


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

| | | |
|--|--|---|
|  UKAS MEDICAL 8628 Accredited to ISO 15189:2022 | Wye Valley NHS Trust | |
| | Issue No: 019 Issue date: 20 February 2026 | |
| | Pathology Department Hereford County Hospital Union Walk Hereford HR1 2ER | Contact: Kimberley Elding Tel: +44 (0) 1432 355444 Ext 4277 E-Mail: kimberley.elding@wvt.nhs.uk Website: www.wyevalley.nhs.uk |
| Testing performed at the above address only | | |

Site activities performed away from the location listed above:

| Location details | Activity |
|--|--|
| Blood Issue Fridge Nuffield Hospital Venns Lane Hereford HR1 1DF | Blood Issue Fridge No testing occurs on this site, blood storage only |



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DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---------------------------|--|--|
| HUMAN BODY FLUIDS | <u>Haematological examinations to assist in clinical diagnosis</u> | Procedures documented in relevant equipment manuals and in house documented procedures by the following methods |
| Venous Whole Blood: EDTA | Full Blood Count <ul style="list-style-type: none"> • Haemoglobin estimation • Differential white cell count • Reticulocytes • Red Blood Cells • Platelet (Impedance) • Platelets (Optical) • Mean Cell Volume • Mean Cell Haemoglobin • Mean Cell Haemoglobin Concentration • Haematocrit | Sysmex XN1000 Analysers Haem 11: Operation of Sysmex XN1000 SLS Haemoglobin detection method Flow cytometry method using semiconductor laser Hydrodynamic Focusing (DC method) HA/HA/SOP/040 Hydrodynamic Focusing (DC method) Flow cytometry method using semiconductor laser Calculated from RBC, HCT and HB RBC cumulative pulse height detection method |
| Venous Whole Blood: EDTA | Blood Film staining | Haem 32: RAL Stainer Maintenance and Operation |
| Venous Whole Blood: EDTA | Blood Film reporting of normal and abnormal morphologies including White Blood Cell Differential (% and absolute count) | Manual microscopy Haem 23: Blood film examination |
| Venous Whole Blood: EDTA | Erythrocyte Sedimentation Rate (ESR) | Starrsed ST ESR analyser using modified Westergren Method Haem 23 Erythrocyte Sedimentation Rate (ESR) |



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| HUMAN BODY FLUIDS (cont'd) | <u>Haematological examinations to assist in clinical diagnosis</u> (cont'd) | Procedures documented in relevant equipment manuals and in house documented procedures by the following methods |
| Venous Whole Blood: EDTA | Infectious mononucleosis screen | Latex agglutination Biokit Monogen kit Haem 20 Infectious Mononucleosis Screen (IM) Documented in-house methods to meet the requirements of the Sickle Cell and Thalassaemia Antenatal screening programme as defined in the laboratory QA evidence requirements |
| Venous Whole Blood: EDTA | Identification and quantification of normal and abnormal Haemoglobins | Sebia Capillarys 3 Tera – capillary zone electrophoresis Haem 44 - Capillary Zone Electrophoresis for Variant Haemoglobins |
| | Blood coagulation Studies | Sysmex CS2500 Optical, turbidimetry |
| Citrated blood | Activated partial thromboplastin time. | Haem 34: APTT using CS2500 |
| Citrated blood | Prothrombin INR | Haem 33 PT/INR using CS2500 |
| Citrated blood | Fibrinogen | Haem 36: Fibrinogen using CS2500 |
| Citrated blood | Lupus anticoagulant D- Dimer | Haem 6 Lupus anticoagulant |
| Citrated blood | Inhibitor screen | Haem 37: Inhibitor screen using CS2500 |
| Citrated blood | INR Activated partial thromboplastin time Prothrombin time | KC4 coagulometer - mechanical end point detection) Haem 52: PT/INR using KC4 |
| Venous Whole Blood: EDTA | Solubility test – presence of Haemoglobin S | Microgen Products S Test – solubility test based on decreased solubility of HbS Haem 21: Solubility Test |



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| HUMAN BODY FLUIDS (cont'd) | <u>Haematological examinations to assist in clinical diagnosis</u> (cont'd) | Procedures documented in relevant equipment manuals and in house documented procedures by the following methods |
| Venous Whole Blood: EDTA | Detection of Malarial pLDH and HRP11 antigens | Immunochromatographic assay using Core Malaria Pan/Pv/Pf Kit Haem 5: Malaria parasite |
| | Detection of Malaria Parasites | Malaria Parasite staining and microscopy Thin Film – Giemsa pH7.2 stain. Thick Film Field's stain Haem 5: Malaria parasite |
| Bone Marrow | Detection of abnormal and normal Bone Marrow morphologies | Perls Prussian blue manual stain. Manual microscopy Bone Marrow examination Haem 32: RAL Stainer Maintenance and operation Haem 27: May-Grunwald Giemsa Stain |
| | <u>Blood Transfusion examinations to assist in clinical investigations</u> | Procedures documented in relevant equipment manuals and in house documented procedures by the following methods |
| Venous blood EDTA; Red cells | Blood Grouping by antigen detection: A, B and O groups Rh D grouping Rh grouping system: C c E e K grouping system: K MN grouping system: MN Ss grouping system: Ss Duffy grouping system: Fya Fyb Kidd grouping system: Jka Jkb | Processing samples for blood grouping and antibody screening on Ortho Vision– BT 108: Processing for Blood Grouping and Antibody Screening on the Ortho Vision Or Manual blood grouping BT 120: Manual Blood Grouping by Ortho Red Cell Phenotyping using Ortho Technology BT 125: Red Cell Phenotyping using Ortho Technology |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Venous blood EDTA; plasma</p> <p>Venous blood EDTA; plasma</p> | <p><u>Blood Transfusion examinations to assist in clinical investigations</u> (cont'd)</p> <p>Detection and identification of the following Antibodies:</p> <p>ABO blood group antibodies: anti-A, anti-B</p> <p>Rh blood group antibodies: anti-Cw, anti-C, anti-c, anti-E, anti-e, anti-D</p> <p>Kell blood group antibodies: anti-K, anti-k, anti-Kpa</p> <p>MNSs blood group antibodies: anti-M, anti-N, anti-S, anti-s</p> <p>Duffy blood group antibodies: anti-Fya, anti-Fyb</p> <p>Kidd blood group antibodies: anti-Jka, anti-Jkb</p> <p>Detection and identification of the following Antibodies:</p> <p>Lewis blood group antibodies: Anti-Le(a), anti-Le(b)</p> <p>P blood group antibodies: Anti-P1</p> <p>Lutheran blood group antibodies: Anti-Lua</p> | <p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods</p> <p>Processing samples for blood grouping and antibody screening on Ortho Vision BT 108: Processing for Blood Grouping and Antibody Screening on the Ortho Vision</p> <p>Or</p> <p>Manual blood grouping by Ortho SOP BT 120: Manual Blood Grouping by Ortho</p> <p>BT 126: Antibody Investigation by Ortho</p> <p>Processing samples for blood grouping and antibody screening on Ortho Vision– BT 108: Processing samples for blood group and antibody screening on the ortho vision</p> <p>Or</p> <p>Manual blood grouping by Ortho SOP BT 120: Manual Blood Grouping by Ortho</p> <p>BT 78: Manual Antibody screening by Ortho</p> <p>BT 126: Antibody investigation by Ortho</p> |



