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## Freedom of Information request to Public Health Wales

<b>FOI Reference:</b>	<b>FOI 350</b>
<b>Date request received</b>	<b>20 May 2020</b>
<b>Date information is due to be sent</b>	<b>17 June 2020</b>

### Information Requested:

I'm conducting some research into 'false negatives' when it comes to the PCR testing taking place across Wales. I was hoping you could give me some information on the following:

Advise on whether data is being collated on the accuracy of PCR tests being used if so, when this data will be available? if available how probable (in percentage) is the chance of getting a 'false negative' with a PCR test in Wales?

Do the PCR tests rolled out in Wales differ in any way from those in England?

If a 'false negative' result is suspected, or deemed inaccurate by a medical professional what do Public Health Wales suggest as a next step for testing?

### Information provided for the answer:

#### When discussion the sensitivity and specificity of any diagnostic test it needs be considered in relation to a number of different elements

There is a difference between the clinical sensitivity of an assay, the sampling sensitivity and the sensitivity of the assay itself.

#### **Clinical sensitivity**

The clinical sensitivity depends upon the virus being present at the sampling site at the time of sampling and this varies between the different phases of the illness. For this infection, the figures quoted for this is in the

literature range from between 38% to 90%. Published literature at this time is often not peer reviewed and therefore should be considered with this in mind.

In the clinical scenario we believe the clinical sensitivity of the assay to be in the region of 90% in the first week of infection

### **Sampling sensitivity**

The sampling sensitivity of the assay depends on the quality of the sample taken and the presence of the virus at the sampling site.

The samples types and swabs we use in Wales are the sample types that we have been using for the last 10 years as they are the samples types that we use for our UKAS accredited respiratory assays.

### **The sensitivity of the assay**

The initial in house assay developed in January 2020 has an analytical sensitivity of around 10 viral copies /ml. This assay was developed from WHO publications and SOP\*

All of the assay that we now use have been compared to the original in house assay to determine how they compare with original in house assay.

### **Positive and negative predictive values of diagnostic tests.**

As with all diagnostic tests they have to be considered as part of a jigsaw, which takes into account the clinical presentation, the prevalence in the population, the quality of the sample submitted and the quality of the assay used

All diagnostic tests can have a positive and negative predictive value, which has to be calculated.

$$\text{Positive predictive value, PPV} = \frac{\text{True Positives}}{\text{True Positives} + \text{False Positives}}$$
$$\text{Negative predictive value, NPV} = \frac{\text{True Negatives}}{\text{True Negatives} + \text{False Negatives}}$$
$$\text{Predictive value of a positive test} = \frac{\text{sensitivity} \times \text{prevalence}}{[(\text{sensitivity} \times \text{prevalence}) + (1 - \text{specificity})(1 - \text{prevalence})]}$$

To answer the specific questions:

### **Advise on whether data is being collated on the accuracy of PCR tests being used if so, when this data will be available?**

Given the complexity of this question it is extremely difficult to answer. The laboratory collects all data regarding the diagnostic tests used for the investigation of this virus.

This data is used in a variety for a variety of reason, one of which is to ensure the laboratory processes are working well to minimise errors

The laboratory engages with other diagnostic groups across the UK and Europe to monitor its performance against other diagnostic services

The performance of this assay is monitored and the protocols used will be submitted at the next UKAS inspection to ensure that this service becomes a UKAS accredited service.

**If available, how probable (in percentage) is the chance of getting a 'false negative' with a PCR test in Wales?**

The probability of getting a false negative results in Wales is the same as the as it is in England, Scotland and Northern Ireland.

Many of the assays we are using in Wales are the same assays as the rest of the UK and Europe.

**Do the PCR tests rolled out in Wales differ in any way from those in England?**

No we use many of the same platforms that England does to provide a test result.

The samples types and swabs we use in Wales are dry throat swabs. The laboratory has been this sample type using for the last 10 years. These are the samples types that we use on our UKAS accredited respiratory assays. The method is published in Journal of Virological methods

**If a 'false negative' result is suspected, or deemed inaccurate by a medical professional what do Public Health Wales suggest as a next step for testing?**

As with every diagnostic test used, they have to be interpreted in the context of the clinical history and examination. No diagnostic test can provide the full picture, but contribute to information that the clinicians used to make a diagnosis. Repeat tests are recommended in certain circumstances, as are alternative tests to look for alternative diagnosis.

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

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