

# Inhaled/Food Allergen Specific IgE Antibody

Home Test

Koch Biotechnology (Beijing) Co., Ltd



# COMPANY PROFILE



## MANUFACTURING BASE

FULLY AUTOMATIC PRODUCTION AND PROCESSING

**15000m<sup>2</sup>**  
Facility



## R&D CENTER

IVD PRODUCT R&D

**40Sets**  
Automatic production line



## TRANSFORMATION CENTER

PRODUCT MASS PRODUCTION

**3Categories**  
Reagents

Koch Biotechnology (Beijing) Co., Ltd, established in March 2015 in Beijing, is a high-tech enterprise focusing on development and application of in vitro rapid test products. Koch Biotech integrates with R&D, manufacturing and sales for in vitro diagnostic reagents and equipment.

Koch Biotech has the mature production and quality management system which strictly comply with ISO13485:2016 to ensure the product performance and quality. Koch Biotech attaches great importance to talent training and scientific and technological innovation. Four international R&D centers of Koch Biotech work closely with global experts, scientific research institutions, medical and health institutions, to gain insight into local customer needs, and bring efficient diagnostic solutions to meet global diagnostic challenges through constant innovation.

Koch Biotech has established networks on R&D, clinical evaluation, sales and services in Europe, Asia, Africa, South America and other regions, focusing on POCT diagnostic reagents and instruments, TAL Test Reagents, automatic diagnostic workstations, biological raw materials and consumables. Koch Biotech provides the complete product solutions through technological innovation.



- ★ NATIONAL HIGH-TECH ENTERPRISES
- ★ TECHNOLOGY SMES
- ★ BEIJING "EXPERTISE AND INNOVATION SMES
- ★ PMDA CERTIFIED CERTIFICATION
- ★ ISO 13485 CERTIFIED



## Allergy?

Allergy is a special pathological immune reaction, also known as hypersensitivity reaction or allergic reaction, induced by immune system, recurrent hypersensitivity reaction. It is manifested that when the body receives a certain allergen through various channels such as inhalation, ingestion, injection or contact, there may be a strong reaction in a certain tissue or organ, or even the whole body, causing various dysfunction or tissue damage.



### Inhalation Allergy

Inhalation allergic reactions that occur due to inhalation of sensitizing substances. Symptoms are mainly manifested in the respiratory tract, and common clinical cases such as hay fever, allergic rhinitis, bronchial asthma, etc. Inhalation of allergens can also cause allergic reactions outside the respiratory tract.

### Food Allergy

A food allergy is an immune system reaction that occurs shortly after eating a particular food. Even the slightest sensitized food can trigger signs and symptoms such as digestive problems, hives, or emphysema. Food allergies can cause for some people severe symptoms and even life-threatening severe allergic reactions.



# Why do allergen Test?

Diagnosing and confirming allergens is the first step in the diagnosis and treatment of allergic diseases!

## What are the common allergic diseases?

**Respiratory allergic reactions: allergic rhinitis, allergic asthma....**

**Allergic reactions of the digestive tract: allergic gastroenteritis ....**

**Skin allergic reactions: specific dermatitis, eczema, urticaria....**



**400 million**

People with allergic rhinitis

Allergic rhinitis affects 10% to 30% of the adults. It is the most common non-infectious rhinitis and seriously affects the quality of life of patients.



**300 million**

People with allergic asthma

Every year, 1 million people worldwide die directly or indirectly from asthma or asthma-induced diseases, 25% of which can be avoided through timely diagnosis and treatment.



**250 million**

People with food allergies

allergic reactions are prone to occur  
e.g. anaphylactic shock

**30-40% of the global population has suffered or is suffering from allergic diseases, and the cases increase continuously.**

It is estimated that by 2050, more than 4 billion people worldwide will suffer from asthma, allergic rhinitis and atopic dermatitis!

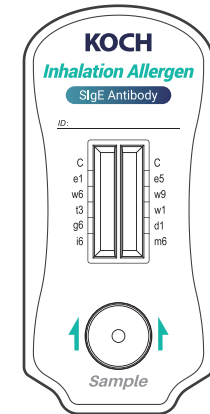
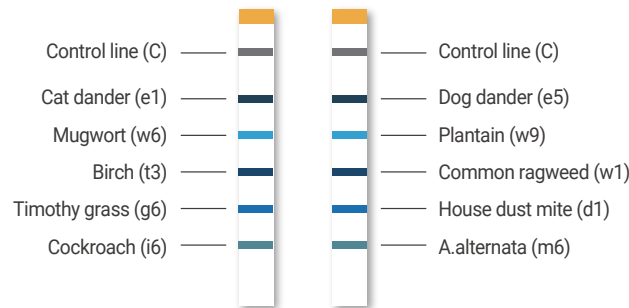
## Significance of Allergen Testing

The prevention and treatment methods of allergic diseases include allergen avoidance, desensitization therapy and omalizumab treatment, etc., which require the identification of allergen types, so early laboratory allergen detection is very important for early diagnosis, treatment and prevention.

