

Call for action over unreliable private online hormone tests

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A large private laboratory is still processing finger prick tests for estrogen levels, which are sold by private retailers online, despite warnings they are unreliable, reveals an investigation published by *The BMJ*.



Journalist Emma Wilkinson reports that Eurofins, a large <u>laboratory</u> based in the UK, is still carrying out finger prick tests for oestradiol despite problems being identified in 2021 and two other laboratories and one <u>online retailer</u> withdrawing the tests over concerns that the results might not always be accurate.

Finger prick tests for oestradiol are sold by online retailers for between £50 and £180, depending on what is included in the test. They are often used by people on HRT or going through IVF to track menopause or fertility levels and can impact decisions around the need for drugs or further tests.

Eurofins' own internal study, launched in 2021, found finger prick (also known as capillary) <u>blood samples</u> were more likely to record lower oestradiol levels than venous samples. But it carried on processing the tests on behalf of online retailers after telling them about the discrepancy.

Insiders from the company, who have since left, told *The BMJ* that in their view the results from the company's internal studies showed the test was unreliable and that they should have stopped processing it.

One former employee said the fact Eurofins carried on processing these tests once potential problems had been identified showed "a lack of duty of care and regard for patients."

Other companies who also identified problems with the accuracy of the test said the issue appeared to be with the type of test tube used and switched to a different kit.

The BMJ contacted Eurofins and it sent a response but said it did not want it published.



Meanwhile, experts say these findings raise questions about the validation and regulation of online tests and laboratories.

There is currently no system for robustly assessing whether new tests, or new instances of existing tests, work, says Bernie Croal, president of the Association for Clinical Biochemistry and Laboratory Medicine (UK). "The Medicines and Healthcare Products Regulatory Agency and the National Institute for Health and Care Excellence only scratch the surface."

Similarly, there is no regulator of laboratories, private or NHS, in the UK. The United Kingdom Accreditation Service (UKAS) gives certain laboratory processes or tests a stamp of accreditation but says that it is not a regulator. There is no obligation to have a test accredited by UKAS and non-accredited tests are still given to patients.

UKAS told *The BMJ* it is not a "regulatory, monitoring, or policing authority" and its scope is limited to the activities and locations included in a company's schedules of accreditation

Jessica Watson, a GP in Bristol who also researches the use of tests in primary care, said there were several concerns.

"There is a risk that results might be misinterpreted or be misleading—and that could have implications for women if they believe that they are more or less fertile, for example, even if that just steers their decision making a little bit," she told *The BMJ*. "And if that is causing confusion or increased anxiety, they will probably contact their GP for advice and that has a knock on effect on NHS services which are massively overstretched."

She added, "The whole field of home testing kits is progressing rapidly but it doesn't feel as if the frameworks for legislation are able to keep



up."

David Wells, chief executive of the Institute of Biomedical Science, is trying to raise awareness around the lack of regulation of online tests and laboratories. "One of the things we're starting to do, working with other professional bodies, is to take a more proactive approach to providing advice to clinicians and the public," he said.

More information: Emma Wilkinson et al, Call for action over unreliable private online hormone tests, *The BMJ* (2023). DOI: 10.1136/bmj.p1898

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