The home health testing market is thriving and it is surprising to find out just how many products are available independently of health care professionals. Tests can now be carried out at home for illnesses ranging from diabetes and stomach ulcers to genetic tests for inherited medical conditions. A growing interest in personal health by consumers is fuelling the demand for home test kits which can be purchased from pharmacies or online. For some people the attraction lies in being able to maintain control over health related issues while others may simply be embarrassed to visit their GP, or find it too difficult or expensive.

How does it work?
Advances in technology mean that self testing is becoming cheaper and easier. Most procedures use a sample of urine, blood or faeces and some of the tests only take a few minutes to carry out. The results are shown by a colour change in the test material. Other tests require more complex equipment or knowledge for interpretation. In such cases, a sample must be posted to a laboratory to be tested. The results are then returned directly to the user or to their doctor.

Implications of home tests
Self-testing for illness removes health professionals from the early stages of testing and detecting illnesses. Healthcare kits pose few, if any, problems for those with specific skills and training but may not be as clear-cut for people who, for instance, have never taken a blood sample before. Their doctor’s medical knowledge experience of identifying illnesses and ability to assess the impact of their health history on the results are all omitted from the process. While they tend to only have a small margin of error, the tests are not always 100% accurate and a specialist would be able to advise patients about this. Other factors such as a patient’s diet may affect the results and mean that alternative tests are needed. Furthermore if a patient gets a positive reading for a HIV/AIDS or cancer test the need for counselling may be overlooked. Healthcare specialists have no way of knowing that these tests are being carried out privately or when people need support.

Effects on healthcare system
Screening tests can save lives by catching a disease at an early, more treatable stage. Preventive methods of treatment can be employed to halt or slow the progression of an illness. This in turn can result in reduced costs related to hospital care, surgery and medicines.
Blood pressure indicates the amount of work that your heart has to do to pump blood around the body. The normal level of blood pressure is usually about 120 (systolic) over 80 (diastolic), but this can vary with age, general wellbeing and activity levels. High blood pressure rarely presents symptoms so it is essential that adults over 40 check their blood pressure regularly. Home monitoring is recommended by many experts because a patient’s blood pressure may be elevated during a visit to the doctor but normal in more familiar surroundings. The higher quality electronic devices are easy to use and more accurate than finger monitors. Before you take your blood pressure, sit and relax for about five minutes. Avoid coffee and chocolate for about 30 to 60 minutes before the test because caffeine can skew the results.

Becoming more active, eating healthily, losing even a little weight, quitting smoking and drinking less alcohol may be enough to keep blood pressure at a reasonable level but some people may need medication and it is important to discuss this with your GP.

Breathalyser
The legal limit for drinking if you are driving in Ireland is 0.8g/l. This alcohol level is measured in blood or breath, using either a blood alcohol test or a breathalyser. Although 0.08pc blood/alcohol is the legal limit, the actual safe limit to drive can be as low as 0.02pc. There are a number of models of breath alcohol analysers on the market for use by consumers which are less expensive and usually much smaller than the devices used by the Gardaí. They are also likely to be less accurate, but can give a useful indication of the user’s blood alcohol level. It is legal to use a breathalyser but it should only be used as a general guide to the level of alcohol in your body and not be relied on to ensure you remain below the legal limit. If you are in any doubt do not drive.

Cholesterol
Cholesterol is needed in the human body but an elevated blood cholesterol level is one of the major risk factors for coronary heart disease. Good ‘HDL’ cholesterol protects the body while the bad ‘LDL’ kind contributes to hardening of the arteries. Home health tests look for the presence of HDL and total cholesterol. However, variations in cholesterol test results are common, and variability may be greater with home cholesterol test kits, especially if you are not fasting. Cholesterol management requires careful clinical assessment so before investing in a home test kit, consult your doctor.

Coeliac disease
This is a digestive disorder which prevents people from being able to eat wheat, barley, oats or rye. A home test for elevated antibody levels can be done by pricking your finger with blood. Tests can provide a result within ten minutes and are about 95% accurate. Patients who test positive often require a biopsy of the intestine to confirm the diagnosis. It is important to note that you can have a negative test result if no gluten has been consumed in the lead up to the test.

Diabetes
Diabetes is a condition where your blood sugar level is higher than normal. It is possible to diagnose yourself using a cheap, simple test that can be bought at any pharmacist. However, it takes much more than a single blood sugar test to control diabetes. Blood glucose monitoring requires that you test your blood sugar regularly, keep track of the readings and adjust your prescribed treatment accordingly. While self-monitoring can be useful in some people’s approach to self-care, in order to obtain maximum benefit people with diabetes need access to the right education and support.

Allergies & intolerances
A food allergy occurs when your immune system reacts to proteins in a food you have eaten. Food intolerance is a reaction to chemicals found in foods. Food allergies can be identified by skin prick tests or RAST blood tests. Most blood kits on the market involve sending away a blood sample or attending a clinic. There are no laboratory tests for food intolerance and the only way to identify the culprits is through following an elimination diet and then carefully reintroducing foods and monitoring reactions. It is important to discuss symptoms with your GP and ask to be referred to a specialist for treatment.

