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Thursday 17th December 2020

The Rt Hon Matt Hancock MP  
Secretary of State for Health & Social Care  
39 Victoria Street  
London  
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Dear Mr Hancock

### **Testing for Coronavirus and Government lockdown policies**

I am writing to you as Chairman of Reform UK (formerly the Brexit Party).

#### **A      THIS LETTER**

This letter concerns a very important aspect of the Government's response to the Coronavirus pandemic; in particular the approach of the public health authorities to the matter of testing people for SARS-CoV-2, the virus which causes the illness known as Covid-19 ("Covid").

Although initially dismissed by the Government's experts in the early stages of the epidemic as unimportant in the battle to contain the spread of the virus, this policy was quickly changed in April and the importance of ramping up the country's testing capacity became a major priority. This has continued to be the case ever since. The Government has placed a huge emphasis upon the importance of Covid testing. This has reached the point where hundreds of thousands of tests are being conducted every day throughout the UK. The numbers of "positive" cases of Covid identified from this testing have featured prominently in Government messaging about the situation and have been heavily relied upon in seeking to justify the various lockdown measures imposed on the country. Case numbers are still evidently an important part in shaping policies towards Covid restrictions.

Reform UK and many others, including highly qualified experts in the medical and scientific community, have become increasingly concerned, however, by the growing evidence of serious flaws in the whole approach to testing and in particular by the inherent weaknesses of the use of the reverse transcription polymerase chain reaction test ("PCR test") that remains the primary test used in the UK to detect Covid infections.

There is now a sufficient body of evidence and unanswered questions which raise serious doubts as to the integrity of PCR based Covid infection data used by the Government to inform the public about the virus and to make legislation supposedly aimed at curbing infections. As a political party, we seek in the public interest, answers to various questions raised in this letter. Since Ministers are taking decisions which affect the lives and livelihoods of millions of people, in many cases based on data derived from mass testing using PCR tests, there are clearly legitimate public interest concerns which need to be addressed.

We therefore trust that this letter will be taken seriously, and we look forward to a constructive, informative and timely response.



## **B**      PCR TESTING

### **The PCR test itself**

The basic process for conducting the PCR tests for SARS-CoV-2 is well documented. The following description of it is taken from a document published by Public Health England<sup>1</sup>

The first step in the PCR test for SARS-CoV-2 is to extract the viral RNA from the sample to purify, stabilise and concentrate it, to increase detection of samples containing low quantity of virus. The purified extract is added to a biochemical reaction mixture that includes primers (i.e. short stretches of nucleic acid that match parts of the target organism genome), nucleotide bases (the building blocks of nucleic acids), enzymes (to initiate and complete the reaction) and fluorescently labelled probes (i.e. short stretches of nucleic acid that recognise and stick to the reaction product (the reaction indicator).

The sample reaction mixture is subjected to repeated thermal cycles so that copies of the viral target are doubled per cycle leading to exponential rise. Labelled probes emit a fluorescent signal in the presence of newly synthesised target. The earlier that exponential increase occurs, the higher the quantity of virus in the sample.

The precise data detailing these features of the test for each sample are not published by the Government. All that is made available are the numbers of tests conducted and those which have been shown up as "positive" (i.e. have detected Covid-specific RNA).

However, it is now well documented that one of the major disadvantages of the PCR test as a diagnostic tool is that a mere positive result is not, in itself, proof that the person who has tested positive is still infected with live virus or that they are capable of infecting anyone else. To quote from the same PHE document:

*"RT-PCR detects presence of viral genetic material in a sample but is not able to distinguish whether infectious virus is present."*

The PHE document also points out the potential for tests to be significantly affected by how they are conducted in the field (i.e. in the real world) rather than under laboratory conditions:

*"The quantity of intact virus in upper respiratory swabs will be affected by factors that are endogenous and exogenous to laboratory methods."*

Other independent studies from reputable sources have made similar findings about the limitations of PCR tests.

