

## Written evidence submitted by HCSA (COR0007)

### Introduction

HCSA is a nationally recognised trade union and professional association, which represents all grades of hospital doctor. The purpose of this briefing is to bring to the attention of the committee a number of ongoing issues with the testing regime for COVID-19

### Top Lines

- In those with known Covid-19 infection PCR tests have a false-negative rate of up to 30 percent. HCSA is therefore deeply concerned about examples of a single negative test result being used to 'clear' NHS members of staff to return to work as false negatives may be interpreted as inferring an erroneous non-infectious state
- The Government and Public Health England have refused requests from MPs and HCSA to provide transparency on the eight key testing platforms that have been used to carry out more than four million tests. This includes the names of the manufacturer of each test, their sensitivity and specificity and the names of any tests that are no longer in use.
- The lack of transparency for PCR tests stands in stark contrast to the Government's decision to publish its assessment of two antibody tests. No independent assessments of PCR tests have been published and it is unclear whether they have even taken place.
- It is concerning that the SAGE recommendation for testing of all healthcare staff, symptomatic and asymptomatic has not been implemented.

### Comment from Dr Paul Donaldson, HCSA General Secretary:

"We are deeply concerned and frustrated at the systematic refusal to provide even basic information about the reliability of the testing regime. While significant information has been provided about the new antibody tests, a wall of silence seems to have been erected around issues relating to the PCR tests, which have been used more than four million times.

"A reliable testing regime is central to the next stage of our response to COVID-19. Without a greater level of transparency being provided, we are unable to say with confidence that such a system is currently in place.

"Separately, statements by PHE officials and others place the incidence of false negatives somewhere between 20 and 30 percent. If confirmed, this is a worryingly high rate that raises the prospect of many infected individuals, possibly without symptoms, being passed fit to return to healthcare settings where they will transmit the virus to colleagues and patients."

## Background

### PCR tests and false-negative results

- Polymerase chain reaction (PCR) tests, often described as antigen tests, detect the genetic information of the virus, which is only possible when someone is actively infected. They can provide a good indication of who is infected so that they can be managed appropriately, including through the use of isolation and contact tracing.
- However, errors can occur at several stages of the PCR testing process, which gives rise to a false negative rate of up to 30 percent. This means that they are more useful for confirming the presence of an infection than in giving someone the all-clear in a suspected case.
- A report by the Mayo Clinic<sup>1</sup> is clear about the risks presented by false-negative results: *“as tests become more available, observing principles of evidence-based clinical reasoning concerning the meaning of diagnostic tests is essential. For negative tests in particular, failure to do so has direct implications for the safety of the public and health care workers and for the success of efforts to curb the pandemic.”*
- PCR tests were introduced at an early stage of our response to Covid-19 and were initially used for all suspected cases. However, on 12 March the Government restricted testing to those who were admitted to hospital<sup>2</sup>, before gradually increasing the number of groups eligible for testing.
- On 17<sup>th</sup> March, NHS England and Improvement set out a plan<sup>3</sup> to establish targeted staff testing for *“symptomatic staff who would otherwise need to self-isolate for 7 days.”*
- HCSA expressed concern at the time at the use of PCR tests for negative screening for staff, as the significant false negative rate could lead to test-negative cases returning to work and spreading the virus to colleagues and patients.
- Clearly without repeat PCR testing to confirm a negative result, staff should not be told to return to a clinical setting, but our members have raised a number of examples of this taking place.

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<sup>1</sup> Mayo Clinic (2020) *COVID-19 Testing: the threat of false-negative results*. [https://www.mayoclinicproceedings.org/article/S0025-6196\(20\)30365-7/pdf](https://www.mayoclinicproceedings.org/article/S0025-6196(20)30365-7/pdf) <sup>2</sup> Prime Minister’s Office (2020) *PM statement on coronavirus: 12 March 2020*.

