Portfolio for Assessment for the ACS Certificate of Attainment

XXXX

Clinical Immunology

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COMPETENCES REQUIRED FOR APPLICANTS TO ATTAIN STATE REGISTRATION AS CLINICAL SCIENTISTS					
MODALITY:	**Clinical Immunology**	**SUBMODALITY: (if applicable)**		**APPLICANT'S NAME:**	**XXXX XXXX**

APPENDIX 1

This set of documents must be completed and returned in your portfolio.
Please complete the three header sections above on each page.
Refer to the Specific Competences document for guidance in completing this document.
Use typescript or black ink and block capitals for all sections.

EXPERIENCE: The candidate should be able to demonstrate that he/she has worked in an environment that has enabled the individual to receive training and gain experience relevant to the competences set out below.

SCIENTIFIC

HPC Standards of Proficiency Codes for Clinical Scientists	AREA OF COMPETENCE	INDICATE SECTION(S) IN PORTFOLIO WHERE COMPETENCE IS DEMONSTRATED
3a.1p	• understanding the science that underpins the specialty (modality) and the broader aspects of medicine and clinical practice	Sections: 1.1 2.1 2.3 2.4
3a.1g	• demonstrating a strong base of knowledge appropriate to the specialty and to the investigations and therapeutic options available	Sections: 2.1 2.6
2b.1g 2b.1p	• experience of searching for knowledge, critical appraisal of information and integration into the knowledge base	Sections: 1.1 1.2 2.1 2.2
2b.1g	• ability to apply knowledge to problems associated with the routine provision, and development, of the service	Sections: 3.1.1 3.1.3 3.1.4 3.1.6
2a.1p	• ability to identify the clinical decision which the test/intervention will inform	Sections: 2.1 2.3.4 3.1.5 5.3
2c.1p	• ability to make judgements on the effectiveness of procedures	Sections: 3.1.3 3.2.2 3.2.3 5.2
3a.2g	• application of the knowledge base to the specialty (modality) and to the range of procedures/investigations available	Sections: 3 5

Created: 16 August 2002
Modified: 1 July 2003
Reference: DOC-ACS002-Generic Competences
Version: Rev-02 – Codes related to HPC Standards of Proficiency documents (g=generic; p=profession specific)

COMPETENCES REQUIRED FOR APPLICANTS TO ATTAIN STATE REGISTRATION AS CLINICAL SCIENTISTS					
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CLINICAL

HPC Standards of Proficiency Codes for Clinical Scientists	AREA OF COMPETENCE	INDICATE SECTION(S) IN PORTFOLIO WHERE COMPETENCE IS DEMONSTRATED
2b.1p	• ability to provide interpretation of data and a diagnostic (therapeutic) opinion, including any further action to be taken by the individual directly responsible for the care of the patient	Sections: 3.1.5 3.1.6
3a.1p	• understanding of the wider clinical situation relevant to the patients presenting to his/her specialty	Sections: 2.1 2.5 3.3 5.3 5.4
2b.3p	• ability to develop/devise an investigation strategy taking into account the complete clinical picture	Sections: 2.1 2.6 3.1.5
3a.2p	• understanding of the clinical applications of his/her specialty and the consequences of decisions made upon his/her actions/advice	Sections: 2.1 2.3 2.4 3 5.3
3a.2p	• awareness of the evidence base that underpins the use of the procedures employed by the service	Sections: 2.1 2.3 2.4 3.3

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TECHNICAL

HPC Standards of Proficiency Codes for Clinical Scientis	AREA OF COMPETENCE	INDICATE SECTION(S) IN PORTFOLIO WHERE COMPETENCE IS DEMONSTRATED
3a.2p	• understanding of the principles associated with a range of techniques employed in the modality	Sections: 2.1 2.3 2.4
3a.2p	• knowledge of the standards of practice expected from these techniques	Sections: 2.1 2.3 2.4
2b.4p	• experience of performing these techniques	Sections: 2.3 2.4 3.1.1 4 5.2
2b.4p	• the ability to solve problems that might arise during the routine application of these techniques (troubleshooting)	Sections: 2.3 2.4 3.1.3
2c.2g	• understanding of the principles of quality control and quality assurance	Sections: 2.1 2.1.10 2.3 2.3.11 3.1.4
2c.1p	• experience of the use of quality control and quality assurance techniques including restorative action when performance deteriorates	Sections: 2.3.11 3.1.1 3.1.4 3.2.2

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RESEARCH AND DEVELOPMENT

HPC Standards of Proficiency Codes for Clinical Scientists	AREA OF COMPETENCE	INDICATE SECTION(S) IN PORTFOLIO WHERE COMPETENCE IS DEMONSTRATED
2b.1p	• ability to read and critically appraise the literature	Sections: 1.1 1.2 2.1 2.2
2b.1p	• ability to develop the aims and objectives associated with a project	Sections: 1.2 1.3 2.2 4
2b.1p	• ability to develop an experimental protocol to meet the aims and objectives in a way that provides reliable and robust data (i.e. free of bias)	Sections: 1.2 1.3 2.2 3.2 4
2b.1p	• ability to perform the required experimental work ability to produce and present the results (including statistical analysis)	Sections: 1.2 1.3 2.2 3.2 4
2b.1p	• ability to critically appraise results in the light of existing knowledge and the hypothesis developed and to formulate further research questions	Sections: 1.2 2.2 4
2b.1p	• ability to present data and provide a critical appraisal to an audience of peers – both spoken and written	Sections: 1.2 1.3 2.2 4

