



# Gluten Detection

Why using a monoclonal antibody-based test is advantageous over a polyclonal antibody-based test?



G12 <sup>®</sup> Monoclonal Gluten Antibody	Polyclonal Gluten Antibody
All batches of antibody identical: <ul style="list-style-type: none"> <li>• standardization of test kits</li> <li>• more consistent and reproducible results</li> </ul>	Batch to batch variability of antibody: <ul style="list-style-type: none"> <li>• no standardization of test kits</li> <li>• results less consistent and reproducible</li> </ul>
Same level of quality amongst different lots of test kits	Varying levels of quality amongst different lots of test kits
Antibody specifically detects target epitope that is toxic to celiac individuals	Non-specific interaction of the antibody with the target toxic fragment
Increased specificity: <ul style="list-style-type: none"> <li>• no cross reactivity with non-toxic cereals</li> <li>• less False Positive results</li> </ul>	Decreased specificity: <ul style="list-style-type: none"> <li>• increased chance for cross reaction to non-toxic cereals</li> <li>• higher chance of False Positive results</li> </ul>
Greater sensitivity in ALL matrices: <ul style="list-style-type: none"> <li>• fewer False Negative results</li> </ul>	Lower sensitivity in difficult matrices: <ul style="list-style-type: none"> <li>• more False Negative results</li> </ul>
Defined target peptide sequences are detected: <ul style="list-style-type: none"> <li>• QPQLPY (gliadin - wheat)</li> <li>• QPQQPY (secalin - rye)</li> <li>• QPQLPF (hordein - barley)</li> </ul>	



# What is the Romer Labs® G12® Monoclonal Antibody?

- The G12® antibody was raised against the toxic fragment that causes a celiac response
- The G12® antibody targets the most immuno-toxic proteins for those intolerant to gluten
- The G12® antibody is capable of detecting potential immuno-toxic varieties of oats

In 2008, the Codex Alimentarius Committee published the CODEX Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (CODEX STAN 118 – 1979) highlighting the use of immunologic methods utilizing **antibodies that should react with the cereal protein fractions that are toxic** for persons intolerant to gluten.

Following these demands the **AgraQuant® Gluten G12® ELISA Test Kit** and **AgraStrip® Gluten G12® Lateral Flow Kit** have been developed. Both Test kits employ the **G12® monoclonal antibody which targets the most immuno-toxic proteins for those intolerant to gluten** and, thereby, are taking food safety assurance analysis in a new direction.

The  $\alpha$ 2-gliadin fragment of 33 amino acids in length was identified as the primary initiator of inflammatory responses in Celiac Disease.

Sequence of the immuno-toxic 33-mer: **LQLQFPFQPQLPYQPQLPYQPQLPYQPQLPYQPQPF**  
(L = Leucin, Q = Glutamine, P = Proline, F = Phenylalanine, Y = Tyrosine)

Where the **G12® monoclonal antibody specificity** is developed directly against this portion for a variety of cereals:

- QPQLPY (gliadin - wheat)
- QPQQPY (secalin – rye)
- QPQLPF (hordein - barley)



**AgraQuant® Gluten G12® ELISA Test Kit**



**AgraStrip® Gluten G12® Lateral Flow Kit**