CLINICAL IMMUNOLOGY DIGITAL SPECIALIST PORTFOLIO MODULES

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Clinical Immunology Digital Specialist Portfolio Modules

- Quality - See separate document for LOs
- Immunological Techniques
- Connective Tissue Disease
- Antiphospholipid Syndrome
- Rheumatoid Arthritis
- Coeliac Disease
- Autoimmune Liver Disease
- Pernicious Anaemia
- Renal Disease
- Neurological Disease
- Organ Specific Autoimmunity
- Myeloma and Associated Conditions
- Disorders of Immunoglobulin levels
- Complement Deficiency
- Cellular Immunodeficiency
- Allergy and Anaphylaxis

Please note

All learning outcomes (LOs) are met through two pieces of evidence, Q&A as agreed with a training officer and an additional piece of work as selected by the candidate.

A statement of work and reflective statement on each module will be required which will include sign off by the trainer stating that the candidate works in accordance with laboratory procedures, the competence for which should be evidenced in-house and is not part of the portfolio submission.

Indicative Content outlines background knowledge that may be required to meet the LOs and/or knowledge and competences expected to be demonstrated across multiple modules. Knowledge of areas highlighted in the indicative content may be examined during the viva.

Module Title	Immunological Techniques
Module code	7124
Rationale/ Aims	The candidate will gain a comprehensive understanding of all techniques used within immunology laboratories including method principle, advantages and limitations. They will be able to critically evaluate the methods and understand when and why confirmation methods are used. The candidate will understand underlying principles including fluorescent compound properties and antibody-antigen kinetics.
Learning outcomes	1. Explain the principles, advantages and limitations of methodologies used in practice, include: • Indirect immunofluorescence (including microscopy) • Enzyme linked immunosorbent assay (ELISA) • Fluorescence enzyme immunoassay (FEIA) • Chemiluminescent immunoassay (CLIA) • Immunoblot • Multiplex • Electrophoresis (CZE and gel methods) • Immunofixation • Immunotyping • Nephelometry • Turbidimetry • Flow cytometry (including compensation and gating) 2. Describe the following methods: • Isoelectric focussing • Radioimmunoassay • Radial immunodiffusion • Double diffusion • Functional assays • Haemagglutination • Particle agglutination 3. Critically evaluate IIF, ELISA, FEIA, CLIA, immunoblot and multiplex assays. 4. Explain the properties of different fluorescent compounds and how these are utilised in automated immunofluorescence readers. 5. Explain antibody-antigen reaction kinetics, including affinity, avidity, prozone and antigen excess. 6. Define the following terminology and give workplace specific examples: • Qualitative • Quantitative • Analytical sensitivity • Analytical specificity • Clinical sensitivity • Clinical specificity • Accuracy • Precision • Linearity • Limit of detection 7. Describe with examples common testing algorithms used within immunology and the rationale for selecting each method within the algorithm.

Indicative Content	Candidates will require knowledge and understanding of: Techniques used within immunology laboratories including principle, advantages and limitations. Sensitivity and specificity of assays and how this is used to determine when confirmation methods are used. Fluorescent compound properties. Antibody-antigen kinetics. Candidates must be able to run assays, troubleshoot as required and perform all aspects of quality assurance including maintenance, IQC, EQA, calibration, record keeping, non-conformance reporting.

