SAS-3 and SAS-4 systems INT-SOP-136 and 137: | B |
| Serum | Cryoglobulins | Electrophoresis using Helena Nexusanalyser: | B |
| Serum | Abnormal proteins detected from above methods | INT-SOP-137 | B |
| Serum | Serum Free Kappa Light chains Serum Free Lambda light chains Light chains ratio | Optilite Analyser (binding site) INT-SOP-131 | B |
| Serum | Adrenal Antibodies ANA (Hep2) ANCA Crithidia Endomysial antibodies IgG/IgA Mitochondrial antibodies SM Antibodies GPC antibodies LKM antibodies Ovarian antibodies Phemphigus/phemgoid antibodies Purkinje cell antibodies Ribosomal antibodies Striated muscle antibodies | Manual method using indirect Immunofluorescence and microscopy INT-SOP-21 | B |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunological examination activities for the purposes of clinical diagnosis:</u> (cont'd) | Documented in house methods and manufacturers instructions for | |
| Serum | Confirmatory tests : ENA antibodies LKM antibodies Mitochondrial antibodies Purkinje antibodies Neuronal antibodies | Manual immunoblotting method using Euroblot Assays INT-SOP-22: | B |
| Whole blood | Detection of the following: ENA blot: Ro60, Ro52, La, Sm, RNP, SCI-70 and Jo-1 Liver blot: SLA/LP, M2, LC-1 and LKM Mito blot: M2, M4 and M9 Neuronal blot: Yo, Hu, Amphiphysin, CV2, Ri and Ma2/Ta | Immunoblotting using Euroline Blotmaster INT-SOP-161 | B |
| Serum | | Beckman Coulter Navios and TQ Prep analysers using Flow cytometry: INT-SOP-40INT-SOP-79 | B |
| Whole Blood | Lymphocyte subsets: CD4 CD8 CD19 CD56 CD3 HLA B27 | INT-SOP-42 | |



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| HUMAN BODY FLUIDS (cont'd) Serum/Plasma | <u>Immunological examination activities for the purposes of clinical diagnosis:</u> (cont'd) Autoantibodies: ANCA (MPO/PR3) Cardiolipin IgG CCP antibodies ENA antibodies GBM antibodies Tissue Transglutaminase ab Ds DNA 16 IgG precipitans to: Farmers Lung A.fumigatus (m3) Avain (Ge90,Ge91,Ge92) Budgie (Ge90) C.albicans (m5) M.faeni (Gm22) Parrot (Ge92) Pigeon (Ge91) Total IgE Mast cell tryptase Specific IgE as follows: Grass (g6) Grass Mix (gx 3) Rape Pollen (w207) Lupin (w207) Weed mix (wx3) Silver birch (t3) Olive (t9) Tree pollen mix (tx8) House dust mite (d1) Cat (e1) Horse (e3) Dog (e5) Guinea pig (e6) Rat epithelium (e73) Budgie droppings (e77) (e200) | Documented in house methods and manufacturers instructions for Immunocap 250 using Fluorescent enzyme immunoassay: INT-SOP-41 | B |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunological examination activities for the purposes of clinical diagnosis:</u> (cont'd) | Documented in house methods and manufacturers instructions for | |
| Serum/Plasma (cont'd) | Specific IgE: Budgie feathers (e78) (e201) Rabbit (e82) Hamster (e84) Chicken feathers (e85) Mouse epithelium (e88) Parrot feathers (e213) Pigeon feathers (e215) Chicken droppings (e218) Poultry feather mix (ex17) Caged bird feather mix Nut mix (fx1) Seafood mix (fx2) Cereal mix (fx3) Food mix (fx5) Fruit mix (fx17) Nut mix 2 (fx22) Meat mix 2 (fx23) Citrus fruit mix (fx29) Spice mix (fx71) Spice mix 2 (fx72) Meat mix 1 (fx73) Egg white (f1) Milk (f2) Cod (f3) Wheat (f4) Rye (f5) Barley (f6) Oat (f7) Corn-Maize (f8) Rice (f9) Sesame seed (f10) Pea (f12) Peanut (f13) Soya bean (f14) White bean (f15) Hazelnut (f17) Brazil nut (f18) Almond (f20) Crab (f23) Shrimp (f24) | Immunocap 250 using Fluorescent enzyme immunoassay: INT-SOP-41 | B |



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|-------------------------------|--|---|---------------|
