CERTIFICATION

AOAC® *Performance Tested*SM

Certificate No.

011601

The AOAC Research Institute hereby certifies the test kit known as:

3M™ Gluten Protein Rapid Kit

manufactured by

3M
Food Safety Department
3M Center, Bldg 275-5W-05
St. Paul, MN 55144

This method has been evaluated in the AOAC® *Performance Tested Methods*SM Program and found to perform as stated by the manufacturer contingent to the comments contained in the manuscript. This certificate means that an AOAC® Certification Mark License Agreement has been executed which authorizes the manufacturer to display the AOAC *Performance Tested*SM certification mark along with the statement - "THIS METHOD'S PERFORMANCE WAS REVIEWED BY AOAC RESEARCH INSTITUTE AND WAS FOUND TO PERFORM TO THE MANUFACTURER'S SPECIFICATIONS" - on the above mentioned method for a period of one calendar year from the date of this certificate (December 08, 2020 – December 31, 2021). Renewal may be granted at the end of one year under the rules stated in the licensing agreement.

Scott Coates

Scott Coates, Senior Director
Signature for AOAC Research Institute

December 8, 2020
Date

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3M
Food Safety Department
3M Center, Bldg 275-5W-05
Saint Paul, MN 55144 USA

KIT NAME(S)
3M™ Gluten Protein Rapid Kit
*formerly known as Elution Technologies Gluten Rapid Test Kit

CATALOG NUMBERS
L25GLU

INDEPENDENT LABORATORY
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APPLICABILITY OF METHOD
Target analyte – Gluten

Matrixes – Buckwheat, chocolate syrup, dry cereal, pasteurized soy milk, rice flour, incurred bread dough, CIP Clean in Place solution, stainless steel

Performance claims - The 3M™ Gluten Protein Rapid Kit utilizes the Poly-G antibody to detect the toxic alpha- gliadin fragment of the gluten globulin compound from wheat, rye, barley, and their cultivars. The LOD for food products, including raw ingredients, finished products and CIP, is 5 ppm gluten, or 5 µg gluten per ml per 100 cm² swabbed surface area. Samples containing greater than 10 ppm gluten may show positive results in 5 minutes or less.

REFERENCE METHOD
OMA 2012.01 Gliadin as a Measure of Gluten in Foods Containing Wheat, Rye, and Barley, Immer, U., Haas-Lauterbach, S., (2012) J. AOACI Vol. 95, No. 4 1118-1124 (4)

ORIGINAL CERTIFICATION DATE
January 20, 2016

CERTIFICATION RENEWAL RECORD
Renewed annually through December 2021

METHOD MODIFICATION RECORD
1. **January 2018 Level 1**
2. **January 2019 Level 1**
3. **December 2019 Level 1**
4. **June 2020 Level 1**
5. **December 2020 Level 1**

SUMMARY OF MODIFICATION
1. **Ownership changed from Elution Technologies to 3M Food Safety, update kit name and supporting documentation**
2. **Conversion of inserts and labels to 3M formatting.**
3. **Editorial/clerical changes.**
4. **Editorial changes to accurately reflect upper limit as 10,000 ppm.**
5. **Addition of 2 general warning statements regarding allergens.**

Under this AOAC® *Performance Tested*℠ License Number, 011601 this method is distributed by:
NONE

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NONE

PRINCIPLE OF THE METHOD (1)
The 3M™ Gluten Protein Rapid Kit is a rapid immunochromatographic lateral flow test device which utilizes a purified proprietary poly-clonal antibody developed by ICL against the alpha –gliadin fraction of gluten.

DISCUSSION OF THE VALIDATION STUDY (1)
This study demonstrates that the 3M™ Gluten Protein Rapid Kit can detect gluten in a broad spectrum of matrixes, without cross-reactivity or interference; additionally, the assay has been shown to detect gluten in an incurred sample at 15 ppm, as well as detecting gluten spiked at high concentrations with no hook effect. Food matrix samples containing greater than 10 ppm gluten had a combined POD of 0.967 at 5 minutes with 95% CI of 0.93, 0.98, while food matrixes containing 5 ppm to 10 ppm gluten had a combined POD of 0.581 with 95% CI of 0.53, 0.63. Thus, if a sample reports positive in 5 minutes, it is possible that it contains less than 10 ppm gluten; however, it is probable that it contains >10 ppm.
There was good correlation between sponsor and independent labs for chocolate syrup and corn flakes spiked with PWG at fractional recovery levels, as well for both matrixes spiked at 5 ppm, 10 ppm and 20 ppm; chocolate syrup was also spiked with a secondary reference material, NIST Wheat Flour SRM 1567b, at both 3.5 ppm and 5 ppm with good correlation. Additionally, stainless steel swabbing results were similar for both labs, with a fractional recovery level of 2.5 µg/ml/100cm². While both sponsor and independent labs found a low fractional recovery level of 1 ppm for corn flakes, PODs for corn flakes spiked at 0 ppm were 0.00 for both labs indicating no false positives results in this matrix.

