



CERTIFICATION

AOAC Research Institute *Performance Tested Methods*SM

Certificate No.
012501

The AOAC Research Institute hereby certifies the method known as:

OnSite[®] Gluten Test Kit

manufactured by

Microbiologique, Inc.
8315 Lake City Way NE
Seattle, WA 98115 USA

This method has been evaluated and certified according to the policies and procedures of the AOAC *Performance Tested Methods*SM Program. This certificate indicates an AOAC Research Institute Certification Mark License Agreement has been executed which authorizes the manufacturer to display the AOAC Research Institute *Performance Tested Methods*SM certification mark on the above-mentioned method for the period below. Renewal may be granted by the Expiration Date under the rules stated in the licensing agreement.

A handwritten signature in black ink, appearing to read "Bradley A. Stawick".

Bradley A. Stawick, Senior Director
Signature for AOAC Research Institute

Issue Date
Expiration Date

January 23, 2025
December 31, 2025

METHOD NAME

OnSite® Gluten Test Kit

CATALOG NUMBER

PA-44

ORIGINAL CERTIFICATION DATE

January 20, 2025

PRINCIPLE OF THE METHOD

The OnSite® Gluten Test is a lateral flow assay that rapidly detects gluten derived from wheat, barley, and rye in select foods as well as on environmental surfaces. The kit is based on the monoclonal antibody 2D4 configured in sandwich format. 2D4 replicates the characteristics of the R5 antibody while additionally detecting deamidated gluten as well¹. To operate the kit, the sample is briefly extracted, diluted in a running buffer, and then directly applied to the device. The fluid is then wicked across the reagent zone, which includes a procedural control line (C) and a test line (T). The test outcome is interpreted by visualizing the appearance of these lines at 10 min.

CERTIFIED CLAIM STATEMENT: The OnSite Gluten Test Kit is certified for the detection of Gluten within the scope of Tables 1 and 2.

Table 1. Method Performance Claims for Foods

| Matrix | Test Portion | Gluten Detection Level with POD ₉₅ ^a | | |
|----------------------------|--------------|--|----------|----------|
| | | 5 mg/kg | 10 mg/kg | 20 mg/kg |
| Rice flour | 1 g | 5 mg/kg | 10 mg/kg | 20 mg/kg |
| Oat flour | 1 g | 5 mg/kg | 10 mg/kg | 20 mg/kg |
| Spice Mix | 1 g | 5 mg/kg | 10 mg/kg | 20 mg/kg |
| Bread with incurred wheat | 2 g | 5 mg/kg | 10 mg/kg | 20 mg/kg |
| Bread with incurred barley | 2 g | 5 mg/kg | 10 mg/kg | 20 mg/kg |
| Bread with incurred rye | 2 g | 5 mg/kg | 5 mg/kg | 5 mg/kg |

^aIdentical results observed in the method developer study and the Independent Laboratory study.

Table 2. Performance Claims for Environmental Surface

| Matrix | Gluten Source | Surface Size | Gluten Detection Level with POD ₉₅ |
|----------------------------|---------------|--------------|---|
| | | | 11 µg/cm ² |
| Stainless steel (Swabs) | Wheat flour | 10 x 10 cm | 1.00 ^a |
| | | | (0.84, 1.00) |
| | | | 0.95 ^b |
| | | | (0.760, 1.00) |

^aResults from the Method Developer Laboratory study.

^bResults from the Independent Laboratory study.

Table 3. Method Selectivity

| Gluten Sources | Cross-Reactivity | | Results | |
|----------------|------------------|--------------|---------|----------------------------------|
| | No. Tested | No. Positive | Blank | Interference 110 mg/kg Gluten |
| Wheat flour | 39 ^a | 0 | 0 | 39 ^a |

^aComprising of 9 legumes/ flours, 7 grain flours, 4 tree nuts/flours, 3 rice flours, 3 starch flours, 2 milk products, 2 beverages, 2 seeds/ flour, 2 animal protein products, 2 dried fruit/flour, 2 food additives, 1 plant flour, and 1 egg product.

Table 4. Method Summary

| No. | Date | Summary | Supporting Data |
|-----|--------------|-------------------------|----------------------|
| 1 | January 2025 | Original Certification. | Certification Report |