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CDC issue 'lab alert' on PCR tests

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Viral infections | Tests and Screening

The Emergency Use Authorisation (EUA) that was granted in the US to allow laboratories to implement use of a largely experimental CDC SARS-CoV-2 test in Feb 2020 is being withdrawn.

Major concerns have been widely reported over the accuracy of the PCR COVID test as performed by government contract laboratories including the UK Lighthouse laboratories that were rushed out in 2020. In the UK, senior public health laboratory staff have expressed their dismay at the lack of quality in the new Lighthouse laboratories, and similar sentiment has been expressed in the US. The lack of quality was even reported by the BBC as chaotic and dangerous.

Unsuitable test for virus screening

The scientific flaws in the methodology and at the molecular level have all been previously documented. As reported in 'The test that caused a pandemic?' "a large number of false positive results are generated by this test, even under controlled laboratory conditions, making it completely unsuitable as a reliable virus screening method".

Diagnostic testing results inform medicine and politics

The reason why accurate testing is important is because diagnostics underpins all medicine. If the diagnosis is not right, then the treatment won't be either. It possibly comes then as no surprise that the Emergency Use

Authorisation (EUA) that was granted in the US to allow laboratories to use the SARS-CoV-2 test starting back in Feb 2020 is being withdrawn. The only surprise is perhaps that the decision has taken so long.

Lab alert

The US Centre for Disease Control (CDC) have issued a "Lab Alert", and the new guidance states; "clinical laboratories and testing sites that have been using the CDC 2019-nCoV RT-PCR assay select and begin their transition to another FDA-authorized COVID-19 test". CDC also state that the choice of FDA approved assay should be combined to include influenza.

Despite petitions requesting the government to release the 'false positive rate' (FPR) data, this information was never released. We consequently had no idea how many of the reported positives were real. No test is 100% accurate and the trouble with PCR is that by increasing the number of chain reaction (Ct) cycles, the less accurate the test becomes and the more likely it is to pick up irrelevant and non-infectious pieces of nucleic acid. The increased number of cycles also considerably increases the risk from sample contamination. Without the FPR information the results are pretty meaningless.

Furthermore in the context of screening high numbers of people, the FPR becomes a huge factor. For example even if the test is, say, 99% accurate and you test 1M people, the FPR alone will cause 10,000 positives, which will be reported as "cases". Sound familiar?

Validate and verify the new diagnostic kits

The UK usually follows suit from the US and so we should expect a similar announcement here too. Whatever testing kits the labs decide to buy, the CDC are saying that the new tests will need to be validated and verified, "within their facility before beginning clinical testing". Validation and verification should always be done anyway as a formal requirement of laboratory operation (UKAS). This process is essential in order to the check the quality, accuracy and performance of the laboratory's fundamental diagnostic role. Let's hope that this time we are provided with all testing accuracy information - including the false positive rate data.

Testing times

When systems get rushed out there is a big risk that quality systems and quality control will be the first victims. UKAS the body responsible for granting accreditation of new laboratories say, "As demand for testing and the number of private providers of testing continues to grow, the need for the public to have confidence in the testing remains as important as ever. Recognising the time it takes to establish a reliable testing service and gain accreditation, UKAS has agreed to provide some preliminary assessment that can be used to provide information about the competence of these testing services that are being established, through necessity, at pace". UKAS currently face 500 new lab applications for COVID alone!

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