For example, Ireland's Health Protection Surveillance Centre produced a report on "*Notes on the Utility & Limitations of PCR*" in which they concluded:

1.      *"PCR does not distinguish between viable virus and non-infectious RNA*
2.      *In individuals infected with SARS-CoV-2 PCR can often detect viral RNA for many days and weeks after the resolution of clinical syndrome....."*<sup>2</sup>

The Muge report<sup>3</sup> based upon 79 published studies of Coronavirus concluded as follows:

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<sup>1</sup> [Understanding cycle threshold \(Ct\) in SARS-CoV-2 RT-PCR \(publishing.service.gov.uk\)](https://publishing.service.gov.uk)

<sup>2</sup> <https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/outbreakmanagementguidance/PCR%20weak%20results%20guidance.pdf>

<sup>3</sup> Muge Cevik, Matthew Tate et al., 'SARS-CoV-2, SARS-CoV-1 and MERS-CoV viral load dynamics, duration of viral shedding and infectiousness: a living systematic review and meta-analysis' (29 July 2020) <https://www.medrxiv.org/content/10.1101/2020.07.25.20162107v2>



*"Maximum duration of SARS-CoV-2 RNA shedding reported in URT, LRT, stool and serum was 83, 59, 35 and 60 days, respectively..... No study to date has detected live virus beyond day nine of illness despite persistently high viral loads. SARS-CoV-2 viral load in the upper respiratory tract appears to peak in the first week of illness, while SARS-CoV-1 and MERS-CoV peak later. Conclusion: Although SARS-CoV-2 RNA shedding in respiratory and stool can be prolonged, duration of viable virus is relatively short-lived. **Thus, detection of viral RNA cannot be used to infer infectiousness.**" [emphasis added]*

A real-life example of this phenomenon is the well documented case of the three British men who tested positive for Covid-19 whilst in Venice on 17 August, having been ill for 4 days. As of 17 September, they were stuck in a quarantine facility and unable to leave due to still testing positive for Covid.<sup>4</sup> They posed no risk to anyone of passing on Covid by that stage. Yet the PCR test results meant they were unable to be released from isolation.

Finally, the Government's Chief Scientific Adviser, Sir Patrick Vallance confirmed the limitations of the RT PCR test when questioned by the House of Commons Scientific Committee on 2 November when he said this:

*"PCR.....is very sensitive and picks up lots of things, even very small amounts of RNA. **That is probably one of the reasons it picks up people who are not actually infectious but those with residual RNA from having a virus. In that sense it is a false positive in terms of infectiousness.**"<sup>5</sup> [emphasis added]*

The upshot of all this, is that just because there happen to be say, 10,000 "new" cases of Covid reported based on positive PCR test results, does not mean that there are 10,000 more *new* infections. Those results could include people who had the virus many weeks earlier and who no longer have it in the sense of being able to spread it to anyone else.

Moreover, there is also the potentially serious problem of out and out false positives where people who do not – and never have had – Covid are held as being "positive" following PCR tests.

Much has been made of how accurate PCR tests are in terms of their specificity and sensitivity in detecting Covid (over 95%). However, these headline rates of accuracy are not realistic because they are the product of testing in a wholly artificial environment. In other words, they do not reflect the reality of how most PCR tests are actually conducted in the field and how the resulting samples end up being transported and analysed.

On 3 June 2020, SAGE produced a paper for Public Health England entitled "*Impact of false-positives and false-negatives in the UK's COVID-19 RT-PCR testing programme*" ("3 June Paper"). The June Paper frankly set out many of the issues arising with PCR tests.<sup>6</sup> It made the point that although the PCR tests have very high sensitivity and specificity ratings of over 95%, these are the product of evaluation under laboratory conditions where skilled professionals are undertaking tests under optimum, controlled conditions. In other words, much the like the official fuel consumption figures often cited for cars, they are not based on "real life" conditions. The June Paper explains this as follows:

*"The RT-PCR assays used for the UK's COVID-19 testing programme have been verified by PHE, and show over 95% sensitivity and specificity. This means that under laboratory conditions, these RT-PCR tests should never show more than 5% false positives or 5% false negatives.*

*It is important to remember that laboratory testing verifies the analytical sensitivity and analytical specificity of the RT-PCR tests. They represent idealised testing. In a clinical or community setting there may be inefficient sampling, lab contamination, sample degradation or other sources of error that will lead to increased numbers of false positives or false negatives.*

*The diagnostic sensitivity and diagnostic specificity of a test can only be measured in operational conditions."*

<sup>4</sup> <https://www.bbc.co.uk/news/uk-wales-54188163>

<sup>5</sup> <https://committees.parliament.uk/oralevidence/1122/default/> at 1496

<sup>6</sup> [S0519 Impact of false positives and negatives.pdf \(publishing.service.gov.uk\)](https://publishing.service.gov.uk/S0519_Impact_of_false_positives_and_negatives.pdf)



