

# Medical Devices Information Notice

## Food Intolerance Testing

**FINAL**

**HPRA Information Notice: IN2018(01)**

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### ISSUE

The Health Products Regulatory Authority (HPRA) would like to inform the public and healthcare practitioners that products being promoted as food intolerance tests cannot diagnose food intolerance and advises members of the public not to act on the results of these tests without expert advice from a doctor or registered dietitian.

The HPRA has carried out a market surveillance review of the types of food intolerance tests available in Ireland. In addition, the HPRA has consulted with experts to examine the safety and performance of these tests.

Food intolerance is a diagnosis that needs to be made by a clinician or dietitian and it cannot be made based on a single blood test or other test method.

### Background

The HPRA published a medical device information notice in March 2015 ([IN2015 \(02\)](#)) in relation to food intolerance testing. In that notice, the HPRA highlighted concerns regarding an increased prevalence of food intolerance tests and associated services being offered in a variety of contexts such as in certain pharmacies, postal based services, food intolerance centres and other clinics. This updated information notice summarises the work that has been undertaken, provides an explanation of food intolerance and offers advice to the general public.

### What is food intolerance?

'Food intolerance' is a condition for which the underlying medical causes are not yet known. Food intolerance is a term sometimes used to describe various unpleasant symptoms such as indigestion, bloating or flatulence which can occur after eating certain foods but the cause is uncertain.

It is important to be aware that a food allergy is a completely different condition to a food intolerance. Food allergies can cause serious allergic reactions or anaphylaxis. This can lead to rapid swelling of the face and lips (angioedema) and difficulty breathing and requires immediate medical care.

The most important differences between a food allergy and a food intolerance are:

- An allergy produces specific symptoms, such as swelling of the lips, which can develop within minutes of eating the food. On the other hand, an intolerance tends to be associated with more general symptoms, such as indigestion and bloating, which may develop several hours after eating.
- Only a tiny particle of food is needed to trigger a food allergy.
- The symptoms of a food allergy can be life threatening, whereas symptoms associated with intolerance, unpleasant as they may be, are not.

### **What type of tests are available?**

The HPRA has identified a number of different types of products presented as food intolerance tests on the Irish market. While these tests usually use a blood sample, tests involving hair or saliva samples have also been identified.

As the cause of food intolerance is as yet unknown, any test which claims to indicate an intolerance to food is of little clinical validity. In other words, a positive or negative test result is unlikely to be specifically related to any particular symptom or clinical condition.

Many of the tests available on the Irish market examine a blood marker known as 'immunoglobulin G' (IgG). This is a blood marker which increases in every person following exposure to proteins found in food and this is to be expected as part of the normal function of the immune system in every person.

It has not yet been shown that an increase in IgG is anything other than a marker that someone has recently eaten a certain food.

Our market surveillance identified other forms of tests offering a variety of different proposed mechanisms to detect an intolerance to food. Examples include bioresonance and genetic testing. The scientific basis for these tests remain unclear and unproven.

### **What is the role of the HPRA?**

The HPRA is the competent authority in Ireland for the regulation of medical devices which includes *in vitro* diagnostic (IVD) devices. Some IVD devices are used as part of food intolerance testing services.

The HPRA does not approve or certify IVD devices before they are placed on the market in Ireland. Manufacturers of IVD devices are required to declare that their product meets the relevant European legal requirements. If the IVD is a 'self-test' device, whereby the test delivers a result to the lay person in their home environment, an independent review is carried out by organisations known as 'Notified Bodies' under EU legislation.

It is also important to note that the HPRA does not have a role in regulating the advice and associated services that are offered in settings such as pharmacies or food intolerance clinics. The function of the HPRA is to monitor the products that have been placed on the market for sale to ensure that they are safe and that they perform as intended by the manufacturer.

### **What should I do if I think I might have a food intolerance?**

If you have a concern that you may not tolerate certain foods well or are experiencing gastrointestinal symptoms, in particular after eating certain foods, it is recommended that you first visit your doctor. He/she will be able to take your medical history, examine you and guide you through the next appropriate steps. Once your doctor has ruled out other potential causes of your symptoms, the consideration of an intolerance to food may be appropriate.

The only clinically valid method for diagnosis and treatment of food intolerance is an elimination diet. This involves eliminating a particular food from your diet to detect whether your symptoms resolve, or disappear altogether as a result. Food intolerance can be diagnosed, only after a reintroduction of the eliminated food. If symptoms return this makes it very likely that the eliminated food is responsible for the symptoms. An elimination diet should only be undertaken in close consultation with a registered dietitian, who can provide specialist advice on maintaining a balanced diet throughout the elimination tests.

## **RECOMMENDATIONS**

The HPRA advises members of the public with concerns about a food intolerance to:

- 1** Firstly visit your doctor if you have a concern that you may not tolerate certain foods well or are experiencing gastrointestinal symptoms, in particular after eating certain foods. Your doctor will take your medical history, examine you and guide you appropriately. It is important to ensure that your gastrointestinal symptoms are not caused by any other underlying medical conditions.
  
- 2** Never rely on food intolerance tests alone for the purpose of a diagnosis or as the basis for dietary change. This is especially important with regards to vulnerable populations such as children, women of child bearing potential and the elderly, for whom maintenance of a nutritious diet is very important.
  
- 3** Be aware of the distinction between food intolerance and food allergy, which represents a completely different condition and which can be life-threatening. It is also important to be

aware that food intolerance is not the same as other conditions such as Coeliac disease or lactose intolerance, for which the cause is known.

- 4 Be aware that some products, often claiming to have health benefits, may have little or no scientific evidence of this benefit. People with concerns about their health should in the first instance seek advice from their healthcare professional.
- 5 Submit a user report to the HPRA at [devicesafety@hpра.ie](mailto:devicesafety@hpра.ie) if you have suffered an adverse effect as a result of food intolerance tests.
- 6 Exercise care when purchasing health products or services over the internet or through postal services.

For further information, see the HPRA's published consumer advice leaflet: '[Self-test products](#)' and '[Buying medical devices online](#)' both of which are available on the HPRA website.

## HPRA CONTACT INFORMATION

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