| HUMAN BODY FLUIDS (cont'd) | <u>Immunological examination activities for the purposes of clinical diagnosis:</u> (cont'd) | Documented in house methods and manufacturers instructions for | |
| Serum/Plasma (cont'd) | Specific IgE: (cont'd) Tomato (f25) Pork (f26) Beef (f27) Carrot (f31) Orange (f33) Potato (f35) Coconut (f36) Blue Mussel (f37) Tuna (f40) Salmon (f41) Haddock (f42) Strawberry (f44) Yeast (f45) Garlic (f47) Onion (f48) Apple (f49) Egg yolk (f75) Hard cheese (f81) Chicken meat (f83) Kiwi (f84) Celery (f85) Melon (f87) Mustard (f89) Mango (f91) Banana (f92) Cacao (f93) Pear (f94) Peach (f95) Avocado (f96) Pecan nut (f201) Cashew nut (f202) Pistachio nut (f203) Lemon (f208) Pineapple (f210) Blackberry (f211) Mushroom (f212) Paprika/sweet pepper/capsicum (f218) Coffee (f221) Lentil (f235) | Immunocap 250 using Fluorescent enzyme immunoassay: INT-SOP-41 | B |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunological examination activities for the purposes of clinical diagnosis:</u> (cont'd) | Documented in house methods and manufacturers instructions for | |
| Serum/Plasma (cont'd) | Specific IgE: (cont'd) Cherry (f242) Pine nut (f253) Plum (f255) Walnut (f256) Grape (f259) Chilli pepper (f279) Curry-Santa Maria (f281) Turkey meat (f284) Sweet chestnut (f299) Lime (f306) Green bean (f315) Rape seed (f316) Raspberry (f343) Omega-5-gliadin (f416) Honey Bee (i1) Common Wasp (i3) Mosquito (i71) Bumblebee (i205) A.fumigatus (m3) Mould mix (mx1) Latex (k82) Sunflower seed (k84) Maxitase (k204) Savinase (k205) Penicillin G (c1) Penicillin V (c2) Amoxicillin (c6) Chlorohexidine (c8) Gelatin (c74) Suxamethonium (c202) Morphine (c260) nGal d 2 Ovalbumin (f232) nGal d 1 Ovomuroid (f233) nGal d 3 Conalbumin (f323) rAra h 8 Peanut (f352) rGly m 4,soya (f353) rAra h 1 Peanut (f422) rAra h 2 Peanut (f423) rAra h 3 Peanut (f424) cCor a 8 Hazelnut (f428) | Immunocap 250 using Fluorescent enzyme immunoassay: INT-SOP-41 | B |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunological examination activities for the purposes of clinical diagnosis:</u> (cont'd) | Documented in house methods and manufacturers instructions for | |
| Serum/Plasma (cont'd) | Specific IgE: (cont'd) rAra h 9 Peanut (f427) rCor a 1 Hazelnut (f428) rCor a 14 Hazelnut (f439) rCor a 9 Hazelnut (f440) rJug r 1 Walnut (f441) rJug r 3 LTP Walnut (f442) rAna o 3 Cashew nut (f443) rBet v 2 Profilin Birch (t216) r Bet v 1 PR-10 Birch (t215) rApi m 1 phospholipase A2 Honey bee (i208) rVes v 5 Common Wasp (i209) rVes v 1 phospholipase A1 common wasp (i211) MUXF3 CCD Bromelin (o214) | Immunocap 250 using Fluorescent enzyme immunoassay: INT-SOP-41 | B |
| Whole blood | Endo IgA and IgG, crithidia, skin, paraneoplastic, islet cell, adrenal, and ovarian antibodies. | Indirect Immunofluorescence (IIF) using Quantalyser QL3000 INT-SOP-162 | B |



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| HUMAN BODY FLUIDS (cont'd) | <u>Andrology 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 procedures INT-SOP-101 INT-INS-115 | A D |
| Semen | <u>Fertility testing</u> pH Sperm morphology excluding TZI scoring Sperm concentration Sperm motility | Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021), manual method / documented in-house procedure INT-SOP-37 Colorimetric strips Stained slides (Papanicolau) microscopy (Bright field) Improved Neubauer counting chambers and Microscopy (Phase contrast) Microscopy (Phase contrast) | A D |



