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MORINAGA

# Rapid Test Pro II for

Egg	(Cat.# M2261)	Total Milk	(Cat.# M2269)
Gluten	(Cat.# M2263)	Buckwheat	(Cat.# M2264)
Peanut	(Cat.# M2265)	Crustacean	(Cat.# M2267)
Walnut	(Cat.# M2268)	Cashew	(Cat.# M2260)
Soya	(Cat.# M2266)	Shellfish	(Cat.# M2270)

For the Quick Detection of Protein of Allergenic Ingredients in Foods and on Food-processing Equipment

### 10 tests

For Research or Laboratory Use Only Not for Use in Diagnostic Procedures Please read full descriptions in this manual before use

### Manufactured by:

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## <u>Warnings</u>

1. Do not combine reagents from different lots.

- 2. Store the kit at 2-8°C (35-46°F), and DO NOT FREEZE
- 3. Do not use the kit after the expiration date indicated on the box.

### 1. Intended Use

Rapid Test Pro II is intended for the quick detection of protein from allergenic ingredients in unprocessed samples, processed food, on environmental surfaces (swab test) and in rinse water.

<u>NOTE:</u> For the analysis of environmental surfaces (swab test) and rinse water, we recommend using the Rapid Test Easy kits.

### 2. Description of the Product

- A qualitative test in lateral flow immunoassay format for visual detection
- Provides test results in 15 minutes (Including sample preparation: within 30 minutes)
- Improved recovery of protein from both unprocessed and processed food products by using the patented extraction solution<sup>1-4)</sup>
- Rapid Test Pro II for Total Milk has two test lines on a test stick to detect casein and β-lactoglobulin respectively
  Performance characteristics of each kit are shown in Tables 1-10.

### Table 1 Performance characteristics of Ranid Test Pro II for Foo

	Food:	5 μg/g (5 ppm) egg protein		
Limit of detection	Surfaces (swab	test): 1 μg egg protein/100 cm <sup>2</sup>		
	Rinse water:	Rinse water: 5 µg/mL (5 ppm) egg protein		
Specificity	The antibody reacts with ovalbumin.			
Table 2. Performance chara	cteristics of Rap	id Test Pro II for Total Milk		
		Food: 4 µg/g (4 ppm) casein		
Line 4	Limit of	Surfaces (swab test): 0.8 µg casein/100 cm <sup>2</sup>		
	detection	Rinse water: 4 µg/mL (4 ppm) casein		
(black, upstream side)		(4 $\mu$ g/g casein correspond to 5 $\mu$ g/g (5 ppm) milk protein)		
	Specificity	The antibody reacts with casein.		
	Limit of detection	Food: 0.5 μg/g (0.5 ppm) β-lactoglobulin		
		Surfaces (swab test): $0.1 \mu\text{g}\beta$ -lactoglobulin/100 cm <sup>2</sup>		
Line 2		Rinse water: 0.5 μg/mL (0.5 ppm) β-lactoglobulin		
(red, downstream side)		$(0.5 \text{ µg/g} \beta$ -lactoglobulin correspond to 5 µg/g (5 ppm) milk protein)		
	Specificity	The antibody reacts with β-lactordobulin		
Table 3 Performance chara	cteristics of Ran	id Test Pro II for Gluten		
Table 5. Terrormance chara	Eood:			
	Fuurfaces (swah	test): 0.8 ug gluten/100 cm <sup>2</sup>		
Limit of detection	Binge weter	Aug/ml (4 ppm) gluten pretein		
	Kinse water.	$4 \mu g/m (4 ppm) gluten protein$		
Onesifisity	(4 µg/g gluten d	orrespond to 5 µg/g (5 ppm) wheat protein)		
Specificity	The antibody re	acts with gliadin <sup>*</sup> .		
Cross reacts to barley and	rye	d Teet Des T. des Destaubent		
Table 4. Performance chara	cteristics of Rap	Id lest Proll for Buckwheat		
	Food:	5 μg/g (5 ppm) buckwheat protein		
Limit of detection	Surfaces (swab	test): 1 µg buckwheat protein/100 cm <sup>2</sup>		
	Rinse water:	5 μg/mL (5 ppm) buckwheat protein		
Specificity	The antibody re	acts with multiple buckwheat proteins.		
Table 5. Performance chara	cteristics of Rap	id Test Pro II for Peanut		
	Food:	5 μg/g (5 ppm) peanut protein		
Limit of detection	Surfaces (swab	test): 1 μg peanut protein/100 cm <sup>2</sup>		
	Rinse water:	5 μg/mL (5 ppm) peanut protein		
Specificity	The antibody re	acts with multiple peanut proteins.		
Table 6. Performance chara	cteristics of Rap	id Test Pro II for Crustacean		
	Food:	5 μg/g (5 ppm) crustacean protein		
Limit of detection	Surfaces (swab	test): 1 µg crustacean protein/100 cm <sup>2</sup>		
	Rinse water:	5 µg/mL (5 ppm) crustacean protein		
Specificity	The antibody re	acts with crustacean tropomyosin.		
Table 7. Performance chara	cteristics of Rap	id Test Pro II for Walnut		
	Food:	5 µg/g (5 ppm) walnut protein		
Limit of detection	Surfaces (swah	test): 1 ug walnut protein/100 cm <sup>2</sup>		
	Rinse water	5 ug/ml (5 ppm) walnut protein		
Specificity	The antibody re	acts with walnut 2S albumin		
Table 8 Performance chara		id Test Pro II for Cashew		
	Eood:	Fugla / Entrol october protein		
limit of data -time	FUUU:	test). 1 us each au protein (100 cm <sup>2</sup>		
Limit of detection	Surfaces (swab	test): 1 $\mu$ g cashew protein/100 cm <sup>2</sup>		
0 10 11	Rinse water:	o µg/m∟ (o ppm) casnew protein		
Specificity	The antibody re	acts with cashew 2S albumin.		
Table 9. Performance chara	cteristics of Rap	id Test Pro II for Soya		
	Food:	5 μg/g (5 ppm) soya protein		
Limit of detection	Surfaces (swab	test): 1 μg soya protein/100 cm²		
	Rinse water:	5 μg/mL (5 ppm) soya protein		
Specificity The antibody reacts with β-conglycinin.				
Table 10. Performance char	acteristics of Ra	pid Test Pro II for Shellfish		
	Food:	5 μg/g (5 ppm) shellfish protein		
Limit of detection	Surfaces (swab	test): 1 µg shellfish protein/100 cm <sup>2</sup>		
	Rinse water:	5 µg/mL (5 ppm) shellfish protein		
Specificity	The antibody re	acts with shellfish tropomyosin**.		