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COMMUNICATION

HPC Standards of Proficiency Codes for Clinical Scientists	AREA OF COMPETENCE	INDICATE SECTION(S) IN PORTFOLIO WHERE COMPETENCE IS DEMONSTRATED
-	• ability to assess a situation and act accordingly when representing the specialty	Sections: 3.1.2 3.1.3 3.1.6 5.3
1b.2p	• ability to respond to enquiries regarding the service provided when dealing with clinical colleagues	Sections: 2.3.2 3.1.1 3.1.6 5.3
1b.4g	• ability to communicate with patients, carers and relatives, the public and other healthcare professionals as appropriate	Sections: 2.3.2 3.1.2 3.1.3 3.1.6 5.3
1b.5p	• ability to communicate the outcome of problem solving and research and development activities	Sections: 1.2 2.2 3.1.3 4
2b.1p 1b.5p	• evidence of presentation of scientific material at meetings and in the literature	Section: 2.2

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PROBLEM SOLVING

HPC Standards of Proficiency Codes for Clinical Scientists	AREA OF COMPETENCE	INDICATE SECTION(S) IN PORTFOLIO WHERE COMPETENCE IS DEMONSTRATED
2a.2g 2c.1g	• to assess a situation	Sections: 3.1.1 3.1.3 3.1.4 3.1.5 3.2.2 3.2.3 5.4
2b.1g	• determine the nature and severity of the problem	Sections: 3.1.3 3.2.3
2b.1g	• call upon the required knowledge and experience to deal with the problem	Sections: 3.1.3 3.2.3
2b.1g	• initiate resolution of the problem	Sections: 3.1.3 3.2.3
-	• demonstrate personal initiative	Sections: 2.2 3.1.2 3.1.3 5.5

MANAGEMENT

HPC Standards of Proficiency Codes for Clinical Scientists	AREA OF COMPETENCE	INDICATE SECTION(S) IN PORTFOLIO WHERE COMPETENCE IS DEMONSTRATED
-	• to understand the principles of management	Sections: 2.1.10 2.3.10 3 5.5
2c.2g 3a.3g 2c.2p	• to understand the principles of quality assurance, audit, safety and accreditation relevant to a specific discipline	Sections: 2.1.10 2.3 2.4 3.1.4 3.2.3 5.4

Note:

The above are the generic competences that must be met by all Clinical Scientists. These competences have also been mapped onto specific subjects. Copies of these can be obtained from the ACS Administrative Office and the website.

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1 Pre Grade A Training

1.1 BSc (Hons) Physiology

From XXXX to XXXX I attended the University of XXXX and studied for a Bachelor of Science degree in Physiology. This was a four-year full time modular degree and gave me a good grounding in a number of scientific disciplines. Honours modules studied included cellular pathology, physiology, pharmacology, neurobiology, molecular biology, immunology and statistics. Twenty five percent of the Honours course was dedicated to practical modules, giving me an introduction to many of the techniques and concepts used in clinical and research laboratories, and much experience in report writing and data handling. In the final semester I took a "recent advances" module that required a large amount of study and evaluation of the recent literature on several different topics, before answering exam questions on developments in the field.
I graduated from XXXX in June XXXX with an upper second class honours degree in Physiology.

1.2 BSc Project

In the final year of my degree I spent twelve weeks carrying out a research project in the Pharmacology Department at the University of XXXX, under the supervision of Dr XXXX. The title of my thesis was "The involvement of Arachidonic Acid in the late stages of ACTH secretion from permeabilized AtT-20 cells". The aim of the project was to further characterise the mechanism of stimulus-secretion coupling for ACTH and to further define the role of arachidonic acid and its metabolites in this process. The techniques employed in this research included cell culture and cell counting, electropermeabilisation of the AtT20 cells, cell stimulation experiments and radioimmunoassay for the quantification of ACTH. A thesis of 10000 words was submitted, and both oral and poster presentations were made to fellow students and supervisors. This work gave me an insight into academic research and experience in the personal initiative and independence required in this field. I also gained valuable experience in the handling and analysis of data.

1.3 Student Placement, XXXX

In the summer vacation between my penultimate and final years at XXXX I undertook a placement at XXXX. I worked in the Quality Control Virology/Immunology Department and completed three different projects – one as part of a team and two alone. My individual assignments were to use commercial ELISA methods to determine the levels of 1) antibodies to

pneumococcal capsular polysaccharide (IgG and IgG2) and 2) parvovirus B19 (IgG) in different batches of intravenous immunoglobulin (IVIG) preparation.

I also tested the stability of these antibodies by assaying IVIG stored at different temperatures for various lengths of time, as these data were required for the licensing of the product. Whilst working on these projects I identified a quality control error with one of the ELISA kits which resulted in XXXX being reimbursed for all kits used and all further kits from the manufacturers being required to include an amendment sheet. The third project I was involved with was to design and implement a method to evaluate and validate a robotic ELISA processor as part of a team with another placement student. This gave me my first experience of the procedures used for equipment validation and provided a valuable introduction to emerging automated technology. Full reports were written for each project with an oral presentation being given to the department at the end of my placement.
My placement at XXXX was very beneficial as it gave me experience of working to strict GLP and GMP standards in a professional scientific environment. It also gave me an insight into working in industry.