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| <p>HUMAN BODY TISSUE AND FLUIDS</p> <p>FFPE Non-gynae cytology cell Blocks</p> <p>Fixed, fresh and frozen tissue, excisional and incisional biopsies and surgical resection specimens</p> | <p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Basophilic and Eosinophilic structures</p> | <p>Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):</p> <p>Supported by:</p> <p>Tissue Dissection: Manual methods using documented procedures INT-SOP-4, INT-SOP-120, INT-SOP-117, INT-SOP-118, INT-SOP-119, INT-SOP-116, INT-SOP-134</p> <p>Cryotomy: Leica cryostat INT-SOP-8</p> <p>Tissue Processing: Using the Leica Peloris and Eprexia Revos INT-SOP-2, INT-SOP-152</p> <p>Embedding: INT-SOP-3 Using Thermo Histostar</p> <p>Section Cutting: INT-SOP-3 Thermo Paratrimmer Using Leica microtomes</p> <p>Automated H&E staining using Sakura Prism Plus with integrated G2 coverslipper. INT-SOP-6</p> | <p>C</p> |



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| HUMAN BODY TISSUE AND FLUIDS (cont'd) | <u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd) | Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant): | C |
| FFPE and Non-gynae cytology cell blocks | Special staining of histopathology examinations to assist in detection of clinical abnormalities: | Special staining In-house manual documented procedures based on manufacturers' manuals as relevant using : Agilant Artisan Link stainer, Thermo Stain Mate stainer INT-SOP-10 | |
| | Acid Mucins/Neutral Mucins | Alcian Blue Periodic Acid Schiff (PAS) | |
| | Carbohydrates and Mucins | PAS | |
| | Amyloid | Congo Red | |
| | Elastin, Connective tissue | Verhoeffs Elastin van Gieson | |
| | Connective tissue, muscle | Masson Trichrome | |
| | Copper associated Protein | Orecin stain (Shikata) | |
| | Fungi | Grocotts Hexamine silver | |
| | Iron deposition | Perl's Prussian Blue | |
| | Reticulin | Gordon and Sweet's silver impregnation | |
| | Spirochetes, H.pylori | Warthin Starry stain | |
| | Acid fast bacilli | Ziehl Nielsen | |
| | Bacteria | Manual staining: Gram stain | |
| | <u>Immunohistochemistry examination activities for detection of:</u> | Immunohistochemistry Microscopic examination supported by in-house documented procedures based Leica Bond III: Using SOPs INT-SOP-10 | C |
| FFPE | Epithelial Cells | AE1/AE3 | |
| | Benign and malignant prostate | AMACR/P63 | |
| | Normal Germinal centre T | Bcl2 | |
| | Cells and Mantle Zone B cells | | |
| | Epithelial cells | BerEP4 | |
| | Ovarian Epithelial cells | CA125 | |
| | Smooth muscle cells | Caldesmon | |
| | Mesothelial cells, normal testis | Calretinin | |
| | Epithelial cells | Cam 5.2 | |
| | T Cells | CD3 | |



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| HUMAN BODY TISSUE AND FLUIDS (cont'd) | <u>Immunohistochemistry examination activities for detection of:</u> (cont'd) | Immunohistochemistry Microscopic examination supported by in-house documented procedures based on Leica Bond III: Using SOPs INT-SOP-10 | C |
| FFPE (cont'd) | Germinal centre cells of Tonsil, endometrial stromal cells, normal kidney B Cells Hodgkin cells, Reed-Sternberg cells Endothelial cells Endothelial cells Lymphocytes Neuroendocrine cells Macrophages B cells Mast cells, Stem cells, Cajal cells, melanocytes, basal (skin) and mammary duct epithelial Neuroendocrine cells CEA glycoproteins Squamous epithelium Epithelial cells Thyroid follicular cells Colonic epithelial cells Basal cells, filamentous keratins from glandular to stratified squamous Mesothelioma Cytomegalovirus Striated and smooth muscle cells Gastro Intestinal Stromal tumours (GIST) | CD10 CD20 CD30 CD31 CD34 CD45 CD56 CD68 CD79a CD117 Chromogranin A CEA CK 5/6 CK7 CK19 CK20 CK34BE12 (HMWCK) Claudin 4 CMV Desmin DOG-1 D240 ERG E-Cadherin EMA ER (EP1) | |