The importance of accuracy in the carrying out of PCR tests and how significant this is to the resulting policy response is then summarised as follows:

*"Operational false-positives and false-negatives will have significant impact in the way we respond to the COVID-19 pandemic..."*

As of 3 June, it is clear that the Dept of Health & Social Care had not attempted to carry out any assessment of how accurate (or otherwise) the PCR testing was in operational terms (i.e. in the real world). The paper added, that steps needed to be taken to identify this as a priority:

*"We have been unable to find any data on the operational false positive and false negative rates in the UK COVID-19 RT-PCR testing programme. This short paper suggests this must be measured as a priority, and makes recommendations on managing operational false positive and false negative rates."*

The paper concluded:

*"The UK operational false positive rate is unknown. There are no published studies on the operational false positive rate of any national COVID-19 testing programme....."*

*".....Unless we understand the operational false positive rate of the UK's RT-PCR testing system we risk overestimating the COVID-19 incidence, the demand on track and trace, and the extent of asymptomatic infection."*

The paper identified a number of issues which could lead to false positives. These included such things as cross reactions with other genetic material, contamination during sampling, contamination during swab extraction, contamination with PCR amplicon, contamination of PCR laboratory consumables.

Issues which could lead to negative results include poor sampling technique, sample degradation, sampling too early and sampling too late.

The factors that can cause misleading results in PCR tests are a concern because not only – as the SAGE paper says – does there not appear to be any data about the accuracy of PCR tests in real world operational conditions, but there is evidence that many of the factors cited as concerns in the paper are happening in practice.

It is thus extraordinary that on 14<sup>th</sup> October, over 4 months later, Lord Bethell in the House of Lords admitted that the Government still did not know the operational false positive rate (OFPR). You however had expressed a view on TalkRadio previously on 18 September, that the False Positive Rate (FPR) for the PCR test was 1% of all tests carried out. Please confirm the source of that claim by yourself. It appears to us that between you both and the Government, you have no scientific evidence apparently on which to base an *operational* false positive rate. Dominic Raab, the Foreign Secretary, stated on Sky News on 23 September that the "*false positive rate was very high and only 7% of tests will be successful in identifying those who have the virus.*"

### **Cambridge University screening programme**

Another graphic illustration of how unreliable PCR tests are can be found from studying the results of the Cambridge University (CU) Covid-19 asymptomatic screening programme. The results of this programme have been published by CU.<sup>7</sup> CU do at least have the very sensible policy of double testing any positive result so as to try and be more certain that it is a true positive.

Their results are very revealing.

Since October, 18% of the positive PCR test results turned out to be false positives. Alarmingly, in the most recent week of results, it has turned out that every single one of the 11 of positive PCR test results turned out to be false positives – a failure rate for 100% for the PCR positive results.

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<sup>7</sup> [Asymptomatic COVID-19 screening programme | University of Cambridge](#)



According to the CU website, these tests have been carried out at a laboratory which is one of the networks of so-called "Lighthouse laboratories" ("Lighthouse labs"). The public would assume that such a lab would be staffed with experienced and trained personnel in what is, as far as we are aware, a purpose designed facility equipped specifically to conduct this testing programme. Yet they still failed miserably to produce correct results. This was not the first week of the CU programme to show a significant false positive rate. At the very least such a disastrous result and previous weeks' results suggests considerable inconsistencies in the conduct of the tests or inherent in the very nature of the PCR tests themselves.

At least in the case of the CU false positives, the occupants of the 11 households concerned were given the all clear after confirmatory tests were conducted. But had it not been for those confirmatory tests, all of the occupants of those 11 households would have been forced to needlessly self-isolate for 14 days – for no good reason.

If we extrapolate the results from the CU programme to the PCR results returned nationwide using other Lighthouse Labs, including those which may have even less stringent controls and less well trained staff, it suggests that not only are very large numbers of people being wrongly diagnosed as infected with Covid-19, but even greater numbers of people through contact tracing are being wrongly forced – on penalty of huge fines - to self-isolate on a false basis. For those who cannot work from home, this can be devastating. The knock-on effects for the economy do not bear thinking about.

The false positives issue will also feed through into how people are dealt with in healthcare settings. For example, patients admitted to hospital may be wrongly diagnosed as Covid-positive and cohorted with Covid-infected patients. We know that hospital acquired Covid infections are a serious problem.

