

## 1. Purpose of Guidance

**This is a guidance document and not the standards to be assessed against.**

Guidance on the scope and direction of Virology testing is required to:

- Ensure that the assessment and accreditation process is applied fairly to all applicant laboratories
- Enable CPA officers to assess whether a Virology Assessor is required
- Enable applicant laboratories to understand when direction by a \*Consultant Virologist (see section 3 below for definitions) will be required to satisfy CPA Standard B1
- Enable applicant laboratories to understand how the requirements for CPA Standard B1 should be met
- Provide Guidance on expected standards for Assessors
- Enable PAC members and CPA officers to make consistent decisions in relation to Virology examinations carried out by an applicant laboratory

## 2. Scope of Specialist Virology Services

2.1 CPA will expect clinical direction from a \*Consultant Virologist/Consultant Healthcare Scientist or a \*\*\*Consultant Microbiologist with an interest in Virology and will send one or more Virology Assessors when the repertoire includes some or all of the following examinations, regardless of where they are performed or the volume of tests. The amount of specialist virology input will vary depending upon the range of laboratory services being provided and the clinical groups of patients being cared for. If appropriate, this can be provided on a sessional basis, however the \*Consultant Virologist/Consultant Healthcare Scientist must be contactable, during normal working hours as a minimum, to provide clinical and laboratory advice via the telephone.

The following tests are examples which would be considered by CPA as 'specialist virology':

- Confirmatory tests and markers for blood borne viruses – HIV, hepatitis B and C
- In house virology molecular assays
- Commercial molecular assays with antiviral treatment, infection control and public health importance e.g. CMV PCR, hepatitis C PCR and genotyping, HIV resistance testing
- Virology IgM assays with treatment, infection control and public health importance (e.g. hepatitis A IgM)
- Cell culture

In addition there are Specialist Hospital Units and Services which need on site Specialist Virology Services:

- Solid organ transplant units
- Haematological transplant units
- Specialist hepatology units
- Infectious Diseases units
- Specialist HIV units

2.2 Laboratories carrying out these examinations must apply for assessment in Virology. It is incumbent on the laboratory to justify the quality of the service provided where tests are only carried out infrequently. Arrangements must be viable and appropriate to the needs of the service in the judgment of peer assessors, including appropriate out of hours provision. Where reporting is carried out by BMS staff, there must be evidence of specific training and competence, and reporting rules must be agreed with the visiting consultant virologist [G5.1, G5.3].

2.3 Microbiology laboratories should refer all or part of their specialist virology tests to Specialist Virology Centres (SVC) or Specialist Virology Units (SVU) (as designated by the UK Clinical Virology Network or equivalent) if they do not have a \*Consultant Virologist/Consultant Healthcare Scientist or a \*\*\*Consultant Microbiologist with an interest in Virology in their laboratory, the range depending on availability of expertise locally. Other microbiology laboratories wishing to perform any of the above tests in-house must have formal SLA arrangements with an SVC for consultant virologist advice and result interpretation. Microbiology laboratories must have a documented repertoire of all virological

tests available to their users, stating whether these are performed in-house or referred onwards. The methodologies used must be recorded and the suitability of the laboratory to which samples are referred assessed as in CPA Standard E6.

- 2.4 A virology assessor may not be required if none of the types of examinations or specialist units listed in 2.1 are declared in the repertoire of the laboratory. A microbiology assessor with experience in molecular assays should be sent to laboratories performing any commercial molecular assays not listed in 2.1.

### 3. Consultant Input to Meet Standard B1

#### 3.1 Definitions

\*Consultant Virologist – a Medical Consultant Virologist or Consultant Healthcare Scientist who has evidence of training or experience in virology as exemplified by eligibility for inclusion on the specialist register (if medically qualified) and completion of the FRCPATH (or equivalent) examination in Virology

\*\*Consultant Microbiologist – a Medical Consultant Microbiologist or Consultant Healthcare Scientist who has evidence of training or experience in Medical Microbiology and Virology as exemplified by inclusion on the specialist register (if medically qualified) and completion of the FRCPATH (or equivalent) examination in Medical Microbiology and Virology. He/she will have the level of knowledge necessary to diagnose and manage common viral infections.