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| HUMAN BODY FLUIDS (cont'd) | <u>Blood Transfusion examinations to assist in clinical investigations</u> (cont'd) | Procedures documented in relevant equipment manuals and in house documented procedures by the following methods |
| Venous blood EDTA; plasma | Compatibility testing; - Compatibility testing of patients' plasma with donor cells | Ortho Vision BT 86: Processing samples for crossmatching on the Ortho Vision Or Manual crossmatching BT82: Manual Crossmatching using Ortho Technology |
| Venous blood EDTA; whole blood | Direct Antiglobulin Test (Direct Coombs) | BT 35: Direct antiglobulin test using Ortho Technology |
| Venous blood EDTA; red cells | Red cell phenotyping | BT 125: Red Cell Phenotyping using Ortho Technology |
| Venous blood EDTA; whole blood | Kleihauer for foetal/maternal bleed estimation reported as ml foetal red cells in maternal circulation | Acid elution – Kleihauer – Betke method. BT 127: Kleihauer test |
| | <u>Biochemistry examinations for the purpose of clinical diagnosis</u> | Procedures documented in relevant equipment manuals and in house documented procedures by the following methods |
| | Quantification of: | Roche c501 Turbidimetric method |
| Urine & CSF | Total Protein | Chem 106: Urine/CSF Total Protein |
| Urine | Albumin | Chem 100: Urine Microalbumin |
| Serum/Plasma | Caeruloplasmin | Chem 35: Serum/Plasma Caeruloplasmin |
| Serum/Plasma | Transferrin/Iron Binding Ca | Chem 41: Serum/Plasma Transferrin |
| Serum/Plasma | Immunoglobulins G | Chem 89: Serum/Plasma IgG |
| Serum/Plasma | Immunoglobulins A | Chem 88: Serum/Plasma IgA |
| Serum/Plasma | Immunoglobulins M | Chem 90: Serum/Plasma IgM |



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| Serum/Plasma | A1 Antitrypsin | Chem 113: Serum/Plasma A1-Antitrypsin |
| Serum/Plasma | Complement C3 | Chem 97: Serum/Plasma Complement |
| Serum/Plasma | Complement C4 | Chem 114: Serum/Plasma Complement C4 |
| Serum/Plasma | Rheumatoid Factor | Chem 103: Serum/Plasma Rheumatoid Factor |
| Serum/Plasma | CRP | Chem 91: Serum/Plasma CRP |
| Serum/Plasma | Lactate Dehydrogenase | Roche c501 UV enzymatic assay Chem 28: Serum/Plasma Lactate Dehydrogenase (LDH) |
| Serum, Plasma & CSF | Lactate | Roche c501 analyser Lactate Oxidase method Chem 27: Plasma/CSF Lactate |
| Serum, Plasma & CSF | Glucose | Roche c501 analyser Hexokinase method Chem 27: Plasma/CSF Glucose |
| Serum, Plasma & Urine | Sodium | Roche c501 analyser ISE method Chem 105: Serum/Plasma/Urine Electrolytes |
| Serum, Plasma & Urine | Potassium | Roche c501 analyser ISE method Chem 105: Serum/Plasma/Urine Electrolytes |
| Serum, Plasma & Urine | Quantification of: Urea | Roche c501 Analyser Chem 102: Serum/Plasma/Urine Urea |
| Serum, Plasma & Urine | Magnesium | Chem 99: Serum/Plasma/Urine Magnesium |