Thanks to both my time at XXXX and the immunology content of my BSc, I developed a strong interest in immunology and applied for a Grade A Clinical Immunologist training post during the final year of my degree.

2 Grade A Training

In September XXXX I took up the position of Regional Grade A trainee in Clinical Immunology at XXXX Hospital, XXXX in the Immunology department. My training consisted of practical experience gained through rotating around the department and secondments to other laboratories, and theoretical training in the form of a Masters Degree in Medical Immunology.

2.1 MSc Medical Immunology

During the first two years of my training I studied for a Master of Science degree in Medical Immunology at the University of XXXX. This was a two-year part time degree course consisting of lectures, seminars, tutorials and practical sessions, as well as the submission of a research project thesis. The course was aimed at both scientists and clinicians working in clinical immunology and in research. It set out to provide students with the background to, and knowledge of, recent advances in the physiology of the immune system and the impact these advances are having on the understanding, diagnosis and treatment of immunological disease processes. The course has been designed to meet the specific training requirements for the MRCPath in Immunology.

The course comprised ten modules, taught at several different centres:

Centres listed here

The award of the MSc degree was based on performance in two written essay papers, a practical examination, the research project, submission of a satisfactory practical folder and an oral examination.

Breakdown of Modules

2.1.1 Molecular Immunology

This module provided a grounding in the molecular biology of the immune system and was designed to bring all students up to date with recent advances in the field before progression to more medically oriented modules later in the course. Major topics covered included the nature of antigens, immunoglobulin structure and function, antigen-antibody interactions, antibody affinity, the genetic basis of antibody diversity, complement, the major histocompatability complex, B cells and antibodies, mannose binding lectin and monoclonal antibodies.

Practical techniques covered included purification of immunoglobulins, measurement of antibody affinity, gel electrophoresis, western and dot blotting, techniques for antibody labelling and quantification of immunoglobulins.

2.1.2 Cellular Immunology

Following on from the molecular immunology module, this module was designed to cover both the basic principles of cellular immunology and the more recent advances in the field, with a view to setting the scene for future modules that would deal with pathological and clinical aspects of immunology. Topics covered included:

- T cells – ontogeny and function
- B cells – ontogeny and function
- Accessory cells – dendritic cells, natural killer cells, monocytes, macrophages
- Cellular Interactions – acquired and innate immune systems, B and T cells
- Cytokines – co-ordination of the immune response, signalling, interactions

2.1.3 Organ-Specific Autoimmunity

This module first looked at the theoretical basis of autoimmunity and explored the mechanisms that might lead to a breakdown in tolerance and to autoimmune disease.

Several diseases were then studied in depth, looking at their pathophysiology, clinical presentation, immunodiagnosis and the therapies used to treat them. These diseases included autoimmune thyroid disease, type 1 diabetes, autoimmune skin blistering diseases, autoimmune liver diseases, myaesthenia gravis, multiple sclerosis and autoimmune gut disease.

2.1.4 Non Organ-Specific Autoimmunity

This module addressed systemic autoimmune disease, starting with the diagnosis of autoimmune rheumatic disease and the interpretation of diagnostic tests. Animal models of autoimmunity and the possible role of infection in the pathogenesis of autoimmune disease were also considered. Diseases studied in depth included SLE, vasculitis, rheumatoid arthritis, Sjogren's syndrome, polymyositis and scleroderma. The final section of the module looked at current therapies for non organ-specific autoimmune diseases and the use of immunotherapy.

2.1.5 Cancer and the Immune System

The initial lectures in this module covered an introduction to neoplasia and a general overview of blood cell maturation, lineage and markers. Teaching then turned more specifically to tumour immunology, the impact cancer can have on the immune system, and the immunological consequences of anti-cancer therapy. Topics covered included malignant lymphoma, monoclonal antibodies in diagnosis and treatment, tumour antigens, serum markers, and the role of cytokines in the host-tumour relationship. The final part of the module addressed the current and potential uses of immunotherapy, cancer vaccines and gene therapy in the treatment of cancer.

2.1.6 Infectious Diseases

This module commenced with an overview of the mechanisms of host defence against infective agents (bacteria, viruses, fungi, protozoa and helminths) and the ways in which these agents can evade the immune system. Undesirable effects of the host response were also covered such as tissue damage and infective shock.

A number of clinical syndromes arising from infection were studied including tuberculosis, leprosy, gastrointestinal infections, viral hepatitis, influenza, viral haemorrhagic fevers, schistosomiasis, meningococcal disease, malaria, fungal diseases and prion disease. Lastly there was a focus on vaccination, looking both at current practices and possible future approaches.

2.1.7 Extrinsic Allergic Disease

This module covered the spectrum of allergic disease and addressed its increasing importance in the light of rising prevalence in both adults and children. Particular attention was paid to the involvement of different cell types and inflammatory mediators in allergy, and how knowledge of the different mechanisms involved can contribute to development of therapeutic strategies. The immunobiology of IgE was studied, along with the role of T cells, mast cells, basophils, eosinophils and macrophages. After this initial look at the processes involved in allergy the immunopharmacology, immunopathogenesis and clinical features of asthma, allergic rhinitis, urticaria and anaphylaxis were covered. The final part of the module concentrated on the diagnosis and treatment of allergic disease, with particular emphasis on immunotherapy.

Practical demonstrations included the measurement of IgE, in situ hybridisation, immunohistology, skin prick testing and nasal/bronchial provocation testing.

