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Attention of	Dr Tracey Cooper
Department	Chief Executive Public Health Wales
Address	2 Capital Quarter Tyndall Street Cardiff CF10 4BZ
Your Reference	
My Reference	PHW/WJ/TC/01
Date	6 July 2020
Subject	**Covid-19 RT-PCR testing process**

Dear Dr Tracey Cooper

I refer to the Covid-19 testing process known as "*real-time reverse transcription–polymerase chain reaction (real-time RT-PCR).* There is mounting evidence, from eminent members of the medical profession, of serious issues with this testing process. Those challenging the validity of the testing process include; Dr Andrew Kaufman, Dr Rashid Buttar, Professor Dolores Cahill, Professor Knut Wittkowski, Dr Judy Mikovits, Dr Shiva Ayyadurai and others.

Technical information regarding the testing process is set out in Annex 01 below. If you wish to challenge any of the information presented you are welcome to do so in your formal response. In view of continuing serious concerns an investigation has been initiated to establish the facts. To inform the investigation I would be grateful if your Freedom of Information team could arrange to provide the following information.

1. Why is the real-time RT-PCR test being used for clinical diagnosis contrary to recommendations from test designer / manufacturer.

2. How many "***amplification cycles***" in the real-time RT-PCR testing process are necessary to confirm the presence of a coronavirus.

3. What supporting scientific / medical evidence is available to Public Health Wales to confirm that the real-time RT-PCR testing process can identify the presence of the Covid-19 strain of coronavirus.

4. In presenting Covid-19 mortality statistics, to inform Welsh Government *policy* and *process,* how does Public Health Wales differentiate between "***death from Covid-19***" and "***death with a corona-virus***".

5. Two international emergency codes have been issued by World Health Organisation to enable clinicians to record detail on death certificates. Code U07.01 and code U07.2. Why has the second code been issued to enable death from Covid-19 to be recorded without an RT-PCR test being undertaken. Do you accept that this can dramatically distort Covid-19 mortality statistics that are used to drive government policy and process.

As Covid-19 testing, and mortality, statistics drive Welsh Government *policy* and *process* with decisions taken by ministers on a weekly basis affecting the livelihoods of millions of people during the economic lock-down period your prompt reply would be appreciated.

I look forward to your formal response, in your role as Chief Executive of Public Health Wales, when you have been briefed on the issues and received the requested information from your FOI team. Thank you.

Yours sincerely

W Jones

Annex 01

Details of [a] RT-qPCR testing process [b] safety data sheet and [c] WHO death-recording codes

Real-time reverse transcription–polymerase chain reaction (real-time RT-PCR) is a method for detecting the presence of specific genetic material from any pathogen, including a virus. Special markers, most frequently fluorescent dyes, are used. Some viruses such as the coronavirus (SARS-Cov2) only contain RNA, which means they rely on infiltrating healthy cells to multiply and survive. Once inside the cell, the virus uses its own genetic code — RNA in the case of the coronavirus — to take control of and 'reprogramme' the cells so that they become virus-making factories. In order for a virus like the coronavirus to be detected early in the body using real-time RT-PCR, scientists need to convert the RNA to DNA. This is a process called 'reverse transcription'. They do this because only DNA can be copied — **or amplified** — which is a key part of the real-time RT-PCR process for detecting viruses. Scientists amplify a specific part of the transcribed viral DNA hundreds of thousands of times. Amplification is important so that instead of trying to spot a minuscule amount of the virus among millions of strands of genetic information, scientists have a large enough quantity of the target sections of viral DNA to accurately confirm that the virus is present. The RNA is reverse transcribed to DNA. The mixture is then placed in a RT-PCR machine. The machine cycles through temperatures that heat and cool the mixture to trigger specific chemical reactions that create new, identical copies of the target sections of viral DNA. The cycle repeats over and over to continue copying the target sections of viral DNA. A standard real time RT-PCR setup usually goes through 35 cycles, which means that by the end of the process, around 35 billion new copies of the sections of viral DNA are created from each strand of the virus present in the sample. As new copies of the viral DNA sections are built, the marker labels attach to the DNA strands and then release a fluorescent dye, which is measured by the machine's computer and presented in real time on the screen. The computer tracks the amount of fluorescence in the sample after each cycle. When the amount goes over a certain level of fluorescence, this confirms that the virus is present. Scientists also monitor how many cycles it takes to reach this level: the fewer the cycles, the more severe the viral infection is.`