Module Title	Connective Tissue Disease
Module code	7121
Rationale/ Aims	This module enables the candidate to interpret results of tests associated with connective tissue disease and their diagnostic value. The candidate will have a comprehensive understanding of the pathogenesis and epidemiology of connective tissue disease and the diagnostic value of the associated antibodies. The candidate will be able to identify factors which affect result interpretation and describe local testing protocols. .
Learning outcomes	1. Describe the pathogenesis and epidemiology of autoimmune connective tissue diseases including SLE, Sjogren's syndrome, systemic sclerosis (SSc, diffuse and limited) and idiopathic inflammatory myopathies. 2. Summarise the incidence of antibodies present in connective tissue disease and discuss their prognostic and diagnostic value, including the difference between myositis specific and myositis associated antibodies, using examples from practice where appropriate. 3. Recognise the nuclear and cytoplasmic ANA patterns of antibodies associated with connective tissue disease and describe the locations of targets of antibodies. 4. Demonstrate the local testing protocols for ANA, DNA, ENA and myositis antibodies. 5. Discuss the laboratory's role in the diagnosis of connective tissue diseases, comparing local practice with diagnostic guidelines and classification criteria. 6. Describe the pathogenic pathway of double stranded DNA antibodies. 7. Discuss histological findings of skin and kidney biopsies in SLE patients. 8. Describe the utility of C3 and C4 in distinguishing between SLE, Sjogren's syndrome, SSc and myositis. 9. Describe the link between malignancy and myositis and explain the clinical utility of antibodies in risk stratification. 10. Describe, with examples from local practice, the association of DNA antibodies with non-rheumatological disease.
Indicative Content	Candidates require knowledge and understanding of Connective tissue disease including the pathogenesis, epidemiology, associated antibodies and histological markers of disease. Factors which may affect result interpretation. Methods for routine analysis, local reflex testing algorithms, how to troubleshoot problems and awareness of alternative methodologies available. IQC and EQA across all assays.

Module Title	Antiphospholipid Syndrome
Module code	7125
Rationale/ Aims	This module will enable the candidate to interpret results of tests associated with antiphospholipid syndrome (APS) and their diagnostic value. The candidate will gain a comprehensive understanding of the pathogenesis and epidemiology of APS and the diagnostic value of the associated antibodies. The candidate will be able to explain the relationship between the associated antibodies and the role of the laboratory in diagnosis of APS.
Learning outcomes	1. Describe the pathogenesis and epidemiology of antiphospholipid syndrome. 2. Distinguish between primary and secondary APS. 3. Discuss the significance of APS in pregnancy. 4. Summarise the incidence of antibodies present in APS, the significance of different isotypes and their diagnostic value, using examples from practice where appropriate. 5. Compare, with examples, the laboratory role within current diagnostic guidelines and local practice. 6. Describe the relationship between: a. Beta-2 glycoprotein 1 antibodies b. Cardiolipin antibodies c. Prothrombin antibodies d. Phosphatidylserine antibodies 7. Describe where in the coagulation cascade antiphospholipid antibodies are involved.
Indicative Content	Candidates will require knowledge and understanding of: APS, including the difference between primary and secondary disease, diagnostic guidelines, the nature and significance of lupus anticoagulant activity, and the incidence of and relationship between associated antibodies. The coagulation cascade and where APS associated antibodies are involved. Factors which may affect result interpretation and protocols for reflex testing. Methods for routine analysis, how to troubleshoot problems and awareness of alternative methodologies available. IQC and EQA across all assays.

Module Title	Coeliac disease
Module code	7126
Rationale/ Aims	This module will enable the candidate to interpret results of tests associated with coeliac disease and their diagnostic value. The candidate will gain a comprehensive understanding of the pathogenesis and epidemiology of coeliac disease and the diagnostic value of the associated antibodies. The candidate will be able to identify factors which affect result interpretation and describe both the recommended and local testing protocols.
Learning outcomes	1. Describe the pathogenesis and epidemiology of coeliac disease. 2. Describe the relationship between coeliac disease and dermatitis herpetiformis. 3. Discuss the incidence of antibodies present in coeliac disease and their diagnostic value, using examples from practice where appropriate. 4. Explain the factors which affect result interpretation and summarise local protocols to confirm results. 5. Compare, with examples from practice, the laboratory role within NICE guideline NG20 and local practice. 6. Recognise the endomysial antibody pattern on IIF and distinguish between this and other antibodies that may react with the tissue substrate. 7. Identify when jejunal biopsy is required in the diagnosis of coeliac disease. 8. Discuss HLA DQ2/DQ8 associations in coeliac disease.
Indicative Content	Candidates will have knowledge and understanding of: Coeliac disease including pathogenesis, epidemiology, relationship to dermatitis herpetiformis, HLA associations and the incidence of associated antibodies. Factors which may affect result interpretation and protocols for reflex testing. Methods for routine analysis, how to troubleshoot problems and awareness of alternative methodologies available. IQC and EQA across all assays.

