

## Laboratories, Accreditation and the new kid on the block: Coronavirus or SARS-CoV 2

This was the title of a talk given by **Dr Tamara Heath** by Zoom on 17<sup>th</sup> July 2020

She introduced the subject by describing **Pathology** as the study of the causes and effects of disease or injury. It refers to the study of disease in general, incorporating a wide range of bioscience research fields and medical practices. In medicine it is the branch that deals with the laboratory examination of samples of body tissue for diagnostic or forensic purposes. A related branch is molecular pathology, the study of DNA and RNA sequencing, genes, and genetics. Virology is the study of viral infections, such as rubella, herpes, hepatitis and HIV – and now Covid.

Pathology is also described as the engine room of healthcare. She said that pathology laboratories are mainly staffed by highly trained women. She showed a picture of a 1930s laboratory, where this was the case, with nice wooden furniture. A modern laboratory had stainless steel and formica (and a smiling man!) – also a pretty woman using a microscope.

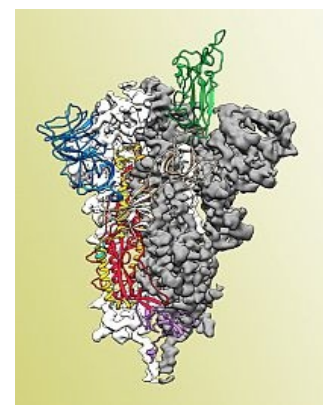
**Accreditation of a laboratory** is paramount – a test done in one laboratory should give the same result if repeated in any other accredited laboratory. The UK National Accreditation Service (UKAS) is responsible for determining, in the public interest, the technical competence and integrity of organisations such as those offering testing, calibration and certification services. A new laboratory has to install all the kit, have it certified, engage staff, do tests and have the results confirmed by other laboratories – before it can start business. The kit has to have bear a CE Mark (Conformité Européenne) to show that it complies with the EU’s health, safety, and environmental protection standards. The two principal suppliers of diagnostic analysers are Abbott in the USA and Roche in Switzerland – there is no British supplier. There are 225 analysers in the UK.

Accreditation can take months. Unless very well endowed the amount of kit and number of staff will be limited. At the Princess Royal University Hospital, Orpington, where Dr Heath works they are equipped to do up to 30 tests a day, normally sufficient, but not when Covid testing is added.

**Validation for a new test** can take 6 weeks. First one has to set up for it, then get it certified. If running a certification test for another laboratory, or to validate one’s own laboratory for a new test (eg Covid) it takes up time on the analyser that the test runs on, delaying other testing. Staff doing the validation are then not doing their normal tasks causing more delay. If other staff are available to perform the “normal” tasks and this is another cost, the “new” staff have to be trained and competency assessed before being allowed to work unsupervised. Overtime has to be authorised, yet another cost. Staff working longer hours become tired. Laboratories are running at almost 100% capacity - but samples have to be analysed by an accredited laboratory.

The Corona Virus has a spike at the top (shown green in the picture), above the main viral body. The spike pierces the target cell, allowing the virus to infect it. The spike is from Bats, the virus body from Chimpanzees.

A virus is a microscopic package of genetic material in an envelope. The genetic material can be either DNA or RNA. DNA is a two-strand molecule which holds the genetic code for an organism. RNA is generally a one-strand molecule that copies, transcribes and transmits parts of the genetic code to proteins so that they can synthesise and carry out functions that keep organisms alive and developing. A virus such as the coronavirus (SARS-CoV-2), which causes COVID-19, only contains RNA, and relies on infiltrating healthy cells to multiply and survive. Once inside the cell, the COVID-19 virus uses its RNA to take control of and reprogramme it into a virus making factory, the virus released when the cell dies.



“Real time RT–PCR” is one of the most widely used laboratory methods for detecting viruses, including the COVID-19 virus. “RT” is Reverse Transcription, of RNA into complementary DNA, using a specific enzyme, and specific primer DNA fragments which attach themselves to the (transcribed) virus. The DNA can then be amplified - doubled at each of usually 35 stages of a Polymerase Chain Reaction, “PCR”, to an observable amount. “Real time” means that the outcome

can be seen as the process proceeds, through the use of a fluorescent dye; and the scale of infection from how soon it is observed.

A sample is collected from the parts of the body where the COVID-19 virus gathers, such as a person's nose or throat (this gathering is not continuous – a swab taken at the wrong time may miss the Covid). The sample is treated with several chemical solutions to remove substances such as proteins and fats so only RNA is left. This is a mix of the person's own RNA and, if present, the virus's RNA. It takes at least 3 hours to get the result of a test.

As an aside, Dr Heath spoke about a pioneer of epidemiology – Dr John Snow, in 1854, mapped the spread of cholera in Soho noting where deaths had occurred. He saw that all these were clustered about the Broadwick Street pump. He had the pump handle removed and the cholera outbreak ceased. Nothing was then known of bacteria, nor had it been proved that contaminated water was implicated. (The pump, sans handle, has recently been reinstated.) That same year Filippo Pacini first isolated *Vibrio cholerae* as the cause of cholera but his discovery was not widely known until Robert Koch (who also discovered the cause of tuberculosis), working independently 30 years later, publicized the knowledge and the means of fighting the disease.

There were several questions after the talk – most about present unknowns, such as when a vaccine might become available, to which Dr Heath's response was that she did not know either.

She said: Herd Immunity takes 60-80 years to develop; about 93% of the population had not had a test of any description; a Saliva test was no better than a swab.

Apart from being socially disadvantaged, dark skinned people in our climate produce less Vitamin D, needed in the body for the production of the immune system's T-cells. Some people with a healthy number of T-cells stop the Covid virus in its tracks – and produce no antibodies; others may or may not show symptoms, but produce plentiful antibodies; such people are being sought for their antibodies to inject into people less fortunate, and speed their recovery.

Politicians got short shrift. The Prime Minister spoke of 1000 tests a day – swabs perhaps, but results? How; by whom and with what equipment? Tracing contacts for HIV or SDIs has been done for years; it would have helped to have begun it without waiting three weeks.

Precautions would have to be taken until vaccination was widespread.