

COVID-19 Pandemic and the Role of Biomedical Scientists



European Association for Professions in Biomedical Science (EPBS)

Key Points

- SARS-CoV-2 is the greatest health challenge to the world of the century.
- Testing, vaccination and public health measures are the cornerstones for recovery.
- Testing must be undertaken and interpreted accurately.
- Failure to provide a quality assured testing program will lead to the failure of the recovery of commerce, travel and a return to a normal way of life.
- As the virus mutates there is an increasing requirement for nucleic-acid sequencing capacity.
- Biomedical Scientists are the experts in clinical diagnostic testing. They have, and will continue to, provide this quality assured service.

The emergence of Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) infection continues to present the greatest health challenge to Europe and to the rest of the world, which began in 2019. Management of this pandemic has challenged Governments, Health Authorities and the Medical and Nursing professions. One other profession, normally hidden from public view, the Biomedical Scientist, has stepped into the limelight and their contribution to the diagnosis and monitoring of the progression of this disease has been, and will remain, critical for SARS-CoV-2 management. The profession of Biomedical Science is regulated within Europe. The regulations confirm that the scientists undertaking the testing in laboratories have the knowledge, skills and competencies to verify the testing system, undertake the analysis and ensure the results are fit for purpose.

While much has been written about the healthcare staff on the front line during this pandemic, those in patient facing roles, the contribution of Biomedical Scientists to the control of this pandemic must not be underestimated. For a virus almost unknown in 2019 there have been almost 3 billion tests carried out within 18 months by Biomedical Scientists. This testing has been performed while continuing to maintain the routine clinical

diagnostic laboratory workload required to ensure adequate population health.

In addition to the analysis, the Biomedical Scientists have worked with clinical colleagues to ensure that the correct specimens are submitted for analysis and that the microbiologists and infectious disease teams are provided with analytical results and surveillance data. They have interacted with public health teams. They have provided the statistical data necessary for health providers and governments to manage the pandemic and make informed decisions.

The pace with which analytical methods were developed for SARS-CoV-2 was remarkable. Clinical Diagnostic Laboratories in Europe are configured in different ways with different funding models than other countries. These variations meant that the capacity to respond for the required testing varied. The *In Vitro* Diagnostic (IVD) industry worked with remarkable speed to prepare testing kits for use on existing platforms. Virology laboratories, with research capacity, quickly developed 'in house' methods for testing. Scientists all over the world worked cooperatively to identify the genetic material and share primers to develop robust molecular testing methods. This, perhaps, led to the impression that this is easy to do. It is not. Staff trained in

specimen collection are trained to collect these samples from patients such as Doctors, Nurses and Biomedical Scientists. If other groups, or indeed individuals, are drawing samples they should be trained by competent staff, either directly or via viewing material placed online by the World Health Organization. The specific knowledge skills and competencies of a Biomedical Scientist are required to ensure that the testing systems are verified as fit for purpose in a given testing environment. All clinical diagnostic analysis must be subject to Internal Quality Control and External Quality Assurance. Irrespective of the setting where testing is provided the same guiding principles must apply for both patient safety and quality health outcomes.

In the beginning there was a lack of preparedness and the ability of healthcare systems to respond to this pandemic across the globe. This was particularly true in terms of clinical diagnostic capacity. Over the past decades there has been an assumption that this specialty is becoming simplified with the introduction of automated instruments and integrated information technology (IT) systems. There has been a trend to use non-professionally qualified staff and to reduce investment in the professional development and career pathways for Biomedical Scientists. This has been a mistake. As the pandemic unfolded it was evident that there were insufficient qualified Biomedical Scientists in Europe to undertake the range and volume of testing required. As waves of the virus pass through populations and mutations occur, it is clear the concept of zero SARS-CoV-2 is no longer a possibility. The world must all learn how to live with this virus. It is clear the virus can, and will, mutate to maintain an infectious advantage. It is likely that there will be a continued need to provide testing services for both symptomatic and asymptomatic cases, for contact tracing, to monitor the mutations of the virus and to establish immunity to permit normal life to be re-established safely.

The impact of and response to SARS-CoV-2 (COVID-19) in Europe has not been uniform, it should be consistent at a national, regional and global level. It needs to be informed by, and adapt to, the evolving evidence and science.

Without robust testing systems and a European wide coordinated approach to testing regimens the resumption of normal life and commerce will be delayed.

The COVID-19 pandemic has had a huge impact on international travel, including in Europe. As part of the European strategy to re-establish free movement the Digital COVID Certificate (EUDCC) was developed and implemented. The purpose of these digital certificates is to show that an individual can travel and cross borders without a (tangible) risk of carrying the virus. For safety of the citizens it is imperative that all testing processes are quality assured. Without this assurance the EUDCC cannot succeed, and free movement will be prohibited. It is the position of the European Association for Professions in Biomedical Science (EPBS) that only regulated healthcare professionals, ideally Biomedical Scientists, should carry out such testing for the issuing of these certificates. The European Centre for Disease Prevention and Control (ECDC) is supporting scaling up of nucleic-acid sequencing and neutralization assay capacity in European Union/European Economic Area Member States.⁽¹⁾ This development is both welcome and vital for the coordinated European response to the pandemic. It will also require investment in the education and training of additional Biomedical Scientists in Europe to be sustainable.

The Biomedical Scientists of Europe, represented by EPBS, are the diagnostic partners in this fight. We will continue to work for the health benefit of our countries and together we can harness a resource that is at the disposal of the EU. Work with us, take advantage of our knowledge skills and competencies, give us the tools we need to deliver the service required bring us into the discussion and, as we have demonstrated, we will deliver.

(1) European Union/European Economic Area (EU/EEA): The EU is an economic and political union of 27 countries in Europe, collaborating with an additional three countries as members of the EEA. EU/EEA operates an internal market, which allows free movement of goods, capital, services and people between member states.