The Royal College of Pathologists
Pathology: the science behind the cure

Best practice recommendations

Guidance on the scope and clinical direction of immunology testing

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Author: Dr Ravishankar Sargur

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Produced by	Dr Ravishankar Sargur, Consultant Immunologist, Sheffield Teaching Hospitals NHS Foundation Trust
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The Royal College of Pathologists
6 Alie Street, London E1 8QT
T: 020 7451 6700; www.rcpath.org

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Foreword

Best practice recommendations (BPRs) published by the Royal College of Pathologists should assist pathologists in providing a high standard of care for patients. BPRs are systematically developed statements intended to assist the decisions and approach of practitioners and patients about appropriate actions for specific clinical circumstances. They are based on the best available evidence at the time the document was prepared. It may be necessary or even desirable to depart from the advice in the interests of specific patients and special circumstances. The clinical risk of departing from the BPR should be assessed and documented.

A formal revision cycle for all BPRs takes place every 5 years. The College will ask the author of the BPR to consider whether or not the recommendations need to be revised. A full consultation process will be undertaken if major revisions are required. If minor revisions or changes are required, a short note of the proposed changes will be placed on the College website for 2 weeks for members' attention. If members do not object to the changes, a short notice of change will be incorporated into the document and the full revised version will replace the previous version on the College website.

This BPR has been reviewed by the Professional Guidelines team. It was placed on the College website for consultation with the membership from 8 December 2025 to 6 January 2026. All comments received from the membership were addressed by the authors to the satisfaction of the Clinical Director of Quality and Safety.

This BPR was developed without external funding to the writing group. The College requires the authors of BPRs to provide a list of potential conflicts of interest. These are monitored by the College's Professional Guidelines team and are available on request. The author of this document has declared that there are no conflicts of interest.

The following stakeholder was consulted during the preparation of the best practice recommendation:

- Dr Adrian Heaps, Immunology Profession Council, Association of Laboratory Medicine.

1 Introduction

This is a guidance document and not a standard to be assessed against. The following represents guidance produced by the United Kingdom Accreditation Service (UKAS)

Technical Advisory Committee in Immunology and the College Immunology Specialty Advisory Committee.

1.1 Who is this for?

- Immunology laboratories, to ensure appropriate structure and processes are in place to deliver a safe and high-quality service.
- Clinical directors and managers of the service to help plan resources required to provide a safe and effective immunology laboratory service.
- Immunology assessors, regarding the requirements for professional direction to ensure that they are assessing a minimum standard of safe professional practice in all laboratories that have an immunology repertoire, whether at a hub laboratory or satellite/spoke/remote laboratory service. The guidelines need to be flexible enough to encompass the wide range of individual practice, yet have certain core attributes that can be generally agreed to be minimum standards.
- Non-immunology assessors (clinical chemistry/haematology), who assess immunological examinations in blood science laboratories/multi-disciplinary laboratories (see section 2.2).
- Applicant laboratories, to understand what the assessors will be expecting to find.

1.2 Guidance on the scope and direction of immunology testing

This guidance is required to:

- ensure that the assessment and accreditation process is applied consistently to all applicant laboratories
- enable UKAS officers to assess whether an immunology assessor is required
- enable applicant laboratories to understand when direction by a consultant immunologist (see section 3.1 below for definitions) will be required to satisfy ISO 15189:2022[1] sections 5.2 and 6.2
- enable applicant laboratories to understand how the requirements for ISO 15189:2022 should be met
- provide guidance on expected standards for assessors
- enable peer assessors and UKAS officers to make consistent decisions in relation to immunology examinations carried out by applicant laboratories

- ensure that laboratories providing immunological services demonstrate their competencies and appropriate clinical oversight across their scope of practice.

2 Scope of immunology for the purposes of this guidance

2.1 Need for assessment in immunology and oversight from immunologist

Sessional input from a consultant immunologist will be assessed when the repertoire – regardless of the analytical platform – includes some or all the following examinations, irrespective of volume:

- autoantibody screening with reporting of positive results, patterns and titres
- all complement examinations, apart from C3 and C4
- all cellular immunology examinations
- all specific immunoglobulin E and functional allergy examinations
- all autoantibodies (including ds-DNA, extractable nuclear antigen, antineutrophil cytoplasmic antibodies, endomysial and tissue transglutaminase, and organ-specific autoantibodies; anti-cyclic citrullinated peptide antibodies, paraneoplastic and glycolipid antibodies), except for those specifically identified below (see sections 2.3 and 2.4).

