

You're worried you might have,
a serious medical condition.
Is a home testing kit the answer?

Don't try

Visit your local pharmacy or surf the internet and you'll find a growing number of home testing kits for sale. In this health conscious age, these products have found a niche, pandering to our fears of developing a range of major diseases. But are they a good idea? To find out, *Health Which?* chose six disease areas: high cholesterol, bowel and prostate disorders, osteoporosis, diabetes and Alzheimer's disease. We bought 11 kits from pharmacies or via the internet. Then we recruited key medical experts in each disease area, along with a laboratory manager at a large London hospital, to assess the kits and decide whether they're appropriate for use at home.

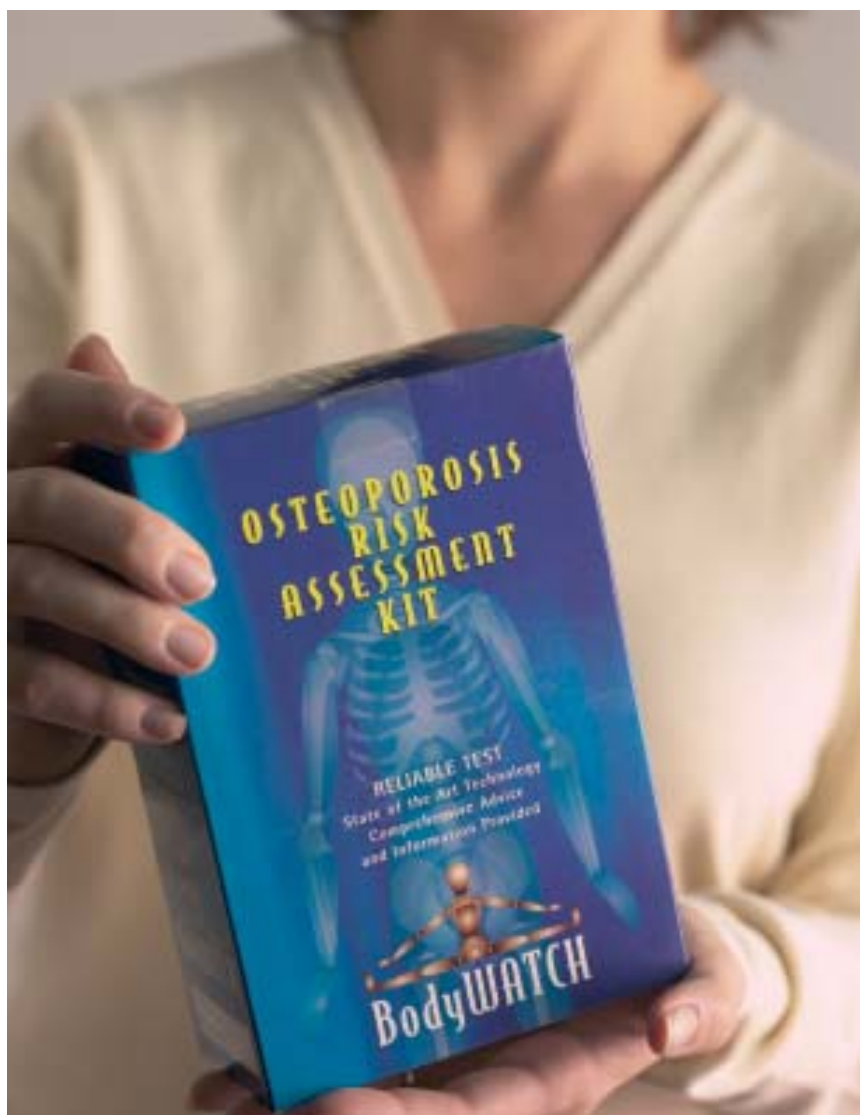
The experts wanted four of the kits to be withdrawn from sale because they are misleading and unreliable: BodyWATCH's Osteoporosis Risk Assessment Kit and HomeChec's Early Alert Alzheimer's Home Screening Test, and both the Boots and BodyWATCH cholesterol tests.

For the diabetes, prostate and bowel disorder kits, our experts said that, although the tests were likely to give a result of some value, crucially, all expressed concern at people being presented with a potentially shattering result without explanation, support and counselling from a professional.

Overall our experts' main concern was that, although the tests are careful not claim to diagnose a specific disease or replace seeing a GP, the user would automatically assume a connection between the result and a specific disease.