| | Normal duct epithelial cells, ductal carcinoma Normal and neoplastic epithelium Normal Breast, breast carcinoma | | |



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| HUMAN BODY TISSUE AND FLUIDS (cont'd) | <u>Immunohistochemistry examination activities for detection of:</u> (cont'd) | Immunohistochemistry Microscopic examination supported by in-house documented procedures based on Leica Bond III: Using SOPs INT-SOP-10 | C |
| FFPE (cont'd) | Epithelial cells breast and bladder Placental syncytiotrophoblasts and cytotrophoblasts Hepatocytes Melanocytes Leydig and Sertoli cells in testis Neuroendocrine tumors Proliferating cells in germinal centres Melanocytes Germ Cells Epithelial cells of urogenital tract Human Papilloma Virus Squamous epithelium Colonic adenocarcinoma Basal cells and squamous cells Breast carcinoma Prostate secretory and ductal epithelium Melanocytes Schwann cells, nerve processes, melanocytes Smooth muscle cells Neuroendocrine cells Thyroid follicular cells Thyroid follicular cells Epithelial cells and mesenchymal cells Fallopian tube epithelial cells, Renal glomeruli | GATA 3 Glypican HepPar1 HMB45 Inhibin INSM1 Ki-67 (MIB1) Melan A NKX3.1 OCT 3 / 4 PAX 8 P16 P57 P40 P53 P63 PR PAP SOX 10 S100 SMH Synaptophysin SATB2 SALL4 Thyroglobulin TTF-1 Vimentin WT1 | |



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| <p>HUMAN BODY FLUIDS</p> <p>Fine needle aspirations (various sites) Serous effusions (pleural, ascetic, pericardial) Urine Cyst Fluids Peritoneal Washings Cerebrospinal Fluid</p> <p>Air dried prepared slides of above</p> | <p><u>Diagnostic Cytopathology (Non-Gynaecological) examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p> | <p>Macroscopic and microscopic examination</p> <p>Documented in-house procedures In conjunction with manufacturer's instructions for Thermo Cytospin 4 and Sakura Prism PlusStainer with integrated G2 coverslipper Using INT-SOP-62, INT-SOP-6 INT-INS-34 Automated staining PAP and H&E stain Manual staining Giema And light microscopy</p> | C |
| <p>HUMAN BODY TISSUE AND FLUIDS</p> <p>Slides of stained preparations derived from Human tissue and fluids</p> <p>Whole slides of stained preparations</p> | <p><u>Cellular Pathological examination activities for the purposes of clinical diagnosis</u></p> <p>Morphological assessment and diagnosis</p> <p>Morphological assessment and diagnosis</p> | <p>Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):</p> <p>Olympus / Nikon Microscopes light and fluorescence using INT-SOP-99 Ctology Microscopy and RCPATH guidelines</p> <p>Digital scanning (Whole Slide Imaging – WSI) using Hamamatsu S360 and S60; Dynamyx software INT-SOP-146</p> | C C |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Serological examination activities for the purpose of clinical diagnosis</u> (cont'd) | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Diasorin Liaison XL using CLIA and SOP INT-SOP-148 | B B |
| Serum | HIV Ag/Ab VZ IgG Measles IgG Mumps IgG CMV IgG CMV IgM EBV VCAG EBV CAM EBV NAG Rubella IgG Toxoplasma IgG Mycoplasma IgG Parvovirus IgG Parvovirus IgM Hepatitis E IgG & IgM Hepatitis B e Antigen (HBeAg) Hepatitis B e antibody(HBeAb) Hepatitis B anti-core IgM | | |