The false positives will also affect the statistics for the numbers of supposedly Covid-infected patients being admitted to hospitals as well as to the figures for deaths recorded as being attributable to Covid.

#### **Swansea University report into impact of False Positives**

In a separate evaluation published on 26<sup>th</sup> November for the January 2021 edition of Clinical Medicine, a Public Health Wales microbiology and infectious diseases consultant, Dr Brendan Healy, reported the results of their research on false positives. In 5,110 PCR tests there were 26 single gene low level positives. Upon retesting, 19 of the 26 were found to be negative, thus showing that 73% of single gene positive results were in fact false positives.<sup>8</sup>

Dr Healy concluded:

*“False positive results have the potential to cause harm in both high and low prevalence settings. Careful interpretation of laboratory results is required at all times. Low level positive results in a single gene need to be interpreted with caution based on the clinical context. The Ct value can also provide useful information when assessing results and clinicians need to become familiar with the interpretation of these results. Results should also be conveyed detailing the number of genes positive and the Ct value – not simply in a binary fashion”*

So, here is a UK public Health official making major recommendations into the interpretation of positive results which are substantially at odds with the approach being adopted by the four nations of the UK.

It is thus hardly a surprise that a Portuguese appeals court recently ruled, having considered the available evidence, including from scientific literature published in the UK, that PCR tests were "unreliable" and not fit for purpose and that they did not justify the continued detention and isolation of individuals. In Italy we now understand such is the concern over PCR testing that legal cases have been commenced against the PCR testing companies. It is interesting to note that in Norway, positive PCR test results of asymptomatic people are double checked with a second test to be surer of the finding. This may partly explain why their cases are much somewhat lower than the UK's.

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<sup>8</sup> [The impact of false positive COVID-19 results in an area of low prevalence | RCP Journals](#)



Closer to home, we are of course aware that the regulations requiring persons to self-isolate in response to the contact tracing service have been the subject of a recent judgement in *Francis v Secretary of State for Health and Social Care [2020] EWHC 3287 (Admin)*. However, that case did not challenge the rationality or otherwise of relying upon a flawed test (i.e. the PCR test) as grounds for compelling individuals to self-isolate. Furthermore, the reliance upon PCR tests is of course more fundamental as it appears to be shaping the wider legislative response to the pandemic.

### **Lighthouse laboratories – issues**

A key element of the Government's Covid testing infrastructure was the establishment of a number of Lighthouse labs to undertake the processing of PCR test samples at scale. These were established in the Summer at various locations across the UK. They include the facility at which the CU testing programme described above was carried out.

However, a number of reports have appeared in the press and media about issues arising in the Lighthouse labs. These have included concerns about the health and safety of employees due to lax practices, but also allegations concerning poor practices which may result in cross contamination of samples, again, potentially leading to misleading test results. Examples of these reports are:

[Coronavirus testing lab 'chaotic and dangerous', scientist claims - BBC News](#)

[Dispatches uncovers serious failings at one of UK's largest COVID-Testing Labs | Channel 4](#)

<https://www.independent.co.uk/news/health/coronavirus-testing-lighthouse-labs-safety-whistleblowers-b1041495.html>

In the face of such worrying reports, what assurances can DHSC give us that the Lighthouse labs are being run properly and that the kinds of practices alleged in the above reports are not going on at other sites?

Because of the extreme sensitivity of the PCR test, it does not take much imagination to see that failure to follow proper sample handling protocols could easily result in cross contamination which in turn could well contribute to inaccurate and misleading results.

Mindful of how important the factors are that can influence test outcomes, the June Paper concluded with some important recommendations. These included the need for the following steps:

- 1) An External Quality Assessment (EQA) must be carried out for the UK National COVID-19 RT-PCR testing programme. This would introduce known positive and known negative samples into the testing programme. Samples would be submitted blindly, to ensure they follow an identical process as operational samples. This would provide a national estimate for the operational false positive and false negative rates. This could be carried out quickly, and at relatively low cost.
- 2) A continual rolling EQA (a low volume of blind samples submitted every day) should be used to monitor performance of labs across the UK COVID-19 RT-PCR testing network. Labs with higher false positive and false negative rates would be alerted and could improve their performance.

Can the DHSC confirm whether or not these recommendations were ever acted upon and implemented?

If so, what are the results?

In respect of 1, what are the operational false positive and false negative rates of the PCR tests carried out to produce the figures on which the Government relies in making policy (i.e. the real false positive and false negative rates achieved in practice – as opposed to those achieved under perfect laboratory conditions)?

