

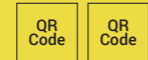


**10 Allertyze**  
Rapid Test  
Common Food Allergens

## Food Allergen Specific IgE Antibody

Test Kit (Colloidal Gold)

### Instruction For Use



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

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

**[ REF NUMBER ]**  
ALG-FC001-1: 1 Test/Kit  
ALG-FC001-5: 5 Tests/Kit  
ALG-FC001-25: 25 Tests/Kit

**[ INTENDED USE ]**  
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.

Allergen list:

Allergen code	Common name	Latin name
f1	Egg white	Gallus spp
f2	Cow's milk, milk	Bos spp
f3	Cod, Codfish	Gadus morhua
f4	Wheat, Common wheat, Bread wheat, Dinkel wheat	Triticum aestivum
f13	Peanut, Groundnut, Monkeynut	Arachis hypogaea
f14	Soybean, Soya Bean, Soy, Soya	Glycine max
f20	Almond, Sweet Almond, Bitter Almond	Amygdalus communis

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almonds as one of the most common allergens in many countries. Almond allergy may lead to oral allergy syndrome, allergic rhinitis, asthma, and atopic dermatitis. Almond sensitized individuals should avoid direct or indirect consumption of almond.

**Crabs:** The main route of crab allergen exposure is ingestion of crab meat and the secondary route is occupational exposure (inhalation or contact). Allergens in crabs can induce oral food allergy symptoms and also reactions including urticaria, angioedema, eczema, gastrointestinal symptoms (diarrhea, vomiting), systemic reactions (anaphylactic shock), and respiratory symptoms. Major allergens identified in crab are tropomyosin and arginine kinase. The most important pan-allergen in crab and other shellfish is tropomyosin, which causes cross-reactivity with other crustaceans, mollusks, mites, cockroaches, and parasites. In sensitized individuals, it is advised to avoid crab meat intake and exposure to crab meat (handling) to prevent crab allergic reactions.

**Shrimp** is considered to be a highly allergenic food, causing severe reactions, such as anaphylaxis. The shrimp allergen is present in its abdominal and tail muscle regions. Children are found to have a lower incidence of shellfish allergy than adults. Shrimp allergy is primarily caused due to consumption of shrimp meat and secondarily due to handling of shrimp. Exposure of shrimp in sensitized individual can induce anaphylaxis, skin symptoms, urticaria, and angioedema, gastrointestinal symptoms, respiratory symptoms. In sensitized individual, it is advised to avoid shrimp meat intake and exposure to shrimp meat (handling) to prevent allergic reactions.

**Scallop** is a commercially important bivalve mollusk, globally found in polar to tropical countries. The primary route of scallop allergen exposure is oral, while the secondary route is through skin contact(handling, or cutting scallop) or inhalation of aerosols(cleaning, cooking, drying, and scrubbing) at scallop processing industries. Occupational exposure can induce asthma or contact urticaria among workers in scallop-processing

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plants. The basic step to avoid scallop allergic reaction in a sensitized individual is to avoid ingestion of all the bivalve mollusk species, cephalopods, and crustacean species.

**[ 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

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f23	Crab, Snow Crab, Queen crab, blue crab, Mud crab, King crab	Chionocetes spp
f24	Shrimp	Pandalus borealis
f338	Scallop, Great scallop, Farm scallop, Atlantic scallop	Pecten spp

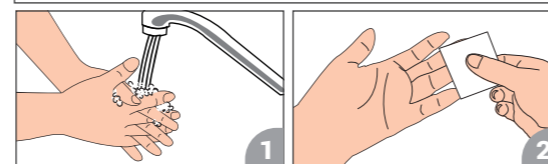
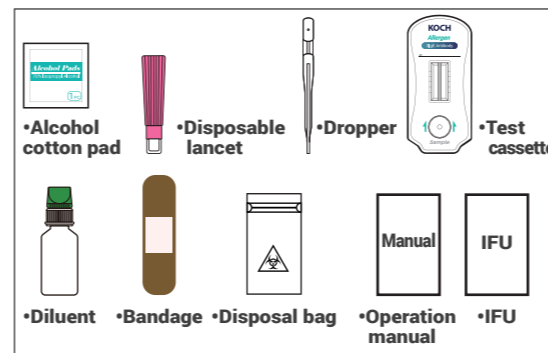
**[ SUMMARY ]**  
Allergic reaction is a special pathological immune response, which is an abnormal reaction of the human body to one or more originally harmless substances. Exogenous or endogenous antigens (allergens) stimulate the mononuclear phagocytic system of the body's lymph nodes, liver, spleen and other organs. Cause plasma cells to react and produce specific antibodies<sup>[1]</sup>. 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<sup>[2]</sup>. 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%<sup>[3]</sup>. 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

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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

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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<sup>[4]</sup>.

**Food:**  
**Cow's milk:** Cow's milk is a major cause of adverse reactions in infants, and hidden exposure is common. Casein (cheese) is a heat-stable allergen, while Whey proteins are altered by boiling. Milk and Milk derivatives are used in a wide variety of confectionery products. Cow's milk protein may be found in house dust and in other non-food sources such as a powder in latex gloves and dermatological powders.

**Egg white** is rich in proteins and is regarded as highly allergenic. The egg has been considered one of the most common food allergy sources, particularly in infants and children. Around 0.5 - 2.5% of young children within a normal population have been found to be allergic to eggs. Egg white consumption may lead to allergic symptoms, such as gastrointestinal reactions, respiratory symptoms, cutaneous reactions, and anaphylaxis among egg white allergic patients. Therefore, egg-allergic individuals are usually recommended to avoid egg and egg-based food products strictly.