| Serum | Syphilis TPHA and RPR | Arlington Scientific TPHA and RPR manual kits | B |
| Plasma Faeces Faeces | HBsAg Interferon Gamma GDH Helicobacter pylori antigen | | |
| Faeces | C. difficile GDH | Dynex DS2 using Enzyme linked immunoassay: INT-SOP-14 | D |
| Serum | HIV ab/ag confirmation | Biorad HIV Geenius using immunochromatography INT-INS-285 | B |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Molecular examination activities for the purpose of clinical diagnosis</u> | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: | B |
| Genital Swab/Urine | Chlamydia DNA N.gonorrhoeae DNA T.vaginalis DNA M.genitalium DNA | Abbott AlinityM system using PCR: | B |
| Plasma/serum | Hepatitis C viral loads | | |
| Nose/Throat swabs | HIV 1 viral load SARS CoV 2 Influenza A Influenza B RSV | | |
| Faeces Genital swabs, Ocular swabs and urine | SARS CoV2 Flu A/B RSV Norovirus N.gonorrhoeae confirmation C.trachomatis confirmatio | Cepheid Genexpert using PCR | B D B B |
| DNA/RNA taken from Nose & Throat swabs in viral transport medium | Extended respiratory PCR – Sars-Cov-2, Influenza A, Influenza B, RSV, Bocavirus, Bordetella pertussis, Legionella pneumophila, Mycoplasma pneumoniae, Rhinovirus/Enterovirus, Chlamydia pneumonia, Adenovirus, Human metapneumovirus, Parainfluenza 1-4; Seasonal coronavirus OC43, NL63, HKU1 and 229E | Qiagen Qiasat PCR INT-SOP-159 | B |



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| <p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Routine samples:</p> <p>Cellular and fluid material contained on swabs, catheter tips and IUCDs Aspirates Fluids Genital samples Pus Samples from sterile sites Semen Tissues/Bone Urine</p> <p>Swabs , Fluids, urines, tips and sputum</p> <p>Urine</p> <p>Blood</p> <p>CSF, CAPD, Ascitic fluid</p> <p>Genital swabs</p> | <p><u>Microbiological examination activities performed for the purpose of clinical diagnosis</u></p> <p>Isolation and characterisation of microorganisms of clinical significance</p> <p>Isolation of MRSA</p> <p>Quantification of white and red blood cells, bacteria and epithelial cells</p> <p>Detection of microbial growth and general isolation and characterisation of microorganisms of clinical significance</p> <p>Detection and identification of White blood cells and red blood cells</p> <p>Tricho Bacterial vaginosis</p> | <p>In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs)</p> <p>Manual inoculation, incubation and culture using:</p> <p>INT-SOP-128 INT-SOP-89 INT-SOP-71 INT-SOP-52 INT-SOP-72</p> <p>Manual culture on chromogenic agar using SOP INT-SOP-29</p> <p>Automated urinalysis, image capture and recognition using: SOP INT-SOP-128 and IRIS IQ 200</p> <p>Liquid media culture using SOP INT-SOP-54 in conjunction with manufacturers instructions for Biomerieux BacTAlert 3D</p> <p>Light microscopy and counting chamber: INT-SOP-50</p> <p>Light microscopy using wet prep and gram stain: INT-INS-263</p> | <p>B D</p> |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Microbiological examination activities performed for the purpose of clinical diagnosis</u> (cont'd) | In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) | B D |
| CSF / Ascitic | General isolation and characterisation of micro-organisms of clinical significance | Manual inoculation and media culture using SOPs INT-SOP-50, INT-SOP-52 | |
| Respiratory specimens : | General isolation and characterisation of micro-organisms of clinical significance | Manual media culture using SOPs INT-SOP-73 | |