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| | Quantification of: (cont'd) | Roche c501 Analyser |
| Serum and plasma | Inorganic Phosphate | Chem 104: Serum/Plasma/Urine Phosphate |
| Serum and plasma | Uric acid | SOP Chem 107: Serum/Plasma/Urine Uric Acid |
| Serum and plasma | Amylase | Chem 54: Serum, Plasma and Urine Amylase |
| Serum and plasma | Calcium | Chem 53: Serum, Plasma and Urine Calcium |
| Serum and plasma | Creatinine | Chem 112: Serum, Plasma and Urine Creatinine |
| Serum and plasma | Total Protein | Chem 40: Serum/Plasma Total Protein |
| Serum and plasma | Albumin | SOP Chem 37: Serum/Plasma Albumin |
| Serum and plasma | Bile Acids | SOP Chem 110: Serum/Plasma Bile Acids |
| Serum and plasma | Cholesterol | Chem 36: Serum/Plasma Cholesterol |
| Serum and plasma | Direct (conjugated) Bilirubin | SOP Chem 108: Serum/Plasma Direct Bilirubin |
| Serum and plasma | Iron | Chem 30: Serum/Plasma Iron |
| Serum and plasma | Gamma GT | Chem 31: Serum/Plasma Gamma Glutamyl Transferase |
| Serum and plasma | HDL Cholesterol (LDL Calculated) | Chem 33: Serum/Plasma HDL Cholesterol |
| Serum and plasma | Paracetamol | Chem 98: Serum/Plasma Paracetamol |
| Serum and plasma | Total Bilirubin | Chem 29: Serum/Plasma Total Bilirubin |



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| Serum and plasma | Triglycerides | Chem 42: Serum/Plasma Triglycerides |
| Serum and plasma | Alcohol | Serum, Plasma and Whole Blood Ethanol (Alcohol) |
| Serum and plasma | Alkaline Phosphatase | Chem 38: Serum/Plasma Alkaline Phosphatase (ALP) |
| Serum and plasma | ALT | Chem 39: Serum/Plasma Alanine Transaminase (ALT) |
| Serum and plasma | AST | Chem 34: Serum/Plasma Aspartate Transaminase (AST) |
| Serum and plasma | Creatine Kinase | Chem 92: Serum/Plasma Creatine Kinase (CK) |
| Serum and plasma | Theophylline | Chem 55: Serum/Plasma Theophylline |
| Serum and plasma | Salicylate | - Salicylate Hydroxylase Chem 56: Serum/Plasma Salicylate |
| Serum and plasma | Angiotensin Converting Enzyme | Buhlmann FAPGG Kinetic Chem 115: Serum/Plasma ACE |
| Serum and plasma | Gentamicin | Cedia EIA Chem 95: Serum/Plasma Gentamicin |
| Serum and plasma | Vancomycin | EIA Chem 94: Serum/Plasma Vancomycin |
| Serum and plasma | Hydroxybutyrate | Biostat enzymatic endpoint Chem 111: Serum/Plasma BOH-Butyrate |
| Serum and plasma | Fructosamine | Nitro Blue Tetrazolium oxynitroanilide Chem 96: Serum/Plasma Fructosamine |



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| Faeces | Detection of Faecal Occult Blood | HM-JACKarc analyser Immunoturbidimetric Chem 74: Faecal Immunochemical Testing |
| Urine & faeces | Urinary and Faecal Reducing Substances (semi-quantitative) | Manual Method – Benedicts Reagent Chem 72: Urinary and Faecal Reducing Substances |
| Serum, Plasma & Urine | Quantification of: Osmolality | Advanced Instruments OSMO1 Depression Chem 69: Serum and Urine Osmolality |
| Venous Whole Blood: EDTA/Fluoride | HbA1c | Sebia Capillarys 3 Tera – capillary zone electrophoresis Chem 118: HbA1c Analysis on Sebia Capillarys 3 Tera Systems |
| | Quantification of: | Roche e601 Analyser– Chemiluminescent Immunoassay |
| Serum & Plasma | CEA | Chem 11: Serum/Plasma CEA |
| Serum & Plasma | hsTroponin T | Chem 66: Serum HS Troponin |
| Serum & Plasma | Thyroid Stimulating Hormone | Chem 15: Serum/Plasma TSH |
| Serum & Plasma | Free T4 | Chem 62: Serum/Plasma FT4 |
| Serum & Plasma | Testosterone | Chem 64: Serum/Plasma Testosterone |
| Serum & Plasma | Free T3 | Chem 63: Serum/Plasma FT3 |
| Serum & Plasma | Ferritin | Chem 10: Serum/Plasma Ferritin |



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| | Quantification of: (cont'd) | Roche e601 Analyser– Chemiluminescent Immunoassay |
| Serum & Plasma | Vitamin B12 | Chem 45: Serum/Plasma Vitamin B12 |
| Serum & Plasma | Folate | Chem 21: Serum/Plasma Folate |
| Serum & Plasma | BHCG | Chem 8: Serum/Plasma HCG |
| Serum & Plasma | Progesterone | Chem 23: Serum/Plasma Progesterone |
| Serum & Plasma | Digoxin | Chem 47: Serum/Plasma Digoxin |
| Serum & Plasma | Thyroid Peroxidase Antibodies | Chem 5: Serum/Plasma Anti-Thyroid Peroxidase Antibodies (TPO) |
| Serum & Plasma | AFP | Chem 12: Serum/Plasma AFP |
| Serum & Plasma | Cortisol | Chem 25: Serum/Plasma Cortisol |
| Serum & Plasma | Follicle Stimulating Hormone | Chem 9: Serum/Plasma FSH |
| Serum & Plasma | Oestradiol | Chem 60: Serum/Plasma Oestradiol |
| Serum & Plasma | Luteinsing Hormone | Chem 13: Serum/Plasma LH |
| Serum & Plasma | Ig E | Chem 7: Serum/Plasma IgE |
| Serum & Plasma | Prolactin | Chem 65: Serum/Plasma Prolactin |
| Serum & Plasma | Macroprolactin | Chem 22: Serum/Plasma Macroprolactin |
| Serum & Plasma | Prostate Specific Antigen | Chem 58: Serum/Plasma PSA |
| Serum & Plasma | CA125 | Chem 46: Serum/Plasma CA125 |
| Serum & Plasma | Total 25 hydroxy Vitamin D | Chem 24: Serum/Plasma Vitamin D |
| Serum & Plasma | Parathyroid Hormone | Chem 68: Plasma Parathyroid Hormone (PTH) |