2.1.8 Transplantation Immunology

This module covered the clinical and immunological aspects of solid organ and stem cell transplantation. Initially transplantation in general was covered including the MHC, antigen presentation, allorecognition and cellular and humoral mechanisms of graft rejection. Tolerance induction and the effects of cytokine polymorphisms and minor histocompatability antigens on transplant outcome were also studied. Bone marrow and stem cell transplantation were covered in depth, including graft versus host disease, the graft versus leukaemia effect, immunological reconstitution following stem cell transplant and post transplant monitoring. Also studied in depth were renal and heart transplantation, blood transfusion and the prospects of xenotransplantation for the future.

At the end of the module the serological, molecular and cellular techniques used in tissue typing were covered, as well as post transplant therapy (including immunosupressive drugs and immunomodulation).

2.1.9 Immunodeficiency

This module started by covering haemopoietic and immune-cell maturation pathways in an introduction to the primary immunodeficiencies caused by genetic defects therein. The genetics, molecular basis and clinical features of B cell, T cell, neutrophil and complement deficiency syndromes were studied in depth, in conjunction with the investigation of immunodeficiency.

Also covered were antibody deficiencies and their diagnosis and treatment, and secondary immune deficiencies with a focus on HIV and AIDS. Strategies for treating immunodeficiencies and the infections resulting from these conditions were considered in the final part of the module.

2.1.10 Immunodiagnosis, Quality Control and Laboratory Management

This module had two main aims:

1. To analyse and clarify how laboratory practice in immunology interacts with clinical decision making in the diagnosis of disease and the care of patients.
2. To identify the various ways in which criteria of 'quality' determine the operational management and output of an immunological laboratory service within current and future settings of the NHS.

Major topics covered included:

- Immunology lab tests: nature and purpose
- Quality Control and Quality Assurance
- Clinical Performance of Immunological Laboratory Tests
- Laboratory-Clinical Standardisation
- IQC and EQA in Cellular Immunology
- Management:
  - Accreditation
  - Clinical Governance
  - Laboratory and Clinical Audit

Not only did the MSc course provide an excellent theoretical training in Medical Immunology, it also provided a forum for students to meet and build contact with members of the Immunology community. This is an important part in the development and training of a clinical scientist as these contacts are an invaluable point of reference for the future.

In September XXXX I was awarded the MSc in Medical Immunology with Distinction.

2.2 MSc Project

The MSc guidelines stated that the time allowed for the research project practical work should amount to at least 40 days (the equivalent of six full-time weeks) over the two years of the course. The final project thesis was to comprise 10000 words of text.

My project was titled 'Rheumatoid Factor Concentrations in Gold-Treated Rheumatoid Arthritis Patients' and was undertaken in collaboration with Dr XXXX, Consultant Rheumatologist at XXXX Hospital.

Project Abstract:

This study aimed to develop isotype-specific rheumatoid factor assays to assess modulation of IgM, IgA and IgG rheumatoid factor concentrations in gold-treated rheumatoid arthritis patients and controls. The investigation was performed to define further the effect of gold-treatment on isotype-specific rheumatoid factor concentrations in rheumatoid arthritis, as other researchers have reached no consensus of opinion.

Isotype-specific ELISA methods to measure IgM, IgA and IgG rheumatoid factor concentrations were designed, developed and validated. All three assays performed with acceptable levels of imprecision and were linear over a wide concentration range.

The ELISA methods were used to quantify IgM, IgA and IgG rheumatoid factor levels in two groups of rheumatoid arthritis patients. The first group of patients (n=76) had been treated with gold salts (sodium aurothiomalate) and no other disease-modifying anti-rheumatic drug (DMARD). The control group of patients (n=91) had been treated with standard DMARDs, but not gold, D-penicillamine or prednisolone.

There was no significant difference between the IgM and IgG rheumatoid factor concentrations in the gold-treated patients and the controls. However, IgA rheumatoid factor was found to be significantly lower ($p=0.03$) in the patients receiving gold-therapy than in the controls.

A number of studies have suggested that IgA rheumatoid factor is a good diagnostic and prognostic marker in rheumatoid arthritis, and that total rheumatoid factor concentrations are of limited use in monitoring patients with rheumatoid disease.

This study concluded that gold therapy in rheumatoid arthritis has a selective effect on IgA rheumatoid factor that is not seen for IgM, IgG or total rheumatoid factor.

Throughout the course of the research I was required to provide regular updates on my progress, both in written and oral format, to members of the MSc Coordinating Committee. I also gave oral presentations of the completed work to peers in my department, fellow students on the course and to the XXXX Hospital rheumatologists at one of the weekly rheumatology meetings. In March XXXX I presented the results of this study as a poster at the Cellular and Molecular Sciences Open Day at XXXX Hospital.

The completion of the practical work and the thesis for the Masters project required much personal initiative and development of problem-solving skills. Assay development, optimisation and validation formed a large part of the work and required systematic organised planning and execution. Good time management skills were imperative when trying to build time for research into the normal routine workday.

I was awarded a distinction for my thesis.

2.3 Laboratory experience in training laboratory

In addition to the theoretical knowledge gained through completion of the Masters degree, as a Grade A trainee I was required to gain substantial practical experience in the clinical immunology laboratory and this was monitored by the completion of the British Society for Immunology Training Manual for 'A'-grade clinical scientists. I rotated through each of the sections of the department spending time running each bench independently, once trained.

