


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

| | | |
|--|---|---|
|  <p>8612 Accredited to ISO 15189:2022</p> | Belfast Health and Social Care Trust Issue No: 009 Issue date: 24 March 2026 | |
| | Department of Immunology Kelvin Building Royal Victoria Hospital Grovesnor Road Belfast BT12 6BA United Kingdom | Contact: Denise Difallah Tel: +44 (0) 28961 51562 E-Mail: Denise.Difallah@belfasttrust.hscni.net Website: www.belfasttrust.hscni.net |
| Testing performed at the above address only | | |

DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|--|---|
| HUMAN BODY FLUIDS Serum unless otherwise specified | <p><u>Immunology examination activities for the purpose of clinical diagnosis</u></p> <p><u>Detection of:</u></p> <p>Antinuclear antibody specificities (ANA) on Hep2 cells</p> <p>Detection of antibodies to antigens in HEp2 cells including anti centromere antibody</p> <p>Detection of antibodies against dsDNA using Crithidia luciliae</p> <p>Detection of IgA (and IgG) antibodies to endomysium</p> | <p>Documented procedures & manufacturer's instructions for Helmed slide processor/diluter and Indirect Immunofluorescence with specific reference to:</p> <p>I-31 Detection of anti-nuclear and anti-centromere antibodies by indirect immunofluorescence using Hep2 cells</p> <p>I-31 Detection of anti-nuclear and anti-centromere antibodies by indirect immunofluorescence using Hep2 cells</p> <p>By indirect immunofluorescence. Aesku nDNA Crithidia Luciliae, 10-well slides IFA Kits</p> <p>I-32 Detection of antibodies against dsDNA using crithidia luciliae by indirect immunofluorescence</p> <p>By Aesku EMA (Endomysium) IgA 5 well slides IFA kit</p> <p>I-27 Detection of anti-endomysial antibodies (IgA/IgG) by indirect immunofluorescence</p> |



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| <p>HUMAN BODY FLUIDS</p> <p>Serum unless otherwise specified (cont'd)</p> | <p><u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p><u>Detection of:</u> (cont'd)</p> <p>Detection and quantitation of gastric parietal cell autoantibodies</p> <p>Detection of anti-neutrophil cytoplasmic antibodies (ANCA)</p> <p>Detection of Anti smooth muscle antibody</p> <p>Detection of Anti liver kidney antibodies (LKM)</p> | <p>Documented procedures & manufacturer's instructions for Helmed slide processor/diluter and Indirect Immunofluorescence with specific reference to:</p> <p>By Aesku Rodent Tissues (rat/mouse/LK/LKS), rLKS rat wrapped, 10-well slides IFA Kits I-25 Detection of liver and gastric parietal cell antibodies by indirect immunofluorescence</p> <p>By indirect immunofluorescence using Aesku ANCA Ethanol, 12-well slides IFA Kits I-30 Detection of anti-neutrophil cytoplasmic antibodies (ANCA)</p> <p>By Aesku Rodent Tissues (rat/mouse/LK/LKS), rLKS rat wrapped, 10-well slides IFA Kits I-25 Detection of liver and gastric parietal cell antibodies by indirect immunofluorescence</p> <p>By Aesku Rodent Tissues (rat/mouse/LK/LKS), rLKS rat wrapped, 10-well slides IFA Kits I-25 Detection of liver and gastric parietal cell antibodies by indirect immunofluorescence</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum unless otherwise specified (cont'd)</p> | <p><u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p><u>Detection of:</u> (cont'd)</p> <p>Anti-mitochondrial antibody (M2)</p> <p>Anti intrinsic factor antibodies (IFA)</p> <p>Detection and quantification of Total IgE</p> <p>Detection and quantification of specific IgE:</p> <p>Almond (F20) Alpha gal (Galactose-alpha1,3-Galactose) (O215) Alternaria alternata (M6) Amoxicillin Ampicillin Apple (F49) Aspergillus fumigatus (M3) Aubergine (F262)</p> | <p>Documented procedures & manufacturer's instructions for Helmed slide processor/diluter with specific reference to:</p> <p>By Aesku Rodent Tissues (rat/mouse/LK/LKS), rLKS rat wrapped, 10-well slides IFA Kits I-25 Detection of liver and gastric parietal cell antibodies by indirect immunofluorescence</p> <p>DS2 ELISA processor using QUANTA Lite Intrinsic Factor ELISA kit I-346 Intrinsic Factor & I-622 Dynex DS2</p> <p>Documented procedures & manufacturer's instructions for Thermo Scientific Phadia Immunocap 250 (Fluorescence Enzyme Immunoassay (FEIA))with specific reference to: I-44 Procedures common to the operation of the thermofisher Phadia 250</p> <p>I-46 Measurement of total and specific IgE by Phadia Immunocap 250</p> <p>I-46 Measurement of total and specific IgE by Phadia Immunocap 250</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum unless otherwise specified (cont'd)</p> | <p><u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p><u>Detection of:</u> (cont'd)</p> <p>Detection and quantification of specific IgE: (cont'd)</p> <p>Avocado (F96) Banana (F92) Barley (F6) Beech (T5) Beef (F27) Black pepper (F280) Blackberry (F211) Blue mussel (F37) Blueberry (F288) Brazil nut (F18) Buckwheat (F11) Budgerigar droppings (E77) Budgerigar feathers (E78) Carrot (F31) Casein (nBos d8) (F78) Cashew nut (F202) Cat dander (E1) Celery (F85) Cheese (cheddar type) (F81) Cherry (F242) Chicken (F83) Chickpea (F309) Chilli pepper (F279) Chlorhexidine Chocolate (F93) Coconut (F36) Coffee (F221) Common wasp (I3) Conalbumin (F323) Cow dander (E4) Cow's milk (F2) Crab (F23) Cucumber (F244) Dermatophagoides farinae (D2) Dog dander (E5) Egg white (F1) Egg yolk (F75) Epithelial mix (EX1)</p> | <p>Documented procedures & manufacturer's instructions for Helmed slide processor/diluter with specific reference to:</p> <p>I-46 Measurement of total and specific IgE by Phadia Immunocap 250</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum unless otherwise specified (cont'd)</p> | <p><u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p><u>Detection of:</u> (cont'd)</p> <p>Detection and quantification of specific IgE: (cont'd)</p> <p>Feather mix (EX71) Fish (cod) (F3) Garlic (F47) Gelatin (bovine) (C74) Ginger (F270) Gluten (F79) Goat's milk (F300) Grape (F259) Grapefruit (F209) Grass pollen mix (GX1) Green bean (F315) Green pea (F12) Green pepper (F263) Guinea pig (E6) Haddock (F42) Hamster epithelium (E84) Hazel nut (F17) Hazel pollen (T4) Honey bee (I1) Horse dander (E3) Horse fly (I204) House dust mite (D1) Kidney bean (F287) Kiwi (F84) Lactoglobulin (nBos d5) (F77) Latex (K82) Lemon (F208) Lentil (F235) Lepidoglyphus storage mite (D71) Lime (F309) Linseed (F333) Lobster (F80) Lupin seed (F335) Macadamia nut (F345) Mackerel (F206) Maize corn (F8) Mango (F91) Melon (F87) Mosquito (I71)</p> | <p>Documented procedures & manufacturer's instructions for Helmed slide processor/diluter with specific reference to:</p> <p>I-46 Measurement of total and specific