**Cod** is a cold-water fish, which can survive in nearly freezing to 20°C temperature and found in both fresh and marine water. Cod protein content is usually between 15-20% of their body weight. The route of exposure is mainly an oral route through consumption, but touch and inhalation of fish and related products can as well trigger allergic reactions. Codfish allergy symptoms can affect single or multiple organs, ranging from mild to severe anaphylaxis. Clinical symptoms start in less than 1 min after fish exposure. This can lead to cutaneous, GI (oral allergy syndrome, laryngeal edema, spasm, diarrhea, vomiting), and respiratory and severe anaphylaxis in some cases.

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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)<sup>[5]</sup>(Fig 3 & 4).

Table 1. Recommended Skin Puncture Sites for different aged people<sup>[5]</sup>

	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

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**Wheat:** wheat grain is high in nutritional content and is processed into several food items. Allergic reactions to wheat are mainly attributed to its protein content. The wheat proteins are classified as gluteins (gliadins and glutenins) and non-glutens ( $\alpha$ -amylase inhibitors, lipid transfer proteins and avenin-like proteins). It is considered as the third most common allergy, after cow's milk and egg in many countries. Wheat allergy can be induced by oral ingestion, or by inhalation of wheat flour as well as through skin contact. There are several allergens (~28) identified from wheat, of which major allergens are found from the gluten family, in addition to some of the non-gluten proteins.

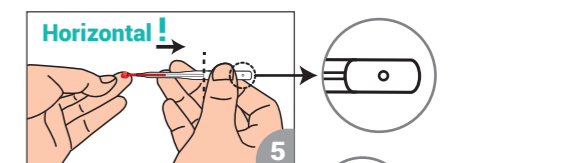
**Peanuts** are consumed across the world. Currently, 16 peanut allergens have been identified and the seed storage proteins being stable to cooking and digestion. Peanut allergens belong to diverse protein families leading to IgE-mediated cross-reactions among different members of the legume families, other plant foods such as tree nuts and also pollen. Peanut allergy usually begins in childhood and persists throughout the affected individual's lifetime. Typical clinical symptoms of peanut allergy usually occur soon after peanut ingestion. Individuals with peanut allergy are of elevated risk of anaphylaxis compared to other food allergies, with over 90% of food-induced anaphylaxis-related fatalities occurring in peanut sensitized individuals.

**Soybean** is a rich and inexpensive source of proteins for both human and animal foods. Soy is one of the "big eight", a group of eight allergens responsible for 90% of all allergic reactions to foods. Allergy with soy as the primary sensitizer is more common in children than in adults and by the age of 10 years approximately 70% of allergic children will outgrow their allergy. The most common treatment of soy allergy is avoidance of soy products. The avoidance strategy should depend on the severity of the reaction and the reaction-eliciting dose.

**Almonds** are one of the most important nut species belonging to Rosaceae family. Various studies reported

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the blood would be leaked(Fig 5).



**5. Place the sample:**  
Squeeze the blood collected (serum, plasma, whole blood) with the bulb of the dropper into the sample hole on the cassette within 30 seconds. During this process, please keep the hole in the bulb blocked(Fig 6).

**6. Add the diluent solution:**  
Unscrew the green cap of the diluent vial and then squeeze 4 drops of diluent into the sample hole on the cassette(Fig 7).

**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.

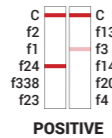
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**[ INTERPRETATION OF RESULTS ]**

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
f2	Cow's milk
f1	Egg white
f24	Shrimp
f338	Scallop
f23	Crab
f13	Peanut
f3	Cod
f14	Soybean
f20	Almond
f4	Wheat

**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.



**[ DISCLAIMER ]**

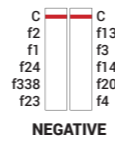
You are requested to always read the labels, warnings, and directions provided with the product before using it. In the event of any safety concerns or for any other information about a product please carefully read any instructions provided on the label or packaging or contact your GP or physician.

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.

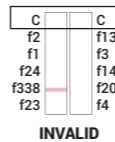
**[ REFERENCE ]**

- 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).
- Elkayam O, Tamir R, Pick AI, Wysenbeek A. Serum IgE concentrations, disease activity, and atopic disorders in systemic lupus erythematosus. *Allergy*; (1995).
- 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).
- 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.
- 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.
- Chafen JJ, Newberry SJ, Riedl M, et al. Diagnosing and managing com-mon food allergies: a systematic review [J]. *JAMA*, 2010, 303 (18): 1848-1856.

**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 ]**

- 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.
- Those with clinical symptoms and negative test results need further clinical tests.
- 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.
- The concentration results measured by other test methods or other manufacturers' kits cannot be directly comparable with the results measured by this product.
- False positive test results may occur due to the cross-reactivity of the tested allergen with other allergens.
- 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

**[ 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 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.

be comprehensively analyzed in combination with the patient's clinical performance and other laboratory tests<sup>[6]</sup>.

**[ 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  
Serum/plasma specimens can be stored for 7 days at

**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 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

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.

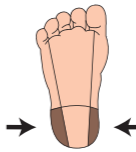


Figure 8. Recommendations for Skin Puncture Sites in Newborn Infants less than one year old. Shaded areas indicated by arrows represent recommended areas for infant puncture.

- 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:

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<sup>[5]</sup>.

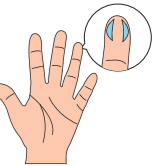


Figure 9. Recommended Skin Puncture Site in Older Children and Adults.

**[ PRODUCT PERFORMANCE INDEX ]**

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



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