\*\*\*Consultant Microbiologist with an interest in Virology – a Medical Consultant Microbiologist or Healthcare Scientist who has completed the FRCPATH (or equivalent) examination in Medical Microbiology and Virology and is eligible for inclusion on the specialist register if medically qualified, but who has in addition undertaken further specialist training in Virology for at least one year in a Specialist Virology Centre and who has maintained these skills by dedicating a significant commitment of their ongoing CPD to maintain and enhance their virology skills undergoing appropriate continuing professional development in virology. Evidence of maintenance of these skills is to be specifically reviewed at annual appraisal.

- 3.2 Single Handed Virology Consultants. The Royal College of Pathologists does not support single-handed clinical practice in any discipline. However, CPA recognises that there may be single-handed \*Consultant Virologists and that this situation is likely to change only slowly. The workload of the laboratory will determine whether Standard B2.1 is satisfied. For single-handed consultants, robust arrangements must be made to provide clinical advice and direction during periods of leave and sickness. Appropriate nominated Consultants must be identified who are able to provide on-site supervision if required. (See Guidelines for Single-Handed Consultant Practice in Medical Laboratories)

- 3.3 Note 1 at Standard B2.1 identifies the requirements for the provision of cover for disciplines where there is no on-site consultant. Particular attention is drawn to the requirement of regular on-site visits to advise on specialist virology issues (frequency depending on the needs of the local service) [B2.1 Note 1b], the ready availability of interpretative advice [G5.1] and awareness of the users of the availability of clinical advice [G5.3]. Remote electronic authorisation and review of results are specifically encouraged, although these are not standards. Remote reporting cannot substitute for the requirement for on site visits [B2.1 Note 1b], but may supplement such a visit. The CPA PAC accepts that, in the interests of efficiency, it may be appropriate for the weekly session to be flexibly worked as one day/fortnight.

- 3.4 CPA will expect the contractual arrangements covering the provision of the consultant virologist input to be clear and in writing [B2.1 Note 1a], and assessors will ask to review this documentation. (See note 1.) The following aspects should be included:

Executive accountability is required to ensure that:  
appropriate equipment is selected and commissioned [D1.2]  
an appropriate users' handbook is available [E1.2]  
an appropriate examination repertoire is selected [F1.1]  
procedures are reviewed [F2.1]  
reporting is carried out effectively [G2]  
clinical advice is available [G5]  
appropriate clinical audit is undertaken (H1)



The visiting Consultant Virologist will:  
undertake review of EQA performance [H5]  
participate in the quality improvement system [H6]  
participate in the Laboratory Management system [A1.4,1.5]  
be responsible for supervision of virology-specific training [B9]

Note 1. Examples of documentation could be a service level agreement or as part of the consultant job plan, though not exclusively.

#### 4. Recognised models for provision of virology services in the United Kingdom

- 4.1 Specialist Virology Centres provide a comprehensive range of virology testing as well as specialist advice to their local users as well as to other microbiology laboratories. Specialist Virology Centres will be staffed by more than one \*Consultant Virologists/Consultant Healthcare Scientists and sufficient numbers and grades of Biomedical Scientists with appropriate virological/serological/molecular training.
- 4.2 Specialist Virology Units provide an extended range of virology tests to their local users/or local network, but with agreed access to more specialist testing and advice from an SVC. The SVU must be directed by a \*Consultant Virologist or a \*\*\*Consultant Microbiologist with an interest in Virology who should be available on site to provide clinical advice and interpret results.
- 4.3 Microbiology Laboratories may provide a limited range of virology tests to their local users. A \*\*Consultant Microbiologist/Consultant Healthcare Scientist or a \*\*\*Consultant Microbiologist/Healthcare Scientist with an interest in Virology must have responsibility for the testing and reporting of the virology assays. When appropriate, samples giving positive, equivocal or negative results should be sent to a SVC or SVU for confirmation. There will be agreed access to specialist testing and advice from one or more SVCs or SVUs as appropriate.
- 4.4 Where blood science laboratories routinely provide virology screening tests a Consultant Microbiologist/Virologist must have responsibility for testing and reporting and a microbiology or virology assessor, as appropriate, will be required to assess the laboratory. These Consultants must have an appropriate CPD profile.