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| HUMAN BODY FLUIDS (cont'd) | <u>Biochemistry examinations for the purpose of clinical diagnosis</u> (cont'd) | Procedures documented in relevant equipment manuals and in house documented procedures by the following methods |
| | Quantification of: (cont'd) | Roche e601 Analyser– Chemiluminescent Immunoassay |
| Serum & Plasma | BNP | Chem 49: Serum/Plasma BNP |
| Serum | Plasma Protein | Imm 14: Serum Protein Electrophoresis |
| Serum | Paraprotein Quantification | Imm 14: Serum Protein Electrophoresis |
| Serum | Detection of Cryoglobins | Imm 11: Cryoglobulin Analysis |
| Plasma | Ammonia | SOP CHEM 1 |
| | Paraprotein Typing | Sebia Hydrasys 2 Immunofixation |
| | Detection, quantification and typing of: | Electrophoresis Imm 12: Serum Immunofixation - Typing of Paraproteins |
| Urine | Bence Jones Protein | Sebia Hydrasys 2 - Gel electrophoresis Imm 15: Urine Bence Jones Protein |
| | Quantification of: | |
| CSF | CSF Xanthochromia | Uvikon XS Spectrophotometer Direct spectroscopy SOP Chem 146: CSF Xanthochromia |



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| HUMAN BODY FLUIDS (cont'd) | <u>Biochemistry examinations for the purpose of clinical diagnosis</u> (cont'd) | Procedures documented in relevant equipment manuals and in house documented procedures by the following methods |
| Serum / Plasma/ Urine/ Sweat | Chloride | Corning/Sherwood 925 Chloride Analyser – Coulometry Chem 76: Serum/Plasma/Sweat Chloride Analysis |
| Faeces | Faecal Calprotectin | Phadia ImmunoCap 250 Analyser using indirect enzyme reaction Imm 17: Analysis of Faecal Calprotectin |
| | <u>Immunology examinations for the purpose of clinical diagnosis</u> | Procedures documented in relevant equipment manuals and in house documented procedures by the following methods |
| | Detection and Quantification of: | Phadia ImmunoCap 250 Analyser – ELISA method Imm 7: Operation and maintenance of the Immunocap |
| Serum / Plasma | Double Stranded DNA Antibodies | Imm 3: Detection of dsDNA Antibodies Using the ImmunoCap |
| Serum / Plasma | Anticardiolipin G | Imm 6: Detection of Cardiolipin Antibodies Using the ImmunoCap 250 |
| Serum / Plasma | Anticardiolipin M | Imm 6: Detection of Cardiolipin Antibodies Using the ImmunoCap 250 |
| Serum / Plasma | Glomerular Basement Membrane Antibodies | Imm 9: Detection of Glomerular Basement Membrane Antibodies Using the ImmunoCap 250 |
| Serum / Plasma | PR3 | Imm 1: Detection of MPO and PR3 Antibodies Using the ImmunoCap |
| Serum / Plasma | MPO | Imm 1: Detection of MPO and PR3 Antibodies Using the ImmunoCap |
| Serum / Plasma | Tissue Transglutaminase Antibodies | Imm 5: Detection of Tissue Transglutaminase antibodies |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunology examinations for the purpose of clinical diagnosis (cont'd)</u> | Procedures documented in relevant equipment manuals and in house documented procedures by the following methods |
| Serum / Plasma | Extractable Nuclear Antibodies (ENA) Profile 6 tests SS-A/Ro SS-B/La Sm RNP Scl70 Jo-1 | Phadia ImmunoCap 250 Analyser – ELISA method Imm 8: Extractable Nuclear Antibody (ENA) Screen Using the ImmunoCap 250 Combi ELISA Kit Imm 48: Detection of Extractable Nuclear Antibodies (ENA Profile) Imm 7: Operation and maintenance of the Immunocap |
| | Quantification of Allergen Specific IgE: | Phadia Immunocap 250 Analyser Immunoassay Imm 4: Specific IgE Testing Imm 7: Operation and maintenance of Immunocap |
| Serum / Plasma | Egg White | |
| Serum / Plasma | Wheat | |
| Serum / Plasma | Milk | |
| Serum / Plasma | Cod | |
| Serum / Plasma | Peanut | |
| Serum / Plasma | Soya Bean | |
| Serum / Plasma | Hazelnut | |
| Serum / Plasma | Brazil Nut | |
| Serum / Plasma | Almond | |
| Serum / Plasma | Shrimp | |
| Serum / Plasma | Coconut | |
| Serum / Plasma | Cheese | |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunology examinations for the purpose of clinical diagnosis</u> (cont'd) | Procedures documented in relevant equipment manuals and in house documented procedures by the following methods |
| | Quantification of Allergen Specific IgE: | Phadia Immucap 250 Analyser Immunoassay Imm 4: Specific IgE Testing Imm 7: Operation and maintenance of Immucap |
| Serum / Plasma | Cashew | |
| Serum / Plasma | Walnut | |
| Serum / Plasma | Food Mix | |
| Serum / Plasma | Seafood Mix | |
| Serum / Plasma | Nut Mix | |
| Serum / Plasma | Cat | |
| Serum / Plasma | Horse | |
| Serum / Plasma | Dog | |
| Serum / Plasma | House Dust Mite | |
| Serum / Plasma | Tree | |
| Serum / Plasma | Mixed Tree | |
| Serum / Plasma | Grass | |
| Serum / Plasma | Aspergillus | |
| Serum / Plasma | Mixed Mould | |
| Serum / Plasma | Latex | |
| Serum / Plasma | Bee | |
| Serum / Plasma | Wasp | |
| Serum / Plasma | Blue Mussel | |



