

Independent SAGE Statement on COVID-19 testing at Immensa Health Clinic (Dante Laboratories), Wolverhampton

Independent SAGE has previously identified [the risks and inadequacies of the outsourcing of COVID testing within the UK](#). These issues go back to February 2020, at which time the perceived “lack of laboratory capacity within Public Health England” to deal with the growing pandemic led to the UK government decision to establish “NHS Test and Trace” with a budget of more than £35bn. The operating plan of Test and Trace included the setting up of independent Lighthouse Laboratories and entering contracts with several other private providers and test suppliers. We now know that such contracts were issued following direct approaches to Ministers, [bypassing normal evaluation and due diligence procedures](#). Our criticism of this process also included a concern about separating out testing from the response to test results, and lack of assimilation into local public health structures. Indeed, in August 2020, [a group of more than 60 UK clinical virologists](#) condemned this outsourcing approach and argued that the UK network of NHS, public health and academic laboratories could provide high quality testing for the UK, within an existing integrated and cost-effective network.

It is in this larger context that the failure of the Immensa Health Clinic laboratory should be viewed. The UK Health Security Agency announced on 15<sup>th</sup> October 2021 that the lab would be required to stop all Covid-19 testing. This decision was taken approximately five weeks after the problem first began and three weeks [after anomalies in testing data in the South-West of England were first identified](#) by a member of the public. After [concerns were raised in the media](#) about individuals with positive lateral flow results testing negative by PCR and Public Health England/UKHSA [announced they were investigating these discordant results](#), it took them over a week to isolate the source of the problem. During that time they were [still issuing the following guidance](#) “If you get a positive LFD test it’s important to make sure that you then get a follow up PCR test to confirm you have Covid-19”. The length of time it took to spot there was an issue and then act on it allowed an estimated 43,000 people with Covid-19 to be told - wrongly - that they tested negative. Many of these people would have gone to school, to work and out into the community wrongly believing they were safe to do so. We are now seeing a marked surge in infections in communities served by the Immensa Health Clinic, particularly across the South West of England. This surge in infections will lead to increased pressure in hospitals in the region and ultimately to unnecessary deaths.

In the aftermath, Dr Jenny Harries, CEO of UKHSA, announced that the laboratory in question was fully accredited, [only for this to be promptly contradicted by the UK accreditation service \(UKAS\) itself](#). To date, the nature of the contractual arrangement between the UK government and Immensa Health Clinic has not been forthcoming and nor do we know any further details about quality assurance processes at the lab. Even basic quality assurance within the lab and within UKHSA should have identified the problem within a matter of days.

This incident highlights the need for some urgent actions, and reconsideration of the COVID testing environment, as follows:

1. Rapid publication of the report of the UKHSA review process undertaken of Immensa Health Clinic, including the speed of response to early reports of problematic results, and the failure of internal laboratory control and oversight measures within the laboratory.
2. Publication of the process and decision making for awarding the contract to Immensa Health Clinic.
3. Publication of the original contract with Immensa Health Clinic including oversight of quality and accreditation of the lab.
4. Details of the role of PHE/UKHSA in the awarding and monitoring of this and other outsourced laboratory contracts.
5. Details of the clinical, public health and governance response to the laboratory failure including the potential for retesting of original stored samples, and enhanced surveillance of those communities affected.
6. Details of measures to assure other labs are meeting the standards required.
7. The need to rapidly re-assemble PHE , NHS and aligned university laboratory capacities, and their clinical leaderships, to drive future laboratory support of COVID response. This should be associated with the migration of outsourced contracts back to such a consortium wherever possible.