In respect of 2, if this has been implemented, what is the result of the monitoring of lab performance and which laboratories have been alerted and requested to improve their results?



The results of the CU test programme referred to above has illustrated how important it is to monitor the accuracy of PCR tests so that the numbers of positive cases are not exaggerated.

The concerns are that PCR tests were never designed to be done on a mass scale by unqualified staff and as the Government ramped up testing in the late Summer, since then the cases increased, quite possibly due to the increasing incidences of cross contamination.

## **C THE LIVERPOOL MASS TESTING PILOT**

Starting from 6 November, a mass testing programme was conducted in Liverpool. This was the first using the new Innova Lateral Flow test which presumably the Government has considerable confidence in since we understand it has placed orders with Innova for over £600 million to buy such tests.

After the Innova test kit began being used in Liverpool, the Innova LFT test was the subject of an evaluation by a Public Health England programme using the expertise of the Government's Porton Down laboratories and the University of Oxford. This was designed to identify potential antigen detection tests that could be used for mass community testing. The report on this evaluation concluded:

*"To date, the performance characteristics of the Innova LFD in the evaluations performed to date are good with a low failure rate, high specificity 99.6% and high viral antigen detection".<sup>9</sup>*

According to the Liverpool local authority's recently published report<sup>10</sup>, between 6 November and 9 December a total of 73,956 PCR tests were carried out, of which 3.8% (2,802) tested positive.

During that same period, a total of 122,943 tests were carried out using LFT tests of which just 0.7% (881) were positive.

The percentage of positive results achieved through using the LFT tests was thus dramatically lower than when using the PCR tests – less than 1 in 5 times the rate of positive results.

There is no explanation given in the report to account for the massive difference between the two types of tests. This huge difference underlines the point we made earlier concerning the use of PCR tests, namely that it is misleading to assume that just because they achieve a high sensitivity and specificity when tested under laboratory conditions, they will achieve anything like the same results when used outside of that environment. Indeed, the report itself is rather confusing. The report says this about the latest position:

*"At the current COVID population prevalence in Liverpool, between 1 in 2 to 1 in 5 people who test positive with a lateral flow test might be a false positive. They will require confirmatory Polymerase Chain Reaction (PCR) testing."*

This is hard to follow. Why, when the percentage of people who test positive with an LFT test is so much lower than for PCR tests, is it suggested that LFTs are returning significant false positives? The Porton Down report says the LFT only produces 0.3% false positives, which is of course less than you personally stated is the false positive rate for PCR at 1%. On this basis the Liverpool City council statement makes no sense; they infer 20-50% false positives for LFT tests. Are they confused? How can we trust the data when major City Councils are confused themselves?

The LFT Porton Down tests achieved a sensitivity of 78.6% but performed best when used by skilled laboratory staff. This fell to 73% when operated by trained healthcare professionals. Sensitivity went down to 58% when used by self-trained members of the public. The Porton Down study also concludes that the LFT tests detected 95% of those persons with a high viral load. In other words, the test's ability to identify those most likely to be capable of spreading the virus is particularly good.

Liverpool results are anything to go by, if LFT tests replaced PCR testing, it would seem that there would be a very substantial reduction in the number of positive Covid cases being reported across the UK. Interestingly

<sup>9</sup> [UK evaluation PHE Porton Down University of Oxford final.pdf](#)

<sup>10</sup> [covid-daily-postcode-surveillance\\_04122020.pdf \(liverpool.gov.uk\)](#)



Liverpool, since 9<sup>th</sup> December, have stopped publishing the comparative PCR v LFT data, perhaps because they have been told it is embarrassing and does not suit the establishment narrative?

This could have important consequences. Liverpool appears to have escaped from being placed under so-called Tier 3 restrictions because of the lower numbers of people testing positive through use of the LFT tests. If this happened in Liverpool, why can it not happen in other areas which may well have been allocated to a much more destructive set of restrictive measures, than if they had been able to demonstrate a lower prevalence of Covid in their areas?

Why has the Government been prepared to place Liverpool in a lower risk category of Tier, on the face of it, based largely on the results of LFT tests, whereas other regions of the UK have been forced into harsher Tiers than might otherwise be the case because of numbers of cases resulting from PCR tests?