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| HUMAN BODY FLUIDS (cont'd) Serum / Plasma | <u>Immunology examinations for the purpose of clinical diagnosis</u> (cont'd) Quantification of Allergen Specific IgE: Cereal mix Chesnut Chicken meat Chickpea Crab Egg Yolk Kiwi Lobster Macadamia nut Peach Pecan nut Penicilloyl G Penicilloyl V Pine nut Pistachio Rabbit epithelium Salmon Sesame seed | Procedures documented in relevant equipment manuals and in house documented procedures by the following methods Phadia Immucap 250 Analyser Immunoassay Imm 4: Specific IgE Testing Imm 7: Operation and maintenance of Immucap |



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| | Quantification of Allergen Specific IgE: | Phadia Immucap 250 Analyser Immunoassay Imm 4: Specific IgE Testing Imm 7: Operation and maintenance of Immucap |
| Serum / Plasma | Shrimp | |
| Serum / Plasma | Tomato | |
| Serum / Plasma | Tune | |
| Serum / Plasma | Feather (poultry) mix | |
| Serum / Plasma | Grain mix | |
| Serum / Plasma | Weed mix | |
| Serum / Plasma | Tree mix (early) | |
| Serum / Plasma | Tree mix (late) | |
| Serum / Plasma | Ara h1 peanut component | |
| Serum / Plasma | Ara h2 peanut component | |
| Serum / Plasma | Ara h3 peanut component | |
| Serum / Plasma | Ara h6 peanut component | |
| Serum / Plasma | Ara h8 peanut component | |
| Serum / Plasma | Ara h9 peanut component | |
| Serum / Plasma | Cor a1 hazelnut component | |
| Serum / Plasma | Cor a8 hazelnut component | |
| Serum / Plasma | Cor a9 hazelnut component | |
| Serum / Plasma | Cor a14 hazelnut component | |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunology examinations for the purpose of clinical diagnosis</u> (cont'd) | Procedures documented in relevant equipment manuals and in house documented procedures by the following methods |
| | Quantification of Allergen Specific IgE: | Phadia Immucap 250 Analyser Immunoassay Imm 4: Specific IgE Testing Imm 7: Operation and maintenance of Immucap |
| Serum / Plasma | Ana o3 cashew component | |
| Serum / Plasma | Peach Pru p3 LTP component | |
| Serum / Plasma | Gal d 1 Ovomuroid egg component | |
| Serum / Plasma | Gal d 2 egg component | |
| Serum / Plasma | Bet v1 PR-10 birch component | |
| Serum / Plasma | Bet v2 birch component | |
| | Detection and Quantification of: | Phadia Immucap 250 Analyser Immunoassay Imm 7 Operation and Maintenance of the Immucap 250 |
| Serum / Plasma | Quantification of Cyclic Citrullinated Peptide (CCP) Antibodies | Imm 2: Detection of Cyclic Citrullinated Peptide (CCP) Antibodies Using the ImmunoCap 250 |
| Serum / Plasma | Extractable Nuclear Antibodies (ENA) Screen 1 test (U1RNP (RNP 70, A, C), SS-A/Ro (60kDa, 52kDa), SS-B/La, Centromere B, Scl-70, Jo-1 proteins, Sm proteins) | Imm 8: Extractable Nuclear Antibody (ENA) Screen Using the ImmunoCap 250 |
| Serum / Plasma | Beta 2 Glycoprotein IgG and IgM | Imm 57: Detection of Beta-2-Glycoprotein IgG and IgM antibodies |
| Serum/ Plasma | Intrinsic factor antibodies IgG | Imm 57: Detection of Beta-2-Glycoprotein IgG and IgM antibodies |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunology examinations for the purpose of clinical diagnosis (cont'd)</u> | Procedures documented in relevant equipment manuals and in house documented procedures by the following methods |
| Serum/ Plasma | Detection and Quantification of: Detection of Sm antibodies (SmDP-S Wells) | Phadia Immucap 250 Analyser Immunoassay Imm 7 Operation and Maintenance of the Immucap 250 Imm 48: Detection of Extractable Nuclear Antibodies |
| Serum / Plasma | Tryptase Antibodies | Phadia Immucap 250 Analyser Immunoassay Imm 7 Operation and Maintenance of the Immucap 250 Imm 59: Detection of Tryptase Antibodies Using the ImmunoCap 250 |
| Serum / Plasma | Myositis Immunoblot (Mi-2 alpha, Mi-2 beta, TIF1g, MDA5, NXP2, SAE1, Ku, PM-Scl100, PM-Scl75, Jo-1, SRP, PL-7, PL-12, EJ, OJ, Ro-52) | EUROBlot Master analyser EUROLine Scanner Immunoblot and EUROLine Autoimmune inflammatory Myopathies 16Ag (IgG) Imm 52: Detection of Myositis Antibodies Imm 62: Operation Procedure for EUROBlot Master and Use of EUROLineScan Software |
| Serum / Plasma | Systemic Sclerosis Immunoblot (Scl-70, CENP A, CENP B, RP11, RP155, Fibrillarin, NOR90, Th/To, PM-Scl100, PM-Scl75, Ku, PDGFR, Ro-52) | EUROBlot Master analyser EUROLine Scanner Immunoblot and the EUROline Systemic Sclerosis (Nuceoli) profile (IgG) Imm 53: Detection of Systemic Sclerosis Antibodies Imm 62: Operation Procedure for EUROBlot Master and Use of EUROLineScan Software |
| Serum / Plasma | Anti-Nuclear antibodies | Fluorescent microscopy using the EuroImmun IF Sprinter EuroStar III (Microscope) and FITC-labelled anti-human antibodies Imm 43: Detection of Anti-Nuclear Antibodies (ANA) Imm 27: Euroimmun Sprinter |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum / Plasma</p> <p>Serum / Plasma</p> <p>Serum / Plasma</p> | <p><u>Immunology examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Anti-neutrophil cytoplasmic antibodies (ANCA)</p> <p>Endomysial IgA Antibodies</p> <p>Liver autoantibodies screen (IIF)</p> | <p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods</p> <p>Fluorescent microscopy using the EuroImmun IF Sprinter EuroStar III (Microscope) and FITC-labelled anti-human antibodies Imm 47: Detection of Anti Neutrophil Cytoplasmic Antibodies (ANCA) Imm 27: Euroimmun Sprinter</p> <p>Fluorescent microscopy using the EuroImmun IF Sprinter EuroStar III (Microscope) and FITC-labelled anti-human antibodies microscope Imm 50: Detection of Endomysial Antibodies Imm 27: Euroimmun Sprinter</p> <p>Fluorescent microscopy using the EuroImmun IF Sprinter EuroStar III (Microscope) and FITC-labelled anti-human antibodies Imm 49: Detection of Tissue Autoantibodies Imm 27: Euroimmun Sprinter</p> |



