

INCLUDES
**MY ALLERGY
PLAN™**



IMMUNETECH

MY ALLERGY TEST®

INSTRUCTIONS FOR USE

Read All Directions Before Use

**FIND THE CAUSE.
DISCOVER RELIEF.**

MYALLERGYTEST®

The MyAllergyTest is used with a fingerstick blood sample to determine if you have allergies to 10 of the most common allergens. The MyAllergyTest is for the collection and transport of a capillary blood sample to a clinical laboratory for analysis and reporting directly to the consumer allergen specific IgE test results. No physician order is required for a consumer to purchase MyAllergyTest, order that the test be run, or receive test results. MyAllergyTest is intended for use with the MyAllergyTest System used in the clinical laboratory that runs the test and reports test results to consumers. MyAllergyTest is intended for home use by the lay consumer (Over-the-Counter).

The 10 allergens tested are:

Timothy Grass

Bermuda Grass

Mountain Cedar

Short Ragweed

Alternaria (mold)

Egg White

Milk

Wheat

Cat

House Dust Mite

MyAllergyTest lab results are quantitative, consistent, and clinically proven to be as accurate as standard allergy tests conducted by physicians and labs nationwide.¹ ImmuneTech is a Clinical Laboratory Improvement Amendments (CLIA) certified, high-complexity reference laboratory.

OVERVIEW



STEP 1. Review Kit Contents.



STEP 2. Get a Blood Sample.



STEP 3. Attach the Bar Code Labels.



STEP 4. Mail the Blood Sample.

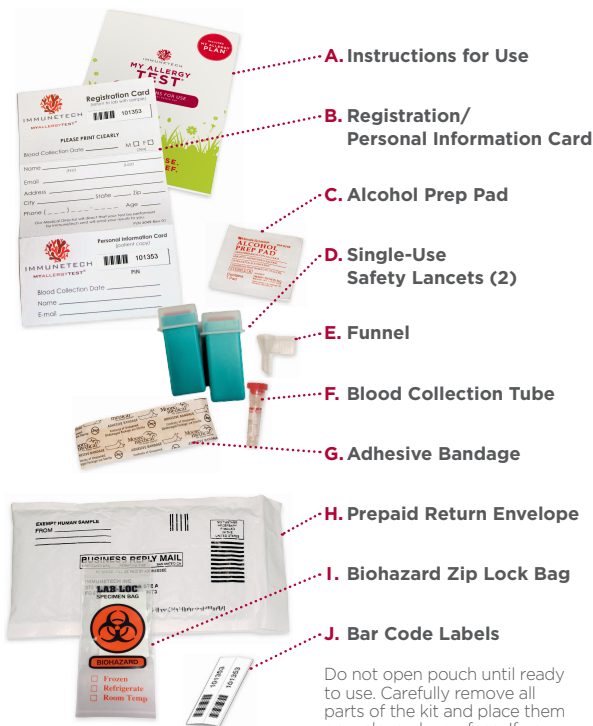


STEP 5. Get Your Results.

Questions?

Call **(650) 312-1066** M-F from 9:00 AM to 5:00 PM PST or email **customersupport@immunetech.com**.

STEP 1: Review Kit Contents




Do not open pouch until ready to use. Carefully remove all parts of the kit and place them on a clean, dry surface. If any part of the test device is broken or opened, do not use.

IMPORTANT: Before you stick your finger, read all directions carefully.

STEP 2: Get A Blood Sample

IMPORTANT: High fat meals may affect test results. For best results, collect the blood sample before eating or several hours after a meal.

**Registration Card**
(return to lab with sample)

attach barcode label here

PLEASE PRINT CLEARLY

Blood Collection Date _____ M ☐ F ☐
(Day)

Name _____
(First) (Last)


Email _____

Address _____

City _____ State _____ Zip _____

Phone (____) _____ Age _____

Our Medical Director will direct that your test be performed by Immunetech and will send your results to you.
PIN 5003 R05

**Personal Information Card**
(patient copy)

attach barcode label here

PIN

Blood Collection Date _____

Name _____

E-mail _____



A. Prepare Your Cards

Fill in all the required spaces, top and bottom, on the Registration/Personal Information Card.

