

PCR Tests

Product type: Nucleic acid testing (NAT) technologies that use polymerase chain reaction (PCR) for detection of SARS-CoV-2

Date: 13 January 2021

WHO-identifier: 2020/5, version 2

Target audience: laboratory professionals and users of IVDs.

Purpose of this notice: clarify information previously provided by WHO. This notice supersedes WHO Information Notice for In Vitro Diagnostic Medical Device (IVD) Users 2020/05 version 1, issued 14 December 2020.

Description of the problem: WHO requests users to follow the instructions for use (IFU) when interpreting results for specimens tested using PCR methodology.

Users of IVDs must read and follow the IFU carefully to determine if manual adjustment of the PCR positivity threshold is recommended by the manufacturer.

WHO guidance Diagnostic testing for SARS-CoV-2 states that careful interpretation of weak positive results is needed (1). The cycle threshold (Ct) needed to detect virus is inversely proportional to the patient's viral load. Where test results do not correspond with the clinical presentation, a new specimen should be taken and retested using the same or different NAT technology.

WHO reminds IVD users that disease prevalence alters the predictive value of test results; as disease prevalence decreases, the risk of false positive increases (2). This means that the probability that a person who has a positive result (SARS-CoV-2 detected) is truly infected with SARS-CoV-2 decreases as prevalence decreases, irrespective of the claimed specificity.

Most PCR assays are indicated as an aid for diagnosis, therefore, health care providers must consider any result in combination with timing of sampling, specimen type, assay specifics, clinical observations, patient history, confirmed status of any contacts, and epidemiological information.

The international order

The UK decided to restore democratic powers by leaving the EU. We can now improve, amend or remove laws and spending programmes as we see fit. The government proposes, Parliament responds and public opinion is brought to

bear on the process. If a government makes a mess of using its powers it will be replaced at the next election so the voters are in ultimate control.

Various contributors here believe that green policies and covid policies are somehow the work of hidden powerful advisers and forces. They are, on the contrary very public, and have been through substantial governmental processes. Whilst we have removed the overarching powers conferred by the EU Treaties and enforced by an active and powerful court, our country is still under a number of other important Treaties which governments of most political persuasions will observe and enforce. Anti pandemic policy has been heavily influenced by our membership of the World Health Organisation. The UK's green enthusiasm has been locked in by the Climate Change Act enacted by the Labour government and accepted by the incoming Conservative one, and by UK agreement to the Paris and other international conference commitments made globally. I was one of just a handful of MPs who did not support the legislation.

The structure and culture of UK government is to abide by international rules and Agreements. There is no need to look for hidden influences urging these policies when they have been signed up to in a public way so the whole might of the UK official machine is bent on enforcing and complying with them. It is true the CV 19 policies are advisory. It is true the green policies require our consent and there is no strong enforcement mechanism like the European Court to make us do them, but government wishes to apply them anyway.

This means if UK citizens do wish to change these policies it is a bit more difficult. There could be arguments about "breaking international law". When the UK ventured a different view of the Northern Ireland protocol as it needed to do some asserted this was breaking a Treaty and not allowed. I think they were wrong as a good argument can be made from the terms of the Protocol and Treaty themselves that there needs to be change to secure one of its prime objectives, the freedom of the UK single market.

In practice countries do renounce or amend Treaties by agreement, or sometimes reinterpret them . What matters is popular will and national law. Some say of course all Treaties must be obeyed, citing the 1713 Treaty of Utrecht which stated Gibraltar is a UK Crown dependency. I of course favour respecting that Treaty. The truth however is the status of Gibraltar rests with the will and views of the people who live there. It is because 99% voted to stay British that they will stay British and observe the Treaty. If they voted 99% to be Spanish of course there would be change whatever the Treaty says.

So my advice to those of you who disagree with the health or green policy, understand you need to change the policy of the government which in turn will need to amend its promises and proposals to the international community if you succeed.

Lobbying

It's not much of a story that someone who was Prime Minister six years ago lobbied the Treasury on behalf of a business he is employed by, only to be turned down. To make it interesting the ex PM would have to break the rules over conduct out of office, and he would need to be successful in his lobbying. We are told neither of these conditions were met.

The facts are not going to get in the way of those who nonetheless want a debate about lobbying. Energetic lobbying is a part of a healthy democracy. Charities spend large sums on their lobbying for legislative change and access to spending programmes. Businesses organise themselves into trade Associations and nationwide lobbying bodies to get favourable changes of policy for their sectors. Trade Unions spend large sums on setting out their policy demands. The BBC and other media regularly give privileged slots on news and comment programmes for lobby groups to make their case prior to interrogating any Minister who dares to say No to the lobby proposal. Maybe the media is too kind to these lobbyists and ought to question their motives and views more thoroughly before running their demands.

