


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

|   |   |   |
|---|---|---|
|  <p>Accredited to<br/>ISO 15189:2012</p> | <h3>Frimley Health NHS Foundation Trust</h3> <p>Issue No: 002 Issue date: 09 May 2019</p>   |   |
|   | <p>Department of Immunology<br/>Berkshire and Surrey Pathology<br/>Services (BSPS)<br/>Delivery Point 3<br/>St Peter's Hospital<br/>Guildford Road<br/>Chertsey<br/>Surrey<br/>KT16 0PZ</p> | <p>Contact: Elaine Inglis<br/>Tel: +44 (0)1932 723042<br/>Fax: +44 (0)1932 875129<br/>E-Mail: <a href="mailto:fph-tr.bspsquality@nhs.net">fph-tr.bspsquality@nhs.net</a><br/>Website: <a href="http://www.nhs pathology.fph.nhs.uk">http://www.nhs pathology.fph.nhs.uk</a></p> |
| <p><b>Testing performed at the above address only</b></p>   |   |   |

### DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of measurement                   | Standard specifications/ Equipment/Techniques used  |
|---------------------------|---|---|
| HUMAN BODY FLUIDS         | <u>Immunological examinations for the purpose of clinical diagnosis</u> | In house documented methods incorporating manufacturers' instructions where relevant  |
| Serum                     | Anti-Cardiolipin (IgG, A, M screen, IgG and IgM typing) antibodies      | Enzyme Linked Immunosorbent Assay (Elisa) using in-house documented procedures: IMM-ASPH-SOP-051<br>In conjunction with manufacturer's instructions for Dynex DS2 |
| Serum                     | Acetylcholine Receptor antibodies                                       |   |
| Serum                     | dsDNA antibodies  |   |
| Serum                     | ENA screen and typing (Ro, La, RNP, Sm, Scl-70, Jo-1)                   |   |
| Serum                     | GAD antibodies  |   |
| Serum                     | Haemophilus Influenzae antibodies                                       |   |
| Serum                     | Intrinsic factor antibodies   |   |
| Serum                     | Tetanus toxoid antibodies   |   |
| Serum                     | Thyroid peroxidase antibodies   |   |
| Serum                     | TSH receptor antibodies   |   |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd)   | In house documented methods incorporating manufacturers' instructions where relevant  |
| Serum                      | Adrenal antibodies   | Manual indirect immunofluorescence using in-house documented procedures: IMM-ASPH-SOP-016   |
| Serum                      | Endomysial IgA antibodies  |   |
| Serum                      | Endomysial IgG antibodies  |   |
| Serum                      | Epidermal (skin) antibodies  |   |
| Serum                      | Pancreatic Islet Cell antibodies   |   |
| Serum                      | Ovarian antibodies   |   |
| Serum                      | Autoimmune Profile:<br>Smooth muscle<br>Anti-mitochondrial<br>Gastric parietal cell<br>Liver kidney microsomal antibodies<br>Anti-nuclear antibodies (ANA) | Indirect Immunofluorescence using in-house documented procedures: IMM-ASPH-SOP-015<br>In conjunction with manufacturer's instructions for Werfen QUANTA-Lyser 240 |
| Serum                      | ANCA IgG antibodies  |   |
| Serum                      | Anti-Nuclear antibodies  |   |
| Urine                      | Bence Jones Protein (free light chains)  | Electrophoresis using in-house documented procedures: IMM-ASPH-SOP-019<br>In conjunction with manufacturer's instructions for Sebia Hydrasys                      |
| Serum                      | C1 Esterase Inhibitor (antigenic)  | Nephelometry using in-house documented procedures: IMM-ASPH-SOP-007<br>In conjunction with manufacturer's instructions for Siemens BNII                           |