2.3.1 General Competencies

Many basic principles were covered at the beginning of my training and put into practice throughout the rest of my time in the lab. These included general laboratory health and safety (including the filling-in of COSHH forms and the carrying out of risk assessments), confidentiality (and the extent to which the data protection act covers patient record sheets, computer records and phone calls) and the use of the pathology computer system. I compiled and updated many standard operating procedures throughout the training period and participated in the preparation for Clinical Pathology Accreditation during my first year.

2.3.2 Specimen Reception

In the time I spent covering specimen reception I became familiar with the regulations, both internal and external, covering specimen collection, transport, handling and storage. This period of my training gave me a good insight into the working of the lab as a whole, and the co-ordination, co-operation and planning needed for the service to run smoothly. One of the duties of the person covering specimen reception was to be responsible for the collection of blood samples for cryoglobulin analysis both from outpatient blood test rooms and from the wards. This involved close contact with the patients and with other hospital staff and provided an opportunity to develop communication skills with these groups. Many routine phone calls were handled by specimen reception including dealing with queries on which blood tubes to use, sample requirements for tests and prices of various tests. The handling of these calls provided further experience in communicating with other healthcare professionals.

2.3.3 Protein Electrophoresis

I gained extensive experience in this section of the laboratory, later becoming responsible for training and supervising new members of staff while I was covering the routine. Serum protein electrophoresis was performed by capillary zone electrophoresis using the Beckman CZE, whilst urine protein electrophoresis was performed on Beckman SPE agarose gels. Both serum and urine immunofixation employed Beckman IFE agarose gels. As well as running the practical side of the section I gained extensive experience in the reading and interpretation of the gels, with a senior clinical scientist confirming my readings. Due the laboratory's position as a XXXX I gained valuable exposure to, and awareness of, some of the more unusual phenomena such as IgD paraproteins, the presence of heavy chain only and 'sticky' IgM, and the procedures for dealing with each instance.

2.3.4 Autoimmune Serology

I spent a significant length of time training in and then working in and training others in the autoimmune serology section of the laboratory. This area demands a high degree of competency before independence can be achieved, due to the level of subjectivity involved in the reading and interpretation of indirect immunofluorescence patterns. The techniques employed in this area of the laboratory were ELISA and indirect immunofluorescence, both of which require very good technical competence as a result of the 'hands-on' nature of the procedures.

Indirect immunofluorescence testing comprised anti-nuclear antibody (HEp2 cell substrate), anti-neutrophil cytoplasmic antibody, anti-endomysial antibody, anti-skin antibodies (basement membrane and intercellular cement), tissue-specific autoantibodies (using a composite block of rat liver and kidney and mouse stomach), anti-adrenal antibody, anti-ovarian antibody, anti-islet cell antibody, anti-skeletal muscle antibody and anti-reticulin antibody. Many autoantibodies were quantified by ELISA including anti-double-stranded DNA antibody, anti-intrinsic factor antibody and anti-glomerular basement membrane antibody.

One of the tasks performed by those working on the autoimmune serology rota was the selection and testing of material to use for internal quality control purposes. I was responsible for preparing internal quality controls on numerous occasions.

An important part of the clinical training whilst covering this routine was gaining an appreciation of how individual tests link together to provide the clinician with the maximum amount of information possible. As such it was important to have a thorough understanding of the clinical decision which the test was going to inform, especially when ordering follow-up assays after screening tests.

2.3.5 Allergy

Whilst covering the allergy routine I was responsible for measuring total IgE and specific IgE (RAST) levels, mainly in patients with suspected allergic disease. Mast cell tryptase was measured in cases of suspected anaphylaxis and eosinophilic cationic protein was infrequently measured as a monitor of the effectiveness of steroid therapy in asthma.

2.3.6 Quantification of proteins of immunological importance

As the department at XXXX was a XXXX I gained much experience in techniques used to quantify protein levels. The main method used was nephelometry, employing a Beckman Immage Nephelometer to predominantly measure levels of immunglobulins G, A and M, complement components C3 and C4 and rheumatoid factor, but also other proteins of immunological importance such as haptoglobin, alpha-1-antitrypsin, alpha-1-acid glycoprotein and transferrin. A single radial immunodiffusion method was employed to measure IgD levels, while beta-2-microglobulin and C1 esterase levels were measured by turbidimetry using the Roche Cobas MIRA.

2.3.7 Functional complement assays

Functional evaluation of the classical complement pathway was carried out using an ELISA method to detect the formation of neoantigen (membrane attack complex) after incubating patient's serum in wells coated with complement activator. I also had experience of the measurement of functional C1 esterase inhibitor, again using an ELISA-based method.

2.3.8 Neutrophil Function

Neutrophil oxidative burst was measured by a flow cytometric method and the traditional nitrobluetetrazolium (NBT) reduction slide method.

2.3.9 Isoelectric Focusing

This technique was employed for alpha-1-antitrypsin phenotyping and for the detection of oligoclonal bands in the CSF. Significant experience was needed in the reading of the results due to the subjectivity involved. Whilst covering the routine I always read the gels and my readings were second-read by a senior clinical scientist.

2.3.10 Management Issues

Part of my Grade A training involved learning about and becoming familiar with various management issues. To this end I spent time shadowing the laboratory manager and was introduced to issues such as budget setting, stores requisition and purchasing, Clinical Pathology Accreditation, Clinical Governance, audit and staff appraisal.

