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An Integrated, Accurate, Rapid, and Economical Handheld Consumer Gluten Detector

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# Title: An Integrated, Accurate, Rapid, and Economical Handheld Consumer Gluten Detector

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## Abstract:

Celiac disease, characterized by autoimmune reactions to dietary gluten, affects up to 3 million in the US and approximately 0.5%–1% globally. A strict, lifelong gluten-free diet is the only treatment. An economic, simple, accurate, rapid and portable gluten testing device would enable gluten-sensitive individuals to safeguard their food safety. We developed a novel solution, Nima<sup>TM</sup>, a gluten sensor that integrates food processing, gluten detection, result interpretation and data transmission in a portable device, detecting gluten proteins at or below the accepted 20 ppm threshold. We developed specific monoclonal antibodies, an optimized lateral flow immunoassay strip, and one-step aqueous extraction. Compared with reference R5, Nima antibodies (13F6 and 14G11) had 35- and 6.6-fold higher gliadin affinities, respectively. We demonstrated device performance using a comprehensive list of foods, assessing detection sensitivity, reproducibility, and cross-reactivity. Nima<sup>TM</sup> presented a 99.0% true positive rate, with a 95% confidence interval of 97.8%–100%.

**Keywords:** portable gluten sensor; consumer food safety; celiac disease; gluten sensitivity

## Introduction:

Celiac disease (CD) is widely accepted as a systemic immune-mediated disorder in genetically susceptible persons, triggered by ingestion of gluten proteins from foods, including *wheat, rye and barley* (Fasano & Catassi 2012; Shan, Molberg, Parrot, Hausch, Filiz, Gray, et al., 2002). CD has an estimated prevalence of 0.5%–1% globally, approximately 1% among people of European descent (Han, Newell, Glanville, Fernandez-Becker, Khosla, Chien, et al., 2013). It affects up to 3 million people in the US and is four-times more common today than 50 years ago (Rubio-Tapia, Kyle, Kaplan, Johnson, Page, Erdtmann, et al., 2009). Common symptoms include chronic diarrhea, weight loss and abdominal distention (in 40–50% patients) with other manifestations present as well (Collin, Vilksa, Heinonen, Hällström, & Pikkarainen, 1996; Fasano & Catassi 2012; Shan, et al., 2002). Additionally, researchers have reported a population with non-celiac gluten-intolerance, experiencing adverse gluten reactions that are neither allergic nor autoimmune (Sapone, Bai, Ciacci, Dolinsek, Green, Hadjivassiliou, et al., 2012).

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