| Serum                      | Complement C3 and C4   |   |
| Serum                      | Immunoglobulins (G, A, M)  |   |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunological examinations for the purpose of clinical diagnosis</u><br>(cont'd)        | In house documented methods incorporating manufacturers' instructions where relevant  |
| Serum                      | IgG Subclasses:<br>IgG1<br>IgG2<br>IgG3<br>IgG4  | Nephelometry using in-house documented procedures:<br>IMM-ASPH-SOP-007<br>In conjunction with manufacturer's instructions for Siemens BNII  |
| Serum                      | Rheumatoid factor  |   |
| Serum                      | Free Light Chains  |   |
| Serum                      | Classical pathway function (CH100)   | Manual radial immunodiffusion using in-house documented procedures:<br>IMM-ASPH-SOP-020   |
| Serum                      | Alternate pathway function (AP100)   |   |
| Serum                      | Immuno Solid-phase Allergy Chip (ISAC)   | Manual Immunoassay using in-house documented procedures:<br>IMM-ASPH-SOP-029<br>In conjunction with manufacturer's instructions for LuxScan-10K/A using software provided by Thermo Fisher Scientific |
| Whole Blood EDTA           | Immunodeficiency panel (B, T and NK cells)<br>CD4<br>CD8<br>CD19<br>CD16/56<br>CD4:8 ratio | Flow Cytometry using in-house documented procedures:<br>IMM-ASPH-SOP-006<br>In conjunction with manufacturer's instructions for<br>BD FACS Canto II   |
| Whole Blood EDTA           | Lymphocyte subsets:<br>CD4<br>CD8<br>CD19<br>CD16/56<br>CD4:8 ratio                        |   |
| Serum                      | Mitochondrial M2 antibodies  | Manual Immunoblot using in-house documented procedures:<br>IMM-ASPH-SOP-021   |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunological examinations for the purpose of clinical diagnosis</u><br>(cont'd) | In house documented methods incorporating manufacturers' instructions where relevant   |
| Serum                      | Protein electrophoresis:<br>IgG<br>IgA<br>IgM                                       | Capillary Zone Electrophoresis using in-house documented procedures:<br>IMM-ASPH-SOP-022<br>In conjunction with manufacturer's instructions for Sebia Capillarys 2 and Capillarys Flex-2 |
| Serum                      | Glomerular basement membrane antibodies (GBM)                                       | Manual Immunoblot using in-house documented procedures:<br>IMM-ASPH-SOP-017<br>In conjunction with manufacturer's instructions for BioDiagnostics GBM Quickcard                          |
| Serum                      | Detection of the following:<br><br>Aspergillus IgG antibodies                       | Immunoassay using in-house documented procedures:<br>IMM-ASPH-SOP-023<br>In conjunction with manufacturer's instructions for Phadia 250  |
| Serum                      | Budgerigar Protein IgG antibodies   |  |
| Serum                      | Citrullinated Protein antibodies  |  |
| Serum                      | Centromere antibodies   |  |
| Serum                      | Glomerular basement membrane antibodies (GBM) antibodies                            |  |
| Serum                      | Immunoglobulin IgE  |  |
| Serum                      | M. faeni IgG antibodies   |  |
| Serum                      | MPO antibodies  |  |
| Serum                      | PR3 antibodies  |  |
| Serum                      | Parrot proteins IgG antibodies  |  |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd)   | In house documented methods incorporating manufacturers' instructions where relevant  |