WAO White Book on Allergy 2013

# Inhaled Allergen Specific IgE Antibody Test Kit (Colloidal Gold)

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.



## 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

# The Inhaled Allergen Specific IgE Antibody Test Kit detects 10 common allergens

- **Most common cases occur > 10%**

Mainly: Dust Mites, [House dust mite](#), [Mugwort](#)

- **Common cases occur 5%-10%**

Common allergens: [Cat dander](#), [Dog dander](#), [A.alternata](#), [Birch](#), [Plantain](#), [Cockroach](#), [Common Ragweed](#), [Timothy Grass](#), etc



## Mugwort

- Flowering period: late August to early September
- Distribution: Northern region of China
- Pollen is about 25  $\mu\text{m}$  in diameter
- The main sensitizing protein components are Art v 1 and Art v 3 (type of LTP)

## Common ragweed

- The most important cause of hay fever in North American with a population sensitization rate of 10-26%.
- Flowering period: late July to early September
- Distribution: Most of the provinces and cities in North China, Northeast China and the Yangtze River Basin
- Pollen is about 17-19  $\mu\text{m}$  in diameter



## Timothy grass

- Flowering period: June to August
- Distribution: Northeast, North and Northwest China
- Pollen is about 30  $\mu\text{m}$  in diameter

## Birch

- Flowering period: April-May
- Distribution: Northeast, North China, Southwest and other places
- Pollen is about 29x38  $\mu\text{m}$
- Bet v 1 belongs to PR-10 and cross-reacts with many foods of plant origin



## Plantain

- Flowering period: April to August
- Distribution: China, North Korea, Russia and other places
- Plantain allergens also appears cross-reactivity with pollen such as grass, birch, ash or olive pollen

## House dust mite

- Common indoor allergens, mainly caused by respiratory or skin contact
- Accidental injection can also cause systemic allergy symptoms
- Food contaminated with mites (flour), invertebrates that cross-react with mites (shrimp, crab)

### A.alternata

- It is distributed in the air globally, and is the most abundant dominant fungus
- Spore levels peak in summer and autumn (July to October).

### Cat dander

- The diameter is only 0.5-3  $\mu\text{m}$ , easy to stay in the air for a long time, and easy to be inhaled into the lower respiratory tract
- Fel d 1 (a type of secretory globulin): the most sensitizing protein component; The sensitization rate in cat allergic people is more than 95%.

### Cockroach

- Cockroaches are one of the main allergens that cause allergic rhinitis and asthma
- The asthma caused by cockroaches saliva, body, egg sheath and feces and other secretions, the decomposition of these substances small particles floating in the air, the human body inhales to cause disease

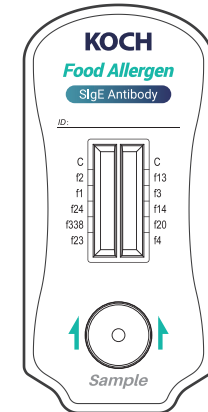
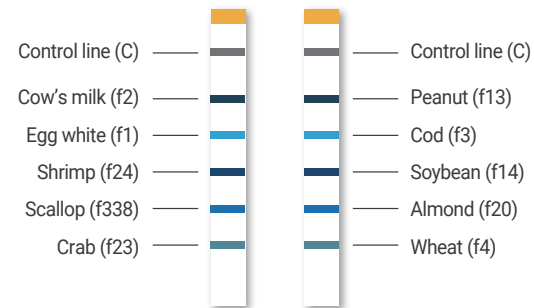
### Dog dander

- The size and distribution characteristics are similar to those of cats
- The most sensitizing protein component: Can F 1 (lipid carrier protein); Can F 5 (kinin-releasing enzyme secreted by the prostate).



# Food Allergen Specific IgE Antibody Test Kit (Colloidal Gold)

This kit is used for qualitative detection of 10 allergen-specific IgE antibodies of Milk, Egg white, Peanut, Soybean, Almond, Wheat, Codfish, Scallop, Shrimp, Crab. It has important reference value for etiological diagnosis of common allergic diseases.



