

PROTIA Allergy-Q 64 Inhalant panel PROTIA Allergy-Q 64 Food panel



Immunoblot assay for the quantitative detection of allergen-specific IgE antibodies in human serum or plasma

[Intended use]

PROTIA Allergy-Q 64 Inhalant, 64 Food panel is an *in vitro* diagnostic test in the quantitative determination of allergen-specific IgE concentrations in human serum or plasma using immunoblotting technique.

[Summary and explanation of the test]

Atopic allergy is a hypersensitive immunological condition mediated by immunoglobulin E (IgE) antibodies. Lymphocyte B cells stimulated by a specific allergen produce IgE antibodies to the antigen. The IgE antibodies bind to the receptors on the surface of mast cells or basophilic leukocytes through Fc region. Subsequent binding of the allergen to cell-bound specific IgE triggers cell degranulation and the release of vasoactive amines causing smooth muscle contraction, itching, swelling and transmucosal leakage of extracellular fluids. The most common clinical manifestations of this biological process are hay fever, asthma, dermatitis, hives and anaphylactic shock. The evaluation of IgE level in patient serum or plasma for various allergens is valuable in the diagnosis and treatment of atopic allergy.

[Test principle]

PROTIA Allergy-Q, a multiplex allergy diagnostic kit, based on the principle of an enzyme immunoassay includes nitrocellulose membranes having various allergens adsorbed at regular interval lines, which makes it possible to test dozens of specific allergens in one test. **PROTIA Allergy-Q** can test variety of allergens in one test by employing a new technique to arrange membranes in parallel compared to other products having just one lane membrane. If allergen-specific IgE antibodies bind to the antigens, they are immobilized on the membrane after the washing step. The immobilized IgE antibodies bind to biotin-coupled anti-human IgE antibodies and the biotin is captured by a streptavidin conjugated with alkaline phosphatase. The color is developed after adding the substrate in the last incubation step by the enzyme and the intensity of color is analyzed using a color-measuring device.

[Provided reagents] 1 Kit

No	Name/Symbol	Composition	Quantity
1	Allergen panel Allergen Panel	- Standard (S) and Control (C) lines - Total IgE line - Allergen-specific lines	10 panels x 2 E.A.
2	Sample diluent Sample DIL	- Sodium phosphate - Stabilizer, Preservative (Sodium azide)	10 mL x 1 E.A.
3	Antibody solution Antibody SOLN	- Biotin-conjugated mouse anti-human IgE antibodies - Stabilizer, Preservative (Sodium azide)	10 mL x 1 E.A.
4	Enzyme solution Enzyme SOLN	- Streptavidin-conjugated alkaline phosphatase - Stabilizer, Preservative (Sodium azide)	10 mL x 1 E.A.
5	Substrate solution Substrate SOLN	- Bromochloroindolyl phosphate (BCIP) - Nitro Blue Tetrazolium (NBT)	10 mL x 1 E.A.
6	Washing solution 20x Wash SOLN 20x	- Tris - Stabilizer, Preservative (Sodium azide)	10 mL x 1 E.A.

*Additionally necessary equipment

- Manual method: Q-SCAN+, Q-Smart (Optical measuring device) and Orbital shaker or its equivalent
- Semi-automatic method: Q-SCAN+, Q-Smart (Optical measuring device) and Q-Processor (Automatic device for dispensing reagents, incubation, and washing)
- Fully-automatic method: Q-STATION ELITE (Automatic device for incubation, washing, drying and measuring)

[Appearance]

- Allergen panel: A plastic panel where two white membranes are attached
- Sample diluent: Blue violet liquid
- Antibody solution: Yellow or light-yellow liquid
- Enzyme solution: Colorless or light-yellow liquid
- Substrate solution: Light-yellow liquid
- Washing solution 20x: Colorless liquid

[Assay methods]

1. Preparation of reagents and specimens

(1) Preparation of washing solution (1x)

Dilute the washing solution 20x 20 times with deionized water before test.

Ex) 19 mL deionized water + 1 mL washing solution 20x = 20 mL washing solution 1x

CAUTION The diluted solution should not be re-used and remaining solution should be discarded immediately after use.

(2) Preparation of specimen

Serum or plasma is used in the test. Remove blood cells or any solid matters by centrifugation before test. Hemolyzed or contaminated samples may cause incorrect results. Store the serum/ plasma samples at 2~8°C when they are used for a short period (within 2 weeks) and at -15°C or below for a longer use. Repeated freezing and thawing of serum/ plasma samples should be avoided.

2. Assay procedure

All reagents should be brought to room temperature around 30 minutes before use and mixed well immediately before use. Open the package of allergen panel after equilibrated at room temperature.

CAUTION Allergen panels not used for the test should be immediately put into a sealed aluminum pouch and keep refrigerated.