IgE by Phadia Immuncap 250</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum unless otherwise specified (cont'd)</p> | <p><u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p><u>Detection of:</u> (cont'd)</p> <p>Detection and quantification of specific IgE: (cont'd)</p> <p>Mould mix (MX1)</p> <p>Mouse epithelium (E71)</p> <p>Mugwort (W6)</p> <p>Mushroom (F212)</p> <p>Mustard (F89)</p> <p>Oak (T7)</p> <p>Oat (F7)</p> <p>Octopus (F59)</p> <p>Onion (F48)</p> <p>Orange (F33)</p> <p>Ovalbumin (nGal d2, egg) (F232)</p> <p>Ovomucoid (nGal d1, egg) (F233)</p> <p>Oyster (F290)</p> <p>Paper wasp (I4)</p> <p>Paprika (sweet pepper) (F218)</p> <p>Parrot (E213)</p> <p>Passion fruit (F294)</p> <p>Peach (F95)</p> <p>Peanut (F13)</p> <p>Pear (F94)</p> <p>Pecan nut (F201)</p> <p>Penicilloyl G</p> <p>Penicilloyl V</p> <p>Pine nut (F253)</p> <p>Pineapple (F210)</p> <p>Pistachio (F203)</p> <p>Plum (F255)</p> <p>Poppy seed (F224)</p> <p>Pork (F26)</p> <p>Potato (F35)</p> <p>Pumpkin seed (F226)</p> <p>Rabbit epithelium (E82)</p> <p>Rape seed (F316)</p> <p>Raspberry (F343)</p> <p>Rice (F9)</p> <p>Rye (F5)</p> <p>Rye grass (G5)</p> <p>Salmon (F41)</p> <p>Scallop (F338)</p> | <p>Documented procedures & manufacturer's instructions for Helmed slide processor/diluter with specific reference to:</p> <p>I-46 Measurement of total and specific IgE by Phadia Immuncap 250</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum unless otherwise specified (cont'd)</p> | <p><u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p><u>Detection of:</u> (cont'd)</p> <p>Detection and quantification of specific IgE: (cont'd)</p> <p>Sesame seed (F10) Sheep epithelium (E81) Shrimp/prawn (F24) Silver birch (T3) Soya bean (F14) Spice mix 1 (FX71) Squid (F258) Strawberry (F44) Sunflower seed (K84) Suxamethonium Timothy grass (G6) Tomato (F25) Tuna (F40) Tyrophagus storage mite (D72) Walnut Weed mix (WX1) Wheat (F4) White bean (F15) Yeast (F45) rAna o3, cashew nut (F443) rApi m1 PLA2, honey bee (I208) rAPi m2 Honey bee hyaluronidase (I214) rAPi m3 Honey bee acid phospholipase (I215) rAPi m5 Honey bee allergen C (I216) rAPi m10 Honey bee (I217) rAra h1, peanut (F422) rAra h2, peanut (F423) rAra h3, peanut (F424) rAra h6, peanut (F447) rAra h8 PR-10, peanut (F352) rAra h9 LTP, peanut (F427) rBet v1 PR-10, birch (T215) rBet v2 profilin, birch (T216) rCor a1 PR-10, hazelnut (F428) rCor a8 LTP, hazelnut (F425) rCor a9, hazelnut (F440)</p> | <p>Documented procedures & manufacturer's instructions for Helmed slide processor/diluter with specific reference to:</p> <p>I-46 Measurement of total and specific IgE by Phadia Immucap 250</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum unless otherwise specified (cont'd)</p> | <p><u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p><u>Detection of:</u> (cont'd)</p> <p>Detection and quantification of specific IgE: (cont'd)</p> <p>rCor a14, hazelnut (F439) rJug r1, walnut (F441) Mal d1 apple PR-10 (F434) Mal d3 apple LTP (F435) rPen a1 tropomyosin shrimp (F351) rPhl p12 profilin, timothy grass (G212) rPru p1 PR-10, peach (F419) rPru p3 LTP, peach (F420) rTri a19 omega-5 gliadin, wheat (F416) rPol d5, paper wasp (I210) rVes v1 PLA1, common wasp (I211) rVes v5, common wasp (I209)</p> <p>Screening for extrinsic alveolitis by detection of IgG</p> <p>Screening for