| Sputum Bronchoalveolar lavage Bronchial aspirate, brushings and washings Cellular material contained on swabs Endotracheal tube specimens Nasopharyngeal aspirate Pleural fluid | | | |
| 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 SOP INT-SOP-51 | |
| Faeces and bowel contents | Detection of <i>Clostridium difficile</i> GDH antigen and toxins A & B | Quik chek tox A/B Immunochromatographic assay using SOP INT-INS-259 | |
| Swabs/Faeces | CPE producing bacteria | Manual culture and using chromogenic agar with SOP INT-SOP-29 | |
| Isolates of Enterobacterales | Carbapenemase detection | NG-Biotech Laboratories NG-test Carba5 manual method | B D |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Microbiological examination activities performed for the purpose of clinical diagnosis</u> (cont'd) | In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) | |
| Bacterial cultures (isolated in-house) | Identification and characterisation of micro-organisms | Manual and/or automated identification methods using : SOPs INT-INS-259, INT-SOP-74, INT-SOP-91 Automated methods using Vitek 2 and Vitek compact | B D |
| Bacterial cultures (isolated in-house) Blood Urine | Antimicrobial susceptibility testing and determination of minimum inhibitory concentration (MIC) | SOP INT-SOP-67 by manual disk diffusion using EUCAST guidelines and MIC determination using E-Tests Automated testing by Vitek 2 INT-SOP-91 and Vitek Compact. Direct susceptibility testing on Blood cultures and urines by EUCAST methodology | B D |
| Faeces, fluids, urine & perianal swabs, sellotape slide and suspected parasitic material | Examination for the presence of parasites (ova, cysts, trophozoites and worms including cryptosporidia) of clinical significance | Unstained and iodine stained direct microscopic examination and/or Formol-ether faecal concentration and microscopic examination using: SOPs INT-SOP-51, INT-INS-263 | B D |
| Skin, Hair and nail clippings | Isolation and identification of clinically significant dermatophyte fungi and yeasts | Manual inoculation, media culture, and macroscopic & microscopic examination (stained & unstained) Using INT-SOP-87 | B |
| Sputum, BAL, pleural fluids, tissue | Acid Fast Bacillii | Fluorescent microscopy using Auramine phenol stain and INT-SOP-90 and INT-SOP-263 | B D |
| Sputum, BAL, pleural fluids, tissue | 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: INT-SOP-90, INT-INS-263 in conjunction with Biomerieux BacTAlert 3D and LJ culture slopes | B |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Microbiological examination activities performed for the purpose of clinical diagnosis</u> (cont'd) | In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) | B D |
| Faeces | Detection of Rotavirus | Immunocard Stat RV kit Immunochematographic assay SOP INT-INS-259 | |
| NPA | Detection of RSV | IBinax NOW RSV mmunochematographic assay SOP INT-INS-259 | |
| Aspirates Corneal scrapes Eye (specimens from) Fluids Tissues Bone CSF Ascitic fluids Gum Swabs | Detection and identification of: White blood cells Red blood cells Bacterial cells Yeast cells and fungal hyphae Vincent's organisms | Staining (inc. Gram) and microscopic examination using: INT-INS-263 | |
| Urine | Detection of Legionella urinary antigen | Meridian TRUImmunochematographic assay using SOP INT-INS-259 | B D |
| Urine | Detection of S.pneumoniae urine antigen | Meridian TRU Immunochematographic assay using SOP INT-INS-259 | B D |
| END | | | |