PROTIA Allergy-Q Atopy panel

CE IVD REF PALQ0312

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

[Intended use]
PROTIA Allergy-Q Atopy 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, itch, 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 then 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 - Nitro Blue Tetrazolium	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
1. Manual method: Q-SCAN+, Q-Smart (Optical measuring device) and Orbital shaker or its equivalent
2. Semi-automatic method: Q-SCAN+, Q-Smart (Optical measuring device), Q-Processor (Automatic device for dispensing reagents, incubation, and washing) or its equivalent
3. Fully-automatic method: Q-STATION ELITE (Automatic device for incubation, washing, drying and measuring)

[Appearance]
1. Allergen panel: A plastic panel where two white membranes are attached
2. Sample diluent: Blue violet liquid
3. Antibody solution: Yellow or light-yellow liquid
4. Enzyme solution: Colorless or light-yellow liquid
5. Substrate solution: Light yellow liquid
6. Washing solution 20x: Colorless liquid

[Assay methods]
1. Preparation of reagents and specimens
(1) Preparation of washing solution (1x)
Dilute the concentrated 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℃ when they are used for a short period (within 2 weeks) and at −15℃ 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 before 30 minutes of use and mixed well immediately before use. Open the packaging 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
1) Wet the test membranes completely with 300 µL of diluted washing solution by shaking for 5 minutes and then remove the washing solution (100 rpm is recommended).
2) Fill the allergen panels with 250 µL of sample diluent.
3) Add 50 µL of patient sample and incubate with shaking at room temperature for 45 minutes.
4) Remove the sample solutions from the panels and wash the membranes two times with the diluted washing solution. At every washing, add 300 µL of diluted washing solution, incubate with shaking for 5 minutes and empty the panels. Solution should not remain in the panels.
5) Add 250 µL of antibody solution to the panels and incubate with shaking at room temperature for 30 minutes.
6) Rinse off the membranes as the method (4).
7) Fill the panels with 250 µL of enzyme solution and incubate with shaking for 30 minutes.
8) Rinse off the membranes as the method (4).
9) Add 250 µL of the substrate solution and incubate with shaking at room temperature in a dark room for 20 minutes.
10) Remove the substrate solution from the panels and rinse them off with 250 µL of deionized water.
11) Dry the membranes in the air or with a dryer (Please make sure that the membranes are dried completely).
12) 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 details.

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

Fully-automatic method
1) Set the Q-STATION ELITE with allergen panels and reagents.
2) 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
1) 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

2) 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
1) Detection limit: 0.15 IU/mL
2) Analytical specificity: There is no detectable cross-reactivity with IgA, IgM, IgG or IgD at 2 times of normal physiological levels.
3) 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]
1) For *in vitro* diagnostic use only.
2) **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.
3) 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.
4) False positive test results can be produced by cross reactivity of the antigens tested with other antigens.
5) Do not smoke, eat or drink in areas where samples or test reagents are used.
6) All samples may have a potential to include unknown infectious materials. When handling the samples, wear disposable gloves and wash your hands after test.
7) Do not place needles, knives or any other objects that can cause injury–while handling human samples and the reagents to avoid safety accidents.
8) All patient samples and kit components used should be regarded as the bio-hazard. It should be disposed according to the relevant guidelines.
9) Do not use kits after the expiration date.
10) The allergen panels are packaged with desiccant and should be sealed properly after each use.
11) 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.
12) Substrate solution may contain black precipitates. This is not an abnormal phenomenon 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 distribution.

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℃

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

[Understanding of symbol marks]

LOT	Lot No.	2℃ 8℃	Store at 2-8°C	IVD	*In vitro* diagnostic medical device
	Manufacturing date	CE	CE mark	REF	Catalogue number
	Manufacturer		Use by	EC REP	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 Atopy panel

No(1)	Allergen(2)	Code	Group
1	Total IgE	tIgE	tIgE
2	Egg white	f1	Foods
3	Egg yolk	f75	
4	Milk	f2	
5	α-lactalbumin	f76	
6	β-lactoglobulin	f77	
7	Casein	f78	
8	Peanut	f13	
9	Pea	f12	
10	Soybean	f14	
11	Walnut	f256	
12	Pork	f26	
13	Beef	f27	
14	Chicken	f83	
15	Codfish	f3	
16	Mackerel	f206	
17	Crab	f23	
18	Shrimp	f24	
19	Clam	f207	
20	Silkworm pupa	-	
21	Wheat	f4	
22	Yeast, baker's	f45	
23	Rice	f9	
24	Potato	f35	
25	Peach	f95	
26	Apple	f49	
27	House dust	h1	Indoor
28	*D. pteronyssinus*	d1	
29	*D. farinae*	d2	
30	Cockroach	i6	
31	Cat epithelium & dander	e1	
32	Dog dander	e5	
33	*Candida albicans*	m5	Moulds, Microorganisms
34	*Tricophyton rubrum*	m205	
35	*Aspergillus fumigatus*	m3	
36	*Penicillium notatum*	m1	
37	*Alternaria alternata*	m6	
38	*Staphylococcal enterotoxin B*	m81	
39	Birch-alder mix	tx	Pollens
40	Oak	t7	
41	Grass mix	gx	
42	Common ragweed	w1	
43	Mugwort	w6	
44	Japanese hop	w22	

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