2.3.11 Quality Control and Quality Assurance

These issues were covered in detail and put into regular practice during my training period in the laboratory. Where available, NEQAS schemes were participated in and the results (and any further action required) were discussed in weekly meetings. Both kit quality controls and internal quality controls were run where available and results plotted on Shewart charts to monitor the performance of the assays, following the Westgard Rules. Covering each of the sections in the department gave me full awareness of the issues concerning quality and of the criteria required for assay performance acceptance.

2.4 Secondments

- Immunology, XXXX Hospital – in my first year of training I was seconded to XXXX Hospital Immunology department and received an introduction to the technique of flow cytometry for immunophenotyping and an insight into the day to day routine of a different immunology department.

- Histocompatability and Immunogenetics, XXXX Hospital – I spent time in this laboratory to gain experience in tissue typing and in molecular biological techniques used in immunology. I observed DNA extraction from blood, PCR-SSP tissue typing for HLA A*, B*, Cw*, DRB1* and DQB1* antigens, lymphocyte isolation (from spleen, lymph node and whole blood), cross-matching by flow cytometry and cytotoxicity, complement-dependent cytotoxicity for antibody screening and identification, and ELISAs for HLA antibody specificity definition. In addition I spent half a day in theatre observing a kidney transplant.

- Haematology, XXXX Hospital – here I gained further experience of immunophenotyping by flow cytometry as well as CD4 monitoring for HIV.

- Immunology, XXXX Hospital – I was seconded to XXXX Hospital for an overview of the molecular and protein-based techniques used in the diagnosis of immunodeficiency. I spent a large amount of time receiving instruction from and going through cases with the senior clinical scientist. In the laboratory I was introduced to some of the protein-based techniques recently developed for diagnosis of congenital immunodeficiency including γ-chain expression by FACS analysis (for diagnosis of X-linked SCID) and both JAK-3 and Btk immunoprecipitation and immunoblot analyses (for diagnosis of JAK-3 SCID and X-linked agammaglobulinaemia respectively). In addition I was given a tour of the facilities for, and an introduction to the practical laboratory side of, gene therapy for primary immunodeficiency.

- Immunology, XXXX, XXXX – here I was introduced to more of the methods used in the investigation of cellular immunity. I observed isolation of lymphocytes from whole blood, T cell proliferation assays, neutrophil function tests and methods for intracellular cytokine labelling and analysis by flow cytometry.

As well as the important practical experience in areas not covered by my base laboratory, the secondments provided me with valuable contacts with both scientists and clinicians in other hospitals.

2.5 Meetings and tutorials

- Trainee tutorials – weekly lectures, seminars and department visits were organised jointly between the Imuunology Department and the Department of Clinical Biochemistry and were attended by trainee biomedical and clinical scientists. These tutorials were important as they provided contact with and an appreciation of the work performed by other diagnostic departments. All attendees gave presentations and were involved in deciding the topics to be covered.
- Grand Round, – these weekly presentations provided an opportunity for me to expand my clinical knowledge and interest in areas not necessarily related to immunology.
- Rheumatology Meetings – weekly meetings of the rheumatology department involving case presentations, updates on research or other matters of interest.
- British Society of Immunology Annual Congress, Harrogate XXXX, XXXX, XXXX
- Tumour Immunology meeting at the RSM XXXX
- Genetics of SLE meeting at the RSM XXXX
- Dynamics of Virus Infection meeting at the RCPath XXXX
- Alpha Laboratories ANA meeting, Northwick Park Hospital XXXX

2.6 Certificate of Competence

The British Society for Immunology Certificate of Competence is awarded after successful completion of a minimum of three year's Grade A training. It is assessed by viva and by the satisfactory completion of the training manual. I was awarded the Certificate of Competence in September XXXX.

Following completion of my Grade A training I was fortunate enough to be offered an extra year's contract at XXXX as four year's experience in a clinical immunology laboratory was now required for automatic state registration.

3 Locum Grade B Clinical Immunologist, XXXX Hospital

From September XXXX to September XXXX I was employed by XXXX Healthcare NHS Trust as locum Grade B Clinical Immunologist with responsibility for the autoimmune serology section of the laboratory, covering a colleague on maternity leave. As such I gained valuable experience in running a section of the laboratory, in supervising staff and in having responsibility for the results being reported.

3.1 Responsibilities

3.1.1 Day to Day Routine

As a pre-registrant Grade B Clinical Immunologist I was responsible for the work I was undertaking and the results produced. I was required to organise and prioritise the testing to be done, especially when presented with a heavy workload or with urgent requests. I was responsible for overseeing the activities of the other two members of staff on the section and ensuring that tests were being performed correctly and in an efficient manner.

I participated in a rota within the department that ensured laboratory cover from a qualified member of staff until the end of each day. It was necessary to always have a more senior staff member present to be able to give results by phone, deal with queries, handle any problems arising and supervise the junior staff members.

3.1.2 Training of Staff and Teaching Experience

I was responsible for training and supervising new and inexperienced members of staff in autoimmune serology as well as visiting trainees from the biochemistry department and from local hospitals. I was required to provide both a basic overview of the scientific and technical information concerning the tests and their day to day performance and also more detailed information pertaining to the clinical use of the test and the result, and the QC and QA involved.

In addition to instructing and training staff in my section of the laboratory, I expanded my teaching experience by becoming involved with some of the teaching for the Medical Immunology MSc modules that were taught at XXXX Hospital. This teaching took the form of tutorials and seminars, and I also assisted with some of the practical exercises set for the students.

