Imutest Allergy Check

Read these instructions carefully and familiarise yourself with the contents of the test kit.

Basis of the test

Imutest Allergy Check is a simple, safe and accurate way to find out whether you have an allergy. If you have rheumatic disease (arthritis) the Allergy Check test is NOT suitable for you to use in the diagnosis of a general allergic condition. (Imutest Specific Allergy tests can be used instead, but it should be noted that very weak positive results may be observed even if you do not have a specific allergy).

The test requires only a small amount of blood obtained hygienically and with minimal discomfort and detects antibodies in your blood known as Immunoglobulin E (IgE). High levels are associated with increased susceptibility to allergy.

Imutest results have been proven to compare well to laboratory testing, but no single test to diagnose allergy is completely accurate

The test kit is not suitable for children under 6 years old; a parent should perform the test on children under 16 years old.

The test can be used at any time of the year. You do not need to be having an allergic reaction at the time of testing. It is not necessary to stop any medication before using this product.

Contents each test kit contains:

Keep out of the reach of children; DO NOT ingest parts

- An Instruction leaflet
- A pack containing one sterile finger pricker, one blood tube and one tube of developer solution
- One foil pouch containing a test unit and desiccant sachet (sachet must be yellow or pale greenish yellow to be
 effective; if it is green, contact your local distributor/retailer).
- You will also require a watch or a clock and a clean tissue

Preparing for the test

The test kit should be stored and used at normal room temperature. If it has been stored at a much lower temperature then leave the test kit unopened at room temperature for a minimum of 2 hours. The test unit should be used within 30 minutes of opening the foil pouch.

Wash your hands with soap and warm water; rinse well with warm water; dry with a clean towel - it is important that your hands are warm and dry as this improves the blood flow and makes it easier to collect the blood sample.

Find a quiet place to perform the test, preferably sitting down in front of a table. Then open the:

- Pack containing the sterile finger pricker, blood tube and the tube of developer solution..
- Foil pouched test unit
- Do not pull or move the blue slider until instructed (10 minutes AFTER adding developer solution).
- Place these on a clean, level surface.

Obtaining the blood drop

This is simple and causes little discomfort. Only a small drop of blood is required. DO NOT use the finger pricker if its blue tab (marked \iff) is missing.

- Using gentle pressure, massage the finger from which the sample is to be taken (the middle or ring finger is the best) by GENTLY working the thumb of your free hand up to the tip of the finger several times.
- Twist and pull off the blue tab from the finger pricker to reveal the spring-loaded white contact piece beneath.
- Holding the indented side grips of the finger pricker between the thumb and forefinger of your free hand PRESS the white contact piece FIRMLY against the soft pad of your finger tip until a click is heard.

IT IS IMPORTANT TO PRESS THE FINGER PRICKER VERY FIRMLY AGAINST THE FINGERTIP OTHERWISE THE SKIN WILL NOT BE PUNCTURED.



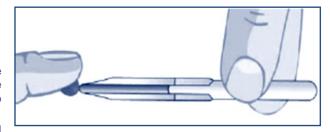
The needle immediately retracts into the pricker for safe disposal and cannot be reused.

Using a dry tissue, wipe away the first sign of blood from the fingertip.

Contact your local distributor/retailer if you have difficulty using the finger pricker or in obtaining a satisfactory amount of blood.

Collecting the blood drop

- With the finger nail pointing upwards (as in diagram) continue to GENTLY massage the thumb of your FREE HAND to the tip of the finger several times until a LARGE DROP of blood appears.
- 2. With the finger nail still pointing upwards, hold the tube HORIZONTALLY, and touch the tip of the tube to the drop of blood (as in diagram). Continue adding blood to the transfer tube until the blood fills the tip to the lines.
- Capillary action will automatically draw blood to the fill lines then stop.



CAUTION:

Filling is automatic: Never squeeze the tube when filling with blood. Using too much or too little blood may give an incorrect result.

Adding the blood to the test unit

To expel the blood, align the tip of the tube into the SMALLER well on the test unit marked: Squeeze the bulb gently to expel the blood into the bottom of the well.

If the blood won't expel, hold the tube vertically over the well by gripping on either side of the black level markers and squeeze the bulb.

Wait approximately 1 minute for the blood to absorb then discard the transfer tube.



Adding the developer

Carefully unscrew the cap from the developer solution bottle and pour **ALL** the contents of the developer tube into the LARGE WELL (see above) just below the sample well, then wait exactly **10 minutes**.

If the liquid in the developer tube is not close to the first rim at the top end of the tube, contact the helpline number below.



DO NOT MOVE OR PICK UP THE TEST UNIT ONCE YOU HAVE ADDED THE DEVELOPER

Reading the result

Only after waiting **exactly 10 minutes** pick up the test unit, keeping it **HORIZONTAL**, and pull the blue slider until you feel it click into place. The test working indicator ✓ will change from blue to white.

Place the test unit back on a level surface and leave undisturbed.

Wait at least a further 20 minutes before reading your result.



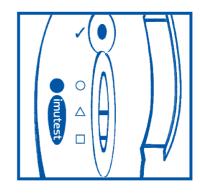
Interpretation of results

Control band: a faint pink band will appear opposite the □ symbol on the test unit; this is used for comparison.

No band should be visible opposite the O symbol.

Your test result POSITIVE if a pink or red band opposite the Δ symbol that is more intensely coloured (darker) than the control \Box band indicates that higher than normal levels of allergy antibodies have been detected.

Some individuals may see positive results within 5 minutes after pulling the blue slider; this is due to very high levels of allergy antibodies being present in the blood. It is necessary to wait 20 minutes to confirm a normal result.