## 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



## 8 common food allergens are responsible for 90% of food allergies<sup>1</sup>, milk and eggs are the most common food allergens in children<sup>2</sup>

Cow's milk	Peanut	Soybean
<ul style="list-style-type: none"> <li>· Food allergies are the most common in children and earliest occurring allergy, but are uncommon with adults</li> <li>· Heat stable: casein (Bos d 8).</li> <li>· Thermal instability: <math>\beta</math>-lactoglobulin (Bos d 5), <math>\alpha</math>-lactalbumin (Bos d 4).</li> </ul>	<ul style="list-style-type: none"> <li>· The sIgE of Ara H2 is the most accurate in diagnosing peanut allergy</li> <li>· Ara h 8 belongs to PR-10, which is very similar to the birch pollen-sensitizing protein component Bet v 1 and is associated with pollen allergy</li> </ul>	<p>At present, there are 44 kinds of allergens in soybeans, which are proteins or glycoproteins in soybeans and their products that can cause allergies to humans or livestock and poultry, which can be roughly divided into three categories: seed storage proteins, structural proteins and defense-related proteins</p>
Almond	Wheat	Cod
<p>amandin is a highly water-soluble globulin that contains a polypeptide that is the main response peptide recognized by human serum IgE in people with almond allergy, which is the main allergen of almonds</p>	<ul style="list-style-type: none"> <li>· Water soluble protein: Tri a14, is the main allergenic protein component that causes flour inhalation allergies such as baker's asthma</li> <li>· Prolamine: Tria19, w5 Gliadin, associated with severe allergic reactions induced by wheat dependence exercise</li> </ul>	<ul style="list-style-type: none"> <li>· The main sensitizing protein is parvalbumin, PV, which has strong thermal stability</li> <li>· There is cross-reactivity of parvalbumin, PV in different fish</li> </ul>
Egg White	Crustaceans: Shrimp, Crab, Scallop	
<ul style="list-style-type: none"> <li>· Heat-stable protein Ovomucoid (Gal d 1)</li> <li>· Heat-labile protein Ovalbumin (Gal d 2), Ovotransferrin (Gal d 3), Egg lysozyme (Gal d 4)</li> </ul>	<p>The main sensitizing protein component is tropomyosin (TM).</p> <ul style="list-style-type: none"> <li>· It is thermally stable and widely found in invertebrates</li> <li>· Cross-reaction between crustaceans is very common</li> </ul>	



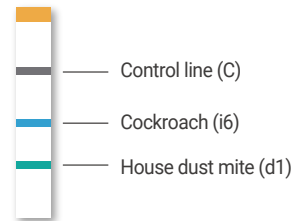
1. Fiocchi A , Brozek J, Schyünemann H , et al . World Allergy Organization ( WAO ) diagnosis and rationale for action against cow ' s milk allergy ( DRACMA ) guidelines[J]. World Allergy Organization Journal ,2010,3(4):1.
2. Burks A W , Tang M , Sicherer S , et al . ICON : food allergy [J]. Journal of Allergy and Clinical Immunology ,2012,129(4):906-920.2.

# Allergy Rapid Test

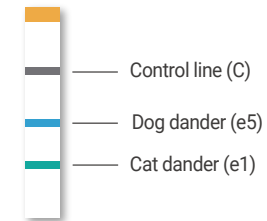
This test kit is used for qualitative detection of allergen-specific IgE antibodies in human whole blood.



