

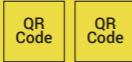


10 Allertyze
Rapid Test
Common Inhaled Allergens

Inhaled Allergen Specific IgE Antibody

Test Kit (Colloidal Gold)

Instruction For Use



www.en.kochbio.cn
IFU V2.0 09/2023

[PRODUCT NAME]
Inhaled Allergen Specific IgE Antibody Test Kit(Colloidal Gold)

[REF NUMBER]
ALG-IC001-1: 1 Test/Kit
ALG-IC001-5: 5 Tests/Kit
ALG-IC001-25: 25 Tests/Kit

[INTENDED USE]
This kit is used for qualitative detection of 10 allergen-specific IgE antibodies of artemisia argyi, common ragweed, house dust mite, cat epithelium, dog epithelium, cockroach, alternaria, plantain, birch, timothy grass, and has important reference value for etiological diagnosis of common allergic diseases.

Allergen list:

Allergen code	Common name	Latin name
d1	House dust mite, Dust mite, European house dust mite	Dermatophagoides pteronyssinus
e1	Cat epithelium,Cat, Domestic cat, Cat dander	Felis domesticus
e5	Dog epithelium,Dog dander, Domestic dog, Hound	Canis familiaris
g6	Timothy, Herd's grass, Cat's Tail	Phleum pratense
i6	Cockroach, Roach, German cockroach	Blatella germanica
m6	Alternaria, Alternaria alternata	Alternaria tenuis

t3	Birch, European white birch, Common birch, Birch tree, European white birch, B. pendula	Betula Verrucosa
w1	Common ragweed, Annual ragweed, Short ragweed, Roman wormwood, American wormwood	Ambrosia artemisifolia
w6	Mugwort, Artemisia argyi, Chrysanthemum weed, Common wormwood	Artemisia vulgaris
w9	Plantain, Ribwort plantain, English plantain, Ribwort	Plantago lanceolata

[SUMMARY]

Allergic reaction is a special pathological immune response, which is an abnormal reaction of the human body to one or more originally harmless substances. Exogenous or endogenous antigens (allergens) stimulate the mononuclear phagocytic system of the body's lymph nodes, liver, spleen and other organs. Cause plasma cells to react and produce specific antibodies^[1]. By now, the body is in a sensitized state. When the sensitized mast cells are in contact with the specific allergen again, the cells are triggered to secrete a large amount of physiologically active substances, resulting in telangiectasia, edema, and leakage.

The most common allergic diseases include hay fever, allergic rhinitis, anaphylactic shock, bronchial asthma, urticaria, eczema, atopic dermatitis, and gastrointestinal dysfunction. There are a wide variety of allergens that cause allergic reactions in humans^[2]. If the substances that cause allergic reactions in the body can be found from the allergens, the allergic reactions can be well prevented and treated. Some studies show that the

incidence rate of allergic diseases in children is 25% - 40%, and the incidence rate in adults is 10% - 30%^[3]. In the future, with the popularization of medical concepts, there will be an explosive growth in the number of people being examined! Allergen detection technology provides professional and scientific detection methods for systematic management and treatment of chronic diseases caused by food and inhalation.

This kit is applicable to people with clinically suspected type I IgE-mediated allergic reactions. The symptoms of anaphylaxis induced by different allergens may be different, and their clinical symptoms are related to the age of patients, genetic factors and exposure to allergens, and the symptoms of allergic individuals are also different^[4].

Weed Pollen :

Mugwort is a perennial root stalk weed that grows along the roadsides, in waste area and infests nursey crops. It is found troublesome in about 25 crops in 56 countries. Mugwort is distributed widely across Europe. It is a common inhaled allergen and is one of the main causes of allergic rhinitis in summer. Mugwort is usually wind-pollinated and inhalation of the pollen grains (spheroidal in shape) is responsible for its allergic reactions. The prevalence of its allergy has been found in several parts of Europe as well as parts of Asia, especially China and Korea. Mugwort pollens are known to trigger type 1 allergic reactions like allergic rhinitis, conjunctivitis and asthma.

