

Institute of Biomedical Science (IBMS) – Written evidence (COV0039)

Diagnostic tests for the virus, including PCR (nucleic acid) tests and antibody tests: their accuracy, reliability, supply and distribution.

The Institute of Biomedical Science (IBMS) is the leading professional body for scientists, support staff and students in the field of biomedical science. Biomedical scientists and clinical scientists testing patient samples in hospital diagnostic laboratories are Health and Care Professions Council (HCPC) registrant professionals. Biomedical scientists and laboratory staff analyse fluids and tissue samples from patients, identifying diseases and providing reports that highlight the effectiveness of potential treatments. Many of our 17,000 highly skilled members across the four nations have played a crucial role in the analysis of COVID-19 samples during the current pandemic.

- 1. National validation of PCR test and assay roll out:** The initial test for the virus (polymerase chain reaction, PCR) was designed by a group of scientists cooperating across Europe including those from Public Health England (PHE) in January 2020. This was achieved in a remarkably short time and is to the credit of everyone involved. It was decided that NHS laboratories would use commercial assays. While these were being evaluated during February, laboratories were working to increase testing capacity by re-deploying and training staff. The IBMS published an article on this issue called '[Coronavirus outbreak – update on UK preparations](#)' on 10 February. From the outset, there were issues with supply of equipment, reagents and testing kits to NHS laboratories.
- 2. Operational issues :** From February, pathology laboratory managers became integral members of Trust strategic command meetings. This allowed the laboratory perspective and information about testing to be factored into discussions about logistics of managing COVID-19 and other patients, as well as staff, on a day to day basis. Laboratories put into place plans to extend working hours and accessed the NHS system to recruit recently retired scientists (previously HCPC registered) and healthcare support workers back into service. The problems with supply of equipment and reagents meant that most laboratories had to use more than one kit (usually on different machines) simultaneously, which increased the challenges with respect to staff training. NHS laboratories were not provided with all the necessary equipment and university research departments were approached for loans of equipment. The IBMS produced a guidance document for laboratories undertaking this work '[COVID-19 Supporting the Virology Service](#)' on 16 March 2020. In the meantime, the Lighthouse Laboratories were being set up independently of the NHS/PHE. They recruited microbiology researchers who were not HCPC registrants. It is a legal requirement that staff in laboratories handling patient samples should be registrants themselves or working under the supervision of registrants. Under the circumstances, the former was probably not possible, since HCPC registrants were all busy in the NHS, but the latter should have happened. Many of the issues which have arisen in respect of sample handling, time taken to produce results, data processing

and reporting could have been avoided if the Lighthouse Laboratory system had been set up by HCPC registered NHS/PHE staff and run in collaboration with them.

3. **Central supply of tests kits and reagents:** There was a move to centralised allocation of kits and reagents, to ensure that all laboratories had the opportunity to maintain testing and to prevent stock piling. National teams should be commended for supporting laboratories and their suppliers to overcome these challenges. However, insufficiencies in the supply chain mean that laboratory network managers are meeting weekly to agree how to allocate available kits in their region. If this UK allocation is not increased ahead of the winter season, it will be a challenge for laboratories to meet the likely demand for COVID-19 testing. Supply of swabs has also been a problem. Each different manufacturer's swab needs to be validated for each PCR system, so wherever possible particular wards or hospitals need to be given the same type of swab to use. Then samples from that source are all tested using the same PCR kit. This is an extra level of logistical complication for the laboratory service managers.
4. **Targets:** Rather than allowing the testing system to expand naturally according to clinical need, government ministers decided to set targets for test numbers at various intervals. Apart from the well discussed issues about what is counted as a 'test', this was not particularly helpful from the point of view of laboratory professionals. Introduction of antibody testing of staff has further increased laboratory workload, while it is not always being made clear that its value is to provide data at population level. The main laboratory tests now being used are robust and reliable, but the immune response to SARS-CoV-2 is not well understood, so the presence of detectable antibodies in an individual do not necessarily indicate immunity and absence does not mean that they did not have COVID-19.

5. Impact on wider teams

The virus outbreak has also impacted on a number of areas of teams and departments:

- Occupational Health Departments – have to deal with swabbing demands/result processing and notification/shielding staff/COVID absences and isolation/antibody testing planning and result processing and notification
- Phlebotomists – redeployed to support swabbing and antibody testing
- Business Intelligence and IT – not all trusts have large pathology support teams to gather data/complete SITREP/stock returns/set up and manage NPEX. Often all falls to lab managers to coordinate.
- Meeting burden – Sheer volume of meetings means 'day job' can't be completed. Need to delegate but laboratory teams are already stretched and really need a single point of contact for information to ensure everything being acted on. Pathology Strategic Command instigated to ensure appropriate communication channel from NHS E/I to Trust Execs, lab teams and network colleagues.

The NHS is well known for being dependent on the good will and professionalism of the staff to meet the needs of the patients. Without this continued good will and continued willingness to go above and beyond in what are very small under resourced pathology teams, COVID-19 testing would not have mobilised as quickly as it has to control the pandemic.

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