We asked the manufacturers to provide evidence that the tests were suitable for home use. HomeChec said it sent a parcel to us, but it never arrived. The company said it couldn't repeat the exercise, despite our offering them extra time. Wellbeing only gave us copies of their customer leaflets and some background information. BodyWATCH say they never received our original letter and couldn't provide information within our deadline. And Boots said the tests we investigated had been 'developed and approved by our medical, quality and pharmacy departments'. Boots said it used a company to run trials with the public, but that these were 'commercially sensitive'.

At the moment, there are no statutory regulations dealing specifically with the control, quality, safety and accuracy of home testing kits. But from



This report was compiled by Felicity Porritt

December 2003, they will have to show they meet the requirements of a new EU directive by displaying 'CE' marking on packing. But as *Health Which?* has already found (see *Medical Devices*, April 2002, page 10), CE-marking is often no more than a marketing gimmick.

As we went to press BodyWATCH had just been taken-over by Wellbeing. Wellbeing told us BodyWATCH products will be re-branded and 'where appropriate alternative technology will be introduced'.

these at home

HIGH CHOLESTEROL

Coronary heart disease (CHD) kills more people in the UK than any other condition. Too much of a particular 'bad' type of cholesterol (LDL cholesterol) in the blood can increase your risk. The risk is particularly high if you have a low level of 'good' (HDL) cholesterol compared to your level of LDL cholesterol.

How the tests work

Boots' Cholesterol Test (£8.50) and BodyWATCH's Total Cholesterol and HDL Cholesterol Test (£13.99 inc p&p) require

you to prick your finger, drop some blood onto a test area then compare the colour against a result chart.

What our experts said

The BodyWATCH test claims to be a 'simple one-step test' but it is in fact two, four-step tests. Our lab expert said this could make them difficult to use and therefore unreliable.

The BodyWATCH test measures your HDL cholesterol level – if this is 1mmol/L or less it claims you may be at increased risk of CHD. It has a separate test to

measure your total cholesterol. But our cardiovascular expert said only a health professional can fully assess a patient's risk, as other factors such as medical history must be taken into account. Someone could be at high risk of CHD despite having a low cholesterol level and vice versa.

The Boots test requires you to completely 'saturate' the test area with a large drop of blood, adding more if you're unsure. But both our cardiovascular and lab experts

claimed, while it's easier to use than the BodyWATCH test, a second application of blood would make the result less reliable.

Verdict

Even though the manufacturers don't say a high result means the user has CHD, people are bound to link the two. Our cardiovascular specialist added: 'These tests are a waste of money because cholesterol levels cannot be used in isolation to assess an individual's risk of heart disease.'

The British Heart Foundation told us such kits could 'either falsely reassure or cause undue anxiety. Testing should ideally be arranged through a GP. Results should always be discussed with a health professional so that advice can be given'.

For more information

The British Heart Foundation
www.bhf.org.uk
☎ 020 7935 0185

Healthline ☎ 0845 924 5500, then once in the system dial your chosen three digit number: **441** cholesterol level and how to reduce it.



DIABETES

There are two types of diabetes. In type 1 the body cannot produce any insulin. In type 2, the body does still make insulin, but either not enough or, more commonly, the body becomes 'resistant' to its own insulin. In both types, the body cannot properly control glucose levels in the blood. People with type 1 need regular doses of insulin to live. Typically type 2 can be controlled, either with dietary changes, or in combination with medication. Complications can include damage to the heart, kidneys, eyes and nerves.

How the tests work

The Boots Diabetes Home Test (£6) and the Wellbeing Diabetes Screening Test (£6) are identical. Both require you to collect a sample of urine in a plastic cup and test for glucose by dipping a strip into the cup. The strip will turn green if glucose is present.

What our experts said

Our experts say vitamin C supplements can interfere with the test. Our diabetes

specialist said this warning should be printed clearly on the box as well as on the leaflet.

The leaflets, both experts said, don't explain that this type of test can produce incorrect results – what are called false-negative and false-positive results.

Verdict

Our experts both agree that the science behind the tests was sound but warned against doing them at home. Only a health professional should interpret the results.

Diabetes UK told us: 'We don't recommend the use of home testing kits. They aren't reliable for diagnosis – giving false reassurance to some and unnecessary worry to others. It's also important that if someone is diagnosed with diabetes they have a doctor or nurse on hand to answer the questions they will inevitably have.'



For more information

Diabetes UK www.diabetes.org.uk
Careline ☎ 020 7424 1030, 9 to 5pm,
Monday to Friday.

Healthline ☎ 0845 924 5500, then once in the system dial your chosen three digit number: **073** diabetes.