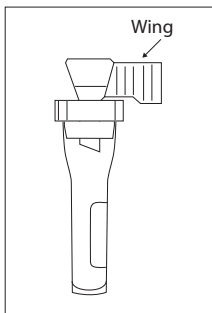
Please print clearly.

The MyAllergyTest laboratory must receive your blood sample within 30 days from blood collection. Please write the date of blood collection on both the Registration and Personal Information Card.

B. Wash and Dry Your Hands

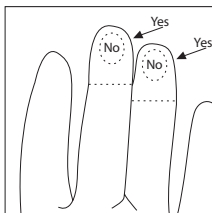
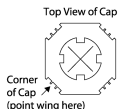
Wash your hands with soap and warm tap water.

Dry your hands thoroughly.



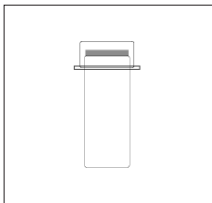
C. Assemble Blood Collection Tube

Push the funnel through the cap of the Blood Collection Tube making sure the wing of the funnel points to the cover of the cap. Do not try to remove the cap from the Tube.



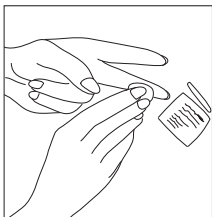
D. Choose Finger and Puncture Site

Choose your middle finger or ring finger. Your finger should be warm and callus-free. For best results, choose an area to the side of the soft pad of the fingertip, on the side of the finger closest to your little finger.



E. Prepare the Safety Lancet

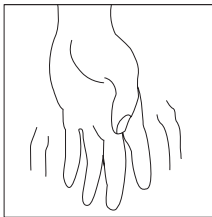
Remove the Lancet's protective cap from the Lancet.



F. Clean the Puncture Site

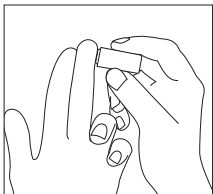
Use the alcohol pad to clean the fingertip. Save the alcohol pad for use after taking your blood sample.

Let your finger dry completely.



G. Shake Your Hand

Stand up and let your hand hang down for 10 seconds. Shake your hand to increase the flow of blood.



H. Stick Your Finger

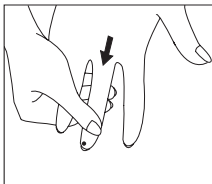
Lay your hand on a clean flat surface to support the finger you are going to stick.

Place the raised platform end of the Lancet on the site you plan to stick, as seen in the picture.

Gently push the Lancet down against the chosen fingertip until you hear a click.

Throughout blood collection, keep your hand below your heart. Standing up should help the flow of blood.

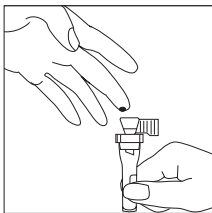
You may not see any blood until you squeeze your finger.



I. Massage Your Hand and Finger

From a standing position, gently massage your hand and finger toward the finger stick site. Start at the top and move down. When the fingertip is filled with blood, gently squeeze the finger right above the finger stick site.

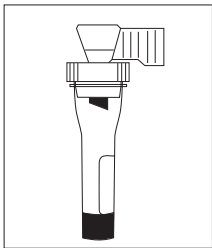
Do not squeeze the finger too hard. Doing so may affect the blood sample. Always keep your hand below your heart.



J. Collect Blood

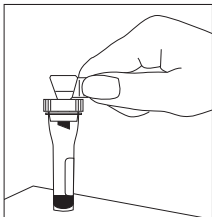
When you see a drop of blood, let the blood flow into the funnel of the Blood Collection Tube. If necessary, you may scrape the blood into the funnel and tap the Tube to allow the blood to go further down into the Tube.

Caution: Blood begins to clot in about 9 seconds. Please collect your sample as quickly as possible.