3.1.3 Trouble-shooting and problem-solving

As the Clinical Immunologist supervising the autoimmune serology section I was responsible for investigating and resolving technical problems arising in the section. Day to day these were mainly minor and easily resolved, however, there were occasions when problems arose that required a more thorough investigation. These problems did not just relate to QC failure but also to issues regarding batches of results that were atypical, inconsistent with previous results or inconsistent with the clinical picture.

One example of this was seen in the ELISA for antibodies to extractable nuclear antigens. A new batch was started and although all of the quality controls were in range the results were not believable due to the fact that three patients were positive for antibodies to SSB (La antigen) alone. This is an unusual finding and would not be expected to occur with this frequency. On investigation it was found that there was a problem with the coating of the wells with SSA (Ro antigen) in that batch. On reanalysis with a new kit batch all three patients were found to have antibodies to both Ro and La.
Additional examples of the day to day problems (both technical and managerial) encountered and resolved include

- High background fluorescence on the slides
- Poor quality tissue on commercial slides
- QC failure – due both the operator-related and kit-related problems
- Staff shortage due to illness or study leave
- Sample mix-ups and transcription errors

Dealing with and resolving kit problems required a large amount of liaison with company representatives, both on the phone, in written reports and in official letters of complaint.

3.1.4 Quality Control and Quality Assurance

I participated in and regularly chaired weekly laboratory meetings discussing quality control issues and general laboratory business. Recent EQA results and internal quality control issues were discussed at each meeting and any problems highlighted for more in depth attention and action. I was responsible for filing the EQA returns for autoimmune serology with NEQAS and for investigating any misclassifications arising. In addition I gave a tutorial to introduce the concept of EQA and the NEQAS returns to the trainees.

3.1.5 Result reporting, authorisation and signing out

After attaining the Certificate of Competence in September XXXX I was qualified to report patient results onto the computer and to authorise these for report printing and for viewing on the ward IT system. This required a good understanding of patterns of results and represented a transition between simply ‘believing the numbers’ to being able to critically judge which results may realistically go together.
Every result report was matched with the original request form and the results checked in the light of the patient and clinical details before being signed out by a senior clinical scientist to be sent to the wards, clinics, GPs or referring hospitals. I regularly participated in these ‘signing-out’ sessions, which took place twice a day. This was an exercise that greatly increased my clinical knowledge and awareness, especially through frequent question and answer sessions with Dr XXXX and Professor XXXX.

3.1.6 Clinical Liaison

One of my duties as a more senior scientist in the laboratory was to take phone calls from clinicians and from referring laboratories, independently handling queries, giving out authorised results and answering basic questions pertaining to tests and results. I was also responsible for handling and troubleshooting minor problems arising through phone calls such as dealing with missed tests or investigating untimely results. In addition I handled requests for urgent tests, afterwards following the sample from receipt, through testing to result phoning and reporting.

3.2 Research

3.2.1 Research Projects

Within the laboratory there were opportunities to participate in research projects, usually in collaboration with clinicians in the hospital. I participated in a number of these projects with my role varying from making collections of relevant samples to performing sample testing and reporting back to the clinicians. These projects included two studies conducted with the rheumatology department looking at 1) the clinical utility of regular quantification of anti-ENA antibodies and 2) the follow-up of rheumatoid arthritis patients treated with anti-TNF alpha therapy, to monitor the safety and efficacy of the treatment. A further study was with Dr XXXX, a plastic surgeon, who was interested in looking at burn healing and the potential benefits of extracting fluid through the burns by a vacuum.

3.2.2 Method Evaluation

Part of my role as pre-registrant Grade B Clinical Immunologist was to look at possible ways of improving the service provided. It was important to be aware of emerging technologies and of any new kits and equipment on the market that might enhance the existing service. Equally important, however, was the constant monitoring of kits and other reagents routinely in use, to ensure they were performing optimally. Following poor performance in the external quality assurance scheme for anti-thyroid peroxidase antibodies it was decided that the existing method should be changed for a more reliable method. A number of kits on the market were rigorously tested and evaluated before deciding on a replacement.

New equipment was also continually evaluated alongside the existing methods, including the Luminex (antibody detection bead technology), the Triturus (a robotic ELISA processor) and the Launch Beeline (a robotic slide processor).

3.2.3 Audit

Regular audit is an important tool in the clinical pathology laboratory to ensure a high quality of service is provided and to highlight any areas requiring improvement. As part of my ongoing training, and to introduce the subject to the trainees, I prepared and gave a talk on audit in the clinical laboratory. This covered horizontal, vertical and examination audits and examples of each.

I was also involved with two horizontal audits conducted in the XXXX, both looking into possible over-requesting of tests. The first was in collaboration with the rheumatology department and looked at requests for immunoglobulin quantification and protein electrophoresis over a period of one year. After the audit had been completed it was decided that there was evidence of over-requesting and new standards were set. These suggested that patients with paraproteins should be followed up with regular immunoglobulin measurements and electrophoresis but that all other patients should have no more that one measurement of immunoglobulins in every twelve-month period. The second horizontal audit was looking at requests for anti-thyroid peroxidase (TPO) antibodies as the number of tests being done had increased markedly over the preceding months. Again it was found that the testing could be rationalised and new standards were set stating that thyroid function tests should always be performed first and then anti-TPO antibodies requested if necessary.

