

Imutest allergy *specific* tests

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

1. Basis of the tests

Imutest allergen specific tests are a simple, safe and accurate way to detect high levels of allergy antibodies called Immunoglobulin E (IgE), in the blood. High levels of IgE are associated with increased susceptibility to allergy.

The test requires only a small amount of blood obtained hygienically and with minimal discomfort.

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

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***

2. 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:

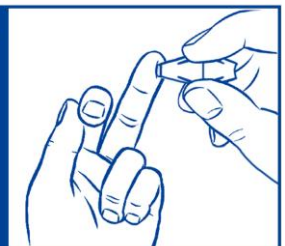
- *Pack containing the sterile finger pricker, blood tube and the tube of developer solution..*
- *Foil pouched test unit*
- *Do not pull or move the blue slider until instructed (15 minutes AFTER adding developer solution).*
- *Place these on a clean, level surface.*

3. 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 \longleftrightarrow) 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.



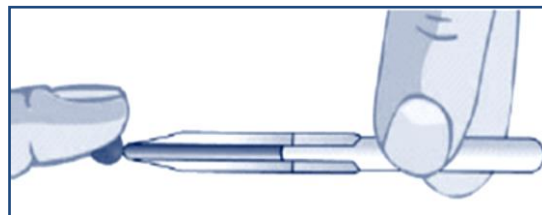
The needle immediately retracts into the pricker for safe disposal and cannot be reused.

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.


4. Collecting the blood drop

1. 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.
3. 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.*

5. 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.



6. Adding the developer

Carefully unscrew the cap from the developer solution bottle and pour **ALL** the contents of the developer bottle into the **LARGE WELL** (see above) just below the sample well, then wait exactly **15 minutes**.

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



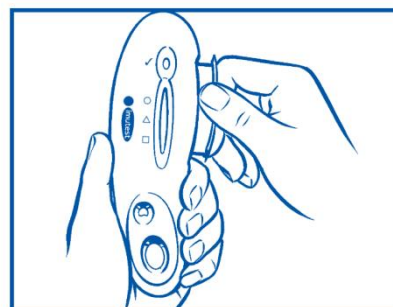
**WAIT EXACTLY
15 MINUTES**

If the developer tube is not completely filled with pale blue liquid, contact your local distributor/retailer.

7. Reading the result

Only after waiting **exactly 15 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. If you have very high levels of IgE antibodies you may see a positive Result within 15 minutes. However it is advisable to wait 30 minutes after pulling the blue slider to confirm a negative result.



8. Interpretation of results

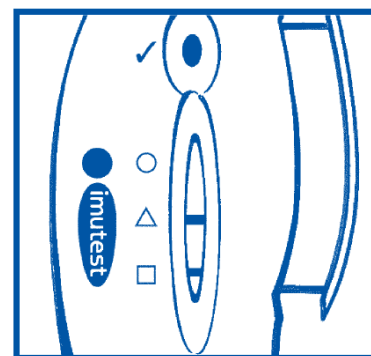
Control line

A pink or red band opposite the Δ symbol indicates the test has worked correctly.

No band should be visible opposite the \bigcirc symbol.

Your test result

A pink or red band opposite the \square symbol (irrespective of the intensity) indicates that high levels of IgE allergy antibodies have been detected and you may have a sensitivity to that specific allergen.



It is essential that you have, or have had at sometime in the past, symptoms for a positive result to be significant. Even a faint pink band opposite the \square symbol should be recorded as a positive result.

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

9. 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.

10. 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.

11. False positive and false negative results

High levels of IgE can be a useful indicator of the risk of allergy 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 or 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.

Some people can have abnormally high IgE levels but may not suffer obvious symptoms. They may be able to cope through the presence of protective antibodies (IgG), or that they rarely come into contact with the offending allergen that could trigger their symptoms. However, they may still develop symptoms in later life.

If you have rheumatoid disease (arthritis) it should be noted that very weak positive results may be observed even if you do not have an allergy.

***** 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 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.

Further information and advice

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

[space for distributor contact details]



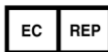
Imutest unit

Imutest Limited,
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IVD

Directive 98/79/EC

CE
0344



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

CE
0050



Becton Dickinson UK Ltd, Oxford, UK



Blood Tube

Safe-Tec Clinical Products
142 Railroad Drive
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