<https://www.gov.uk/government/speeches/pm-statement-on-coronavirus-12-march-2020>

<sup>3</sup> NHS England and Improvement (2020). *Letter to Chief Executives of NHS Trusts and Foundation Trusts*. <https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/urgent-next-steps-on-nhs-response-to-covid-19-letter-simon-stevens.pdf>

- The recent temporary closure of Weston General Hospital, where there has been "an emerging picture<sup>4</sup>" of asymptomatic workers testing positive is a clear example of the risk of relying on a single negative test result.
- **We would urge the committee to call on the Government and NHS bodies to ensure that greater clarity is provided around the interpretation of a negative test result. Individuals with a single negative test result must still be treated as potential carriers of the virus.**
- **In addition, given the prevalence of asymptomatic transmission, we would question why the SAGE recommendation to test all healthcare staff, symptomatic and asymptomatic has not been implemented.**

#### Transparency

- HCSA has also consistently called for transparency on the manufacturers of the tests in use, and their sensitivity and specificity.
- **However, while Public Health England recently released the full results of its assessment of antibody tests, there is no similar data publicly available about the PCR testing system, which has now been used more than four million times. This raises two important questions:**
  - 1. Why haven't independent assessments of PCR been published assuming they have been made?**
  - 2. What assessment has been done on true effectiveness of PCR tests in a field setting as opposed to lab-controlled environment?**
- Responsibility for the testing regime is unnecessarily convoluted, with various aspects divided between Public Health England, the Department for Health and Social Care and a range of commercial operators, which presents a clear risk for confusion to arise. There is a worrying lack of clarity around who has responsibility for the testing of whom, and who is responsible for oversight/follow up of results.
- Dr Paul Donaldson, General Secretary of HCSA wrote to Duncan Selbie, Chief Executive of Public Health England raising a number of questions about the testing regime on 20 April, 28 April and 24 May.
- While a response was provided on 29 May providing the names of four companies providing tests in addition to in-house testing, no response was provided to requests for information about the sensitivity or specificity of the tests, or whether any assessment has been undertaken by either PHE or DHSC.

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<sup>4</sup> BBC News (2020) *Coronavirus: Weston hospital 'to be shut for at least a week.'*  
<https://www.bbc.co.uk/news/uk-england-somerset-52830447>

- From Written Parliamentary Questions, we are able to ascertain that eight key testing platforms have been used to deliver “the majority of testing.<sup>5</sup>” However, in responses to questions from Justin Madders MP<sup>6</sup> and Rosie Cooper MP,<sup>9</sup> the Government has refused to provide details of the manufacturers of the tests in use, their false negative rates, or the names of any tests no longer in use. The only reason that has been offered for this refusal was, “commercial confidentiality.”
- It is deeply concerning that the Government is refusing to provide straightforward information about such a significant response to our response to the pandemic.
- We can only speculate as to whether the official reluctance to reveal the precise effectiveness and even identity of the tests being used was linked to pressure to meet ambitious political targets. However, our concern relates directly to front-line medical staff, their colleagues and patients.
- The success of the new NHS test and trace project is reliant on an effective testing regime being in place. This includes a quick turnaround time for results and the test results themselves being reliable.
- **We would therefore urge the committee to call for urgent transparency on this vitally important issue.**
- **If the tests are inadequate then there should be a clear and transparent acknowledgement of this, and guidance should be reviewed to ensure employers are able to fulfil their legal obligations on health and safety.**

#### Antibody tests

- Unlike PCR tests, which can indicate whether an individual is currently infected with the virus, antibody tests indicate whether someone has previously been infected. They cannot provide an immediate picture because the antibodies are generated after a week or two, after which time the virus should have been cleared.

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<sup>5</sup> *Coronavirus: Screening: Written question – 41079.*

<https://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Commons/2020-04-28/41079/>

<sup>6</sup> Ibid

<sup>7</sup> *Coronavirus: Screening: Written question – 41081.*

<https://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Commons/2020-04-28/41081/>

<sup>8</sup> *Coronavirus: Screening: Written question – 41081.*

<https://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Commons/2020-04-28/41080/>

<sup>9</sup> *Coronavirus: Screening: Written question – 34319.*

<https://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Commons/2020-03-24/34319/>

- The arrival of an effective antibody test is to be welcomed and will no doubt hugely aid our ability to detect those who have previously been infected by Covid-19. As we learn more about the role of antibodies, this could open the door to different ways of working and reduce the level of risk to NHS staff by allocating those who have had the virus to care for Covid-19 patients. But we must be clear that huge uncertainties remain while we do not know the level and length of any immunity which antibodies will offer.
- **While so much is unknown, the new test's arrival should not simply be seen as a green light to reduce PPE and other protections for NHS staff who test positive.**

*June 2020*