Lactose intolerance is the inability to digest a sugar called lactose that is found in milk and dairy products. The tests available include ‘hydrogen’ breath tests to blood self tests and stool tests. It is important to follow all procedures carefully to avoid false positive or negative results. Medical advice should always be sought before cutting a major food group like dairy out of your diet.
Self-testing removes some of the burden from the health services, and can save lives through early screening and disease prevention. It makes it easier for consumers to check for signs of serious conditions, in particular for illnesses which they may feel embarrassed about. There seems to be a distinct trend toward self-monitoring and people are encouraged to actively participate in the management of their health. However, there are also risks involved when patients take matters in their own hands and this is why the advice and expertise of health professionals should not be omitted. Self screening can also lead to false alarms, a false sense of security or unnecessary testing and treatment. It is best to talk to your doctor about which tests are necessary or you could be wasting your money.

Useful websites
 ANEC, the European consumer voice in standardisation www.anec.org
 Coeliac Society of Ireland www.celiac.ie
 Diabetes Federation of Ireland www.diabetes.ie
 Irish Heart Foundation www.isharme.ie
 Irish Medical Organisation (IMO) www.imo.ie
 National Screening Committee UK (NSC) www.nsc.nhs.uk

Multi Drug Test
These rapid one step urine tests are available for the detection of the most commonly abused drugs including ecstasy, cocaine, cannabis and heroin. They claim to provide visible results within five minutes.

Legislative authority
The Irish Medicines Board (see Useful websites) is authorised to act on behalf of the Government to ensure that the requirements of the EU Medical Devices Directive are carried out. The key piece of legislation which applies to self-testing is the in vitro Diagnostic (IVD) Medical Devices Directive (98/79/EC). In order for a product to come within the scope of the in vitro Diagnostic Medical Devices Directive 98/79/EC, it must be intended by the manufacturer to be used for a medical purpose. Self tests kits such as those used to check alcohol levels or for law enforcement purposes do not fall within the scope of the Directive.

Devices for self-testing must be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users. Classification of IVDs is based on perceived risk and self-test IVDs are classified as ‘Significant Risk’. In the past the IMB has had to investigate a supplier’s self-test kits for HIV, chlamydia, syphilis, pregnancy, and cholesterol after the discovery that the HIV tests did not meet medical-device legislation. The products may have been distributed to the public via the internet. This highlights the importance for consumers to buy from recognised sources as there may be potentially defective self-test kits on the market. Labelling and assembling of the kits may be inadequate or have components that are past their sell-by date. According to the IMB ‘obligations are placed on manufacturers to ensure that their self test kits perform as intended and users may report any faults or concerns that they experience when using these devices to the IMB via the user reporting form on the IMB website’

CE marking
Self-test IVDs are freely available on the Irish market as long as they are CE-marked in accordance with the IVD Directive. The CE mark is a mandatory conformity mark on many products placed on the EU market. However, it is the view of the CAI and the wider consumer representative standards group ANEC that the CE mark is overvalued and that consumers are regularly being misled by it. It cannot be relied upon as a definitive indication of either safety or quality. The CAI through ANEC, the European consumer voice in standardisation (see Useful websites), has continued to demand a reclassification by the European Commission of the value they place on the CE mark, and on the advice provided to consumers regarding the mark. Regrettably this has met with little success to date.

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Assessing self-tests
Recognised criteria for assessing self-test kits would enable transparent decisions to be made about whether self-test kits should be placed on the market. The UK National Screening Committee (NSC, see Useful websites) uses set criteria to advise whether population screening programmes should be introduced. Amongst the criteria most relevant to self-tests are:

- The test should be simple, safe, precise and validated
- The test should be acceptable to the population
- The benefit from the test should outweigh physical and psychological harm (caused by the test, diagnostic procedures and treatment)
- There should be agreed policy on follow-up for individuals with a positive test result
- Information explaining the consequences of testing, investigation and treatment should be made available to potential participants.

Workplace testing
In 2005, the Health and Safety Act provided for ‘appropriate, reasonable and proportionate’ compulsory drink and drug testing in workplaces. Some Irish companies such as Ryanair and Iarnród Éireann randomly test staff for alcohol and drugs. Screening is commonly carried out where employees are relied upon to maintain safety as is the case in the transport industry. Technological advances allow a range of drugs such as cannabis, heroin, cocaine, morphine and amphetamines to be quickly detected in saliva. Testing kits can screen for up to ten drugs and drug groups simultaneously. We noted that the services of one Dublin laboratory are employed by more than seventy corporate clients for pre-employment screening, random screening and post-incident screening for drugs and alcohol abuse. The company employs a dedicated team of collectors and testers who are available 24 hours a day to respond immediately to situations requiring their services.

Many companies see screening as a means to improve productivity and reduce absenteeism. In Ireland it is estimated that 3 - 5% of employees who undergo drug screening, test positive for illegal substances. The practice remains controversial as critics argue that employers simply use the tests to control and monitor staff. Employers should ensure that their tests comply with a recognised standard if they use random drug testing and consult with workers and unions before drawing up guidelines.