Sheffield, UK
emmalwilkinson@gmail.com
Cite this as: *BMJ* 2023;382:p1898
http://dx.doi.org/10.1136/bmj.p1898
Published: 30 August 2023

BMJ INVESTIGATION

Unreliable private online hormone tests sold for months despite accuracy concerns

Potentially unreliable online tests for oestrogen were sold for months after questions were raised over their accuracy. Inaccurate results could impact decisions around fertility, medication, or the need for further tests, prompting questions about the regulation of private laboratories. Emma Wilkinson reports

Emma Wilkinson *freelance journalist*

A large private laboratory processed finger prick tests for oestrogen levels, which are sold by private retailers online, for many months despite warnings they were unreliable, *The BMJ* can reveal.

Eurofins County Pathology, a large laboratory based in Guildford, in the UK, continued carrying out finger prick tests for oestradiol, commonly included in online blood tests for hormones, fertility, and menopause, until at least July 2023 despite problems being identified in November 2021 and two other laboratories and one online retailer withdrawing the tests over concerns the results may not always be accurate.

Eurofins' own internal study, launched in 2021, found finger prick (also known as capillary) blood samples 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 in October 2022. In August 2023, the company told *The BMJ* it had stopped processing the tests.

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.

Experts told *The BMJ* that misleading results could impact decisions around fertility, drugs, or the need for further tests.

The findings have raised questions about the validation of home testing kits and the regulation of private laboratories. The United Kingdom Accreditation Service (UKAS) gives certain laboratory processes or tests a stamp of accreditation but says that it is not a regulator.

David Wells, chief executive of the Institute of Biomedical Science, told *The BMJ*, "The home testing and the home sampling arena lacks the level of scrutiny and clinical oversight that a main laboratory serving a hospital accredited by the United Kingdom Accreditation Service (UKAS) and regulated by the Care Quality Commission would have.

"In essence these are sitting slightly outside of most regulations."

Private blood tests

There has been a boom in private blood tests being sold online, with one piece of market research predicting that the global blood testing market will rise by 60% from around $80.5bn in 2021 to $128.bn in 2028.[1]

An array of online companies offers blood tests for a range of conditions and deficiencies. These online retailers send the tests to private laboratories, including Eurofins County Pathology, The Doctors Laboratory, and Inuvi, among others.

Often an online retailer will use multiple labs for the same or different tests. The results are then sent back to consumers by the online retailer, often without the consumer ever knowing which laboratory processed their test.

Problems with finger prick tests

Finger prick tests for oestradiol are sold by online retailers for between £50 and £180, depending on what is included in the test.

Inuvi, a laboratory that processes tests for online retailers, said it was asked to process home testing kits for oestradiol that use capillary blood samples in July 2021. The online retailer would collect the samples in yellow top tubes, which are commonly used for this purpose.

Yellow (also known as gold) top collection tubes are commonly used for a wide range of testing on serum samples. They contain a substance that activates clotting and a gel that acts as a layer between the blood cells and plasma. The separated serum can then be easily removed for testing. Red top collection tubes are less common and are used where results of serum tests might be affected by the separator gel used in the yellow bottle.

When Inuvi carried out internal validation studies, the results showed a "discrepancy" between capillary and venous samples from the same person. The capillary results kept showing lower readings beyond what would be expected, indicating they may be unreliable.

Inuvi chief executive Jonathan Benton said that as a result they did not offer to process this test for the retailers, missing out on potential revenue. Inuvi's view is that this was not simply a reference range problem, where you could amend the range of upper and lower limits that you would expect to see to help

interpret the results, but that it was linked to "the blood-to-gel ratio and contact time in the yellow top tube." It formally told its clients in November 2021 that it would not be processing this test on blood collected this way.

Another large laboratory, Eurofins County Pathology, also began internal studies in 2021 which indicated "consistently lower" oestradiol levels in capillary samples compared with venous blood. It did not, however, inform clients about the outcome of the study until the beginning of October 2022.

Eurofins did get in touch with its online retailer clients to tell them that the results of the capillary tests were lower. It said there was a "negative bias"—a percentage drop across the board for capillary tests compared with venous samples—but unlike other laboratories or retailers it did not stop processing tests on the yellow top tubes immediately. The company told *The BMJ* in August 2023 that it had stopped processing the tests.

One source with knowledge of Eurofins' processes, who had recently left the company and did not want to be named for fear of repercussions, said the results from internal studies showed the test was unreliable: "Some customers who use this are bodybuilders, people who are on hormone replacement therapies, or people who may be going through IVF. It's not an urgent medical test but you would want the result to be as accurate as possible. Every test has implications."

Another person, who also recently left the company and wanted to be anonymous, 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 withdraw finger prick tests for oestradiol

Medichecks is one of the online testing companies that uses Eurofins County Pathology, Inuvi, and The Doctors Laboratory to process customer tests. Eurofins County Pathology was the laboratory processing capillary tests for oestradiol for the company. Medichecks said it withdrew the finger prick test as soon as Eurofins told it of the problem at the end of September last year.

In a statement to customers on its website, Medichecks said it had changed how it tests oestradiol after laboratories said the yellow top tubes "may return lower than expected results." It moved to a new laboratory which had validated oestradiol testing using a different sample collection tube.

"We contacted customers to offer to replace test kits for those awaiting a result, and we offered any customers who had recently received results a free retest, using our CE marked red top collection kit," a Medichecks spokesperson told *The BMJ*.

The Doctors Laboratory said it fully validates all its tests and identified problems with finger prick tests for oestradiol "some months ago" and also withdrew it.

It is concerning when different laboratories or online testing kit providers are coming to different conclusions on the same tests, experts said. Jon Deeks, professor of biostatistics at the University of Birmingham, said, "The whole field needs to have a process to show transparency, to show how things work, because it's all hidden. We should have agreed methods on how decisions are made and we should be able to see those data."

Lack of regulation of laboratories

Experts said the findings raised 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," he says.

Similarly, there is no regulator of laboratories, private or NHS, in the UK. UKAS gives a stamp of approval for overall quality but laboratories can choose what tests to put forward. 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.

UKAS does not cover all aspects of safe and appropriate testing, says Croal. "So, less robust testing areas that are too difficult to accredit can be excluded from accreditation but still provided to the patient.

"Providers of testing need to be regulated or inspected to ensure what they are doing is valid and backed up by quality systems. Poor quality, unregulated laboratory services pose a significant risk to patients and the organisations providing these services," he told *The BMJ*.

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."

Wells 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.

Eurofins Country Pathology told *The BMJ* that it is "committed to patient safety and the integrity of test results, evidenced by our continuous conducting of validation studies and verification work on testing platforms and methodologies. County Pathology UK welcomes further discussion around regulation, and the sharing of best practice to enable patients and healthcare providers to make informed decisions around testing."

This article was updated on 31 August 2023 to reflect further information provided by Eurofins County Pathology and to include a statement from the company.

This feature has been funded by the BMJ Investigations Unit. For details see bmj.com/investigations

Commissioned, externally peer reviewed.

Competing interests: none.

1 Wilkinson E. The rise of direct-to-consumer testing: is the NHS paying the price?*BMJ* 2022;379:. doi: 10.1136/bmj.o2518 pmid: 36288807