PROSTATE DISORDERS

Prostate cancer is common and causes over 9,000 deaths every year in the UK. Symptoms may include frequent trips to the toilet (especially at night), an inability to urinate immediately even when desperate to do so, a weak stream when urinating, lower back pain and blood in the urine. Screening with the PSA (prostate specific antigen) test is controversial. It can't diagnose prostate

cancer, only a biopsy can do that. And 60 per cent of men with a raised PSA level don't have prostate cancer while 20 per cent of men with prostate cancer don't have a raised PSA level.



How the tests work

The Wellbeing (£13.95 inc p&p) and HomeChec (£16.98 inc p&p) prostate disorder tests are identical (both are made by Wellbeing) and give a positive result if the blood sample shows a level of the protein PSA higher than 4ng/ml. The BodyWATCH Prostate Disease Risk Assessment Kit (£9.99 plus p&p) works in a similar way, but uses a lower level – 3ng/ml PSA – as a cut-off for a positive result.

All three tests require you to prick your finger with a lancet and press a drop of blood (or two, in BodyWATCH's case) into a test area and then add some liquid to help absorption. The result appears in an adjacent window.

What our experts said

Our oncologist pointed out that the level of PSA detected as 'positive' isn't necessarily associated with prostate cancer – it could easily be due to simple inflammation and swelling. So a positive test result could be unnecessarily alarming.

By lowering the level for a positive result from 4ng/ml (used as a marker by specialists to prompt further tests) to 3ng/ml, our oncologist said the BodyWATCH test will increase

the number of false positive results – and perhaps needlessly alarm more people.

Both experts pointed out that there are reservations about using PSA as a screening tool for prostate cancer. At present there's no clear proof that it helps prevent deaths from prostate cancer.

Our lab expert said different volumes of blood put in the sample area would affect the result. So he felt there would be 'serious limitations' in the accuracy of the tests.

Verdict

Our experts agreed that people would be seriously affected by the knowledge of a positive result, even though the manufacturers makes no direct association between the tests and prostate cancer. Our oncologist advised that people should always see their GP first. Then you can discuss whether a PSA test is appropriate, given that a positive test result will require further investigations.

For more information

See *Prostate cancer*, October 2002, page 32 for a full set of further contacts.

Healthline 0845 924 5500, then once in the system dial your chosen three digit number: **414** prostate cancer



Cancer Research UK told us:

'People who suspect they may have cancer should be examined by a qualified doctor who will decide the most appropriate tests. The use of home kits for any type of cancer is very dangerous – they can give false-positives and negatives. Cancer tests are only useful in the context of full medical care.'

BOWEL DISORDERS

In the UK, bowel cancer is the third most common cancer in men, and the second most common in women. Possible symptoms include blood or mucus in the stool, changes in bowel habit (for example, development of constipation, diarrhoea or both), pain or discomfort in the stomach, weight loss and extreme tiredness.

How the tests work

Boots' Bowel Home Test (£12.00) and Wellbeing's Self Check Bowel Disorders Test (£13.95 inc p&p) are identical in the way they work, but have different information in their leaflets and on their boxes.

Both provide five tissue tests. You're told to throw the first tissue into the toilet bowl to check there's no disinfectant present (it changes colour if there is). After urinating and flushing, you then empty your bowels and throw another tissue on top – if blood is present at a level of 2mg haemoglobin/100ml or more, the tissue will change colour. You have to repeat the test for two more bowel movements.

What our experts said

Both tests explain that there are many conditions other than cancer that can cause bleeding in the bowel, including piles, ulcers and certain medicines. Our oncologist said this would account for the vast majority of positive results.

Our lab expert explained that this type of test has been available in hospitals and GP practices for some years. But neither manufacturer provided evidence to show it works for faeces tested in the toilet bowl (labs test stool samples directly rather than in water).

Verdict

Our experts said users could be unnecessarily alarmed by false-positive results, or inappropriately reassured by a negative result, even though the manufacturers make no association between the tests and bowel cancer.



For more information

Cancer Research UK
www.cancerhelp.org.uk
020 7061 8355.

Healthline 0845 924 5500, then once in the system dial your chosen three digit number: **023** colon & rectal cancer.



OSTEOPOROSIS

Osteoporosis is a condition in which the bones become less dense and therefore weaker. One in three women and one in 12 men over the age of 50 will develop the condition. It can cause painful and disabling fractures.