Your test result NEGATIVE if a band of similar or less intensity (lighter) than the control band indicates normal levels of allergy antibodies are present (no band may be visible if the antibody level is very low and this is a good indication that you are unlikely to suffer from allergy).

There will be no further change of the result after 20 minutes. The information section overleaf provides further instructions on how to interpret your allergy test result.

It is essential that you have, or have had at sometime in the past, symptoms for a positive result to be significant.

Further help and information can be obtained from www.imutest.com, your pharmacist or doctor.

Important information

Do not take any decision of medical relevance without first consulting your doctor. If this test has been used for monitoring an existing disease you should not change your treatment unless you have received appropriate training.

Cleaning up after the test

To prevent contamination, after use place the test unit, blood collection and developer tubes and used finger pricker(s) into the original box and secure the lid. Dispose of the box in your dustbin.

DO NOT disassemble the test unit. Keep away from children. Do not ingest any parts. For help, contact your local distributor/retailer.

False positive and false negative results

If you have rheumatoid disease (arthritis) the Imutest Allergy Check test is NOT suitable for you to use in the diagnosis of a general allergic condition. Imutest Specific Allergy test should be used instead, but it should be noted that very weak positive results may be observed even if you do not have an allergy.

The Allergy Check test detects individuals with an abnormally elevated IgE level as compared to the current International Reference Preparation for IgE. High IgE levels, coupled with specific allergy symptoms, are indicative of an allergic condition but a high level of IgE, by itself, will not definitely indicate that you are at a high risk of suffering or developing allergies. It is important that you have had allergy symptoms for a positive result to be significant. Neither can normal levels completely rule out a risk of suffering or developing allergies in the future.

Allergy symptoms

It is important that if you suspect you are at risk of suffering from an allergy that you have symptoms associated with that allergen. Some people can have abnormally high allergy antibody levels but have up to now suffered no symptoms.

They may be able to cope through the presence of protective antibodies, or they rarely come into contact with the offending allergen that could trigger their symptoms.

However, they may still develop symptoms in later life and early detection enables avoidance measures to be taken.

Some people with normal allergy antibody levels can also suffer from allergic reactions and it is useful to identify other risk factors associated with allergy, or a cause other than allergy.

NOSE	Itchy, blocked, runny nose, sneezing, nasal congestion and headache		
EYES	Itchy, sore/red or watery eyes		
MOUTH	Itchy, swollen tongue or lips		
FACE	Swelling or itchy face		
THROAT	Dry, sore or itchy throat, coughing, difficulty in swallowing or speaking		
CHEST	Cough, wheeze, breathlessness		
DIGESTIVE SYSTEM	Abdominal pain, cramp, bloating, vomiting, diarrhoea		
SKIN	Eczema, itching, redness, rashes		

Note: Loss of concentration/general malaise/anaphylaxis may also apply.

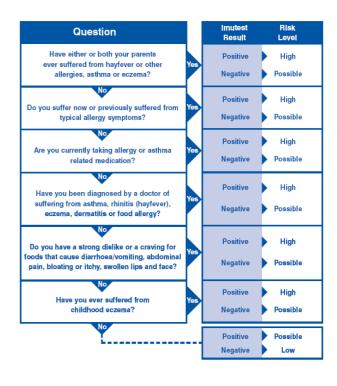
Allergy risk factors

The table to the right indicates the likelihood of your symptoms being related to an allergy; If you have a 'high' or 'possible' risk of allergy it is important to identify the most likely allergy triggers for your symptoms.

Answering a few simple questions can narrow down the search for the likely culprits.

Answering 'yes' to one or more of these questions indicates that you have a risk factor that may contribute to an allergy.

Allergy	Characteristics	1	Imutest specific
FOODS	Are your symptoms triggered after eating certain foods?		Imutest Milk Imutest Egg Imutest Wheat
TREE POLLEN	Do your symptoms get worse in Spring?		Imutest Tree Pollen
HAYFEVER	Do your symptoms get worse in the summer months especially during the grass cutting season?		Imutest Hayfever
DUST MITES	Are your symptoms present all year round? Do your symptoms worsen when making a bed, vacuum cleaning or dusting. Do you suffer from sneezing first thing in the morning?		Imutest Dust Mite
PETS	Do your symptoms worsen when close to certain animals or on entering a room in which a pet has been?		Imutest Cat Imutest Dog



The table above illustrates which of the most common allergies may be causing your symptoms (Refer to the Allergy Symptoms Chart) Place a tick in the table where shown if the answer to the following questions is "YES", or "possibly YES".

*** It is important that once you confirm you have a food allergy you seek medical advice ***

You should not attempt to check your sensitivity by eating a food you suspect may be causing the problem. Similarly, avoidance of common foods such as wheat, eggs or milk should only take place after consultation with a dietician or your doctor as unnecessary avoidance of these foods can lead to nutritional deficiencies.

Confirm your results - Imutest™ specific tests

The first step to reduce your allergy symptoms is to avoid contact with the allergen responsible.

Imutest[™] *specific* allergy tests allow you to confirm your suspicions of whether you have allergy antibodies that react with the more common allergens identified from the list.

Each specific test detects antibodies to a single allergen.

All tests are available from www.imutest.com

Further information and advice

Contact your local distributor or retailer directly, or via "Contact Us" at: www.imutest.com

[space for distributor contact details]



Imutest unit

Imutest Limited, Wilmslow, Cheshire, SK9 5DQ, UK



Directive 98/79/EC

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Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013, Malta



Finger pricker

Becton & Dickinson Company, 1 Becton Drive, NJ, 07417, USA

Directive 93/42/EC





Becton Dickinson UK Ltd, Oxford, UK



Blood Tube

Safe-Tec Clinical Products 142 Railroad Drive Ivyland, PA 18974, USA





EC REP

CEpartner4U BV, 3951 DB Maarn, NL