

Romer Labs® AgraStrip® Gluten G12: A Rapid and Reliable Gluten Testing Solution for the Food Industry

Scott W. Radcliffe*

Romer Labs, Newark, Delaware 19713, United States of America

*Corresponding author: scott.radcliffe@romerlabs.com

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Over recent years the label "gluten free" has been gaining increased significance within the food industry. Public education and awareness has expanded due to outreach by Celiac Disease and gluten intolerance research and advocacy groups, driving the establishment of a gluten free market which, ideally, can be both safe for patients and profitable for manufacturers. The safety of gluten free products has also been improving as a result of clarification of food labeling laws and implementation of rules defining thresholds for "gluten free". For food manufacturers who must incorporate gluten testing into their risk management program, there exists a wide range of testing solutions to choose from. Therefore, the successful test kit manufacturers and analytical labs must provide solutions that are accurate, reliable, sensitive and robust. Romer Labs' AgraStrip Gluten G12, a rapid, lateral flow immunochromatographic method, meets these criteria as recently validated by the AOAC Research Institute under the *Performance Tested Methodssm* (PTM) program.

Since the 2008 revision to Standard 118-1979, the United Nation's Codex Alimentarius Commission has recommended that for foods to be labeled "gluten free," they should not contain more than 20 mg/kg (ppm) gluten. The commission recommends that products be analyzed by validated immunoassay (or equivalent method of equal sensitivity) that is specific to the toxic protein fragment in cereals, and which has a limit of detection (LOD) of 10 ppm or lower. United States Food and Drug Administration ruling 21 CFR 101.91 (2013, implemented 2014), European Commission Regulation No. 41/2009, and Canadian Food Inspection Agency (CFIA) position paper on "Compliance and Enforcement of Gluten Free Claims" supplementing FDR B.24.018 harmonize gluten labelling regulations in the USA, Europe and Canada with the 20 ppm Codex threshold. Manufacturers who test to a stricter standard of 10 ppm may choose to be "certified" gluten-free by the Gluten Free Certification Organization, or GFCO, a branch of the Gluten Intolerance Group. Those companies that are able to test to a 5 ppm standard may be certified by the Celiac Support Association, and display the seal of that organization on their packaging.

Gluten detection for the food industry is performed primarily by immunoassay, mass spectroscopy and DNA-

based methods. The majority of testing is by immunoassay, which is relatively inexpensive, straightforward and reliable, though sensitivity and specificity vary depending on the antibody a kit is based upon. LC-MS/MS is highly sensitive and specific, and can offer the advantage of multiplexing allergens, but extraction and cleanup can be more challenging, and there are significant equipment costs. PCR is also highly sensitive and specific, however while PCR detects DNA markers indicative of glutes, it does not directly detect prolamin or glutenin proteins.

The gluten immunoassays generally exist in either lateral flow or ELISA (enzyme-linked immunosorbent assay) format. Lateral flow devices (LFD) offer the user a rapid and simple detection platform which provides a qualitative result based on presence/absence of gluten around the assay kit LOD. ELISA is a longer and more involved procedure requiring additional lab equipment, but provides the user a quantitative result. The majority of commercial immunoassay methods are based upon the SkerrittmAb 401.21, MendezR5, or, most recently, the MorónG12 detection antibody.

Romer Labs' AgraStrip Gluten G12 is a rapid LFD assay utilizing the G12 antibody, which was raised against the immunotoxic and highly stable 33-mer (LQLQFPQPQLPYPQPQLPYPQPQLPYPQPQPF) fragment of α 2-gliadin, and recognizes the 6-mer peptide QPQLPY, which exists as a triple repeat within the 33-mer. G12 cross-reacts with homologous immunotoxic sequences in barley hordein and rye secalin, as well as avenin, about which debate and research continues. Targeting this peptide gives the G12-based AgraStrip assay high sensitivity, specificity and accuracy.

The AgraStrip Gluten G12 kit is designed to test for glutes in raw ingredients, finished products, environmental swabs and rinse water. This kit includes every necessary assay component. The sample is mixed with extraction buffer and shaken for one minute in the included extraction tubes, and then three drops are passed through a filter tip into the dilution vial. The vial is filled with dilution buffer up to a 5, 10 or 20 ppm mark; establishing LOD's which correspond to thresholds for Celiac Support Assoc., GFCO, and government regulatory agencies, respectively. After mixing, a lateral flow strip is dropped into the diluted extract and incubated for ten

minutes before reading a result based on presence of a blue control line for test validity, and presence/absence of a red test line.

This method was validated by Romer Labs under the supervision of the AOAC Research Institute PTM program against AOAC Official Method 2012.01, "Gliadin as a Measure of Gluten in Foods Containing Wheat, Rye and Barley." The study, "Validation of the AgraStrip Gluten G12 Test Kit" is unique in its scope and size (5000 samples tested) for a lateral flow assay validation, and is published in the Journal of AOAC International (DOI: 10.5740/jaoacint.14-143). Validation studies were performed at the 5, 10 and 20 ppm thresholds (n=150 per threshold) in rice flour, bread, cookies, and stainless steel spiked at five levels with purified gliadin from the Prolamin Working Group. Additional validated matrices of ice cream and dark chocolate were spiked with Sigma-Aldrich wheat gluten standard. Validation studies were reproduced independently by Q Laboratories for rice

flour, incurred bread and stainless steel. Additional studies included screening of 38 gluten free flours and commodities for cross-reactivity and interference, with none observed. The method was also validated for lot-consistency, intra-lot variation, accelerated and real-time stability, and robustness.

AgraStrip Gluten G12 stands out among gluten lateral flow methods for its ease of use and flexible LOD, and through AOAC PTM validation, proves it is a highly sensitive, specific, accurate and reliable immunoassay for the qualitative detection of gluten in raw ingredients, finished products, environmental swabs and rinse water.

Statement of Competing Interests

Author declares that he is currently employed by the manufacturer of AgraStrip Gluten G12, Romer Labs.