Laboratories carrying out these examinations must apply for assessment in immunology. There are no restrictions on the repertoire of immunological testing carried out by a laboratory with sessional consultant immunologist input, except insofar as it is incumbent on the laboratory to justify the quality of the service provided where tests are only carried out infrequently, through appropriate validation or verification, as required. Where reporting is carried out by biomedical scientist staff, there must be evidence of specific training and competence. Reporting criteria and methods must be agreed with the consultant immunologist providing sessional input.

2.2 Immunological examinations in blood sciences and multidisciplinary laboratories

The following immunological examinations may be performed in blood science and multi-disciplinary laboratories:

- rheumatoid factor
- serum immunoglobulins, serum and urine electrophoresis, serum free light chains and cryoglobulins
- complement C3 and C4
- thyroid microsomal/peroxidase antibodies
- intrinsic factor antibodies.

The supervising consultant and scientific staff, where appropriate to their roles, need to demonstrate that they maintain continuing professional development (CPD) competencies in technical performance, clinical use and interpretation of these assays in all clinical contexts (autoimmunity, immune deficiency, immune dysregulation, relevant haematological malignancy, etc.).

Consultant immunologists, consultant biochemists, consultant haematologists and scientific staff providing profession direction and clinical governance for immunological examinations (see 2.1 and 2.2) will require access to the results and input into the authorisation, interpretation, quality control and selection of assays.

There should be evidence of input into establishing clinical requirements of the tests, verification and validation, and ongoing audit to demonstrate conformance with ISO 15189:2022. Application forms should incorporate all immunology tests referred to an immunology laboratory.

3 Consultant input to meet the requirements of the laboratory director (ISO 15189:2022, section 5.2)

3.1 Qualifications

A consultant immunologist is defined as a medically qualified clinical pathologist or Health and Care Professions Council-registered healthcare scientist who has evidence of training and experience in immunology that is exemplified in the UK by completion of FRCPath by examination in immunology [equivalent overseas qualifications]. In the UK, this qualification provides eligibility for inclusion on the General Medical Council Specialist Register for immunology, if medically qualified.

3.2 Principles of appropriate sessional input

3.2.1 Hub laboratories

Professional direction requirements are necessarily more demanding for a hub laboratory. A hub laboratory is a comprehensive laboratory with a large repertoire of immunological examinations and immunology clinical services, and will comprise the major responsibilities of consultant immunologists.

3.2.2 Out-of-hours and cover arrangements

All laboratories providing immunological examinations should be able to provide interpretative and clinical advice on a daily basis and have arrangements to provide clinical advice or interpretation out of hours. It follows that unsupported single-handed practice is a clinical governance risk. Centres should have effective and appropriate processes in place that ensure appropriate cover arrangements. Any arrangement must be subject to regular review and must demonstrably meet the needs of the service.

3.2.3 Satellite services

Many major centres find they are operating a hub and satellite arrangement to cover the requirements for professional direction of satellite immunology services in neighbouring trusts. This requires that appropriate sessions are committed to provide a safe, effective service on both hub and satellite sites. Satellite services would normally be formalised by a service level agreement (SLA) that details the arrangements.

3.2.4 Sessional commitment

Satellite arrangements should not compromise hub activities. An appropriate amount of sessional time should be committed to satellite activities by each of the hub consultants. This is to cover all satellite-related activity, whether carried out at the satellite or the hub, and should take account of time spent travelling. This should be defined in the SLA. Appropriate sessional commitment is to be agreed with the consultant immunologist in an SLA, depending on the repertoire, workload of the satellite lab and the clinical liaison requirements to be delivered to the organisations served by the satellite laboratory.

3.2.5 Executive control

Executive control of the immunology service is essential at hubs and is desirable at satellites. Executive control is defined as input into all the activities of the department, plus day-to-day involvement in the activities of the department as defined below. Executive control includes the ability to influence all necessary managerial and clinical decisions,

including those regarding staffing (recruitment and rotation), to run a safe, effective, clinically appropriate and clinically governable specialist laboratory service. Executive control also incorporates full and meaningful involvement in the future development of the immunology service through the business planning process.

To be effective, these functions must be supported by the management structure and practices of both the hub and satellite departments. They require allocation of appropriate sessions for departmental activities and management/administration (to include relevant managerial and departmental meetings). This should be documented by an SLA, with any satellite department in the job description/job plan of the immunologist.

3.2.6 Guide to sessional time required

A breakdown of the areas of activity and guide to the sessional time required is provided below.