anaphylaxis</p> <p>Detection of mast cell tryptase</p> | <p>Documented procedures & manufacturer's instructions for Helmed slide processor/diluter with specific reference to:</p> <p>I-46 Measurement of total and specific IgE by Phadia Immunocap 250</p> <p>Documented procedures & manufacturer's instructions for Thermo Scientific Phadia Immunocap 250 (Fluorescence Enzyme Immunoassay (FEIA))with specific reference to:</p> <p>I-45 Extrinsic allergic alveolitis testing by Phadia Immunocap 250</p> <p>I-42 Laboratory investigation of suspected anaesthetic reactions</p> <p>I-43 Procedure for the measurement of serum mast cell tryptase by phadia 250</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum unless otherwise specified (cont'd)</p> <p>Serum</p> | <p><u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Autoimmunity Antibodies to:</p> <p>CTD Panel:</p> <ul style="list-style-type: none"> • U1RNP (RNP70, A, C,) • SS-A/RO (60kDa, 52kDa) • SS-B/La, • centromere B • Scl-70 • Jo-1 • Fibrillarin • RNA Pol III • Rib-P • PM-Scl • PCNA • Mi-2 proteins • Sm proteins • Native purified dsDNA <p>If required: Anti-DsDNA and ENA screen:</p> <ul style="list-style-type: none"> • Human recombinant U1RNP (RNP70, A, C) • SS-A/Ro (60 kDa, 52 kDa) • SS-B/La • Centromere B • Scl-70 and Jo-1 proteins • Synthetic SmD3 peptide <p>Typing of ENA Specificities:</p> <ul style="list-style-type: none"> • Anti-Ro (SS-A) (60kDa, 52kDa) • Anti-La (SS-B) • Anti-Sm • Anti-Scl-70 • Anti-Jo-1 • Centromere B • Anti- U1RNP (RNP70, A, C) | <p>Documented procedures & manufacturer's instructions for Thermo Scientific Phadia Immunocap 250 (Fluorescence Enzyme Immunoassay (FEIA))with specific reference to:</p> <p>Thermofisher Phadia 250 ELIA IgG I-44 Procedures common to the operation of the thermofisher Phadia 250</p> <p>I-616 Measurement of CTD Antibodies by ELiA on the Thermofisher Phadia 250</p> |



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| HUMAN BODY FLUIDS (cont'd) Serum unless otherwise specified (cont'd) | <u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd) Functional evaluation of C1 esterase inhibitor | Documented procedures for chromogenic assay with specific reference to: I-262 Functional evaluation of C1 esterase inhibitor evaluation Documented procedures & manufacturer's instructions for Becton Dickinson FacsLyric Flow Cytometry and Sample Preparation with the FacsDuet specific reference to: I-565 Operation of the BD FACSDuet |
| EDTA Blood | Measurement of lymphocyte subset panel: CD3 (T cell) CD4 (T helper) CD8 (T cytotoxic) CD19 (B cell) CD16/56 (NK cell) | I-576 BD FACSLyric: Daily Start-up, Shutdown & Maintenance I-595 Measurement of TBNK by Flow Cytometry I-52 Operation and maintenance of lyse wash assistant (LWA) |
| EDTA Blood | Measurement of neutrophil respiratory oxidative burst | I-576 BD FACSLyric: Daily Start-up, Shutdown & Maintenance I-49 Measurement of neutrophil respiratory burst by flow cytometry |
| Serum | Quantification of: Anti-CCP (Cyclic Citrullinated peptide) antibody Anti-Cardiolipin IgG antibody Anti-Cardiolipin IgM antibody Anti-Beta-2 Glycoprotein IgG antibody Anti-Beta-2 Glycoprotein IgM antibody | Documented in-house procedures and manufacturer's instructions Werfen Analyser; Bio-flash I-571 Procedure for operation of the bio-flash |
| END | | |