

# Simtomax Kit Testing for Coeliac Disease

## What is the Simtomax test kit?

In 2015, the Simtomax test kit was released into certain pharmacies in New Zealand. The kit has been available in Europe for several years, and was marketed in Australia last year. It is not currently licensed by the Food and Drug Administration (FDA) in the USA. It has not been submitted for accuracy testing in New Zealand. Nor has it been compared to other kits. The company that makes the kit (Augurix Diagnostics) claims that it is very accurate if the test is negative, i.e. for detecting people who definitely do not have coeliac disease.

Some independent studies published in medical journals seem to confirm this and some have found that it is not so accurate. Most of these studies have not been done in the community setting, which can make a significant difference to its reliability. It does seem that all the people in the studies who didn't have coeliac disease had negative Simtomax tests, (which is what you would expect) but some of the people who did have coeliac disease also had negative tests. Importantly, some people who tested positive for coeliac disease did not have coeliac disease. The kit has not been tested as much in children.

## False Negatives/Positives

All laboratory tests have false positive and false negative results and doctors are trained to take this into account when considering a diagnosis. For the Simtomax test, if the test result goes negative in a patient who really does have coeliac disease, this is very misleading, because these patients might become confident that they do not have coeliac disease when in fact they do. Also, if the test goes positive, a proportion of these patients will not have coeliac disease. This makes it very important either way, to seek advice from your doctor. It is very important not to base your decision on whether you have coeliac disease just on this screening test.

## Our Stance

At this time **Coeliac New Zealand** cannot recommend that patients use this test kit. The best test at the moment is the one requested by your doctor and done through the laboratory. Even this laboratory test has a small error rate and a biopsy of your small intestine is the "gold standard" for diagnosis.

However, if you do choose to test yourself with Simtomax, keep in mind that a positive result does not prove that you have coeliac disease and a negative test does not prove that you do not have it. Take the test result to your GP and discuss it with him/her. Until there is further local information and testing, it is not recommended that it be used for testing children. Print this page and take it with you to the GP.

## References

Gut 2013;62:A126 doi:10.1136/gutjnl-2013-304907.279

Manufacturer's web site <http://www.augurix.com/simtomax/>

BMC Gastroenterology Journal <http://www.biomedcentral.com/1471-230X/14/186>

Gut Vol 62. [http://gut.bmj.com/content/62/Suppl\\_1/A126.1](http://gut.bmj.com/content/62/Suppl_1/A126.1)