The Government is rolling out the LFT programme across the country which must mean it has real confidence in it. The latest figures are startling. In Merthyr Tydfil, which in early November had the highest cases per 100,000 in the UK, suddenly saw a large fall in case numbers with the mass LFT testing, with just 1.4% positives from over 23,000 LFT tests. This at a time when the rest of Wales was producing 9% positive results using PCR testing. We understand that the Universities of Bristol, Birmingham and St Andrews between them had just 4 positives from over 8,000 LFT tests, a rate of 0.05%. This suggests there is little to no Covid to speak of in those areas.

However, there are new concerns in some quarters that the LFT may be missing about 50% of the cases, as per the Liverpool University report 25<sup>th</sup> November on comparative testing of 3,199 patients. This showed that the LFT tests produced 25 positive cases, but that the PCR test produced 45 positive cases. What this report however fails to consider, in a significant shortcoming, is the false positive rate of the PCR test itself. Your own 1% FPR figure would mean that 32 of the 45 positive results would be false, meaning that the whole report's concerns are misplaced. Thus, the report in fact would re-validate the LFT evaluation data from Porton Down, not cast doubt on it. In truth however, even if the LFTs were missing 50% of the cases, the numbers are still so far below the average daily PCR positive rates, that it still requires full and proper investigation.

The overall point is that there is such real concern over the testing programme in many quarters that it is vital to put this to proper comparative sampling.

On the BBC's Politics Live programme broadcast on 7 December 2020, I specifically raised the issue of LFT tests and how they produced radically different results when compared to PCR tests. I issued a treble test challenge to the Government to clarify the position and confirm whether or not they still had confidence in the use of PCR tests. My suggestion was that 1,000 people or perhaps more should be tested on the same day, using the standard Government PCR test processed in more than one of its' Lighthouse labs, the new Innova LFT test and a separate PCR test which should be separately analysed by an independent specialist laboratory testing facility.

## **D      NHS CAPACITY**

The Government's stated justification for imposing harsher lockdown measures has been based in large part on the proposition that increasing numbers of Covid cases would inevitably lead to rising numbers of Covid admissions, leading sadly to increasing numbers of deaths.

Thus, it is the testing numbers which have been the driver of the policy.

But whilst claiming that the NHS was facing meltdown, the Government has singularly failed to publish specific data showing the state of critical care bed capacity in the NHS by region and – critically by reference to the same period in previous years.

There is no doubt that NHS capacity is tested in most years in the autumn and winter due to the higher prevalence of respiratory illness and flu. Since lockdown measures of the type we have seen in England since March have never previously been used, even when tens of thousands of people were dying of flu, means that it is essential to compare this autumn and winter with previous years.

We invite the Government to make this data available so that the position can be scrutinised.



## **E      SUMMARY**

The Government's policies towards suppression of Covid have been and continue to have huge consequences for the UK, its people and its businesses. The arrival of vaccines against Covid is unlikely to alter that landscape for many months. This is proved by the recent announcement that London is being moved to Tier 3 based on PCR positive results, even though we have shown above the huge discrepancies.

The Government continues to make decisions about how severely its measures should be applied to particular areas of the country on the basis of criteria that, at their heart, depend upon a system of testing using primarily a diagnostic tool of at best uncertain and at worst questionable accuracy. In the race to upscale testing capacity we fear that the Government has not kept as tight a lid on quality control at testing centres and labs as it should have done. Further, we do not appear to have been provided with full and frank information about the *real world* performance of PCR tests.

In other words, as foreshadowed by the authors of the June Paper, the whole approach in terms of legislation and policy towards tackling the virus is at risk of being distorted upon flawed and unreliable data. The result is that far more drastic and harmful restrictions are being placed on the public than are necessary. This renders the whole Government approach as disproportionate to the real threat posed by Covid.

The Government has spent almost £6 billion on the PCR testing programme and many more £ billions on its much-vaunted NHS track and trace programme. Yet because PCR tests do not identify those who are currently infectious as opposed to those who may have come into contact with the virus and long since recovered, this inevitably means that vast numbers of people (including a substantial percentage of NHS workers) are having to needlessly go into self-isolation, when in fact they pose no risk to anyone.

In addition, the World Health Organisation has on 14th December issued updated guidance concerning the elevated risks of false positives for PCR tests, stating: "Users...consider any positive result in combination with specimen type, clinical observations, patient history, and epidemiological information." It also states: "The design principle of RT-PCR means that ...when specimens return a high Ct value, it means that many cycles were required to detect virus. In some circumstances the distinction between background noise and actual presence of the target virus is difficult to ascertain." This WHO intervention is highly significant. It is its first admission that there are major risks of false positives with PCR tests.