|                            | Detection of the following (cont.):  | Immunoassay using in-house documented procedures:<br>IMM-ASPH-SOP-023<br>In conjunction with manufacturer's instructions for Phadia 250 |
| Serum                      | Pigeon serum proteins IgG antibodies   |   |
| Serum                      | Ribosomal antibodies   |   |
| Serum                      | Ro 52 antibodies   |   |
| Serum                      | Ro 60 antibodies   |   |
| Serum                      | Tryptase   |   |
| Serum                      | Tissue transglutaminase IgA antibodies   |   |
| Serum                      | Thyroid peroxidase antibodies  |   |
| Serum                      | Specific IgE:<br><br><b>Drugs:</b><br>Amoxicilloyl<br>Ampicillin<br>Cefaclor<br>Chlorhexidine<br>Penicilloyl G<br>Penicilloyl V<br>Suxamethonium<br><br><b>Dust Mite:</b><br>Dermatophagoides pteronyssinus -<br>House dust mite<br>Dermatophagoides farianae –<br>Storage mite<br><br><b>Epidermals and Animal Proteins:</b><br>Budgerigar feathers<br>Cat dander |   |





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| HUMAN BODY FLUIDS (cont'd) | <u>Immunological examinations for the purpose of clinical diagnosis</u><br>(cont'd)  | In house documented methods incorporating manufacturers' instructions where relevant  |
| Serum (cont'd)             | Detection of the following (cont.):<br><br>Specific IgE: (cont'd)<br><br>Blueberry<br>Brazil nut<br>rBer e 1 Brazil nut component<br>Broccoli<br>Buckwheat<br>Cabbage<br>Cacao<br>Carrott<br>Casein<br>Cashew nut<br>rAna o 3, Cashew nut component<br>Cauliflower<br>Celery<br>Cheddar cheese<br>Cheese mould type<br>Cherry<br>Chick Pea<br>Chicken<br>Chillipepper<br>Clam<br>Coconut<br>Cod Fish<br>Coffee<br>Coriander<br>Crab<br>Crayfish<br>Cucumber<br>Curry mix<br>Date<br>Egg White<br>Egg Whole<br>Egg yolk<br>nGal d1 Ovomuroid Egg component<br>Fig<br>Garlic | Immunoassay using in-house documented procedures:<br>IMM-ASPH-SOP-023<br>In conjunction with manufacturer's instructions for Phadia 250 |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunological examinations for the purpose of clinical diagnosis</u><br>(cont'd)  | In house documented methods incorporating manufacturers' instructions where relevant  |
| Serum (cont'd)             | Detection of the following (cont.):<br><br>Specific IgE: (cont'd)<br><br>Ginger<br>Gliadin<br>Gluten<br>Grape<br>Grapefruit<br>Green Bean<br>Green Pepper<br>Haddock<br>Hake<br>Hazel nut<br>rCor a1 Hazelnut component<br>rCor a 8 hazelnut component<br>rCor a9 Hazelnut component<br>rCor a14 Hazelnut component<br>Herring<br>Honey<br>Hop<br>Kiwi fruit<br>rAct d 8 PR-10, Kiwi component<br>Langust (spiny lobster)<br>Lemon<br>Lentil<br>Lettuce<br>Lime<br>Lobster<br>Lupine Seed<br>Mace<br>Macedemia<br>Mackerel<br>Maize, corn<br>Malt<br>Mandarin/Tangerine<br>Mango<br>Melon<br>Milk Cows<br>Milk Goats | Immunoassay using in-house documented procedures:<br>IMM-ASPH-SOP-023<br>In conjunction with manufacturer's instructions for Phadia 250 |





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| HUMAN BODY FLUIDS (cont'd) | <u>Immunological examinations for the purpose of clinical diagnosis</u><br>(cont'd)  | In house documented methods incorporating manufacturers' instructions where relevant  |