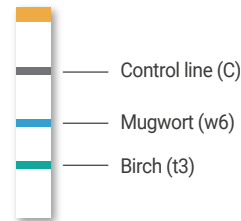
PANEL 1



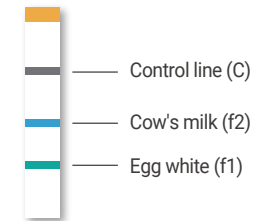
PANEL 2



PANEL 3



PANEL 4



## 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

## Product Advantages

**1 Simple operation**  
One-step operation

**2 Short detection time**  
15 minutes get results

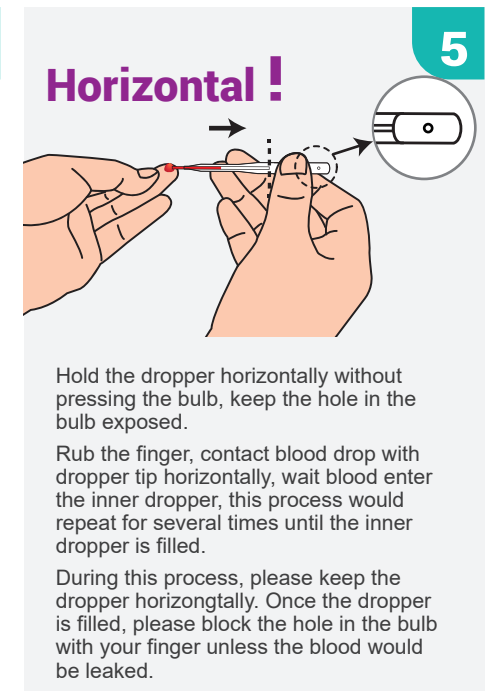
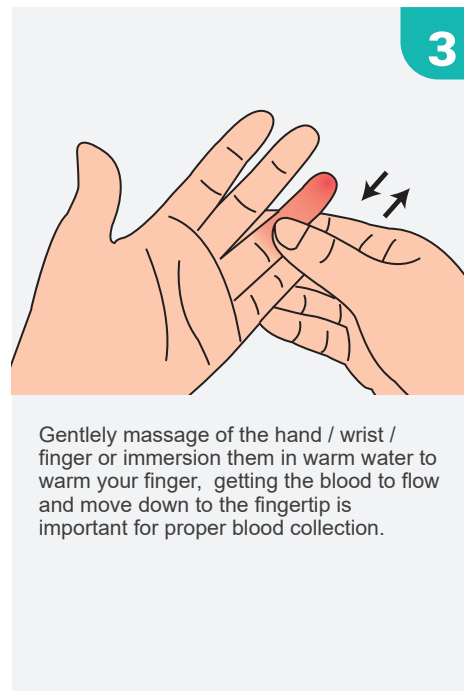
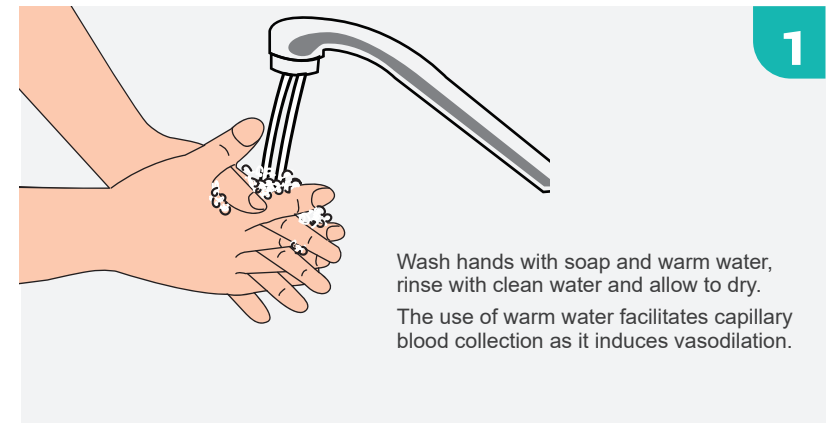
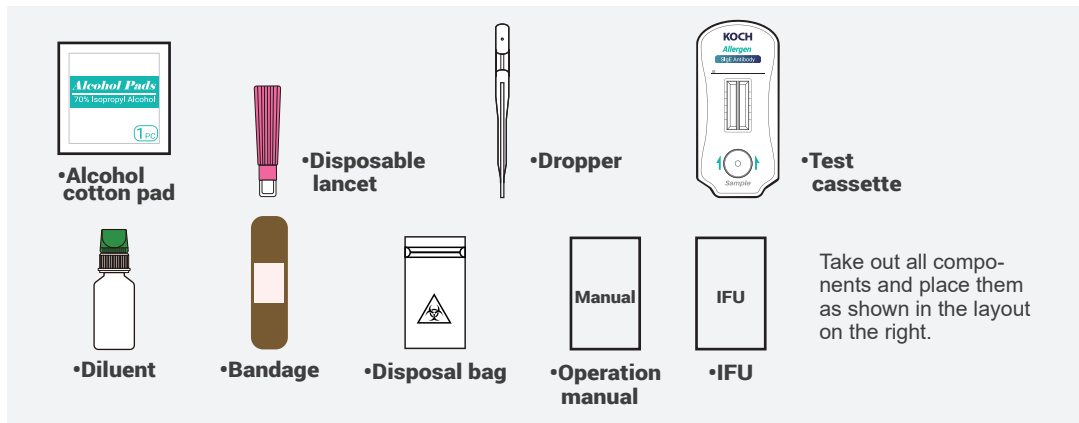
**3 Applicable to many samples**  
Serum, plasma, and whole blood samples