No one disputes the serious risk that Covid poses to those who are clinically vulnerable such as the elderly and those with pre-existing medical conditions. But equally, no one can dispute the enormous harms being caused by the indiscriminate implementation of policies against the entire population, supposedly to protect those in vulnerable groups.

## **F      QUESTIONS TO BE ANSWERED**

We therefore request that you provide us with answers to the following questions:

### **1.      Laboratory testing**

1.1      Have you addressed and implemented the recommendations set out in the June Paper (as defined above), in particular:

1.1.1    Did you implement and carry out an External Quality Assessment (EQA) for the UK National COVID-19 RT-PCR testing programme?

1.1.2    Is there in place a continual rolling EQA (a low volume of blind samples submitted every day) for the purpose of monitoring the performance of labs across the UK COVID-19 RT-PCR testing network?

1.2      If the recommendations referred to in the June Paper were carried out, please provide details of the findings;



- 1.3 If the recommendations in the June Paper were not implemented, why not?
  - 1.4 What certification did all the Lighthouse labs have at commencement and have they maintained that certification and how frequently are they recertified?
  - 1.5 What are the minimum qualifications and experience for those employed at Lighthouse labs who are involved in the process of handling test samples and operating the testing of them?
  - 1.6 How long is training for lab operators at Lighthouse labs, how frequently is competency checked, and by what methodology?
  - 1.7 In the contractual arrangements between government and contractors running the Lighthouse labs, what were the specifications by which a test result would be reported as positive, in terms of cycle threshold, and which specific SARS-CoV-2 genes were to be confirmed as present?
  - 1.8 How often are the Lighthouse labs checked for accuracy of the positive test results, either by repeating the test results with PCR or now using another test such as LFT?
  - 1.9 To your knowledge, has anyone established what went so wrong with the tests carried out by the Lighthouse lab used for the Cambridge University testing program that led to 100% of all positive tests in the most recent week of testing turning out to be false positives?
- 2. PCR tests**
- 2.1 Has the PCR test been tested for accuracy in the same way as the LFT test at Porton Down and in particular has the accuracy of PCR tests been properly assessed in a real world, operational setting, as opposed to within laboratory settings?
  - 2.2 What proportion of PCR test results were reported each month in the following range of cycle thresholds:  
<20, 21-25, 26-30, 31-35, 36-40, >40.
  - 2.3 What is the Government's explanation for the huge difference in results between the numbers of individuals testing positive for Covid using the LFT tests versus those tested using PCR tests?
  - 2.4 In the Liverpool mass testing programme, what was the confirmed positive rate for the people with a positive LFT test result after confirmatory PCR testing?
  - 2.5 Given the continuing high rates of nosocomial infections, why are LFT tests not being used in hospitals - at least as initial screening mechanism - thereby benefiting from the rapid results generated – so that patients can be rapidly isolated if required?
- 3. NHS capacity**
- 3.1 Is there an explanation for the significant fall of all acute respiratory infections since September this year compared to previous years? Has there been misclassification of these cases as COVID?
  - 3.2 What are the details, by region, for the numbers of NHS critical care beds in terms of capacity and patient occupancy since 1 September 2020 and what were the same details for the same period in each of the preceding 5 years?
- 4. Treble Test Challenge and confirmatory testing**
- 4.1 Will you accept our proposal to treble test a sample of at least 1,000 people to validate the results from PCR and LFTs? If not, why not?
  - 4.2 Will you agree that given the fundamental importance of the PCR test to the Government's strategy, that you will now introduce a policy of double checking all positive test results (as Cambridge University



itself sensibly does). This should preferably be done with a different type of test, and if there is an inconsistency, then a third test can take place.

We believe the proposals in 4 above could fundamentally assist the Government with its strategy of reducing incidences of the virus thus getting the country back to normal much faster: they should therefore be adopted immediately.

We look forward to hearing from you in response to these matters as soon as possible and in any event by 4pm on 22 December 2020. We regard this matter as serious, urgent and in the strategic national interest.

Given the national importance of this matter, we are releasing a copy of this letter to the media.

Yours sincerely

A handwritten signature in black ink, appearing to be "Richard Tice".

Richard Tice  
Chairman, Reform UK  
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