| Serum (cont'd)             | Detection of the following (cont.):<br><br>Specific IgE: (cont'd)<br><br>Mint<br>Mushroom<br>Mustard<br>Mutton<br>Oat<br>Octopus<br>Olive (Black, Fresh)<br>Onion<br>Orange<br>Oyster<br>Paprika/Sweet Pepper<br>Parsley<br>Pea<br>Peach<br>rPru p 1 PR-10, Peach component<br>rPru p3 LTP Peach component<br>rPrup4 Profilin, Peach component<br>Peanut<br>rAra h1 Peanut component<br>rAra h2 Peanut component<br>rAra h3 Peanut component<br>rAra h 8 Peanut component<br>rAra h9 Peanut component<br>Pear<br>Pecan nut<br>Pine Nut<br>Pineapple<br>Pistachio<br>Plaice<br>Plum<br>Poppy Seed<br>Pork<br>Potato<br>Pumpkin Seed<br>Rape Seed<br>Raspberry | Immunoassay using in-house documented procedures:<br>IMM-ASPH-SOP-023<br>In conjunction with manufacturer's instructions for Phadia 250 |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd)  | In house documented methods incorporating manufacturers' instructions where relevant  |
| Serum (cont'd)             | Detection of the following (cont.):<br><br>Specific IgE: (cont'd)<br><br>Red Kidney Bean<br>Rice<br>Rye<br>Salmon<br>Sardine<br>Scallop<br>Sesame seed<br>Sheep milk<br>Shrimp<br>rPen a 1 Tropomyosin, Shrimp component<br>Snail<br>Sole<br>Soya bean<br>rGly m 4 PR-10 Soy component<br>nGly m 5, Soy component<br>nGly m 6, soy component<br>Spinach<br>Squid<br>Strawberry<br>Sweet chestnut<br>Sweet potato<br>Tea<br>Tomato<br>Trout<br>Tuna<br>Turkey<br>Walnut<br>rJug r 1, Walnut component<br>rJug r 3, Walnut component<br>Watermelon<br>Wheat<br>rTri a14 Wheat (LTP) component<br>rTri a19 Omega-5 Gliadin, Wheat<br>White Bean<br>Yeast | Immunoassay using in-house documented procedures:<br>IMM-ASPH-SOP-023<br>In conjunction with manufacturer's instructions for Phadia 250 |



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| HUMAN BODY FLUIDS (cont'd) | <p><u>Immunological examinations for the purpose of clinical diagnosis</u><br/>(cont'd)</p> <p>Detection of the following (cont.):</p>   | <p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Immunoassay using in-house documented procedures:<br/>IMM-ASPH-SOP-023<br/>In conjunction with manufacturer's instructions for Phadia 250</p> |
| Serum (cont'd)             | <p>Specific IgE: (cont'd)</p> <p><b>Food Mixes:</b><br/>Nut mix – fx1<br/>Fish mix - fx2<br/>Cereal Mix - fx3<br/>Food mix - fx5<br/>Vegetable mix – fx13<br/>Fruit mix - fx15<br/>Nut mix - fx22<br/>Herb mix - fx70<br/>Spice mix - fx71<br/>Herb and Spice mix - fx72<br/>Fish mix - fx73</p> <p><b>Grass Pollen:</b><br/>Rye Grass<br/>Timothy Grass<br/>rPhl p 1 Timothy component<br/>rPhl p 1, rPhl p 5b Timothy component<br/>rPhl p 2 Timothy component<br/>nPhl p 4 Timothy component<br/>rPhl p 5b Timothy component<br/>rPhl p 6 Timothy component<br/>rPhl p 7, rPhl p 12 Timothy component<br/>rPhl p 11 Timothy component<br/>rPhl p 12 Profilin, Timothy component<br/>Grass mix</p> <p><b>Insect:</b><br/>Cockroach, German<br/>Common wasp<br/>rVes v5 Common Wasp venom component<br/>European hornet</p> |  |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd)   | In house documented methods incorporating manufacturers' instructions where relevant  |
| Serum (cont'd)             | Detection of the following (cont.):<br><br>Specific IgE: (cont'd)<br><br>Fire ant<br>Honey bee<br>r Api m1 Phospholipase A2, Honey<br>Bee venom component<br>Horse Fly<br>Mosquito spp.<br>rPol d 5 Recombinant protein<br>Antigen 5<br>rVes v 1 Yellow Jacket venom component<br><br><b>Occupational:</b><br>Latex ImmunoCAP<br>Sunflower seed ImmunoCAP<br><br><b>Miscellaneous:</b><br>alpha –Gal Thyroglobulin bovine<br><br><b>Mould:</b><br>Alternaria alternria ImmunoCAP<br>Aspergillus fumigatus ImmunoCAP<br>C.Herbarum Immunocap<br>Candida albicans ImmunoCAP<br>Penicillium Notatum ImmunoCAP<br>Mould mix<br><br><b>Inhalant Mix</b><br>Phadiatop<br><br><b>Tree Pollen</b><br>Alder (Grey)<br>Box Elder<br>Hazel<br>Mapleleaf sycamore<br>Oak<br>Olive Tree | Immunoassay using in-house documented procedures:<br>IMM-ASPH-SOP-023<br>In conjunction with manufacturer's instructions for Phadia 250 |