Module Title	Rheumatoid Arthritis
Module code	7128
Rationale/ Aims	This module will enable the candidate to interpret results of tests associated with rheumatoid arthritis and their diagnostic value. The candidate will gain a comprehensive understanding of the pathogenesis and epidemiology of rheumatoid arthritis and the diagnostic value of the associated antibodies. The candidate will be able to describe the clinical and image findings required in the diagnosis of rheumatoid arthritis.
Learning outcomes	1. Describe the pathogenesis and epidemiology of rheumatoid arthritis. 2. Summarise the incidence of antibodies present in rheumatoid arthritis and their diagnostic value, using examples from practice where appropriate. 3. Discuss the significance of different immunoglobulin isotypes of rheumatoid factor. 4. Compare, with examples, the laboratory role within NICE guideline NG100 and local practice. 5. Summarise and discuss the clinical and image findings required in the diagnosis of rheumatoid factor. 6. Summarise HLA associations in rheumatoid arthritis and discuss their importance. 7. Describe conditions other than rheumatoid arthritis that rheumatoid factor is associated with and use examples to demonstrate how this can affect clinical decisions.
Indicative Content	Candidates require knowledge and understanding of: Rheumatoid arthritis including the pathogenesis, epidemiology, diagnostic criteria, HLA associations and the incidence of associated antibodies. The laboratory, clinical and image findings required in the diagnosis of rheumatoid arthritis. Factors which may affect result interpretation. Methods for routine analysis, how to troubleshoot problems and awareness of alternative methodologies available. IQC and EQA across all assays.

Module Title	Autoimmune Liver Disease
Module code	7129
Rationale/ Aims	This module will enable the candidate to interpret results of tests associated with liver disease and their diagnostic value. The candidate will have a comprehensive understanding of the pathogenesis of autoimmune liver disease and the diagnostic value of measuring different antibodies and their clinical association. The candidate will be able to identify factors which affect result interpretation and describe both the recommended and local testing protocols.
Learning outcomes	1. Explain the pathogenesis and epidemiology of autoimmune liver disease. 2. Summarise the incidence of antibodies present in autoimmune liver disease and their diagnostic value, using examples from practice where appropriate. 3. Explain the different patterns seen on Immunofluorescence for antibodies associated with autoimmune liver disease. 4. Demonstrate, with examples from your practice, interpretation of immunology results relating to clinical picture and other pathology results. 5. Discuss factors which may affect interpretation of antibodies associated with autoimmune liver disease, include one example from practice. 6. Appraise published guidelines and classification criteria associated with different autoimmune liver disease. 7. Review the clinical utility of mitochondrial antibody sub-typing.
Indicative Content	Candidates require knowledge and understanding of: Autoimmune liver disease including incidence, pathogenesis, associated antibodies, epidemiology, and clinical manifestation. Factors which may affect result interpretation. Methods for routine analysis, local reflex testing algorithms, how to troubleshoot problems and awareness of alternative methodologies available. IQC and EQA across all assays.

Module Title	Pernicious Anaemia
Module code	7122
Rationale/ Aims	This module will enable the candidate to interpret results of tests associated with pernicious anaemia and their diagnostic value. The candidate will have a comprehensive understanding of the pathogenesis of pernicious anaemia and the diagnostic value of measuring different antibodies and their clinical association. The candidate will be able to identify factors which affect result interpretation and describe both the recommended and local testing protocols.
Learning outcomes	1. Discuss the pathogenesis and epidemiology of pernicious anaemia. 2. Summarise the incidence of antibodies present in pernicious anaemia and their diagnostic value, using examples from practice where appropriate. 3. Explain the pattern seen on Immunofluorescence for antibodies associated with pernicious anaemia. 4. Describe the pathogenetic pathway of gastric parietal cell antibodies. 5. Give examples of clinical scenarios related to disorders of pernicious anaemia. 6. Explain, with examples from practice, factors which may affect interpretation of antibodies associated with pernicious anaemia. 7. Appraise published guidelines and classification criteria associated with pernicious anaemia.
Indicative Content	Candidates require knowledge of: Pernicious anaemia including incidence, pathogenesis, associated antibodies, epidemiology, and clinical manifestation. Factors which may affect result interpretation. Methods for routine analysis, local reflex testing algorithms, how to troubleshoot problems and awareness of alternative methodologies available. IQC and EQA across all assays.