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| <p>HUMAN BODY TISSUE</p> <p>Tissue: biopsy, excision, resection and post-mortem specimens</p> <p>FFPE slides (Formalin fixed paraffin embedded) and frozen sections</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>Demonstration of:</p> <p>Basophilic and eosinophilic structures</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 – Histo 143: BMS Dissection SOP Astec downdraft benches Thermo Cassette printer</p> <p>Tissue processing Epredia Excelsior Tissue Processor AS and Epredia Revos processor Histo 169: Tissue Processing Vantage Tracking System Histo 169, Histo 143 and Histo 85 Tissue Embedding Leica Histocore and sakura embedding centre Histo 85: Embedding</p> <p>Tissue Sectioning Leica microtomes Histo 88 : Microtomy</p> <p>Cryotomy Intra-operative Frozen sections Leica CM1860 UV Cryostat, Microscope Histo 117: Cryotomy</p> <p>Interpretive/diagnostic microscopy and reporting Histo 78: Consultant Histopathologist SOP. Interpretation And Reporting</p> <p>Macroscopic and Microscopic examination</p> <p>Sakura Tissue Tek Prisma Plus Auto and film coverslipper using Haematoxylin and Eosin (H & E) stains Histo 142: H&E Staining Machine and Coverslipper</p> |



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| HUMAN BODY TISSUE (cont'd) Formalin fixed/ paraffin embedded tissue sections. | <u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd) Demonstration of: Acid and Neutral Mucopolysaccharides Amyloid Haematopoietic cells Helicobacter Pylori Reticulin fibres Gram positive and negative bacteria Fungi Elastic fibres, connective tissue and nuclei Tissue morphology, differentiating muscle, connective tissue and cytoplasm Nuclei and connective tissue Fibrin and connective tissue Melanin Connective tissue and muscle | In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Documented in-house procedures for manual Tinctorial Histochemical Special Stains Histo 141: Staining Manual Alcian blue-PAS Congo red Giemsa Giemsa (modified) for Helicobacter Pylori Gordon and Sweets reticulin stain Gram Grocott methenamine silver Elastic van Gieson Haematoxylin and eosin (manual) Or Haematoxylin and eosin (rapid) Haematoxylin Van Gieson (HVG) Martius scarlet blue (MSB) Masson Fontana Masson Trichrome |



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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: |
| Alcohol fixed cell smears | Demonstration of: Differential identification of mesothelial, macrophage and malignant cells in fluid preparations | Special Tinctorial Histochemical Staining continued May Grunwald Giemsa |
| Formalin fixed/ paraffin embedded tissue sections | Removal of melanin to allow visualisation of nuclear features. fungal hyphae, spores and protozoa. | Melanin Bleach Methenamine Silver staining (MST) |
| Frozen tissue sections | Neutral lipid | |
| Formalin fixed/ paraffin embedded tissue sections | Hepatitis B surface antigen and copper associated protein Differential identification of epithelial and other cell types in fluid specimens | Orcein (Shikata's) Papanicolaou |
| | Polysaccharides including glycogen | Periodic acid Schiff (PAS) |
| | Polysaccharides excluding glycogen | Periodic acid Schiff after diastase digestion |
| | Haemosiderin | Perl's Prussian blue |
| | Melanin | Schmorl's technique |
| | Mast cells | Toluidine blue |
| | Calcium salts | Von Kossa |
| | <i>Mycobacterium</i> spp including tuberculosis | Ziehl-Neelsen (ZN) |



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| <p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin fixed/ paraffin embedded tissue sections</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 cells in normal tissues and germ cell tumours</p> <p>Epithelial cells</p> <p>Epithelial cells</p> <p>T cells, B cells in the mantle zone</p> <p>Follicular centre B cells</p> <p>Marker of low molecular weight cytokeratins</p> <p>Intestinal epithelium</p> <p>Mesothelial cells</p> <p>Cells containing carcinoembryonic antigen, principally in the gastrointestinal tract</p> <p>Endometrial glands, appendix, ovary, cervix and luminal cells of the fallopian tube</p> <p>Low molecular weight keratins</p> <p>T cells</p> <p>T cells and mantle zone B cells</p> <p>Immature and germinal centre B cells</p> | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Immunohistochemistry - Automated Method using Ventana Ultra immunostaining platform</p> <p>Histo 82: Immunocytochemistry (ICC) Incorporating the following antibodies:</p> <p>Alpha feto protein</p> <p>AE1/AE3</p> <p>Ber EP4</p> <p>Bcl-2 oncoprotein</p> <p>bcl-6</p> <p>CAM 5.2</p> <p>CDX2</p> <p>Calretinin</p> <p>CEA (Monoclonal)</p> <p>Ca 125</p> <p>CAM5.2</p> <p>CD3</p> <p>CD5</p> <p>CD10</p> |