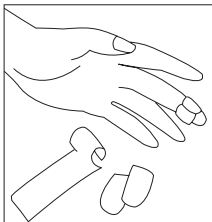


Continue to gently massage your hand and finger toward the finger stick site, and let the blood flow down into the funnel of the Blood Collection Tube.

Collect 4 or 5 drops of blood, or until the blood reaches the bottom of the label on the Tube. If necessary, use the second Lancet, and repeat the above process.

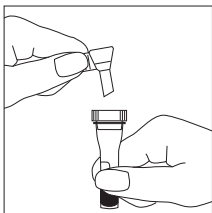


Holding the wing of the funnel, tap the Blood Collection Tube on a table until the blood flows out of the funnel and into the bottom of the Tube.



K. Apply Bandage

After collecting your blood sample, wipe your finger with the alcohol pad and apply the bandage to your finger.



L. Remove the Funnel

Pull the funnel out of the Blood Collection Tube. Make sure the Blood Collection Tube cap is on securely.

M. Safely Dispose of All Materials

Safely dispose of the used Lancet, collection funnel, and all other used materials in your home garbage.

Patient Identification Number (PIN)			
1	12345	2	12345
3	12345		12345
4	12345		

STEP 3: Attach Bar Code Labels

A. Label 1

Attach Label 1 to the **top** of the Registration Card.

B. Label 2

Attach Label 2 to the **bottom** of the Registration Card (Personal Information Card).

Detach and keep the Personal Information Card.

Registration Card
(patient to fill with sample)

attach bar code label here **1**

PLEASE PRINT CLEARLY

Blood Collection Date _____ M ☐ F ☐
(mo) (pm)

Name _____ (first) (last)

Email _____

Address _____

City _____ State _____ Zip _____

Phone (____) _____-____ Age _____

Our Medical Director will attach that your test has performed by ImmuneTech and will send your results to you. PIV 0003 003

Personal Information Card
(patient's copy)

attach bar code label here **2**

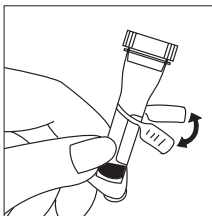
PIN

Blood Collection Date _____

Name _____

E-mail _____

Keep this card in a safe place. You will need your PIN (Personal Identification Number) if you choose to receive your results from our secure website.



C. Label 3

Attach Label 3 to the Blood Collection Tube so that the bar code and number ends are back to back as seen in the picture.

D. Label 4

Attach Label 4 anywhere on the back of the pre-addressed prepaid Return Envelope.

STEP 4: Mail Your Blood Sample

A. Prepare Blood Sample for Mailing

Check that the Blood Collection Tube is fully closed and that Label 3 is attached.

Leave the small paper towel in the Biohazard Zip Lock Bag.

Put the Blood Collection Tube into the Biohazard Zip Lock Bag and seal well. Place the Registration Card in the outer pocket of the Biohazard Bag located on the back of the bag (side without the biohazard symbol).

B. Prepare Envelope

Put the Biohazard Zip Lock Bag in the padded **prepaid** Return Envelope and seal well.

C. Mail Envelope Promptly

ImmuneTech must receive your Registration Card and blood sample **within 30 days** of blood collection.

Place in any US Post Office mailbox.

STEP 5: Get Your Results

Once the ImmuneTech laboratory has received your blood sample, please allow 7-10 days for the sample to be analyzed. There are 2 ways to get the results:

1. Internet

If you provide an email address, you will receive an email directing you to our secure website when your results are ready.

- Visit www.immunetech.com.
- Type in your email address under Lab Results.
- Type in your PIN found on your Personal Information Card.

2. US Mail

If no email address is provided, results will be mailed to the address on the Registration Card.

