



GIG
CYMRU
NHS
WALES

Iechyd Cyhoeddus
Cymru
Public Health
Wales

Freedom of Information request to Public Health Wales

FOI Reference:	FOI 385
Date request received	6 July 2020
Date information is due to be sent	3 August 2020

Information Requested:

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.

Information provided for the answer:

Thank you for your recent request. Answers to your questions are below.

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

The commercial assays used in Wales for the clinical diagnosis of SARS – CoV-2 infection are all CE marked for use in the diagnostic clinical setting for infection with SARS – CoV - 2.

At the beginning of the pandemic an in – house assay was developed using published methods from the scientific community which is attached (ref Eurosurv 25-03-5 pdf)

Although these tests are not yet under UKAS scope, due to the recent emergence of the virus, the Public Health Wales laboratories have adhered to the stringent quality assurance process identified by UKAS; these include validation and verification processes and internal and external quality assurance processes. The expectation is that this service would come under scope for UKAS in the near future. Details of the requirements for UKAS accreditation, for diagnostic services are found here:

<https://www.ukas.com/>

As part of the response to the pandemic, the Public Health Wales laboratory service are using the RT-PCR as determined by the Welsh Government testing plans.

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

The number of amplification cycles can vary with different platforms used. Most platforms use threshold cycles that range from 27 to 43. The threshold cycle is determined by the platform used and is not something that the laboratory services has control over.

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.

As part of the quality assurance process within the laboratory, there are a number of ways that the laboratory ensures confidence in the performance of assays. These include the validation and verification processes detailed by UKAS, the sharing of samples with other laboratories to ensure consistent results, use of QCMD panels and internal quality assurance processes that submit anonymised duplicated samples through the same laboratory process to ensure a consistency of results.

The Public Health Wales laboratory team actively participate in national and internal meetings that share laboratory data and information. At the height of the pandemic, these meetings occurred weekly or biweekly to ensure that the scientific community could share relevant information quickly and effectively. These meetings include the National Virology Cell meeting involving the four devolved UK nations and hosted by PHE, European meetings (ECDC and WHO Global Webinar) and NERVTAG (New and Emerging Respiratory Virus threats advisory group)

Approximately 30% of samples that test positive in PHW laboratories samples are

referred to the Welsh Genomic unit (PenGU) for sequence analysis. The group too, is involved in national, UK wide and international discussions comparing and monitoring sequence variations for SARS-CoV-2.

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".

Public Health Wales rapid reporting of deaths requests that deaths are reported where the reporting clinician considers that COVID-19 has contributed to the causation of the death, and where the death occurs within 28 days of the first positive sample. Beyond this, this rapid reporting system does not attempt to differentiate. The Office for National Statistics data is taken as the definitive (but slightly less timely) source for COVID-19 deaths.

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.

Public Health Wales cannot comment on the reasons for WHO deaths coding and implications for international mortality reporting.

UKAS = UK accreditation Service

QCMD = Quality Control Material for Molecular Diagnosis

ECDC = European Centre for Disease Prevention and Control

WHO = World Health Organisation



385 PCR Testing
eurosurv-25-3-5.pdf



385 PCR Testing
FIND_SARS-COV2_m

If you are unhappy with the service you have received in relation to your request and wish to make a complaint or request a review of the decision, you should write to the Corporate Complaints Manager, Public Health Wales NHS Trust, 3, Number 2, Capital Quarter, Tyndall Street, Cardiff, CF10 4BZ.

If you are not content with the outcome of your complaint or review, you may

apply directly to the Information Commissioner for a decision. Generally, the ICO cannot make a decision unless you have exhausted the complaints procedure provided by the Trust. The Information Commissioner can be contacted at:

Information Commissioner for Wales

2nd Floor
Churchill House
Churchill Way
Cardiff
CF10 2HH

Telephone: 029 2067 8400

Email: wales@ico.org.uk