

FROM SURFACES TO SAFETY: EVALUATING A LATERAL FLOW DEVICE FOR THE DETECTION OF GLUTEN FROM STAINLESS STEEL WET AND DRY SURFACES

PRAKASH NAIR¹, MANPREET KALSI¹ and JASMINE LACIS-LEE²

¹GMO/Allergen Department, BVAQ, Melbourne, Victoria, Australia
²National Sale and Marketing, BVAQ, Salisbury, Queensland, Australia



Introduction

Gluten is a food allergen that refers to a group of proteins present in various cereal grains, such as wheat, barley, rye, and oats, that can trigger immunopathogenic reactions in genetically susceptible individuals, leading to coeliac disease^[1]. The presence of undeclared allergens is the leading reason for recalls in many countries^[2,3]. Fundamental allergen management involves several steps, including cleaning validation and verification. In recent years, lateral flow devices (LFDs) have gained popularity in manufacturing facilities for verifying cleaning efficacy, and in some instances, screening ingredients and products, owing to their simplicity, rapidity and cost-effectiveness. However, their effectiveness can be impacted by several factors, such as sample type, cross-reactivity, ingredient concentration or allergen, surface type, and cleaning agents, which can lead to erroneous outcomes, including false positives or negatives. Due to the limited number of matrices validated by kit manufacturers, end users are advised to review their matrices, to check for suitability and confirm the level of sensitivity, before use^[4].

The aim of this study was to verify a commercially available LFD to detect gluten from selected food matrices on stainless-steel wet and dry surfaces.