Ministers of course need to understand what the business or other interest of a person is when they talk to them or have a meeting with them. This usually flows from the person having to make clear who they represent or work for to get the meeting in the first place. Ministers need to have shed all their own business interests, or to exempt themselves from any decision where there could be a conflict of interest. Much of the detailed commercial interface between government and business is handled by impartial officials who are trained to assess bids and proposals on their merits rather than favouring friends of the government. It appears that the wide ranging access Greensill had to UK government in the Cameron years was arranged by the Cabinet Secretary himself, the ultimate policeman of propriety and procedure in government. The interesting questions about the arrangements then in government relate to why the UK state needed to introduce supply chain finance, and why if the problem was late payment of public sector bills they did not just pay them more quickly. Tragically the Cabinet Secretary died young so we cannot find out from him what led him to give Greensill such access.

Some want to believe that a few billionaires have particularly favourable access to governments and end up making the policies that rule us. The answer to that is Ministers have free choice about who they listen to and which arguments they find attractive. We need to concentrate on what Ministers say and do, as they have the power. Usually the policies which most annoy the critics are international policies embedded in treaties or set out by membership bodies like the UN. In the case of the EU they are of course strongly binding on member states through their own court and legal system. These are more difficult for governments to amend or ignore as that may entail renouncing the relevant treaty.

Ministers have daily to defend their choices to Parliament, the public and

media and if they are taking bad advice they feel the results. Chasing the possible influencers can divert us from the real task of debating and changing what government itself decides to do, or debating any damaging rules and guidance of the international bodies we belong to. Chasing individual outside advisers is only relevant if there is corruption. As Margaret Thatcher wisely said, Ministers decide and advisers advise. That is usually true. Any adviser who overreaches or ceases to please can be dismissed. Oppositions are there in part to call out influence or lobbying which crosses the line from the acceptable.

[New diesel and petrol car sales continue to slump](#)

The UK car sales figures for the first two months of 2021 show a large fall of 87,000 vehicles. The industry is ascribing this to CV 19 and the closure of car showrooms. Doubtless there was a CV 19 effect. There was also an online market people could use, and we did see a rise in the sales of all types of hybrid and electric vehicles over these two months despite closed showrooms and no demonstration drives. You would think it would be the new types of vehicles which would most need display in physical showrooms and demos to persuade people to buy them. The fall in sales of diesel and petrol cars was 96,000, offset a little by the 9,000 extra sales of hybrids and electric cars. The fact that it was cars we knew well that suffered the sales fall implies there is more to this than the anti pandemic measures.

The industry should worry that more of the fall is about the big structural change required by government to move people away from diesel and petrol vehicles. The combination of high new car taxes and the strong pressures not to buy new petrol and diesel cars is damaging volumes considerably. The UK invested billions to be a great centre for diesel engines and diesel cars and now faces a very sharp and severe contraction in this market. Why doesn't the industry acknowledge this problem and talk about it more? Should this transition be slowed or eased in some way? Do new car taxes have to stay so high?

One of the issues being debated is the question of how much extra carbon dioxide is generated by a society going for a shorter working life for cars and more frequent replacement by new vehicles, even where the operating performance of the new vehicle is more fuel efficient. High new car taxes allied to anti diesel and anti petrol car policies may perversely persuade more people to prolong the lives of their traditional vehicles and hold back from buying new. If battery electric vehicles are bought more by the rich and urban dwellers who use them for short journeys or as second cars they will not deliver the environmental benefits their advocates seek.

Why is it that so many people claiming to be friends of the car industry spent several years telling us to worry about the impact on sales of a possible 10% EU tariff which did not materialise, but they are now silent about a far bigger collapse in sales than they forecast as a result of various governments' policies to end the sales of new diesel and petrol cars in a few years time?

My response to Michael Gove's consultation

Dear Michael,

I see you are asking Telegraph readers for their views on vaccine passports.

Your article seemed to be contradictory. It said we cannot rely on the vaccines to give us 100% protection so we need CV 19 passports. You then say we should rely on vaccines in a different way by only allowing vaccinated people to do certain things and give them a passport. How does this add to the protection, as in either case with or without the certificate we rely on the vaccination?

There is the residual issue of the small minority of adults who will not have the vaccine. Many of these will need to be given exemptions for health reasons or pregnancy, defeating the object you see in the control. If the idea has anything to recommend it it is simply to remove a few people that have no officially accepted reason for not being vaccinated from attending various events who might get the disease. They will presumably be offered the alternative of a test which may or may not be accurate. Given we are talking about a very high vaccine take up rate it seems likely there will anyway be little risk of picking up CV 19 as we will have something approaching herd immunity. In the dreadful event of a mutation that defeats the vaccine the system you recommend of course ceases to work and everyone is back at risk.

As you recognise there are technical issues about the use of apps and the necessary paper or card alternatives, and problems with the reliability of data back up. Some non believers without vaccination will operate to cheat the systems. Do we want to become a society where we will need to carry papers to do simple tasks and enjoy entertainments and sports? It is against all my instincts, born into a history based on the journey to freedom and liberty for all.

Yours

John