Manual method

- Wet the test membrane completely with 300 µL of diluted washing solution by shaking for 5 minutes and remove the washing solution (100 rpm is recommended).
- Fill the allergen panel with 250 µL of sample diluent.
- Add 50 µL of patient sample and incubate with shaking at room temperature for 45 minutes.
- Remove the sample solution from the panel and wash the membrane two times with the diluted washing solution. At every washing step, add 300 µL of diluted washing solution, incubate with shaking for 5 minutes and empty the panel. Solution should not remain in the panel.
- Add 250 µL of antibody solution to the panel and incubate with shaking at room temperature for 30 minutes.
- Remove the solution and wash the membrane as the method (4).
- Fill the panel with 250 µL of enzyme solution and incubate with shaking for 30 minutes.
- Remove the solution and wash the membrane as the method (4).
- Add 250 µL of the substrate solution and incubate with shaking at room temperature in a dark room for 20 minutes.
- Remove the substrate solution and wash the membrane with 250 µL of deionized water.
- Dry the membrane in the air or with a dryer (Please make sure that the membrane is dried completely).
- Insert the panels into Q-SCAN+, Q-Smart and Q-STATION ELITE and evaluate the results. Please refer to the manual of each measuring device for more detail.

Semi-automatic method

- Set the Q-Processor with allergen panels and reagents.
- Refer to the operation manual of Q-Processor and follow the directions.
- Dry the membranes as the manual method and evaluate the results using Q-SCAN+, Q-Smart and Q-STATION ELITE.

Fully-automatic method

- Set the Q-STATION ELITE with allergen panels and reagents.
- Refer to the operation manual of Q-STATION ELITE and follow the directions. Q-STATION ELITE will automatically perform the entire procedure of dispensing patient samples and reagents, incubation, washing, drying and measurement.

3. Evaluation and interpretation

- The amount of allergen-specific IgE antibodies are quantitatively analyzed as IU/mL via Q-SCAN+, Q-Smart and Q-STATION ELITE and the class is determined using the below table.

Allergen-specific IgE		
IU/mL	Class	Allergen-specific IgE amount
0.00~0.34	0	Not found
0.35~0.69	1	Weak
0.70~3.49	2	Moderate
3.50~17.49	3	Moderately strong
17.50~49.99	4	Strong
50.00~99.99	5	Very strong
≥ 100	6	Extremely strong

- The amount of total IgE (tIgE) is expressed as IU/mL and can be quantitatively analyzed in the range of 0~2,000 IU/mL.

4. Quality control

The control line (C) should develop strongly. If color intensity of control line is faint, it cannot be read normally by optical measuring devices. In that case, re-test is recommended.

5. Performances

- Detection limit: 0.15 IU/mL
- Analytical specificity: There is no detectable cross-reactivity with IgA, IgM, IgG or IgD at 2 times of normal physiological levels.
- Agreement: 96.0% when compared with a quantitative reference (*in vitro* system) with 384 positive sera for 1,317 allergens and 194 negative sera.

[Precautions for use]

- For *in vitro* diagnostic and professional use only.
- PROTIA Allergy-Q** test can be used for helping the clinical diagnosis and definitive clinical diagnosis or dosage regimens for immunotherapy should be determined by the doctor after all clinical and laboratory findings are evaluated.
- It is possible that discrepancies may occur between the results from **PROTIA Allergy-Q** and those from *in vivo* tests and/or from other *in vitro* tests since there is no national or international standard and the allergen extracts may be different among tests.
- False positive test results can be produced by cross reactivity of the antigens tested with other antigens.
- Do not smoke, eat or drink in areas where samples or products are used.
- All samples may have a potential to include unknown infectious materials. When handling the samples, wear disposable gloves and wash your hands after test.
- Do not place needles, knives or any other objects that can cause injury to avoid safety accidents while handling human samples and products.
- All used patient samples and product components should be regarded as the bio-hazard. It should be disposed according to the relevant guidelines.
- Do not use kits after the expiration date.
- The allergen panels are packaged with desiccant and should be sealed properly after each use.
- Some reagents included in the kit contain sodium azide as a preservative. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides. Immediately after disposal, flush with a large volume of water to prevent azide build-up.
- Substrate solution may contain black precipitates. This may occur in normal preservation condition and has no effect on test results.

- 13) Be careful to avoid the forming of bubbles. Especially when the automatic devices are used, bubbles should be removed before starting a test since they can affect the volume of dispensing.
- 14) If the membranes are not completely dried after the final reaction, the test results analyzed by measuring devices may be incorrect.