Warnings

- Use MyAllergyTest before the expiration date printed on the box.
- There are no age limitations on who can take MyAllergyTest; however, test result interpretation should be conducted by individuals 18 years and older.
- The Safety Lancet is for one-time use only.
- Never use a Safety Lancet that has been used by another person.
- Keep out of reach of children.
- Not for use by hemophiliacs or those taking medicines that thin blood (anticoagulants). Persons on blood thinning therapy should consult a physician before using this test.
- Do not use any part of this test internally.
- Do not collect or leave your blood sample in a place where it may spill or others may come in contact with it.
- This sample collection kit is for self-use or use under a healthcare provider's supervision.
- **High fat meals may affect results.** For best results, collect the blood sample before eating or several hours after a meal.

FREQUENTLY ASKED QUESTIONS

What are allergies?

Allergies are a result of an overreaction of the immune system to substances that usually cause no reaction in most individuals. The substances that cause allergic reactions are known as allergens. Your body thinks the allergen is an invader, and makes antibodies to attack it. People who have allergies have an antibody called immunoglobulin E, or IgE. When allergens first contact the body of a person with allergies, specific IgE antibodies are produced. Each type of IgE has a specific “radar” for one type of allergen only. That’s why some people are allergic only to cats while others seem to be allergic to everything.²

When a person with allergies comes in contact with an allergen, his or her body will show symptoms of an allergic reaction, such as sneezing, wheezing, coughing, and itching. Allergies are not only bothersome, but many have been linked to a variety of common and serious chronic illnesses (such as sinusitis and asthma). However, with proper management and patient education, allergic diseases can be controlled, and people with allergies can lead normal and productive lives.³

What allergens are tested with MyAllergyTest?

Your blood sample will be tested for the following allergens: Timothy Grass, Bermuda Grass, Mountain Cedar, Short Ragweed, Alternaria (mold), Egg White, Milk, Wheat, Cat, and House Dust Mite.

Who should take MyAllergyTest?

Anyone wanting to know if they are “allergic” to the most common allergens should take MyAllergyTest. This test is made especially for you, the general public.

Why is it important to know what I am allergic to?

To help you better manage your allergy symptoms, you must first know what is causing your allergy. For instance, you don't have to get rid of your cat if you are allergic to milk, and you don't need to avoid pollens all year if you have a seasonal allergy to ragweed.

MyAllergyTest gives you the information you need to begin to feel better. Once you know the specific allergens causing your symptoms you can:

1. Avoid exposure to those allergens.
2. Make informed decisions about allergy products.
3. Contact your physician to get specific medical treatment.

An accurate allergy test, such as MyAllergyTest, is an important part of allergy diagnosis, when used along with advice from your healthcare provider.

How accurate is MyAllergyTest?

MyAllergyTest is clinically proven to be as accurate as other standard laboratory testing systems. The MyAllergyTest laboratory tests your blood with a Food and Drug Administration (FDA) cleared allergy testing method.¹

For non-food allergens, the MyAllergyTest System correctly identified 93 percent of the cases, and for food allergens, the MyAllergyTest System correctly identified 90 percent of the cases, when the results were compared to the results obtained with another standard laboratory testing system.¹

What can be done if I test positive for allergies?

For most allergies, avoidance is the best and safest method of treatment. Changes to your environment or to your eating habits may reduce or even stop your symptoms. Do not take any medication based on MyAllergyTest results. Any decision regarding specific medical treatment or medication should not be made until you talk to your physician.

If my test results are negative, does that mean I am not allergic?

No. MyAllergyTest tests for 10 of the most common allergens. While a completely negative test result is strong evidence that you are not allergic to any of the most common allergens, it is possible you may be allergic to a less common, or even rare, allergen.

Do I need to fast or collect my blood at a specific time of day?

No. You do not need to fast and you can test your blood any time of the day. **However, it is best to collect the blood sample before eating or several hours after a meal.**

What can I do to make the blood collection easier?

The following points will make blood collection easier:

- Stand up before and during blood collection.
- Always keep your hand below your heart.
- Wash your hands with warm water.
- Warm your hands by rubbing them together.
- Choose a finger that is warm and callus-free.

- Let the hand with the chosen finger hang at your side for at least 10 seconds.
- Make sure your fingertip is completely dry.
- Rest your hand on a tabletop while using a Lancet. Do not pull your hand away.
- Press the Safety Lancet firmly against the side of the tip of your finger.
- Do not pull your hand away when triggering the Safety Lancet.
- If you like, or you feel uneasy, someone else can help you stick your finger.

