

3M™ Clean Trace™ Surface Protein Allergen Test Performance Study

Overview and Method

The 3M™ Clean-Trace™ Surface Protein Allergen Test can be used to detect protein residues on surfaces and in solutions and, thereby, determine if cleaning has been effective in eliminating proteins including potentially allergenic proteins. However, the interpretation of results will vary depending on the specific application, so it is recommended that users validate the method for their specific requirements.

In this study, performance of the 3M Clean-Trace Surface Protein Allergen Test was evaluated to assess the recovery of protein from allergenic foods applied on stainless steel surfaces. Solutions of different allergenic foods were prepared in distilled water to achieve a final concentration of 5 and 10 µg/mL (5 ppm and 10 ppm) of the food protein (Table 1). A total of 1 mL of the prepared solution was distributed onto a 10x10 cm stainless steel coupon, which resulted in an estimated concentration of 5 µg or 10 µg per 100 cm² of food protein. A total of three coupons per dose level were spiked. Coupons were air dried for 2 hours at ambient temperature. After drying, coupons were sampled and tested with the 3M Clean-Trace Surface Protein Allergen Test following the product instructions. Two 3M Clean-Trace Surface Protein Allergen Test were used as negative controls to aid interpretation of the color change. Solutions were tested with the appropriate 3M™ Allergen Protein Rapid Kit or 3M™ Allergen Protein ELISA Kit, to confirm presence of the specific allergenic food.

Results

Proteins from known allergenic foods sampled from stainless steel coupons spiked with 5 µg and 10 µg per 100 cm² of the target protein were recovered and detected using 3M Clean-Trace Surface Protein Allergen Test (Tables 2A-2E). The color change of the test reaction indicates the level of protein residues recovered from the surface. For each test, the color produced was compared against negative control samples and the 3M Clean-Trace Surface Protein Allergen Test interpretation key for estimation. This study was performed to target a defined concentration of 5 µg of food protein per 100cm². However, the level of proteins detected can be affected by the swabbing technique, source of food protein, food process, cleaning chemicals or sanitizer residual. For this reason, it is important to ensure that the method selected for allergen cleaning verification is fit for purpose, and to verify that it will recover and detect the allergen residues of interest at a defined level.

Conclusions

The 3M Clean-Trace Surface Protein Allergen Test is a suitable test to detect proteins from allergenic foods on stainless steel surfaces.

If you have any further questions regarding the content of this document contact your 3M Food Safety representative.

Table 1. Allergenic food matrices used in the study.

Food Group	Food*	Source of food**
Nuts	Almond	UHT Almond Milk Beverage
	Brazil Nut	Ground Brazil Nuts
	Cashew	UHT Cashew Milk Beverage
	Coconut	UHT Coconut Milk Beverage
	Hazelnut	Ground Hazelnuts
	Pecan	Ground Roasted Pecan Nuts
	Pistachio	Ground Roasted Pistachio Nuts
	Pine Nut	Ground Roasted Pine Nuts
	Walnut	UHT Walnut Milk Beverage
Legumes	Peanut	Peanut Butter
	Soy	UHT Soy Milk Beverage
Seeds	Mustard	Ground Mustard
	Sesame	Ground Roasted Sesame Seeds
Animal	Egg	Pasteurized Egg Beaters
	Bovine Milk	UHT Whole Milk
	Fish	Frozen Raw Cod
Grains	Wheat	All-Purpose Flour

* Solutions of foods were prepared in distilled water to achieve a final concentration of 5 or 10 µg/mL (5 or 10 ppm) of the food protein.

**UHT (Ultra High Temperature Pasteurization)

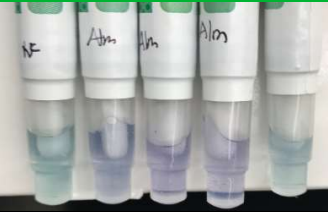

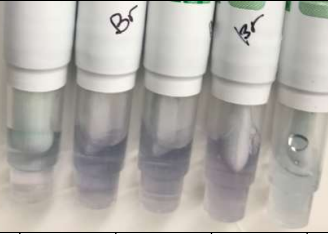
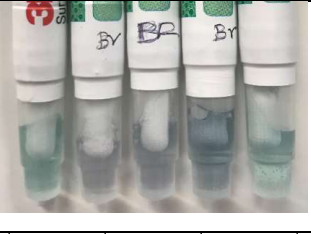
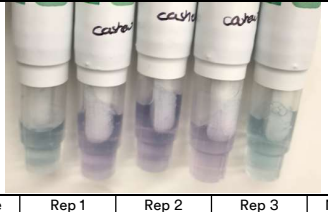
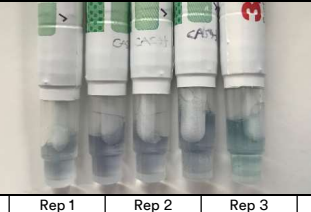
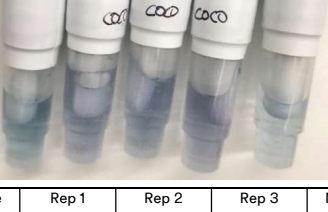
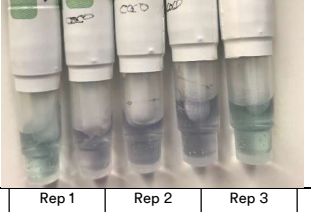
Interpretation Key



The test provides an estimation of protein by means of a color change:

- Green indicates a Negative result – no protein residue on the surface
- Grey is inconclusive
- Purple indicates a Positive result – protein residue is on the surface