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| <p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin fixed/ paraffin embedded tissue sections (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>Immature B lymphocytes</p> <p>B cells</p> <p>Mature B cells and follicular dendritic cells</p> <p>Follicular dendritic cells and EBV transformed blasts</p> <p>Reed Sternberg and Hodgkin's cells</p> <p>Endothelial marker</p> <p>Pan leucocyte marker</p> <p>Marker of neural and peptide cells</p> <p>Macrophages</p> <p>Mast and gastro-intestinal stromal cells</p> <p>Plasma cells</p> <p>Neuroendocrine cells</p> <p>Squamous and myoepithelial cells</p> <p>Glandular and transitional epithelium</p> <p>Gastrointestinal epithelium</p> <p>Cells within squamous epithelium and mantle cell lymphoma</p> | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Immunohistochemistry - Automated Method using Ventana Ultra immunostaining platform</p> <p>Histo 82: Immunocytochemistry (ICC) Incorporating the following antibodies:</p> <p>CD15</p> <p>CD20</p> <p>CD21</p> <p>CD23</p> <p>CD30</p> <p>CD34</p> <p>CD45 (LCA)</p> <p>CD56</p> <p>CD68 (KP1)</p> <p>CD117 (c-kit)</p> <p>CD138</p> <p>Chromogranin A</p> <p>CK5/6</p> <p>CK7</p> <p>CK20</p> <p>Cyclin D1</p> |



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| <p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin fixed/ paraffin embedded tissue sections (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>Muscle intermediate filaments</p> <p>Mast and gastrointestinal tumour cells</p> <p>Cell adhesion molecules and indicative of ductal carcinoma breast</p> <p>Epithelial cells</p> <p>Breast and endometrium</p> <p>Trophoblasts</p> <p>Melanosomes</p> <p>Immunoglobulin producing cells eg plasma cells</p> <p>Leydig and Sertoli cells</p> <p>Proliferation</p> <p>Melanocytes</p> <p>Pan cytokeratin marker</p> <p>mRNA/ p16 HPV biomarker</p> <p>Tumour suppressor gene</p> <p>Basal cell marker</p> <p>Placental Alkaline Phosphatase in the diagnosis of seminoma</p> | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Immunohistochemistry - Automated Method using Ventana Ultra immunostaining platform</p> <p>Histo 82: Immunocytochemistry (ICC) Incorporating the following antibodies:</p> <p>Desmin</p> <p>DOG-1</p> <p>E-CADHERIN</p> <p>EMA</p> <p>Estrogen Receptor</p> <p>HCG</p> <p>HMB 45</p> <p>IgM</p> <p>Inhibin</p> <p>Ki 67</p> <p>MELAN-A</p> <p>MNF116</p> <p>P16</p> <p>P 53</p> <p>P63</p> <p>PLAP</p> |



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| <p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin fixed/ paraffin embedded tissue sections (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>Breast and endometrial glands</p> <p>Prostate</p> <p>Melanocytes, sweat ducts and neuroendocrine cells</p> <p>Muscle mesenchymal marker</p> <p>Neuroendocrine</p> <p>Thyroid and lung adenocarcinoma</p> <p>Mesenchymal marker</p> <p>Wilm's tumour</p> | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Immunohistochemistry - Automated Method using Ventana Ultra immunostaining platform</p> <p>Histo 82: Immunocytochemistry (ICC) Incorporating the following antibodies:</p> <p>Progesterone receptor</p> <p>PSA</p> <p>S100</p> <p>Smooth muscle actin</p> <p>Synaptophysin</p> <p>TTF-1</p> <p>Vimentin</p> <p>WT1</p> |



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| <p>HUMAN BODY FLUIDS</p> <p>Fluids from peritoneal and pleural cavities, brushings from bronchus and biliary tract, bronchial washings and fine-needle aspirations from breast and thyroid. Urine specimens CSF</p> <p>Thin layer preparations from body fluids</p> <p>Joint fluids</p> | <p><u>Cytopathology (Non-Gynae) 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>Demonstration of:</p> <p>Cells (nuclei and cytoplasm) and microorganisms</p> <p>Detection and identification of Crystals</p> | <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Diagnostic cytology (non-gynae) in-house documented manual procedures for preparation Screening and Reporting</p> <p>Histo 7: Non Gynae Prep Manual</p> <p>T2000 Thin Prep Processor Histo 7: Non Gynae Prep Manual</p> <p>Stainer Coverslipper Papanicolaou stain for Non-Gynae Specimens Histo 142: H&E Staining Machine and Coverslipper May-Grunwald Giemsa stain Histo 7: Non Gynae Prep Manual</p> <p>Preparation and examination of Joint fluids for crystals using polarising microscopy Histo 89: Joint Fluid Analysis (Crystals) Centrifuge Histo 7: Non Gynae Prep Manual Leica microscope</p> |