Common ragweed is an aggressive plant with its origin most probably from the regions of Northern America. It is introduced to many countries in Europe, Asia and Africa. The pollen period of ragweed begins in early August, extends to the middle of October, and reaches its peak from the middle of August to the end of September. Ragweed is an important seasonal air-borne allergen and the main inducing factor of allergic rhinitis. Ragweed pollen can exacerbate asthma and allergic conjunctivitis.

Plantain is an annual or biennial herb with elliptical or oval

leaves and yellow-brown to black seeds, which bloom from May to July. People with allergic constitution may have anaphylaxis after taking plantain, and skin rash, facial flushing, nausea and vomiting will occur in the body after allergy. When these adverse phenomena occur, anti-allergy drugs should be taken in time for treatment^[5].

Grass Pollen :

Timothy grass pollens are the principal causes of respiratory allergic disease globally. The IgE reactivity to these allergens is manifested by about 40% of allergic patients and 20% of the general population. Timothy grass (Phleum pratense) is one of the most common grass species of northern and central Europe that produces pollen allergens. May cause allergic asthma, rhinitis, conjunctivitis and other allergic symptoms.

Tree Pollen :

Birch pollen is very easy to cause allergies, especially in the eyes, nose and respiratory system. White birch trees are not only found in forests and bushes, but also planted in urban squares, residential entrances and other places^[6]. It is one most common tree species of Europe producing pollen allergen. Birch pollens are one of the key causes of asthma, allergic rhino conjunctivitis, and allergic rhinitis symptoms.

Animals :

House dust mite is an important species of mites, suitable for living in warm and humid environment. Dust mites mainly live in dust, carpets, pillows, mattresses and indoor decorative furniture rich in biological substances (especially human dander). Dust mites can easily induce allergic rhinitis, allergic asthma, specific dermatitis and other allergic diseases. In most parts of the world, dust mite is an important persistent risk factor for asthma^[7].

Cockroach is one of the main allergens causing allergic rhinitis and asthma. The asthma caused by cockroaches is not caused by direct contact with human body or crawling into the body airway at night, but by secretions such as saliva, body, egg sheath and feces. The decom-

posed small particles of these substances float in the air, and the human body will become sick after inhalation. 20% - 30% of asthma patients are allergic to cockroaches^[8].

Cat dander: It has been documented that cats dander becomes airborne very easily and then is carried by small particles, which in turn transfers it to environments that have not had any exposure to a cat. Sensitization to the cat is strongly associated with asthma, especially in environments free of mite and cockroach. Children with cat allergy and problematic severe asthma have higher levels of IgE antibodies towards cats compared with children with controlled asthma.

Dog dander is obviously an important source of inhaled allergens. Allergic sensitization to dogs is considered to be a risk factor for asthma and rhinitis, and has increased significantly over recent decades for both children and adults. Dog allergen particles are tiny so they easily become airborne, disperse effectively, and can enter small bronchioles to reach lower airways. Dog hair and dander extracts contain many antigens, any of which can bind to IgE antibodies and trigger respiratory symptoms in sensitized individuals. Many of these compounds also cross-react with other mammalian allergens, which poses extended diagnostic and therapeutic challenges.

Mold :

Alternaria alternata is a predominantly outdoor mold, but it can also be found indoors. A. alternata is a cosmopolitan mold and one of the most frequent fungal sensitizers, with a sensitization prevalence varying from 0.2% to 14.4% across the globe. Inhalation of A. alternata spores is associated with upper and lower respiratory hypersensitivity, mainly asthma and allergic fungal rhinosinusitis. Allergic bronchopulmonary mycosis and hypersensitivity pneumonitis may also develop.

[PRINCIPLE]

This kit is based on the principle of colloidal gold immunochromatography. Various allergens are attached to the

test lines. The control line is coated with goat anti-mouse IgG antibody, and colloidal gold-conjugated mouse anti-human IgE antibody were immobilized on the gold-conjugated pad. During detection, the specific IgE antibody in the sample combines with the mouse anti-human IgE antibody on the gold-conjugated pad to form a complex, which moves along the membrane under the action of chromatography. When it passes through the test line, the colloidal gold-conjugated mouse anti-human IgE antibody were captured by the test line and control line to develop color during the chromatography process. The color of the test line reflects the amount of allergen-specific IgE antibodies.