Module Title	Neurological Disease
Module code	7123
Rationale/ Aims	This module will enable the candidate to interpret results of tests associated with Neurological disease and their diagnostic value. The candidate will have a comprehensive understanding of the pathogenesis of a number of autoimmune disorders of the immune system and the diagnostic value of measuring different antibodies and their clinical association. The candidate will be able to identify factors which affect result interpretation and describe both the recommended and local testing protocols.
Learning outcomes	1. Explain the pathogenesis of a number of neurological disorders including myasthenia gravis, paraneoplastic disease, multiple sclerosis, Stiff Person syndrome and Guillan Barre syndrome. 2. Discuss, and demonstrate with examples from practice, how antibodies may be used in the diagnosis of the following conditions: • Myasthenia gravis • Stiff person syndrome • Lambert Eaton myasthenic syndrome • Paraneoplastic disease • Myelin oligodendrocyte glycoprotein antibody associated disease (MOGAD) • Neuromyelitis optical spectrum disorder (NMOSD) • Autoimmune encephalopathies • Immunologically mediated peripheral neuropathies • Multiple sclerosis 3. Summarise the clinical sensitivities and specificities of the following antibodies: • Acetylcholine receptor • Muscle specific kinase (MUSK) • Striated muscle • Glutamic Acid Decarboxylase (GAD) • Volktage gated calcium channel • Paraneoplastic antibodies (Yo, Hu, Ri etc) • MOG • Aquaporin 4 • Voltage gated potassium channel • LGI-1 • CASPR2 • NMDA • AMPA • GABA • Gangliosides 4. Describe interpretation of patterns in oligoclonal banding, how they arise and the conditions each is associated with.

	5. Explain factors which may affect interpretation of antibodies associated with neurological disease. 6. Appraise published guidelines, classification criteria, and testing algorithms associated with neurological disease. 7. Demonstrate awareness of the emergence of novel antibodies associated with neurological disease. 8. Explain challenges in diagnosis of neurological disease during clinical presentation and the impact of delayed diagnosis on patient outcomes.
Indicative Content	Candidates require knowledge of: Neurological disorders of the immune system including incidence, pathogenesis, associated antibodies, epidemiology, and clinical manifestation. Factors which may affect result interpretation. Methods for routine analysis, local reflex testing algorithms, how to troubleshoot problems and awareness of alternative methodologies available. IQC and EQA across all assays.

Module Title	Renal Disease
Module code	7130
Rationale/ Aims	This module will enable the candidate to interpret results of tests associated with autoimmune renal disease and their diagnostic value. The candidate will have a comprehensive understanding of the pathogenesis of small vessel vasculitis and Idiopathic Membranous Nephropathy and the diagnostic value of measuring different antibodies and their clinical association. The candidate will be able to identify factors which affect result interpretation and describe both the recommended and local testing protocols.
Learning outcomes	1. Describe the pathogenesis and epidemiology of autoimmune vasculitis in Including small vessel vasculitis, Anti-GBM Disease and Idiopathic Membranous Nephropathy. 2. Explain the patterns seen on Immunofluorescence for antibodies associated with small vessel vasculitis. 3. Summarise the incidence of antibodies present in autoimmune vasculitis and their diagnostic value, using examples from practice where appropriate. 4. Demonstrate the local testing protocols for ANCA, MPO and PR3. 5. Give examples of clinical scenarios related to autoimmune renal disease. 6. Explain factors which may affect interpretation of antibodies associated with autoimmune renal disease. 7. Appraise published guidelines, classification criteria, and testing algorithms associated with autoimmune renal disease.
Indicative Content	Candidates require knowledge of: Autoimmune renal disease including incidence, pathogenesis, associated antibodies, epidemiology, and clinical manifestation. Factors which may affect result interpretation. Methods for routine analysis, local reflex testing algorithms, how to troubleshoot problems and awareness of alternative methodologies available. IQC and EQA across all assays.