3.3 Meetings

- Weekly Grand Round
- Evidence Based Medicine day, XXXX Hospital Medical School XXXX
- Clinical Aspects of Protein Assays XXXX
- British Society of Immunology Annual Congress XXXX
- Update on Immunodeficiency meeting at the RSM XXXX

4 Research Technician, XXXX Research Institute, XXXX, XXXX

I moved to XXXX in September XXXX and took up a research technician position working for the University of XXXX. I was based in the Department of Pathology and Laboratory Medicine at the XXXX Research Institute, XXXX. The research I was involved in looked at aspects of antiviral defence and type 1 diabetes, principally investigating the role and significance of 2'5'oligoadenylate synthetase (2'5'AS - an enzyme central to innate antiviral defence) in the pathogenesis of type 1 diabetes.

I worked both alone and as part of a team, and was involved in planning, designing and carrying out experiments as well as analysing results and reporting back to the principal investigator. The majority of my work involved:

- measuring 2'5'AS activity in PBMC lysates from both diabetic and non-diabetic children (using P-32 in a reaction and then employing ascending thin layer chromatography to separate the products)
- determining the presence of different isoforms of the enzyme in the same PBMC lysates (SDS-PAGE and Western Blotting)
- cellular experiments with a mouse pancreatic beta cell cell line (cell culture, stimulation and transfection studies)

I also spent time in the Department of Medical Genetics genotyping several genetic markers at the 2'5'AS gene loci (in the same families studied in the enzyme experiments) to determine possible linkage (PCR, gel electrophoresis of DNA on LI-COR DNA analysis system).

As part of my induction and training at the University of XXXX I was required to complete courses and written examinations in laboratory biosafety, chemical safety and radionuclide safety and methodology.

I regularly attended and actively participated in weekly meetings held jointly with several laboratories in the department. These mostly took the form of a journal club, but were also an opportunity to present work of interest to colleagues in other research groups. I gave an oral presentation of my research entitled 'Innate Antiviral Immunity and Type 1 Diabetes' towards the end of my time in XXXX.

My time in XXXX was very valuable to my training as a clinical scientist as it gave me a large amount of research experience, especially in assay development and design, an opportunity to work with a high level of independence and an insight into the world of professional academic research.

5 Pre-registrant Clinical Immunologist, XXXX Hosptial

I recently took up the position of pre-registrant clinical immunologist in the autoimmune serology and allergy section of the Department of Clinical Immunology at XXXX Hospital, XXXX, under the supervision of Dr XXXX.

5.1 Responsibilities

My responsibilities are to work independently performing specialist assays, evaluating methods and equipment, and monitoring performance and quality within the laboratory. Part of my role is to help co-ordinate the administrative activities of the BMS staff and to be responsible for the technical validation of assays and the authorisation of results. In the future I will also have a role in service development and audit.
In addition I have responsibilities for staff training within the section and will have a major role in the training of Grade A trainee Clinical Immunologists, trainee biomedical scientists and specialist registrars.

5.2 Day to Day routine

Currently I am spending time familiarising myself with the daily routine in the autoimmune serology laboratory and I will also rotate through both the cellular and lymphoma laboratories within the department of Clinical Immunology. I have been involved in a number of projects so far including

- Evaluation of an ELISA kit for the determination of anti-intrinsic factor antibodies and comparison with the current kit with a view to a possible change in methods.
- Evaluation of new ELISA kits for anti-filaggrin antibody determination and investigation of their clinical diagnostic utility.
- Testing a preparation of bovine spleen extract for suitability as antigen for the detection of anti-Ro antibodies by counter immunoelectrophoresis.
- The development of a non-isotopic method for reliably detecting scleroderma-specific antibodies to RNA polymerase.

5.3 Clinical Training

I have been encouraged to attend patient clinics to develop my clinical awareness and I regularly sit in on rheumatology clinics (including specialist scleroderma clinics), immunodeficiency clinics, allergy clinics and vasculitis clinics.
In addition to the insight this experience has given me into the full clinical picture of the diseases and pathologies in question, it has also introduced me to a number of consultants who work very closely with the clinical immunology department. I have also gained experience in communicating with patients and their relatives.

As part of my ongoing training I have also started to compile a clinical casebook to illustrate both interesting and typical cases spanning all disciplines of Clinical Immunology.

5.4 Meetings

- Grand Round (weekly)
- Rheumatology meetings
- Internal Audit Workshop and Training (including section on quality management and quality management systems) Feb XXXX
- MRC Path training day – Immunodermatology Feb XXXX
- Biosafety training course March XXXX
- CPA Conference March XXXX

The internal audit workshop comprised instruction in both the theoretical and practical aspects of carrying out audits in clinical pathology laboratories. I conducted a vertical audit of midstream urine microscopy, culture and sensitivity in the microbiology department as part of the training. The CPA vertical audit forms used in inspection for accreditation were used as a template for this audit.
The Quality Management section of the workshop provided an opportunity to discuss implementation and achievement of the new standards for CPA with representatives from other modalities within the Pathology Department. Each department is at a different stage in its preparation for accreditation and it was very beneficial to share ideas and strategies, and to make contacts throughout Pathology.

5.5 Further Training

As part of my commitment to professional and personal development I have enrolled with the flexible learning unit within the XXXX NHS Trust. This provides access to a number of learning materials including books, guides, workbooks, journals, videos and computer-based resources. These permit the study of a variety of topics relevant to progression as a clinical scientist including management issues and personal development strategies (eg finance and budgets, clinical governance, problem solving, quality, leadership and training).