[MATERIALS]

The number of the testing devices of the kit may vary. For the exact number of tests contained, please refer to the actual contents in the box.

• Test cassette	• IFU	• Operation manual
• Diluent	• Dropper	• Disposal bag
• Disposable lancet	• Alcohol cotton pad	• Bandage

[DIRECTIONS FOR USE]

(If the sample is serum/plasma, suck the sample directly with a dropper, and go to step 4, without Step 3.)

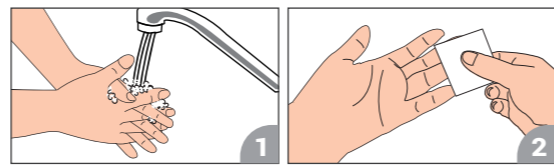
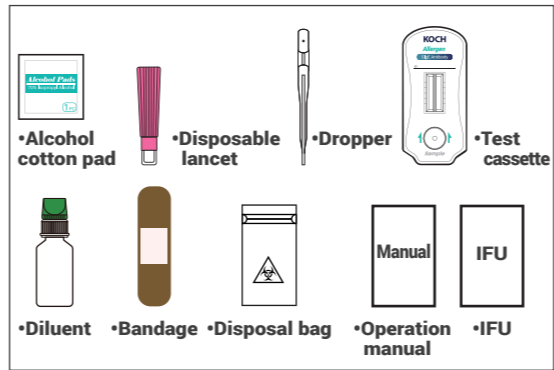
1.Wash your hands:

Wash hands with soap and warm water, rinse with clean water and allow to dry. The use of warm water facilitates capillary blood collection as it induces vasodilation. If this is not possible, use the alcohol cotton pad as an alternative(Fig 1).

2.Prepare necessary components:

Prepare the necessary components as follows: open the foil bag, take out the test cassette; Open the plastic packet

containing the dropper. Clean your finger with alcohol cotton pad(Fig 2).



3.Prick your finger or foot:

Massage the recommended skin puncture sites(see table 1). It is important that the massage is done from the palm of the hand to the finger, to improve blood flow. Then open the plastic packet containing the lancet, remove the protective cap of the sterile lancet. Place the gray end against the recommended skin puncture sites (see table 1) and gently press down until it clicks. If the lancet does not work properly, discard it and use the second one supplied. If the second one is not required, it can be disposed of without special precautions. Children or teenagers below 18 years old should be pricked by

adults.(See detail information for prick in SPECIMEN REQUIREMENT section)^[9](Fig 3 & 4).

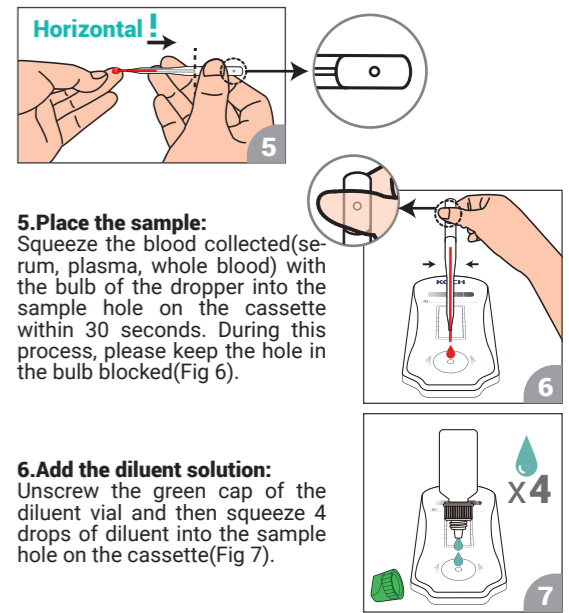
Table 1. Recommended Skin Puncture Sites for different aged people^[9]

	Sites for Collecting Capillary Blood	Recommendations for Skin Puncture Sites
Infant less than one year old	heel	
Children(over one year old) and Adults	the middle finger or ring finger	

4.Collect The Sample:

Hold the dropper horizontally without pressing the bulb, keep the hole in the bulb exposed. Rub the finger, contact blood drop with dropper tip horizontally, wait blood enter the inner dropper, this process would repeat for several times until the inner dropper is filled. During this process, please keep the dropper horizontally. Once the dropper is filled, please block the hole in the bulb with your finger unless

the blood would be leaked(Fig 5).