Module Title	Organ Specific Autoimmunity
Module code	7127
Rationale/ Aims	This module will enable the candidate to interpret results of tests associated with organ-specific autoimmunity and their diagnostic value. The candidate will have a comprehensive understanding of the pathogenesis of a number of organ-specific autoimmune disorders of the immune system and the diagnostic value of measuring different antibodies and their clinical association. The candidate will be able to identify factors which affect result interpretation and describe both the recommended and local testing protocols.
Learning outcomes	1. Explain the pathogenesis and epidemiology of organ specific autoimmune disorders including Addison's disease, autoimmune endocrinopathies, Graves' disease, Hashimotos thyroiditis, Type 1 diabetes, bullous pemphigoid and pemphigus vulgaris. 2. Discuss how antibodies may be used in the diagnosis of Addison's disease and understand their clinical sensitivities and specificities, including antibodies to adrenal cortex. 3. Discuss how antibodies may be used in the diagnosis autoimmune endocrinopathies and understand their clinical sensitivities and specificities, including antibodies to Ovary and Testis. 4. Discuss how antibodies may be used in the diagnosis of thyroid disease and understand their clinical sensitivities and specificities, including thyroid peroxidase antibody, thyroglobulin antibodies and Thyroid Stimulating Receptor antibody (TSH-R). 5. Discuss how antibodies may be used in the diagnosis of Type 1 diabetes and understand their clinical sensitivities and specificities, including antibodies to Islet Cells, GAD, IA2, ZnT8 and Insulin antibodies. 6. Discuss how antibodies may be used in the diagnosis of Autoimmune skin disorders. Understand their clinical sensitivities and specificities, including antibodies to BP180 (epidermal basement membrane) and DSG 1/3 (desmosome). 7. Explain factors which may affect interpretation of antibodies associated with organ specific autoimmunity. 8. Appraise published guidelines, classification criteria, and testing algorithms associated with neurological disease.
Indicative Content	Candidates require knowledge and understanding of: Organ-specific autoimmune disorders including incidence, pathogenesis, associated antibodies, epidemiology, and clinical manifestation. Factors which may affect result interpretation. Methods for routine analysis, local reflex testing algorithms, how to troubleshoot problems and awareness of alternative methodologies available. IQC and EQA across all assays.

Module Title	Myeloma and Associated Conditions
Module code	7133
Rationale/ Aims	This module will enable the candidate to interpret results of tests in the diagnosis of myeloma, monoclonal gammopathies, cryoglobulinaemia and associated conditions. The candidate will gain a comprehensive understanding of the pathogenesis and epidemiology of myeloma, monoclonal gammopathies and cryoblobulinaemia and the clinical significance of abnormal results. The candidate will be able to identify factors which affect result interpretation and describe both the recommended and local testing protocols.
Learning outcomes	1. Describe the pathogenesis and epidemiology of multiple myeloma and associated monoclonal gammopathies. 2. Describe the class and structure of immunoglobulins. 3. Summarise the relationship between serum and urine proteins. 4. Demonstrate the effects of time, temperature, pH, preservatives and sample integrity on immunoglobulins with examples for each of how this is identified during analysis. 5. Demonstrate, using examples from practice, the process for detection, identification and quantification of monoclonal proteins in serum and urine. 6. Discuss, with examples, other conditions associated with abnormal immunoglobulins. 7. Explain cryoglobulinaemia and differentiate between the types. 8. Summarise local cryoglobulin sample collection processes and problems associated with unsuitable samples. 9. Describe the process for detection of cryoglobulin and the clinical significance of abnormal results. 10. Appraise published guidelines and diagnostic criteria associated with different autoimmune liver disease
Indicative Content	Candidates require knowledge and understanding of: Myeloma and associated conditions including pathogenesis, epidemiology, immunoglobulin structure, relationship between serum and urine proteins and types of cryoglobulinaemia. Factors which may affect result interpretation and testing protocols for monoclonal proteins and cryoglobulins. Methods for routine analysis, how to troubleshoot problems and awareness of alternative methodologies available. IQC and EQA across all assays.

