



College statement: standalone virus testing facilities

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The Royal College of Pathologists works for patients and supports the clinical and scientific community responsible for the excellent quality of diagnostic tests in healthcare laboratories all over the world. The College is keen to support urgent advances in practice for patient care related to SARS-CoV-2 and recommends that:

- clinical and accredited scientific leadership is an essential component of all diagnostic testing services
- expansion of diagnostics testing is ideally achieved in partnership with accredited pathology services
- quality standards should apply across all diagnostic services, including stand-alone laboratories.

Across the UK, stand-alone virus testing facilities (the Lighthouse Labs') as well as university-health service partnerships have been rapidly created and deployed to source large capacity for testing for SARS-CoV-2. These facilities aim to test at high volume to ramp up national capacity to massive scale at speed. The rationale for the Lighthouse Labs, as we understand it (the decision was made before the pathology community was involved) was to avoid stressing the NHS and to make use of the considerable enthusiasm and resources of industry and universities that were being offered. This decision was made in the context of the unprecedented circumstances of the epidemic, and the extreme demand for testing services.

The Royal College of Pathologists believes that the capacity and capabilities of the pathology community and resources of the NHS and partner pathology services were under-utilised at an early stage in this. Whilst we consider that any expansion of services would have been more effectively undertaken in partnership with the health service from the outset, we have worked constructively with the decisions that have been made.

Many successful university-health service partnerships have been implemented that integrate with the health service laboratories. Some university systems are working closely with accredited services and are working to similar standards. One such example, is the Crick Partnership with HSL, which provides pathology testing for the NHS, and there are other very good such links and partnerships all over the UK.

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The rapid deployment of non-accredited clinical services run by scientists inexperienced in this type of clinical work has been a particular concern, but we have been offering help and advice, (not all of it accepted, but some of it has been). Standard operating procedures were shared to help progress. The issues around lack of clinical oversight in these centres that we raised have largely been addressed. In particular, we have strongly recommended input from clinical scientists and registered biomedical scientists. We have asked for individuals from accredited systems to be involved, and this has happened in many centres. We especially thank those who have added to their existing heavy duties to support quality and processes in the stand alone centres – you are true professionals with the best interests of patients at the forefront and centre of everything you do.

We have worked with the Chief Scientific Officer for England, responsible for professional development of Healthcare Scientists, who has supported quality review and there are a series of visits from UKAS (United Kingdom Accreditation Service) that are planned in these centres.

We have had concerns about the limited quantities of consumables generally across health services, but appreciate this has been, in part, due to global supply problems. We continue to have concerns about particular consumables being prioritised to the pop up centres, in preference to the NHS, and this has been raised with the head of the Lighthouse Labs and with government. These concerns are have been registered and we will be looking at how things are evolving, in particular given assurances that unused supplies from the Lighthouse Labs may be brought back into the NHS.

There is a fundamental disparity between the requirements (and the associated resource burden and costs) for UKAS type standards in the health service accredited labs, compared with those in the temporary pop up labs. We will need to ensure, as this situation progresses, that quality standards are upheld, and that pathologists and registered laboratory workforce are valued throughout this. There is also food for thought in the extent to which some of the requirements for accreditation are truly required, but that may be a discussion for a different time.

We are grateful that patients and staff are getting the testing they need. Pathology services have been critical to the success of meeting this challenge, and as the targets for NHS testing have been increased the NHS pathology service has been outstanding in its response.

We will continue to champion the profession and ensure that we are not left with a system that takes us back to an unregulated environment. We have assurances that the commitment to transparent and equitable quality standards and regulation will hold for the long term, and the Royal College of Pathologists will be vigilant to ensure this.