How do I get my test results?

You can receive your results through our secure website or US mail.

If you would like to receive your results from our secure website, you will be notified of your test results by email. This will link you to our website, www.immunetech.com, where you will log in with the Personal Information Number (PIN) attached to your Registration/Personal Information Card. All information is confidential. If you would like your results to be available to your physician online, you must give him or her your PIN, email address, and our

website address.

Please completely fill out all information on the Registration/Personal Information Card and make sure you do not lose your PIN!

What do the test results show?

Unlike tests that provide only a “Yes” or “No” answer, MyAllergyTest gives you a Class Value which matches your level of allergic response. MyAllergyTest also gives you ImmuneTech Units per milliliter (IU/mL). Some doctors may use these test results to track the progress of allergy treatment.

Test Results				
	Allergen	IU/mL	Class	Allergic Response
	Timothy Grass	14.93	3	Moderate / High
	Bermuda Grass	0.37	1	Very Low
	Cedar	< 0.35	0	Negative
	Ragweed	< 0.35	0	Negative
	Alternaria (Mold)	71.17	5	High
	Milk	48.63	4	High
	Egg White	< 0.35	0	Negative
	Wheat	< 0.35	0	Negative
	Cat	< 0.35	0	Negative
	Housedust Mite	0.57	1	Very Low

Allergen-Specific IgE Concentration (IU/mL)			
	Class	Test Result	Allergic Response
< 0.35	0	Negative	Negative
0.35 - 0.69	1	Borderline	Very Low
0.70 - 3.49	2	Positive	Moderate
3.50 - 17.49	3	Positive	Moderate / High
17.50 - 49.99	4	Positive	High
50.00 - 100	5	Positive	High
> 100	6	Positive	High

IU/mL = ImmuneTech Units per mL

Additionally you will receive MyAllergyPlan™, a personalized plan that will provide useful tips and helpful links to products and resources that will help

you better manage your symptoms.

Positive Test Result

A positive test result means that your body is making sufficient antibodies to that allergen. Whether you get Class 2-6, the important thing to know is that you are probably “allergic” to that allergen. Knowing your Class may be helpful. Consult with your physician to determine the course of action and treatment.

1. For most allergies, the best and safest action is to stay away from that allergen. Changes to your environment or to your eating habits may reduce or even stop the symptoms.
2. If symptoms persist, consult a physician.

Borderline Test Result

A borderline test result means that your body is making a very small amount of antibody to that allergen. You have the possibility of being allergic. Consultation with a physician is recommended.

Negative Test Result

A negative test result means that the amount of antibody your body is making to an allergen is not enough to be detected. While a completely negative test result is evidence that you are not allergic to any of the most common allergens, it is always possible that you may be allergic to these 10 or other allergens.

IMPORTANT!

Any decision regarding specific medical treatment or medication should not be based only on MyAllergyTest results. Only your physician can decide what medical treatment or medication, if any, is right for you. Do not take any medication based only on MyAllergyTest results. If you have any concerns about your allergies, please talk to your physician.

Limitations of MyAllergyTest

- You must follow all directions to collect and mail your blood sample as explained in the instructions.
- You must collect blood until it reaches the lower edge of the label on the Blood Collection Tube (about 4 to 5 drops of blood). Insufficient blood samples cannot be tested.
- You must mail your blood sample and Registration Card as soon as possible after collection. **Your sample will not be tested if the MyAllergyTest laboratory does not receive it within 30 days of blood collection.**
- You must have your PIN and email address to get your test results from the www.immunetech.com website.

References: 1. MyAllergyTest System. Food and Drug Administration PMN file K020387. 2. Tips to Remember: What is an Allergic Reaction? American Academy of Allergy and Immunology. Patient and Consumer Booklet. 3. Allergy Overview. Allergy and Asthma Association. www.aafa.org.

MyAllergyTest is FDA cleared for In-Vitro Diagnostic Use.



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