Module Title	Disorders of Immunoglobulin levels
Module code	7132
Rationale/ Aims	This module enables the candidate to interpret results of tests associated with disorders of Immunoglobulin levels and their diagnostic value. The candidate will have a comprehensive understanding of the pathogenesis of several disorders of Immunoglobulin levels and the diagnostic value of measuring different antibodies and their clinical association. The candidate will be able to identify factors which affect result interpretation and describe both the recommended and local testing protocols.
Learning outcomes	1. Explain the pathogenesis and epidemiology of disorders of Immunoglobulin levels such as Selective IgA deficiency, Hyper IgM disease Common Variable Immunodeficiency and IgG4 related disease. 2. Discuss, with examples from local practice, how measurement of Immunoglobulins may be used in the diagnosis of immunodeficiency and understand their clinical sensitivities and specificities. 3. Discuss, with examples from local practice, how the measurement of immunoglobulin levels may vary in different clinical presentations e.g. liver disease, HIV, and its utility in the diagnosis of coeliac disease. 4. Discuss, with examples from local practice, how measurement of Immunoglobulins may be used in the diagnosis of Hyper IgM syndrome and other tests which may link in with this diagnosis. 5. Discuss, with examples from local practice, how measurement of Immunoglobulins may be used in the diagnosis of CVID and other tests which will link into this immunoglobulin profile. 6. Discuss, with examples from local practice, how specific antibody responses may be used in the diagnosis of immunodeficiency. Understand their clinical sensitivities and specificities, including antibodies Pneumococcus, Haemophilus influenzae and tetanus toxoid. 7. Discuss, with examples from local practice, how IgG subclass levels may be used in the diagnosis of immunodeficiency and igG4RD. 8. Explain factors which may affect interpretation of immunoglobulin levels. 9. Appraise published guidelines, classification criteria, and testing algorithms associated with disorders of Immunoglobulin levels.
Indicative Content	Candidate requires knowledge and understanding of: Disorders of Immunoglobulins including incidence, pathogenesis, epidemiology, and clinical manifestation. Factors which may affect result interpretation. Methods for routine analysis, local reflex testing algorithms, how to troubleshoot problems and awareness of alternative methodologies available. IQC and EQA across all assays.

Module Title	Complement Deficiency
Module code	7131
Rationale/ Aims	This module enables the candidate to interpret results of tests associated with complement deficiency, disorders of complement dysregulation and their diagnostic value. The candidate will have a comprehensive understanding of the pathogenesis of complement deficiency and dysregulation and the diagnostic value of measuring different complement components and their associated function. The candidate will be able to identify factors which affect result interpretation and describe both the recommended and local testing protocols.
Learning outcomes	1. Explain the different complement activation pathways, effector functions and regulatory mechanisms. 2. Discuss the pathogenesis and epidemiology of complement deficiency and disorders of complement dysregulation including hereditary Angioedema (HAE), acquired angioedema (AAE), atypical haemolytic uraemic syndrome (aHUS), paroxysmal nocturnal haemoglobinuria (PNH) and C3 glomerulopathy (C3G). 3. Compare the results you might find in Hereditary Angioedema Type I, II and III and acquired angioedema. 4. Compare the techniques available for the measurement of complement function. 5. Discuss, with examples, clinical scenarios and abnormal results related to disorders of complement function. 6. Explain, with examples from local practice, the effects of time, temperature, pH, preservatives sample transport and storage temperatures on complement component and functional assay measurement which can affect result interpretation. 7. Discuss the importance of vaccination in patients with primary and secondary complement deficiency. 8. Discuss the role of complement blockade in the treatment of disorders of complement dysregulation and secondary complement deficiency including eculizumab, ravalizumab and other complement therapeutics. 9. Review the importance of complement genetic testing including UK genetics panels for complement PID (R15), HAE, aHUS and C3G.
Indicative Content	Candidates require knowledge and understanding of: Complement Immunodeficiency including incidence, pathogenesis, epidemiology, and clinical manifestation. Factors which may affect result interpretation. Methods for routine analysis, local reflex testing algorithms, how to troubleshoot problems and awareness of alternative methodologies available. IQC and EQA across all assays, including the importance of international schemes due to the shortfall in EQA provision for specialist and functional assays.