- Assay selection, oversight of verification and validation, quality assurance and oversight of incidents and clinical risk assessment: 1–2 sessions.
- Interpretative advice and laboratory supervision (on-site by telephone, email and in person): at least 4 sessions for the hub (appropriate sessions per week for each satellite laboratory flexibly arranged. A consultant opinion should always be available at the hub and readily available to the satellite departments).
- Laboratory hands-on activities: dependent on the service delivered.
- Biomedical scientist, clinical scientist and SpR education and other teaching*:* at least 0.5 session (1 session if SpR on staff).
- Administration: 1 session per individual, 2 additional sessions per hub for the head of department.
- Research: 1 session where relevant, more if academic.
- CPD activities, clinical audit and related activities: 1 session per individual.

The above is intended as guidance to the acceptable minimum. Job plans and SLAs should capture the activity and sessional time. Assessors must recognise that consultant immunologists provide both clinical services and laboratory services. The sessional commitment at the hub and satellite laboratories should be considered at the departmental level. Diagnostic service consultant sessions committed at the hub must reflect the extent

of the repertoire, the complexity of the work and the workload. They will also be influenced by the inclusion of clinical scientists in the laboratory team.

Additional specialist activities or regional or national services (e.g. protein reference unit [PRU], external quality assurance [EQA], specialised immunodeficiency or allergy investigations etc.) should attract additional sessions, which should be clearly identified when introducing and upgrading services.

Clinical sessions must not compromise laboratory commitments and should be laid out in the consultants' job description and job plan. Clinical sessions average between 3 and 6 per week for most consultants and include direct clinical commitments (outpatients, day cases, inpatients and CPD).

Clinical sessions should not be 'double-booked' for laboratory supervision or interpretation. These sessions are allocated to OP and IP activities and any follow-up investigations or administration resulting from these. It is impractical and unsatisfactory to do 2 things at once and is not safe practice or clinically governable.

Alternative means of achieving safe and clinically governable satellite practice that could potentially save time should be used appropriately. These include remote authorisation, telephone and video conferencing, remote troubleshooting, interpretation of high-quality immunofluorescence images, sharing and interpretation of internal quality control (IQA) and EQA data, input into root cause analyses, and clinical liaison using telephone and email, etc. They cannot be a complete substitute for attending the satellite regularly. These would need to be assessed on an individual basis and, where necessary, the practice should audit to verify their safety.

3.3 Satellite and remote laboratory oversight

For satellite laboratory service provision, in meeting the requirements of ISO 15189:2022 5.2 and the needs of the user (ISO 15189:2022 4.3 and 5.3.3), laboratories need to make provisions for cover for disciplines where there is no on-site consultant. Particular attention is drawn to:

- the requirement for on-site satellite visits at appropriate intervals as required by the service
- robust remote working arrangements and electronic links
- the ready availability of interpretative advice and clinical liaison

- users' awareness of the availability of consultant advice.

Remote reporting cannot substitute for the requirement for on-site satellite visits, but may supplement such a visit. UKAS accepts that, in the interests of efficiency, it may be appropriate for the on-site visit session to be flexibly worked and complemented by means such as telephone conferencing, but the minimum should be at least once a month. If any less than this, evidence for efficacy must be provided.

3.4 Assessment of laboratory service

For satellite laboratory service provision, assessment will seek evidence that the contractual arrangements covering the provision of consultant immunologist input is clear and in writing. Assessors will ask to review this documentation. The following aspects should be included.

Executive accountability is required to ensure that:

- appropriate equipment is selected and commissioned (see ISO 15189:2022, section 6.4)
- information for patients and users is available (see ISO 15189:2022, section 7.2.2)
- test selection is fit for purpose (see ISO 15189:2022, section 7.3.1)
- reporting is carried out effectively (see ISO 15189:2022, section 7.4.1)
- clinical advice is available (see ISO 15189:2022, section 7.4.1.3)
- appropriate clinical audit is undertaken (see ISO 15189:2022, section 8.8.3).

The visiting consultant immunologist will:

- undertake review of inter-laboratory comparison (EQA) performance (see ISO 15189:2022, section 7.3.7.3)
- participate in the quality improvement system (see ISO 15189:2022, section 8.6)
- participate in the annual management review (see ISO 15189:2022, section 8.9)
- be responsible for supervision of immunology-specific training (see ISO 15189:2022, section 6.2.5).

Note: Examples of documentation could be an SLA or as part of the consultant job plan, though not exclusively.

The assessors should enquire about or seek information on:

- immunological examinations done in blood science laboratories (see 2.2 in this document)
- clinical governance
- ongoing competencies in technical performance (by CPD of biomedical staff undertaking the procedures)
- the understanding of the relevant analytical and quality issues
- the interpretation of these assays investigating immunological disease (e.g. appraisal and CPD).

4 Reference

1. International Organization for Standardization. *ISO 15189:2022, Medical laboratories — Requirements for quality and competence.* Accessed April 2026. Available at: www.iso.org/standard/76677.html