Methods

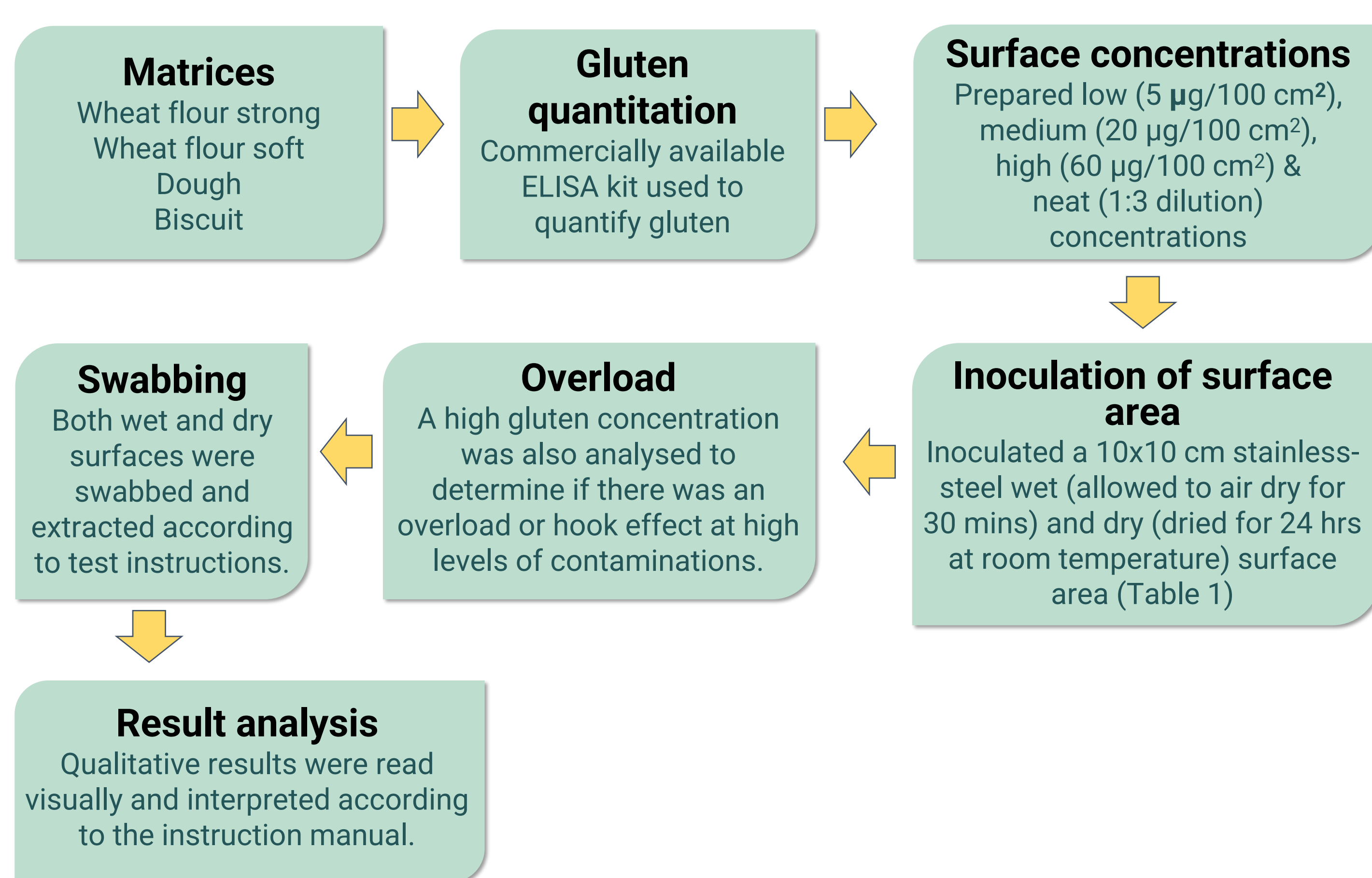


Table 1. Inoculated surface concentrations and number of tests performed

| Samples | Surface Concentrations | LFD tests | |
|--------------|-------------------------------------|-----------|-----|
| | | Wet | Dry |
| Flour strong | Low (5 µg/100 cm ²) | 5 | 5 |
| | Medium (20 µg/100 cm ²) | 2 | 2 |
| Flour soft | High (60 µg/100 cm ²) | 2 | 2 |
| | Neat (1: 3 dilution of sample) | 1 | 1 |
| Dough | | | |
| Biscuit | | | |
| | Negative control | 1 | 1 |

Results

Wet Surfaces

All inoculated concentrations recorded a positive result (Table 2).

Overload line

The high concentrations (neat) of gluten on wet and dry surfaces did not result in any false negative results, indicating that the test has a large analytical range.

Dry surfaces

- The gluten was not detected at a spiked level close to the limit of detection of the kit (5µg/100 cm²) from the wheat strong flour, followed by variable positive result from dough and wheat soft flour (Table 2).
- The baked biscuit was found to have a 100% positive rate at the claimed LOD.
- Furthermore, the LFD exhibited a detection capability of 100% for all other concentrations on dry surfaces.

Negative control

In both wet and dry surface assessments, all negative controls recorded negative results

Conclusion

In conclusion, positive results were obtained for all tested concentrations and matrices when inoculated on a wet surface. However, varying positive results were observed on dry surface at levels close to the LOD of the kit. This highlights the importance of end users verifying the performance of their device for detecting specific allergen presence in their facility and ensuring that the device consistently delivers accurate and reliable results with an appropriate level of sensitivity. Without this critical understanding, LFD may be used for risk-based decisions, even though the limitations of the kit may not be well understood.

In this study, multiple occurrences of faint test lines were observed during reading, highlighting the importance of conducting tests in well-lit areas and by trained personnel to avoid the potential misinterpretation of positive results as negative.

This study further reinforces the importance of verifying LFDs, not only for supporting cleaning procedures, but also for screening ingredients and finished product.

Recommendations

- Given the multifaceted factors that can influence the accuracy of LFDs, end users are strongly encouraged to verify the suitability for their specific application and use them as a screening tool as part of their allergen management program.
- Perform an overload test to evaluate the LFD can detect high levels of analyte without saturating the test line.
- Provide adequate training to individuals to understand the limitations of the LFDs and minimize the risk of false positive or false negative results.
- In cases where the limitations have been established or for assistance in product disposition decisions, complementary methods such as ELISA, should be employed.

| Description | Wet surface concentrations and percent recovery | | | | Dry surface concentrations and percent recovery | | | |
|--------------------|---|-------------------------------------|-----------------------------------|------|---|-------------------------------------|-----------------------------------|------|
| | Low (5 µg/100 cm ²) | Medium (20 µg/100 cm ²) | High (60 µg/100 cm ²) | Neat | Low (5 µg/100 cm ²) | Medium (20 µg/100 cm ²) | High (60 µg/100 cm ²) | Neat |
| Wheat flour strong | 100% | 100% | 100% | 100% | 0% | 100% | 100% | 100% |
| Wheat flour soft | 100% | 100% | 100% | 100% | 20% | 100% | 100% | 100% |
| Dough | 100% | 100% | 100% | 100% | 40% | 100% | 100% | 100% |
| Biscuit | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |

Table 2. Percent recovery of gluten from wet and dry surfaces

Reference

- Coeliac disease, <https://www.wehi.edu.au/research-diseases/immune-health-and-infection/coeliac-disease>, accessed on 18/05/2023.
- ANZ Food Standards Food recall statistics (1 January 2013 – 31 December 2022), <https://www.foodstandards.gov.au/industry/foodrecalls/recallstats/pages/default.aspx>, accessed on 15/05/2023.
- Girdhari M Sharma., Yinqing Ma & Stefano Lucciolli (2023). Recalls associated with food allergens and gluten in FDA-regulated foods from fiscal years 2013 to 2019. Journal of Food Protection, 86(4), <https://doi.org/10.1016/j.jfp.2023.100069>.
- Instruction manual: 3M Gluten protein Rapid kit, Neogen Reveal® 3-D for Gluten, Romer labs AgraStrip® Gluten G12®, SENSIStrip Gluten lateral flow kit and R-biopharm RIDA®QUICK Gliadin.