Module Title	Cellular Immunodeficiency
Module code	7135
Rationale/ Aims	This module will enable the candidate to interpret results of tests associated with cellular immunodeficiency and their diagnostic value. The candidate will gain a comprehensive understanding of the pathogenesis and epidemiology of cellular immunodeficiency and the diagnostic value of determining different cell populations and their associated function. The candidate will be able to identify factors which affect result interpretation and describe both the recommended and local testing protocols.
Learning outcomes	1. Describe blood cell morphology and phenotypic characterisation. This should include CD nomenclature with reference to lineage, maturation and activation. 2. Demonstrate, with examples from local practice, distinguishing between the presence / absence of lymphocyte populations and their different phenotypic manifestations. 3. Discuss the process of neutrophil activation, chemotaxis, phagocytosis and killing. 4. Appraise the use of different techniques in the investigation of neutrophil function. 5. Demonstrate results you might find in chronic granulomatous disease (CGD), a carrier of X-linked CGD and a normal patient. 6. Appraise the techniques available for the measurement of T-cell function. 7. Demonstrate, with examples from your practice, the role of the laboratory in the investigation of cellular immunodeficiency with reference to ESID guidelines, UK national protocols and local practice. 8. Explain the factors which affect result interpretation and summarise local protocols to confirm and further investigate abnormal results.
Indicative Content	Candidates require knowledge and understanding of: Cellular Immunodeficiency including incidence, pathogenesis, epidemiology, and clinical manifestation. Factors which may affect result interpretation and protocols for further investigation. Techniques available for the measurement of T-cell and neutrophil function.

Module Title	Allergy and Anaphylaxis
Module code	7134
Rationale/ Aims	This module will enable the candidate to have a comprehensive understanding of the cause and physiology of allergy and hypersensitivity and the clinical significance of abnormal results. The candidate will be able to explain laboratory and clinical testing and the clinical scenarios where specific IgE analysis may be particularly relevant. The candidate will be able to identify factors which affect result interpretation and describe both the recommended and local testing protocols.
Learning outcomes	1. Describe the 4 types of hypersensitivity. 2. Explain the steps of allergy, from sensitisation to allergic response. 3. Describe the clinical features of allergic diseases. 4. Distinguish between laboratory and clinical allergy testing in diagnosis, with examples of clinical scenarios (e.g. bee/wasp sensitivity, nut allergy, penicillin reaction). 5. Explain, with examples, the purpose of testing specific IgE mixes, whole allergens and recombinant allergens and how these results contribute to clinical decision making. 6. Explain allergen cross reactivity with examples to demonstrate the effect on result interpretation. 7. Demonstrate, with examples from practice, conditions where total IgE measurement is clinically useful. 8. Summarise the IgG precipitins involved in type III hypersensitivity and the diseases associated with each. 9. Explain the clinical utility of tryptase and the purpose of serial measurement in anaphylaxis. 10. Appraise the advice given for tryptase testing in NICE guideline for anaphylaxis CG134.
Indicative Content	Candidates require knowledge and understanding of: Allergy and hypersensitivity including sensitisation, allergic response, anaphylaxis, oral allergy syndrome and atopy. Clinical utility of total IgE, specific IgE, IgG precipitins and tryptase testing in allergy, hypersensitivity and non-allergy investigations. Factors which may affect result interpretation and testing protocols for allergy and hypersensitivity testing. Methods for routine analysis, how to troubleshoot problems and awareness of alternative methodologies available. IQC and EQA across all assays.

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