#### 3. Kit Components

Component	Amount
Extraction Solution*	10 packs (19 mL/pack)
Diluent	1 bottle (12 mL)
Test Stick	10 packs (1 stick/pack)
Pipette (L)	10
Pipette (S)	10
Polypropylene tube (L), 50 mL volume	10
Polypropylene tube (S), 1.5 mL volume	10
Cotton swab	10 packs
Paper tube rack	1

\* *Extraction Solutions* for all test kits are identical. *Extraction Solution* may contain precipitates when refrigerated which should dissolve upon warming to 30–37°C (86–99°F).



Fig. 1. Components (Test Stick, Pipette (L), Pipette (S), and Polypropylene tube (L))

### 4. Materials required but not provided

#### **Precautions**

- All procedures should be performed under contamination-free conditions to obtain reliable results. Make sure to avoid cross-contaminations via equipment, devices, tubes, containers, pipette tips, etc. The use of disposable materials is recommended.
- Homogenizer/blender
- Scale capable of weighing 1.0 $\pm$ 0.1 g
- Vortex mixer
- Water bath\*
- Centrifuge (for 3000 x g) \*

· Heat-resistant glove

- Filter paper\*
- pH test strip
- \*The items may not be required depending on the extraction method or sample condition

### 5. Sample Extraction

#### Precautions

- ✓ Prior to use, bring all reagents to 20-30°C (68-86°F) and gently vortex the contents into a homogeneous solution.
- ✓ Confirm and adjust the pH of Sample Extract close to neutral (pH 6−8) as required.
- $\checkmark$  Wear suitable protective clothing, goggles, and gloves when handling the kit.

### [A. Recommended Extraction Method]

This extraction method is available for all food, environmental surface (swab test) and in rinse water. In particular, this is optimal for highly processed food. Please choose this method for the analysis of baked goods (bread, confectionery), retort foods, processed meat/seafood products, stewing foods.