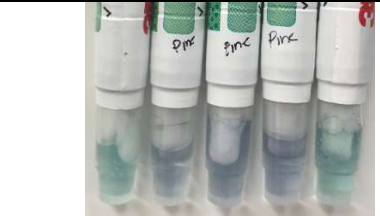
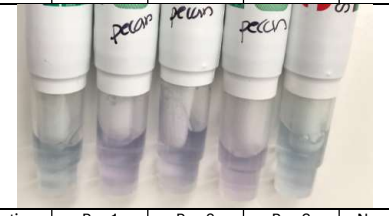
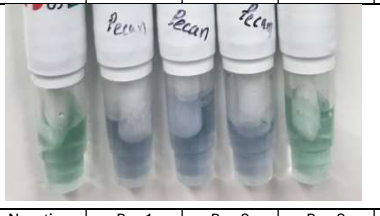


Table 2A. Detection of proteins from allergenic foods utilizing ALLTEC60 at 10 and 5 µg/100 cm² on stainless steel coupons.

Food allergen	ALLTEC60 (10 ppm)					ALLTEC60 (5 ppm)				
	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3	Negative control
Almond										
	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3	Negative control
	-	+	+	+	-	-	+	+	+	-
Brazil Nut										
	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3	Negative control
	-	+	+	+	-	-	+	+	+	-
Cashew										
	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3	Negative control
	-	+	+	+	-	-	+	+	+	-
Coconut										
	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3	Negative control
	-	+	+	+	-	-	+	+	+	-

Interpretation Key



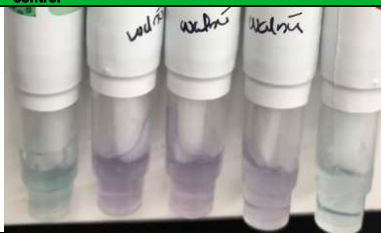

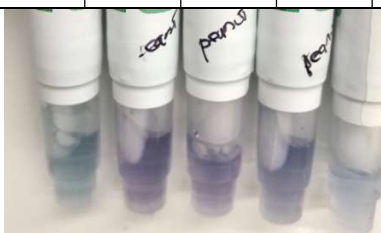

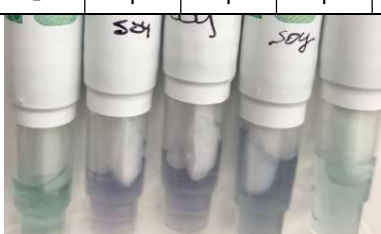
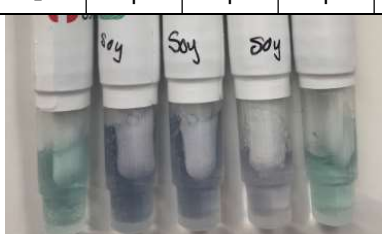
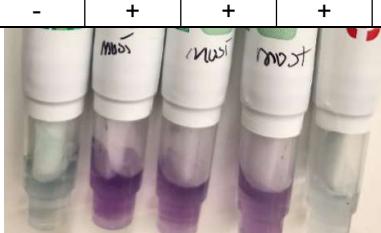
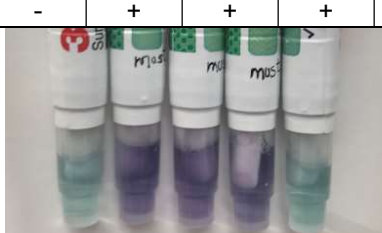
Table 2B. Detection of proteins from allergenic foods utilizing ALLTEC60 at 10 and 5 µg/100 cm² on stainless steel coupons.

Food allergen	ALLTEC60 (10 ppm)					ALLTEC60 (5 ppm)				
	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3	Negative control
Hazelnut										
	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3	Negative control
	-	+	+	+	-	-	+	+	+	-
Pine Nut										
	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3	Negative control
	-	+	+	+	-	-	+	+	+	-
Pecan										
	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3	Negative control
	-	+	+	+	-	-	+	+	+	-
Pistachio										
	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3	Negative control
	-	+	+	+	-	-	+	+	-	-

Interpretation Key







































Table 2C. Detection of proteins from allergenic foods utilizing ALLTEC60 at 10 and 5 µg/100 cm² on stainless steel coupons.

Food allergen	ALLTEC60 (10 ppm)					ALLTEC60 (5 ppm)				
	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3	Negative control
Walnut										
	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3	Negative control
	-	+	+	+	-	-	+	+	+	-
Peanut										
	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3	Negative control
	-	+	+	+	-	-	+	+	+	-
Soy										
	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3	Negative control
	-	+	+	+	-	-	+	+	+	-
Mustard										
	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3	Negative control
	-	+	+	+	-	-	+	+	+	-

Interpretation Key





Table 2D. Detection of proteins from allergenic foods utilizing ALLTEC60 at 10 and 5 µg/100 cm² on stainless steel coupons.

Food allergen	ALLTEC60 (10 ppm)				ALLTEC60 (5 ppm)				Negative control
	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3
Sesame									
	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3
	-	+	+	+	-	-	+	+	+
Egg									
	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3
	-	+	+	+	-	-	+	+	+
Fish									
	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3
	-	+	+	+	-	-	+	+	+
Milk									
	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3
	-	+	+	+	-	-	+	+	+

Interpretation Key



Table 2E. Detection of proteins from allergenic foods utilizing ALLTEC60 at 10 and 5 µg/100 cm² on stainless steel coupons.

	ALLTEC60 (10 ppm)					ALLTEC60 (5 ppm)				
Food allergen	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3	Negative control
Wheat (Concentration adjusted to have 5 or 10 ppm of gluten)										
	Negative control	Rep 1	Rep 2	Rep 3	Negative control	Negative control	Rep 1	Rep 2	Rep 3	Negative control
	-	+	+	+	-	-	+	+	+	-