[Packaging unit] 1 Kit (for 20 Tests)

[Storage conditions] Store at 2~8°C

[Use by] 24 months after the manufacturing date (3 months after open)

[Understanding of symbol marks]

Lot No. Store at 2-8°C *In vitro* diagnostic medical device

Manufacturing date CE mark Catalogue number

Manufacturer Use by European Authorized Representative

Consult instructions for use Be cautious in use and consult instruction for use

[Manufacturer]

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[Test panels]

1. PROTIA Allergy-Q 64 Inhalant panel

No ⁽¹⁾	Allergen ⁽²⁾	Code	Group
1	Total IgE	tlgE	IgE
2	House dust	h1	Common
3	D. pteronyssinus	d1	
4	D. farinae	d2	
5	Cat epithelium & dander	e1	
6	Dog dander	e5	
7	Egg white	f1	
8	Milk	f2	
9	Cockroach	i6	
10	Peanut	f13	
11	Soy bean	f14	
12	Wheat	f4	
13	Alder	t2	
14	Birch	t3	
15	Oak	t7	
16	Common ragweed	w1	
17	Japanese hop	w22	
18	Mugwort	w6	
19	Alternaria alternata	m6	
20	Cladosporium herbarum	m2	
21	Aspergillus fumigatus	m3	
22	Crab	f23	
23	Shrimp	f24	
24	Mackerel	f206	
25	Cultivated rye	g12	
26	CCD	o214	
27	Peach	f95	
28	Apple	f49	
29	Sesame	f10	
30	Acarus siro	d70	
31	Tyrophagus putrescentiae	d72	
32	Sweet vernal/ Orchard grass/ Common reed/ Bent grass	g1/ g3/ g7/ g9	
33	Bermuda grass	g2	
34	Timothy grass	g6	
35	Penicillium notatum	m1	
36	Candida albicans	m5	
37	Hazel	t4	
38	Olive	t9	
39	Maple leaf sycamore	t11	
40	Willow	t12	
41	Cottonwood	t14	
42	White ash	t15	
43	White pine	t16	
44	Japanese cedar	t17	
45	Acacia	t19	
46	Ox-eye daisy	w7	
47	Dandelion	w8	
48	Plantain	w9	

49	Russian thistle	w11	
50	Goldenrod	w12	
51	Common pigweed	w14	
52	Hevea latex	k82	Other
53	Bee venom	i1	Insects
54	Wasp venom	i3	Animals
55	Mouse/ Rat	e71/ e73	
56	Rabbit	e82	
57	Guinea pig	e6	
58	Wool, sheep	e81	
59	Hamster	e84	
60	Horse	e3	

2. PROTIA Allergy-Q 64 Food panel

No ⁽¹⁾	Allergen ⁽²⁾	Code	Group
1	Total IgE	tlgE	IgE
2	House dust	h1	Common
3	D. pteronyssinus	d1	
4	D. farinae	d2	
5	Cat epithelium & dander	e1	
6	Dog dander	e5	
7	Egg white	f1	
8	Milk	f2	
9	Cockroach	i6	
10	Peanut	f13	
11	Soy bean	f14	
12	Wheat	f4	
13	Alder	t2	
14	Birch	t3	
15	Oak	t7	
16	Common ragweed	w1	
17	Japanese hop	w22	
18	Mugwort	w6	
19	Alternaria alternata	m6	
20	Cladosporium herbarum	m2	
21	Aspergillus fumigatus	m3	
22	Crab	f23	
23	Shrimp	f24	
24	Mackerel	f206	
25	Cultivated rye	g12	
26	CCD	o214	
27	Peach	f95	
28	Apple	f49	
29	Sesame	f10	
30	Codfish	f3	
31	Tuna/ Salmon	f40/ f41	
32	Plaice/ Anchovy/ Alaska Pollock	f254/ f313/ f413	
33	Lobster/ Pacific squid	f80/ f58	
34	Eel	f264	
35	Blue mussel/ Oyster/ Clam/ Scallop	f37/ f290/ f207/ f338	
36	Silkworm pupa	-	
37	Pork	f26	
38	Beef	f27	
39	Chicken	f83	
40	Lamb meat	f88	
41	Cheese, cheddar type	f81	
42	Barley	f6	
43	Rice	f9	
44	Buckwheat	f11	
45	Yeast, baker's	f45	
46	Corn	f8	
47	Carrot	f31	
48	Potato	f35	
49	Garlic/ Onion	f47/ f48	
50	Celery	f85	
51	Cucumber	f244	
52	Tomato	f25	
53	Citrus mix	f33	
54	Strawberry	f44	
55	Kiwi/ Mango/ Banana	f84/ f91/ f92	
56	Sweet chestnut	f299	
57	Walnut	f256	
58	Hazel nut	f17	
59	Almond/ Pine nut/ Sunflower	f20/ f253/ k84	
60	Cacao	f93	

- (1) Refer to the picture below for the line numbers.
 (2) Extracted Allergen from