**4 No equipment required**  
Results can be interpreted directly by visual inspection

## Parameter specification

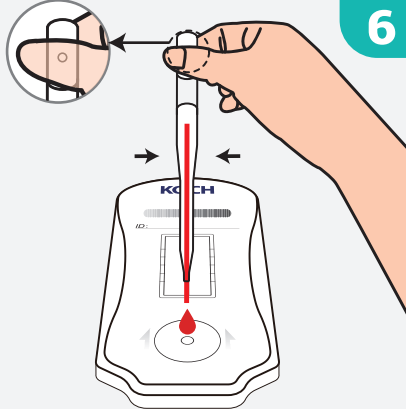
Packing	1 test/box; 5 tests/box; 25 tests/box
Methodology	Colloidal Gold
Storage	Store as packaged in the sealed pouch either at temperature (2°C~30°C)
Shelf life	18 months
Detecting time	15 minutes
Usage	Qualitative detection of 20 allergen-specific IgE antibodies
Sample type	Serum, plasma, whole blood

# Operation Process



## Operation Process

**6**



Once the dropper is filled, please block the hole in the bulb with your fingers unless the blood would be leaked, then squeeze the blood collected into the sample hole on the cassette within 30 seconds.

During this process, please keep the hole in the bulb blocked.

**7**



Unscrew the green cap and squeeze 4 drops of buffer into the sample hole.

Wait 15min and read results.

**8**

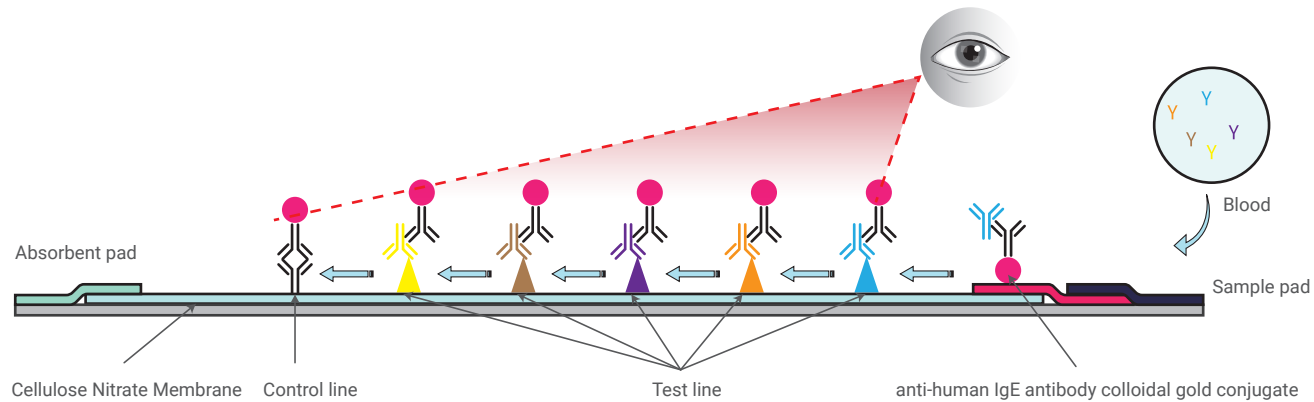


Apply a bandage on the wound after blood collection.

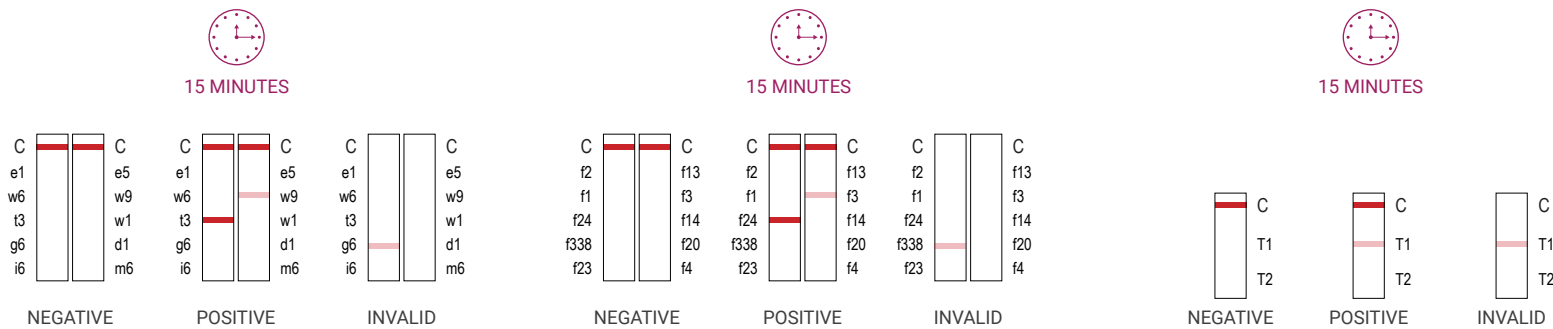
### Attention:

- Test kit should be used immediately after opening the package. If immediate use is not possible, seal and store in a dry place away from light.
- This test must comply with laboratory management standards and strictly prevent cross-contamination. All samples and all kinds of waste should be treated as a source of infection.
- Avoid hemolytic, cloudy, or fatty specimens.
- It is best to use fresh specimens.

# Reaction Principle



# Interpretation of Results



(Please refer to the picture above)

**Positive:** Both the quality control line (C) and the Test line (T) are colored, indicating that allergen-specific IgE antibodies have been detected in the specimen.

**Negative:** The quality control line (C) is colored and the test line (T) is not colored, which means that no allergen specific IgE antibody is detected in the sample.

**Invalid:** The control line cannot appear. Insufficient sample volume or incorrect procedure are the most likely causes of control line failure. Check the procedure and repeat the test using a new test cartridge. If the problem persists, stop using the lot immediately and contact the manufacturer.

## 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.

## Ordering Information

### Ordering Information - Inhaled Allergen Specific IgE Antibody Test Kit (Colloidal Gold)

Rer Number	Product Name	Allergen Types	Specification
ALG-IC001-1	Inhaled Allergen SIgE Ab Test Kit (Colloidal Gold)	Cat dander, Dog dander, Mugwort, Plantain, Birch,	1 Test/Kit
ALG-IC001-5	Inhaled Allergen SIgE Ab Test Kit (Colloidal Gold)	Common ragweed , Timothy grass, House dust mite ,	5 Tests/Kit
ALG-IC001-25	Inhaled Allergen SIgE Ab Test Kit (Colloidal Gold)	Cockroach, A.alternata.	25 Tests/Kit

### Ordering Information - Food Allergen Specific IgE Antibody Test Kit (Colloidal Gold)

Rer Number	Product Name	Allergen Types	Specification
ALG-FC001-1	Food Allergen SIgE Ab Test Kit (Colloidal Gold)	Cow's milk, Peanut, Egg white, Cod, Shrimp, soybean, Scallop,	1 Test/Kit
ALG-FC001-5	Food Allergen SIgE Ab Test Kit (Colloidal Gold)	Almond, Crab, Wheat.	5 Tests/Kit
ALG-FC001-25	Food Allergen SIgE Ab Test Kit (Colloidal Gold)		25 Tests/Kit



# Ordering Information

## Ordering Information - Allergy Rapid Test

Rer Number	Product Name	Allergen Types	Specification
ALG-IC004-1	Allergy Rapid Test		1 Test/Kit
ALG-IC004-5	Allergy Rapid Test	House dust mite , Cockroach.	5 Tests/Kit
ALG-IC004-25	Allergy Rapid Test		25 Tests/Kit
ALG-IC005-1	Allergy Rapid Test		1 Test/Kit
ALG-IC005-5	Allergy Rapid Test	Dog dander, Cat dander.	5 Tests/Kit
ALG-IC005-25	Allergy Rapid Test		25 Tests/Kit

Rer Number	Product Name	Allergen Types	Specification
ALG-IC006-1	Allergy Rapid Test		1 Test/Kit
ALG-IC006-5	Allergy Rapid Test	Mugwort , Birch.	5 Tests/Kit
ALG-IC006-25	Allergy Rapid Test		25 Tests/Kit
ALG-FC004-1	Allergy Rapid Test		1 Test/Kit
ALG-FC004-5	Allergy Rapid Test	Cow's milk , Egg white.	5 Tests/Kit
ALG-FC004-25	Allergy Rapid Test		25 Tests/Kit



**Koch Biotechnology (Beijing) Co., Ltd**

**+86(10)-89282910, +86(10)-89282911**

Address: No.16, Chunlin street, Daxing District, Beijing, China

E-Mail: [marketing@kochbj.com](mailto:marketing@kochbj.com)

Website: [en.kochbio.cn](http://en.kochbio.cn)