7.Wait and read your result:

Wait 15 minutes and read the results referring to the next section for result interpretation.

8.Apply a bandage

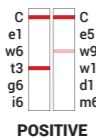
Apply a bandage on the wound after blood collection during waiting for the results.

[INTERPRETATION OF RESULTS]

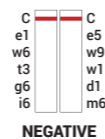
The intensity of the test line is not proportional to the amount of allergen-specific antibodies in the sample. If your test results give you a positive result we recommend that you visit your GP to confidently discuss the results and take appropriate actions to reducing or even possibly eliminating your symptoms.

Detection card identification	Logo interpretation
C	Quality control line
e1	Cat dander
w6	Mugwort
t3	Birch
g6	Timothy grass
i6	Cockroach
e5	Dog dander
w9	Plantain
w1	Common ragweed
d1	House dust mite
m6	A.alternata

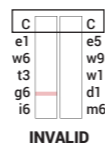
POSITIVE: The control line(C) and any test line(T) are coloured, indicating that the allergen specific IgE antibody corresponding to the test line is detected in the sample. The T line may be less intense (lighter) than the C line and there may be more than one T line coloured. This result means the levels of allergen specific IgE in the blood are higher than normal and you should consult your GP.



NEGATIVE: The control line(C) is coloured and test line(T) is not coloured, which means that the levels of allergen specific IgE is normal or lower than the limit of detection of the allergen.



INVALID: Control lines (C) cannot be displayed. It is invalid test.



[LIMITATIONS]

- 1.The Inhaled Allergen Specific IgE Antibody Detection Kit (Colloidal Gold) is only used for in vitro diagnosis, and the test results are auxiliary diagnosis for clinical diagnosis.
- 2.Those with clinical symptoms and negative test results need further clinical tests.
- 3.The positive results of this kit only cover the allergen test items included in the test cassette, and it cannot be ruled out that the patient is allergic to other allergen items not included in this test cassette. A negative result only means that the specific IgE concentration in the sample is lower than the detection limit, and cannot indicate that the patient is not allergic to the test allergen.
- 4.The concentration results measured by other test methods or other manufacturers' kits cannot be directly comparable with the results measured by this product.
- 5.False positive test results may occur due to the cross-reactivity of the tested allergen with other allergens.
- 6.This kit is not recommended for physical examination of healthy people. The positive or negative test result only represents the positive or negative test result of the specific IgE antibody of the test allergen. The correlation between the test result and the patient's illness is uncertain, and it cannot be used as the only indicator of the patient's illness evaluation. The patient's illness must

Expert Panel Re-port 3(EPR-3): guidelines for the diagnosis and management of Asthma-Summary Report 2007[J]. J Allergy Clin Immunol, 2007, 120 (5 Suppl) . [9]. Clinical and Laboratory Standards Institute. Procedures and devices for the collection of diagnostic capillary blood specimens; Approved Standard[S]. 6th ed. CLSI document GP42-A6. Wayne, PA: CLSI, 2008. [10]. Chafen JJ, Newberry SJ, Riedl M, et al. Diagnosing and managing common food allergies: a systematic review [J]. JAMA, 2010, 303 (18): 1848-1856.

[FAQs]

1.Are the allergy tests suitable for children?

The allergy specific tests are all suitable for children/adults of any age. However the operation for collect the blood is different for children less than 1 year old and older children & adult.

2.My result was negative for milk/egg, am I OK to eat this food now?

If you are unsure about whether or not you have a food allergy (especially if you have exhibited allergy-like symptoms when consuming food), we strongly advise that you consult your GP or physician at the earliest opportunity. It is possible to be allergic to something and have an antibody level below the limit of detection. You may also be allergic to proteins that do not normally cause allergies, or to an allergen that you have not tested for.

3.My result was negative, but I still think I am allergic.

KOCH allergy tests are designed to show positive results down to a level of IgE antibody that is regarded

be comprehensively analyzed in combination with the patient's clinical performance and other laboratory tests [10].