Generally, the test is 80% inaccurate and should only be used for research purpose and not for clinical diagnosis as confirmed by the test designer / manufacturer. An abstract from the product safety data sheet is provided below. No specific test for the Covid-19 strain of corona-virus has been developed as the virus has not, to date, been isolated in a laboratory. The PCR test does not conform to the gold standard [Koch's Postulates] for identifying a virus. The PCR test takes a sample of human cells and amplifies any DNA to look for "viral sequences" i.e. minute traces of non-human DNA that match parts of a known viral genome. The genome of an organism is the whole of its hereditary information encoded in its DNA [or, for some viruses, RNA]. It uses "***amplification***", taking a minute amount of DNA and growing it exponentially until it can be analysed. Any minute contaminations in the sample will also be amplified leading to potentially gross errors of discovery. Additionally, the test only looks for partial viral sequences, not whole genomes, so identifying a single pathogen is virtually impossible, even ignoring the other important issue: "**viral load**". As the PCR test amplifies minute amounts of DNA it cannot assess viral load which is the important question when it comes to diagnosing illness. For a virus to cause illness a massive amount needs to be present in the body. As PCR does not test viral load it cannot determine if a virus is present in sufficient quantity to cause illness. Coronavirus are incredibly common. A large percentage of the world human population will have coronavirus DNA in them in small quantities even if they are perfectly well or sick with some other pathogen. It is this that the PCR test detects. A very high percentage of people who have become sick by other means [flu, bacterial pneumonia, anything] will have a positive PCR test for coronavirus even if the tests are conducted properly and ruling out contamination, simply because coronavirus are so common.

SARS-CoV-2 Coronavirus Multiplex RT-qPCR Kit (CD019RT)

This product is for research use only and is not intended for diagnostic use.

Limitations	1. The detection result of this product is only for clinical reference, and it should not be used as the only evidence for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptoms/signs, history, other laboratory tests and treatment responses. The detection results should not be directly used as the evidence for clinical diagnosis, and are only for the reference of clinicians. 2. The detection result can be affected by operations, including specimen collection, storage and transportation. False negative result may occur if there is any mistakes in the operation. Cross contamination during specimen treatment may lead to false positive result. 3. The detected target sequences of this products are the conservative region of 2019-nCoV's ORF1ab gene and N gene. However, target sequence variations may lead to false negative result.

Safety Data Sheet

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Identifiers

Product Name:	SARS-CoV-2 Coronavirus Multiplex RT-qPCR Kit
Catalog Number:	CD019RT
Relevant Identified Uses: (Disclaimer)	For research and laboratory use only. Not for diagnostic, therapeutic, drug, household or other uses.

Abstract from WHO website

International statistical classification of diseases and related health problems ICD revision 10

Emergency use ICD codes for COVID-19 disease outbreak

The COVID-19 disease outbreak has been declared a public health emergency of international concern.

- An emergency ICD-10 code of 'U07.1 COVID-19, virus identified' is assigned to a disease diagnosis of COVID-19 confirmed by laboratory testing.
- An emergency ICD-10 code of 'U07.2 COVID-19, virus not identified' is assigned to a clinical or epidemiological diagnosis of COVID-19 where laboratory confirmation is inconclusive or not available.
- Both U07.1 and U07.2 may be used for mortality coding as cause of death. See the International guidelines for certification and classification (coding) of COVID-19 as cause of death following the link below.
- In ICD-11, the code for the confirmed diagnosis of COVID-19 is RA01.0 and the code for the clinical diagnosis (suspected or probable) of COVID-19 is RA01.1.