Table 1. Food Matrix Study - Sponsor Lab (1)

Matrix	Spike concentration ppm	Number of replicates	Number of positive results		POD		95% CI	95% CI	Average results from AOAC OMA 2012.01 n=3
			at 5min	at 11min	at 5min	at 11 min	at 5 min	at 11 min	
Buckwheat	0	30	0	0	0.00	0.00	0.00, 0.11	0.00, 0.11	<3
	5	30	17	30	0.57	1.00	0.39, 0.73	0.89, 1.00	5.73
	10	30	26	30	0.87	1.00	0.70, 0.95	0.89, 1.00	9.4
	20	30	29	30	0.97	1.00	0.83, 1.00	0.89, 1.00	15.13
Chocolate Syrup	0	30	0	0	0.00	0.00	0.00, 0.11	0.00, 0.11	<3
	5	30	11	30	0.37	1.00	0.22, 0.54	0.89, 1.00	4.7
	10	30	25	30	0.83	1.00	0.66, 0.93	0.89, 1.00	9.17
	20	30	30	30	1.00	1.00	0.89, 1.00	0.89, 1.00	15.1
Soy Milk	0	30	0	0	0.00	0.00	0.00, 0.11	0.00, 0.11	<3
	5	30	18	30	0.60	1.00	0.42, 0.75	0.89, 1.00	7
	10	30	29	30	0.97	1.00	0.83, 1.00	0.89, 1.00	11.63
	20	30	30	30	1.00	1.00	0.89, 1.00	0.89, 1.00	17.23
Corn Flakes	0	30	0	0	0.00	0.00	0.00, 0.11	0.00, 0.11	<3
	5	30	26	30	0.87	1.00	0.70, 0.95	0.89, 1.00	5
	10	30	30	30	1.00	1.00	0.89, 1.00	0.89, 1.00	8.7
	20	30	30	30	1.00	1.00	0.89, 1.00	0.89, 1.00	15.57
White Rice Flour	10,000	10	10	10	1.00	1.00	0.72, 1.00	0.72, 1.00	N/A

Table 2. CIP Rinse Water Study (1)

Matrix	Spike concentration ppm	Number of replicates	Number of positive results		POD		95% CI	95% CI	Average results from AOAC OMA 2012.01 n=3
			at 5min	at 11min	at 5min	at 11 min	at 5 min	at 11 min	
CIP	0	30	0	0	0	0	0.00, 0.11	0.00, 0.11	<3
	5	30	30	30	1	1	0.89, 1.00	0.89, 1.00	5.6
	10	30	30	30	1	1	0.89, 1.00	0.89, 1.00	9.1

Table 3. Stainless Steel/ Swabbing Study Sponsor Lab (1)

Matrix	Spike concentration (ug/ml/100cm2)	Number of replicates	Number of positive results		POD		95% CI	95% CI
			at 5min	at 11min	at 5min	at 11 min	at 5 min	at 11 min
Stainless Steel	0	5	0	0	0.00	0.00	0.00, 0.43	0.00, 0.43
	2.5	30	0	15	0.00	0.50	0.00, 0.11	0.33, 0.67
	20	5	5	5	1.00	1.00	0.57, 1.00	0.57, 1.00

REFERENCES CITED

1. Emerson-Mason, L., Sobel, R., Bouchard, A., Boghosian, J., and Grace. T., Evaluation of the 3M™ Gluten Protein Rapid Kit (formerly Elution Technologies Gluten Rapid Test) for the Detection for Gluten in Select Foods and Select Environmental Surfaces, AOAC® *Performance Tested℠* certification number 011601.
2. Immer, U., Haas-Lauterbach, S., (2012) J. AOACI Vol. 95, No. 4 1118-1124