[CAUTIONS]

- Read the instructions for use carefully before performing the test. The Test is reliable only if all the instructions are followed correctly.
 - Keep the Test kit out of the reach of children.
 - Do not use the Test after the expiry date or if the package has been damaged.
 - Follow the procedure exactly, using only the specified quantities of blood and diluent.
 - Store the Test components at a temperature between 4°C and 30°C. Do not freeze.
 - Use the cassette and lancet once only.
 - The test is for external use only. DO NOT SWALLOW.
 - In vitro diagnostic device for individual use.
 - Not recommended for people who take anti-coagulant medications (blood thinners) or people suffering from haemophilia.
- After using, please dispose of all components according to your local waste disposal laws. Ask your pharmacist for advice.
- It should be used immediately after opening the package. If it cannot be used immediately, it should be sealed and stored in a dry place away from light.
 - Avoid hemolyzed, turbid, or lipemic specimens.
 - It is best to use fresh specimens.

[STORAGE AND STABILITY]

- Store as packaged in the sealed pouch either at temperature (2°C~30°C).
- Unsealed stability: After the test cassette bag is opened, it should be tested within one hour.
- Transportation stability: It is recommended to carry out under the condition of 2°C~30°C.
- The shelf life of the product is 18 months.

[SPECIMEN REQUIREMENT]

Specimen requirement: serum, plasma, whole blood.
Specimen Storage

by clinicians as the lower end of the disease state range. It is however still possible to be allergic to something and have an antibody level below this range.

You may also be allergic to proteins that do not normally cause allergies, or to an allergen that you have not tested for. If you are concerned, we recommend consulting your GP or physician for further tests.

4.What should I do if the result is positive?

A positive result means that the level of IgE class antibodies detected in the blood is higher than normal. You should consult your GP or physician and show him/her the results of the test. The GP or physician will decide which other tests to perform or refer you to an allergy consultant.

5.How accurate are KOCH allergy tests?

All KOCH products are CE marked and independently assessed by certified EU Notified Bodies. Such assessment includes performance data where the results from KOCH are compared to the results from independent laboratories running the "gold standard" method for IgE testing. These results give an excellent correlation of greater than 90% for both positive and negative samples; resulting in an overall accuracy of greater than 90%.

6.When can the test be used?

The test is recommended in the presence of symptoms typical of allergic reactions, such as

Serum/plasma specimens can be stored for 7 days at 2°C~8°C and for 4 months at -20°C or -80°C. Avoid repeated freezing and thawing of samples.

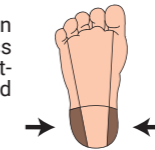
Whole blood samples can be stored for 24hours at 2°C~8°C.

Recommended skin puncture operation procedure for different aged people

1.Infants

In infants less than one year old, punctures to the lateral or medial plantar surface of the heel are generally performed. (See Figure 8.) In almost all infants, the heel bone is not located beneath these areas. Skin puncture must be no deeper than 2.0 mm

Figure 8. Recommendations for Skin Puncture Sites in Newborn Infants less than one year old. Shaded areas indicated by arrows represent recommended areas for infant puncture.



Punctures must not be performed on:

- The posterior curvature of the heel.
- The central area of an infant's foot (area of the arch). Punctures to this area may result in injury to nerves, tendons, and cartilage. The arch area offers no advantage over puncturing the heel and must not be used.
- The fingers of a newborn or infant less than one year old. The distance from skin surface to bone in the thickest portion of the last segment of each finger of newborns varies from 1.2 to 2.2 mm. With available lancets, the bone could easily be injured. In newborns, local infection and gangrene are potential complications of finger punctures.
- A swollen site, because accumulated tissue fluid may contaminate the blood specimen.
- Previous puncture sites.
- Earlobes.

2.Older Children(over one year old) and Adults

When skin punctures are performed on the fingers of adults or older children (over one year old), the following guidelines must be observed:

itching and/or reddened skin, watery eyes and sneezing repeatedly. The test can be carried out at any time of the day.

7.Can the result be incorrect?

The result is correct if the instructions are followed carefully. However, the result may not be correct if: the device comes into contact with other liquids before being used, if the amount of blood is not enough or the number of drops dispensed in the well is more than 5. The dropper supplied allows users to be sure they have collected the right amount of blood.