#### A-1. For food sample

- 1. Grind and mix the test food sample to homogeneity with a contamination-free homogenizer/blender.
- 2. Put 1.0 g (1.0 mL) of the homogenized sample in a Polypropylene tube (L) and add 1 pack of Extraction Solution.
- 3. Close the tube tightly and vortex it for 30 seconds.
- 4. Place the closed tube in a water bath > 90°C (194°F) for 10 minutes.
- 5. Place the tube in water to cool down to ambient temperature.
  - NOTE: Do not cool down below ambient as the sample precipitates at low temperatures.
  - 6. Vortex for 30 seconds.
  - 7. Place the tube in a stand for a few minutes to let the sample settle down, and then collect the supernatant as *Sample Extract.*

**NOTE:** Centrifuge and/or filter with filter paper as required.



Fig. 2. Sample extraction for food sample

#### A-2. For swab test sample

- 1. Thoroughly wipe across (zigzagging) the specified surface area of 10 cm × 10 cm with a *Cotton swab* moistened with purified water 1st pass in diagonal, and a 2nd pass in diagonal perpendicular to the 1st pass.
- Place the swab into a *Polypropylene tube (L)* and add 4 mL of *Extraction Solution* (Sensitivity: 1 µg (0.8 µg for Casein and Gluten, 0.1 µg for β-lactoglobulin) on the swab in the case of adding 4 mL, see Tables 1-10).

\* This kit detects shrimp, crab, lobster, squid, octopus, and oyster proteins.

- 3. Close the tube tightly and vortex it for 30 seconds.
- 4. Place the closed tube in a water bath >  $90^{\circ}C$  (194°F) for 10 minutes.
- 5. Place the tube in water to cool down to ambient temperature.

**NOTE**: Do not cool down below ambient as the sample precipitates at low temperatures.

6. Vortex for 30 seconds. The resulting solution is referred to as Sample Extract.

**<u>NOTE</u>**: Filter it with filter paper as required.



Fig. 3. Sample extraction for swab test sample

#### A-3. For rinse water sample

- 1. Put 1.0 mL of the sample in a Polypropylene tube (L) and add 1 pack of Extraction Solution.
- 2. Close the tube tightly and vortex it for 30 seconds.
- 3. Place the closed tube in a water bath > 90°C (194°F) for 10 minutes
- Place the tube in water to cool down to ambient temperature. 4.
- NOTE: Do not cool down below ambient as the sample precipitates at low temperatures. 5. Vortex for 30 seconds. The resulting solution is referred to as Sample Extract.



Fig. 4. Sample extraction for rinse water sample

### [B. Simplified Extraction Method]

This extraction method is available for food which is not highly processed, environmental surface (swab) tests and rinse water. Please choose this method for the analysis of beverage, ice cream, dairy products, dessert, grain powder, premix and other not heat-treated products. For further information please contact us when you need.

#### B-1. For food sample

- 1. Grind and mix the test food sample to homogeneity with a contamination-free homogenizer/blender.
- 2. Put 1.0 g (1.0 mL) of the homogenized sample in a Polypropylene tube (L) and add 1 pack of Extraction Solution.
- 3. Close the tube tightly and vortex it for 30 seconds.
- NOTE: Centrifuge and/or filter with filter paper as required.



Fig. 5. Sample extraction for food sample

#### B-2. For swab test sample

- Thoroughly wipe across (zigzagging) the specified surface area of 10 cm × 10 cm with a Cotton swab moistened 1. with purified water 1st pass in diagonal, and a 2nd pass in diagonal perpendicular to the 1st pass.
- 2. Place the swab into a Polypropylene tube (L) and add 4 mL of Extraction Solution (Sensitivity: 1 µg (0.8 µg for Casein and Gluten, 0.1  $\mu$ g for  $\beta$ -lactoglobulin) on the swab in the case of adding 4 mL, see Tables 1-10). Close the tube tightly and vortex it for 30 seconds. 3.

### **<u>NOTE</u>**: Filter it with filter paper as required.



Fig. 6. Sample extraction for swab test sample

#### B-3. For rinse water sample

- 1. Put 1.0 mL of the sample in a Polypropylene tube (L) and add 1 pack of Extraction Solution.
- Close the tube tightly and vortex it for 30 seconds. 2.



