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Health Self-Test Kits Require Stronger Oversight, Say Experts

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A recent study has raised serious concerns over the reliability and safety of at-home health testing kits, warning that many lack transparency and proper guidance, putting consumers at risk. The findings come as the self-test market expands rapidly in the UK, prompting calls for tougher regulation and clearer consumer protection.

Researchers at the University of Birmingham reviewed 30 home-use diagnostic kits commonly sold in British shops and online. These products, ranging in price from £1.89 to £39.9, claim to detect conditions such as bowel cancer, vitamin deficiencies, thyroid problems, HIV, and menopause. But according to the two studies published in the British Medical Journal (BMJ), the majority of kits offer little evidence of their accuracy or provide adequate instructions for users.

Of the 30 products reviewed, fewer than half included any reference to the test's accuracy, and less than a quarter offered clear advice on what users should do with their results. Worryingly, nearly half advised people to seek medical advice regardless of their result, something that could increase pressure on health services and add confusion for patients seeking reassurance, not ambiguity.

Professor Jon Deeks, who led the University of Birmingham research, said self-testing has the potential to improve access to care but warned that it must be approached with caution. "Self-tests have a clear potential to improve public health," he said. "However, for them to be beneficial and not harmful, they must be proven to be accurate, easy to use, and supported by clear instructions."

Self-tests have existed in Britain for over 50 years, beginning with pregnancy tests in the 1970s and became widespread during the Covid-19 pandemic, with lateral flow tests used to manage community transmission. Those particular tests were not included in the Birmingham study, which focused on commercial tests sold for general health checks.

One of the central criticisms was a lack of regulatory oversight. The Medicines and Healthcare products Regulatory Agency (MHRA), which is responsible for medical devices in the UK, acknowledged the findings and stated that it is currently "overhauling" safety standards. Joseph Burt, Head of Diagnostics and General Medical Devices at the MHRA, said new transparency measures are being explored, including requiring published summaries of clinical evidence.

The study classified 60% of the kits examined as "high risk," with concerns ranging from exaggerated accuracy claims, some as high as 98%, to missing clinical validation. Currently, manufacturers are not legally required to publish performance data, an issue flagged by both the *BMJ* and the Royal College of General Practitioners, who are calling for greater openness.

Bernie Croal, President of the Royal College of Pathologists, warned that poor-quality tests could result in either "false reassurance" or lead to unnecessary strain on the healthcare system. While the tests may offer privacy and fast results, many are marketed based on convenience and cost, rather than clinical necessity. The *BMJ* noted that access to these kits based on ability to pay rather than clinical need risks widening health inequalities and exploiting vulnerable consumers.

The UK's self-test market is expected to grow significantly, with revenues forecast to reach £660 million by 2030. But with that growth comes responsibility. Experts are urging consumers to check for a CE mark or UKCA mark indicators that a product meets EU or UK safety standards before using any test. Burt added, "We strongly encourage anyone using a self-test to read the instructions carefully and seek medical advice if they're unsure about their result."

In a time when individual responsibility in health is more encouraged than ever, ensuring that people have access to tools that are not only accessible but also accurate and safe is crucial. Without better regulation and transparency, the risks may outweigh the convenience.