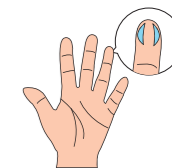
8.How do I interpret the test if the colour and intensity of the test lines and control lines are different?

The colour and the intensity of the lines are not important for the interpretation of the result. The bands must be full and homogeneous. The test is positive regardless of the intensity of the colour of the test band.

• The puncture must be on the palmar surface of the distal phalanx and not at the side or tip of the finger, because the tissue on the side and tip of the finger is about half as thick as the tissue in the center of the finger (see Figure 9). The puncture should occur across the fingerprints, not parallel to them.

- The middle finger and ring finger are the preferred sites, because the thumb has a pulse and the index finger may be more sensitive or callused. The fifth finger must not be punctured, because the tissue depth is insufficient to prevent bone injury[9].

Figure 9. Recommended Skin Puncture Site in Older Children and Adults.



[PRODUCT PERFORMANCE INDEX]

1.The allergen IgE positive reference products in the enterprise reference products shall be tested, and the test results shall not be negative.

2.The allergen IgE negative reference products in the enterprise reference products shall be tested, and the test results shall not be positive.

3. Specificity

Detect samples containing total IgE with a concentration of not less than 60 IU/mL and no specific IgE antibody and the concentration of not less than 700 µg/mL of IgA sample, 500 µg/mL of IgM sample, 7000 µg/mL of IgG sample, The measured results shall not be higher than the minimum detection limit.

Hemolysis with hemoglobin concentration of 10 mg/mL, hyperlipemia with triglyceride concentration of 20 mg/mL, and jaundice with bilirubin concentration of 0.4 mg/mL have no interference with the test results.

4.Hook effect

The hook effect will not occur when the concentration of several specific IgE antibodies contained in the manual reaches 100 IU/mL.

[Symbol Index]

	In vitro diagnostic medical device
	Manufacturer
	Authorized representative in the European Union
	Consult instructions for use
	Catalogue number
	Batch code
	Contains sufficient for <n>tests
	Use-by date
	Temperature limit
	Do not re-use
	Caution



Koch Biotechnology (Beijing) Co., Ltd.
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Caretechion GmbH
Niederrheinstr71,40474 Duesseldorf,Germany



[DISCLAIMER]

You are requested to always read the labels, warnings, and directions provided with the product before using it. In the event of any safety concerns or for any other information about a product please carefully read any instructions provided on the label or packaging or contact your GP or physician.

To confirm any medical condition you should consult with your GP or physician. Contact your health-care provider immediately if you suspect that you have a medical problem. Information and statements about products are not intended to be used to diagnose, treat, cure, or prevent any disease or health condition.

[REFERENCE]

- [1]. Barbee RA, Halonen M, Kaltenborn W, Lebowitz M, Burrows B. A longitudinal study of serum IgE in a community cohort: Correlations with age, sex, smoking, and atopic status. J Allergy Clin Immunol; (1987).
- [2]. Elkayam O, Tamir R, Pick AI, Wysenbeek A. Serum IgE concentrations, disease activity, and atopic disorders in systemic lupus erythematosus. Allergy; (1995).
- [3].Kerkhof M, Droste JHJ, de Monchy JGR, Schouten JP, Rijcken B. Distribution of total serum IgE and specific IgE to common aeroallergens by sex and age, and their relationship to each other in a random sample of the Dutch general population aged 20-70 years. Allergy; (1996).
- [4]. Prescott SL, Pawankar R, Allen KJ, et al. A global survey of changing patterns of food allergy burden in children[J]. World Allergy Organ J, 2013, 6(1): 1-21.
- [5]. Sicherer SH,Wood RA,American Academy of Pediatrics Section On Allergy and Immunology. Allergy testing in childhood: using allergen-specific IgE tests [J]. Pediatrics, 2012, 129 (1).
- [6]. Kristiansen M, Dhami S, Netuveli G, et al. Allergen immunotherapy for the prevention of allergy: a systematic review and meta-analysis[J]. Pediatr Allergy Immunol, 2017, 28 (1): 18-29.
- [7]. National Center for Health Statistics. Trends in Allergic Conditions Among Children: United States, 1997-2011 [EB/OL]. (2013-05) 2020-11-30.
- [8]. National Asthma Education and Prevention Program.