How it works and what our experts said

BodyWATCH's Osteoporosis Risk Assessment Kit (£19.99) requires you to send off a sample of urine to a lab. You then call to get the results just over a week later. The lab measures the level of deoxypyridinoline (dpd) which, BodyWATCH claims, is an indicator of bone loss because 'as more bone is lost then the dpd in the urine increases'.

Our researcher, who is in her late 30s and whose mother has osteoporosis, tried the test. She called the freephone number after seven days and was told the result wasn't ready but that it would be posted the next day. It duly arrived and stated she was 'above the risk level' and to seek further advice from a doctor. She was sent a leaflet about dpd and osteoporosis but no mention of any telephone number to call for advice about the results. Naturally, she was alarmed.

There are different methods that can be used to measure dpd, our rheumatologist explained, and different techniques can produce different results. Neither the kit itself, nor the manufacturer when we asked, stated the method used.

Having a raised level doesn't necessarily mean a higher than usual risk, our rheumatologist pointed out. In reality, levels can be affected by diet, exercise and some illnesses. Levels can be high one day and normal the next.

And the National Osteoporosis Society told us: 'We are very concerned about urine tests for the public which claim to give accurate results about a person's risk of osteoporosis. Urine tests are currently being evaluated in specialist units, to monitor the treatment of people with the disease, but they cannot be used to diagnose or assess the risk in individuals.'

Verdict

Both our experts were adamant this test should not be on the market. The scientific basis behind the test is 'questionable' our lab expert said. Interpreting dpd levels requires specialist knowledge and expertise – even most GPs would have difficulty, according to our rheumatologist. The only reliable way of measuring osteoporosis is with a bone scan.

For more information

National Osteoporosis Society, www.nos.org.uk
 ☎ 01761 471 771 (general enquiries)
 ☎ 0845 4500230 (medical queries).

Healthline ☎ 0845 924 5500, then once in the system dial your chosen three digit number: **293** osteoporosis.



ALZHEIMER'S DISEASE

There are currently 500,000 people with Alzheimer's Disease (AD) in the UK. The most common symptoms are progressively worsening memory loss, problems with language, confusion and an increasing inability to manage daily life. There isn't a straightforward test but a person being assessed would, among other things, be asked questions to test their memory.

How the tests work

The Early Alert Alzheimer's Home Screening Test (£26.98 inc p&p) involves working through 12 scratch-and-sniff cards. There are four options on each card. If you get four or more incorrect answers you are advised to consult a doctor as smell loss, the accompanying leaflet explains, is among the first signs of Alzheimer's.

What our experts said

Both our psychiatrist and lab expert thought the kit was a waste of money as there are many reasons why we might lose our sense of smell. Also, they pointed out, 'smell change' isn't used as one of the main indicators of AD anyway.

Our psychiatrist said even if smell was an indicator of AD, the test would still be flawed. For example, he tried the test on a friend and they found it very difficult to use. He said 'I'm sure neither of us has Alzheimer's'.

Our lab expert said some of the smells could be difficult to interpret because of the American terms, such as 'gasoline' (it's a US-made test



dispatched by HomeChec UK, that we found easily on the internet).

Verdict

Both experts agreed the test should be withdrawn immediately as it isn't suitable for use by anyone and could be positively misleading. Even HomeChec struggled to defend selling the product. They told us that they don't sell many kits – it turns out that most of the ones bought this year had been purchased anonymously by our researcher. In fact, they added in a subsequent conversation, they aren't going to buy in new stocks.

The Alzheimer's Society told us: 'This test could make people very worried. Loss of smell wouldn't be used to diagnose Alzheimer's in the absence of any other assessment.'

For more information

Alzheimer's Society
www.alzheimers.org.uk
 helpline ☎ 0845 3000 336
 Monday to Friday, 8.30 to 6.30.

Healthline ☎ 0845 924 5500, then once in the system dial your chosen three digit number: **175** Alzheimer's disease.

Verdict

We would like all the products assessed here to be withdrawn from sale to the public. No one should do these tests instead of visiting their GP. Only a qualified health professional is able to advise about appropriate tests and assess the results.

Our experts singled out the osteoporosis and Alzheimer's kits as being particularly alarmist as the science they use isn't proven.

Even though the manufacturers don't claim to be diagnosing specific diseases, our experts were unanimous in concluding that every test we looked at could provide false reassurance to some and unnecessary concern to others. □

Your GP should be your first port of call if you're concerned about any of the conditions covered here. Additional information can be found on NHS Direct's website www.nhsdirect.nhs.uk. We've also provided contacts for relevant charities and patient groups. And see page 21 for details of our Research Bulletins.