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Welsh Parliament | Research Service

Testing for COVID-19 using the rt-PCR test

Y Pwyllgor Deisebau | 15 Rhagfyr 2020
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Reference: RS20/14687-2

Petition Number: P-05-1062

Petition title: Abandon the rt-PCR test for covid-19 testing as its unfit for purpose

Text of petition: It has come to light that the NHS only used 35x amplification on PCR testing prior to the alleged pandemic. But now the NHS are using 45x amplification and the amount of false positives increases dramatically. This is utterly absurd! The PCR is not testing for a novel coronavirus - it is testing for the subjects nonspecific endogenous cellular exudation! RNA particles. End the case-demic now and cease all swab rt-PCR now.

At 45x amplification it is clear to those who independently research and have an academic science background that the PCR test is being used to cause fear and hard-hitting headlines.

1. Background

Covid-19 Testing strategy

The Welsh Government's launched its' first national plan for COVID-19 testing on 28 March 2020. The initial phase of testing for COVID-19 focussed on critical workers, and symptomatic patients in hospital and care homes. Since 18 May 2020, anyone in Wales who has coronavirus symptoms can be tested. The primary test used in Wales and the UK from the outset of the COVID-19 pandemic was an antigen test, in the form of the reverse transcription polymerase chain reaction (RT-PCR) test.

The Welsh Government's updated COVID-19 Testing Strategy was published on 15 July 2020, and updated on 23 July 2020. This reiterated the Welsh Government's commitment to the use of the RT-PCR test, stating that:

> We currently have 2 different forms of testing in Wales.
>
> - RT-PCR (virus detection) test, that detects the presence of viral RNA. The test is usually done using a nasal swab taken from the nose or back of the throat. This kind of testing can highlight if someone currently has the infection;
>
> - Antibody test, that detects the antibody response to the SARS-CoV-2 virus, and is used primarily to determine whether a person has been previously infected. At the current time the use of tests is focused on the serosurveillance of defined target cohorts for the purpose of understanding the cumulative level of historical infection.
>
> At the current time, **RT-PCR testing** remains the primary front line test for the diagnosis of infection with SARS-CoV-2 virus.

During November 2020, Welsh Government launched two programmes of mass testing, in Merthyr Tydfil and the lower Cynon Valley. Tests in these programmes made use of Lateral Flow Devices (LFD) which can turnaround results within around 30 minutes. If an individual tests positive via a LFD test, they will be asked to self-isolate immediately and they will be offered a confirmatory traditional RT-PCR swab test.

Evidence on the RT-PCR test

The core principles and recommendations to help guide the use of the reverse transcription RT-PCR test in Wales are provided by the Welsh Government's Technical Advisory Cell (TAC), set out in their report Core principles for utilisation of RT-PCR tests for detection of SARS-CoV-2. This describes the RT-PCR test as:

> …an enzymatic and chemical process by which short strands of ribonucleic acid (RNA) are converted to deoxyribonucleic acid (DNA) and copied in a doubling time reaction (amplification) to concentrations that can be detected and visualised by the human eye.

The TAC report also sets out in relation to the RT-PCR test that:

> This method has been in use for over two decades for the detection of viruses which have an RNA genome in a range of clinical samples, and most recently it is the primary method to confirm the presence of SARS-CoV-2, the virus that causes COVID19, in suspected cases during the pandemic.

Public Health England have stated that 'Molecular diagnostic tests, such as real-time PCR, are the gold standard methods for identifying individuals with an active viral infection, such as SARS-CoV-2 (the cause of COVID-19 disease), in their respiratory tract'.

The TAC report on the RT-PCR test confirmed (p.10) that multiple platforms (representing equipment from different manufacturers) were being used by Public Health Wales (PHW) to support the testing regime. In terms of the number of amplification cycles involved in RT-PCR, PHW responses to Freedom of Information requests (FOI 451 and FOI 461) indicate that:

> The real-time PCR assays in use in Wales for COVID-19 diagnostics all run for 45 cycles however, the cycle number where the sample is defined as RNA NOT DETECTED varies by platform and target gene detected by the system. This is defined by the manufacturer.

The Welsh Government's updated COVID-19 Testing Strategy also noted that:

- The utility of any additional RT-PCR testing should be considered in the wider context of other testing that is taking place, including the 'Test, Trace and Protect' programme;
- The performance of the RT-PCR is at its best when its use is targeted, for example, when used to support diagnosis in symptomatic individuals.

The National Institute for Health and Care Excellence (NICE) and the Medicines and Healthcare products Regulatory Agency have published detailed guidance for test manufacturers in the form of an Evidence standards framework for SARS-CoV-2 and anti-SARS-CoV-2 antibody diagnostic tests. This guidance sets out both the best approaches to evaluating test performance and the minimum reference standards to use, as well as more detailed information about the minimum levels for sensitivity and specificity of tests according to the context in which they are to be used.

PCR tests can produce both false positive and false negative results. The Parliamentary Office of Science and Technology (POST) have published work on Interpreting COVID-19 test accuracy (September 2020) which sets out that:

- No diagnostic or antibody test is 100% accurate. This results in both false positive and false negative results;
- Most tests that detect SARS-CoV-2 infections are benchmarked against the testing type that is seen as the most accurate available so far. This is the RT-PCR test.

This view is echoed by a paper produced in June for the UK Government's Scientific Advisory Group for Emergencies (SAGE).

The summary table of available protocols held by the World Health Organisation (WHO) contains testing RT-PCR protocols from China, France, the United States, Japan, Hong Kong and Germany. The figures from France indicate an amplification cycle of 50 (p.4), whereas those from the USA, Hong Kong and Japan indicate a threshold line of 40 cycles (pp.38-9, 57-8), and 45 for Germany and Thailand (pp.62, 72, 75, 80).

At the same time, in evidence given to the House of Commons Science and Technology Committee on 17 September 2020, Professor Carl Heneghan, Director of the Centre for Evidence-Based Medicine, University of Oxford, outlined his concerns relating to the RT-PCR tests, stating that:

> The test is a very helpful one, but if you just use it in a blanket policy without thinking through the strategy of what test you use and with what threshold, you end up with the problem of false positives. You identify too many people who could have had the infection in the past and you do not pick up the one or two people you have just described, the super-spreaders, where you need to isolate them and get to their contacts. Once we accept that the infection is endemic, we need a process whereby we start to develop our strategy around testing. A cycle

> threshold above 35 generally involves people who are not infectious, yet NHS England documentation that has not been updated since January runs cycle thresholds to 45 that identify people who are not infectious. (Q1283)

Professor Heneghan's questions about the effectiveness of PCR have also been noted in a BMJ briefing, which argues that:

> Another problem with relying on PCR testing alone to define a covid-19 case is that, owing to the sensitivity of the test, it can pick up a single strand of viral RNA—but this doesn't necessarily equate to someone being infected or infectious.

2. Welsh Government response

No response has been received to date from Welsh Government.