Fig. 7. Sample extraction for rinse water sample

### 6. Preparation of Test Solution

- Dispense 900 µL of **Diluent** with a Pipette (L) into a Polypropylene tube (S). 1.
- 2. Add 100 µL of Sample Extract with a Pipette (S) to the Polypropylene tube (S) containing 900 µL of Diluent and mix well. The resulting solution is referred to as Test Solution.

NOTE: For further dilution, dilute the Sample Extract with Extraction Solution appropriately, and then dilute it 10fold with **Diluent**.



#### 8. Results

[A. Rapid Test Pro II for Egg, Gluten, Buckwheat, Peanut, Crustacean, Walnut, Cashew, Soya, and Shellfish]

	Sampl	e application slot Test window Confirma	ation window
(a) Positive			: Egg, Shellfish
		•	: Gluten, Buckwheat, Peanut, Crustacean, Walnut, Cashew, and Soya
(b) Negative	0	•	-
(c) Invalid		•	- : Egg, Shellfish
		•	: Gluten, Buckwheat, Peanut, Crustacean, Walnut, Cashew, and Soya

Fig. 10. Interpretation of results (Rapid Test Pro II for Egg, Gluten, Buckwheat, Peanut, Crustacean, Walnut, Cashew, Soya, and Shellfish)

(a) Positive: A black or red line in a test window together with red color in a confirmation window.

(b) Negative: No line in a test window together with red color in a confirmation window.

No color in a confirmation window. (c) Invalid:

#### [B. Rapid Test ProII for Total Milk]



#### (a-1) Two lines, a black and a red line, in a test window together with red color in a confirmation window (a) Positive:

- (when milk component is contained). (a-2) A black line in a test window together with red color in a confirmation window (when only casein is contained\*).
  - (a-3) A red line in a test window together with red color in a confirmation window (when only whey is contained\*).

(b) Negative: No line in a test window together with a red color in a confirmation window.

(c) Invalid: No color in a confirmation window

\* Since casein, which is commonly available on the market, contains trace amounts of β-lactoglobulin in addition to casein, and whey contains trace amounts of casein in addition to β-lactoglobulin, two lines may also be observed even when testing foods containing only casein or whey.

**NOTE:** If there is no color in a confirmation window, retest with a new **Test Stick**.

False-negative results may occur depending on the condition of the target protein (e.g. degradation). If false-negative results occur at high concentrations of the target protein (hook effect), retest with a diluted Test Solution (see 6. Preparation of Test Solution).

#### 9. References

- 1. Patent No.: JP 5133663.
- 2. Patent No.: AU 2008330507,
- Patent No.: US 8,859,212, 3.
- 4. Patent No.: EP 2224239 (AT, BE, DE, ES, FR, GB, IT, NL, CH)

#### 10. Warranties

Morinaga BioScience, Inc. makes no warranty of any kind, either expressed or implied, except that the materials from which its products are made are of standard quality. Buyer assumes all risk and liability resulting from the use of this product. There is no warranty of merchantability of the product, or of the fitness of the product for any purpose. Morinaga BioScience, Inc. agrees to replace any defective product, but expressly disclaims liability for damages, including special or consequential damage, or expenses arising directly or indirectly from the use of this product.

#### 11. Appendix: Test Flow Chart



Fig. 8. Preparation of Test Solution

### 7. Test Procedures

#### Precautions

- ✓ Prior to use, adjust the temperature of a **Test Stick** to 20-30°C (68-86°F) and open the package just before use. At low temperature, the Test Stick may not work properly.
- ✓ Neither touch the sample application slot nor the test window of a *Test Stick*.
- Place a Test Stick horizontally and add 200 µL of Test Solution to the sample application slot. 1.
- 2. Incubate 15 minutes at room temperature (20-30°C/ 68-86°F) in a flat and horizontal surface.
- 3. Immediately interpret the results according to 8. Results described below.



Fig. 9. Test step

	Vortex for 30 seconds		
	▼	▼	
	Let the sample settle down and collect the	ne supernatant as Sample Extract	
	▼	▼	
6. Preparation of Test Solution	Add 100 $\mu$ L of <b>Sample Extract</b> to 900 $\mu$ L of <b>Diluent</b> and mix well as <b>Test Solution</b>		
	▼	▼	
7. Test Procedures	Add 200 µL of <i>Test Solution</i> to a <i>Test Stick</i>		
	▼	▼	
8. Results	Check results in 15 minutes		