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| HUMAN TISSUES AND FLUIDS | <u>Microbiological examination activities performed for the purpose of clinical diagnosis</u> | In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) |
| Routine samples: | Isolation of microorganisms of clinical significance | Manual inoculation, incubation and culture using: |
| Cellular and fluid material contained on Swabs from eyes, wounds, nose, throat, ears, genital sites, catheter tips, IUCDs, throat, ears, genital sites, Aspirates and Urine | Isolation of microorganisms of clinical significance | MIM4 for processing of routine swabs MIM8- Introduction to the preliminary identification of medically important bacteria MIM21- Staining Procedures MIM1- Investigation of Urines |
| Female genital tract swabs | Diagnosis of bacterial vaginosis | Manual microscopy using MIM4 Processing of routine swabs |
| Swabs, Fluids, urines and sputum | Isolation & identification of MRSA | Manual microscopy and manual inoculation and media culture using MIM4- processing of routine swabs MIM1- Investigation of Urines |
| Urine | Quantification of white and red blood cells, bacteria and epithelial cells | Manual microscopy and manual inoculation and media culture using MIM1 |
| Blood | Isolation of micro-organisms of clinical significance | BacT/Alert Analyser MIM7 -Investigation of Blood Cultures MIM8 -Introduction to the preliminary identification of medically important bacteria |
| Faeces | General isolation and characterisation of micro-organisms of clinical significance | Manual inoculation, incubation and culture using MIM11 Investigation of faecal specimens for bacterial pathogens and their ID |
| Bacterial and yeast cultures (isolated in-house) | Identification and characterisation of micro-organisms | Manual biochemical, enzymatic, staining & microscopic methods using MIM8 Introduction to the preliminary identification of medically important bacteria |



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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 from clinical samples) | Antimicrobial susceptibility testing of clinically significant bacteria | Manual disc and MIC gradient determination using DensiCHEK Plus Photometric device using EUCAST methodology SOP: MIM 25: EUCAST Antibiotic Susceptibility Testing |
| Faeces, fluids, urine & perianal swabs, sellotape slide and suspected parasitic material | Detection of parasites (ova, cysts, trophozoites and worms) of clinical significance | Unstained and iodine stained direct microscopic examination and/or Parasep faecal concentration, centrifugation and microscopic examination using SOP: MIM13 - Investigation of specimens other than blood for parasites |
| Faeces | Detection of Cryptosporidium oocysts | Modified Cold ZN incident-light microscopic examination using SOP MIM13- Investigation of specimens other than blood for parasites |
| Faeces | Detection of <i>Helicobacter pylori</i> antigen | Sentinel Diagnostics Easy Card Qualitative immune-chromatographic assay for detection of <i>H. pylori</i> antigen in faeces using SOP MIM 12 Detection of <i>H. pylori</i> in faeces |
| Skin, Hair and nail clippings | Isolation and identification of clinically significant dermatophyte fungi | Manual inoculation, media culture, and microscopy using: SOP MIM15 Isolation and identification of dermatophytes and other fungi MIM21 Staining procedures |
| Sputum, fluid, urine, tissue and swabs | Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. <i>Mycobacterium</i> spp.) | Liquid TB culture using BacTAlert system, auramine phenol staining and microscopy and confirmation ZN staining using light microscopy using: MIM21 Staining procedures MIM10 Investigation of specimens for <i>Mycobacterium</i> |



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| HUMAN TISSUES AND FLUIDS (cont'd) | <u>Molecular examination activities performed for the purpose of clinical diagnosis</u> | In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) |
| Genital samples and Urine | Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> DNA | RT-PCR Confirmation assay on Cepheid Gene Xpert using Xpert CT/NG SOP MIM14 Cepheid Gene Xpert test procedures |
| NPA, nose/throat swabs | Detection of influenza virus A&B & RSV RNA/DNA | RT-PCR using Cepheid GeneXpert analyser and Xpert Xpress Flu/RSV MIM14 Cepheid Gene Xpert test procedures |
| Faeces | Detection of Norovirus RNA/DNA and <i>Clostridioides difficile</i> RNA/DNA | RT- PCR using Cepheid Gene Expert analyser and Xpert <i>C. difficile</i> BT and Xpert Norovirus MIM14 Cepheid Gene Xpert test procedures |
| Faeces, Rectal swabs, urine, wound swabs | Detection of the carbapenemase producing gene sequences blaKPC, blaNDM, blaVIM, blaOXA-48, and blaIMP-1 | RT-PCR using Cepheid GeneXpert and Xpert Carba-R MIM 14 Cepheid GeneXpert RT-PCR procedures |
| Mycobacterial culture isolates | Detection of <i>Mycobacterium tuberculosis</i> DNA and rifampicin resistance gene | RT-PCR using Cepheid GeneXpert and Xpert MTB/RIF Ultra MIM14 - Cepheid GeneXpert test |
| Nose and throat swabs collected into VTM | Detection of SARS-CoV-2 virus RNA (COVID-19) specific gene sequences ORF1 and ORF8 | AusDiagnostics MT-PREP (automated RNA extraction), MT-Processor and MT-analyser (for liquid handling and PCR) Detection of viral RNA and semi-quantitative analysis. SOP: MIM23 Coronavirus Typing Assay |



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| HUMAN TISSUES AND FLUIDS (cont'd) Faeces | <u>Molecular examination activities performed for the purpose of clinical diagnosis</u> (cont'd) Detection of RNA/DNA: <i>Campylobacter</i> spp. <i>Salmonella</i> spp. <i>Shigella</i> spp. and EIEC Shiga toxins and Shiga-like toxins 1&2 <i>E. coli</i> 0157 <i>Clostridioides difficile</i> toxin B gene <i>Giardia lamblia</i> <i>Cryptosporidium</i> spp. <i>Entamoeba histolytica</i> Norovirus Genotype 1 and 2 Rotavirus A Astrovirus Adenovirus Group F and G Sapovirus | In house documented procedures following current Public Health England (PHE) Standards for Microbiological Investigations (SMIs) AusDiagnostics MT-Prep (for extraction), MT-processor (for liquid handling and PCR), MT-analyser (for PCR and interpretation) Faecal pathogens B 16-well kit MIM22 GPP Molecular investigation of faecal specimens for gastrointestinal pathogens |
| END | | |