PET Allergy Test

Dog's and Cat's Allergy Test

Code MTR7098 - Rev. 04 - 02/02/2022

INTENDED USE

Allergy is a common health problem, affecting approximately 20-25% of people with immediate-type hypersensitivity reactions that manifest in theform of rhinitis, urticaria, dermatitis, gastrointestinal illness, wheezing andrarely anaphylactic shock. The term allergy is often used for type I hypersensitivity reactions (immediate type reactions), whose symptoms generally occur within 30-60 minutes after contact with the allergen.

In addition to producing chronic respiratory problems, allergy interferes with normal growth and development, may cause physical disability and poses substantial social and economic burdensMore importantly, early diagnosis and treatment of allergy has been shown to modify the course of the disease and prevent subsequent development of other conditions such as asthma.

PRINCIPLE OF THE TEST

PET Allergy Rapid Test Device a rapid test for the qualitative determination of cat and dog dander specific Immunoglobulin E (sIgE) in whole blood. The test, in conjunction with other clinical observations, is intended to identify the patient whose allergic symptoms may be mediated by cat/dog dander-specific immunoglobulin E (IgE) Type I hypersensitivity.

The rapid test has been designed to detect cat/dog dander sIgE through visual interpretation of color development in the internal strip. The membrane was immobilized with streptavidin on the test region, the conjugate pad was pre-coated with colored anti-IgE antibody colloidal gold conjugates and the sample pad was pre-coated with biotinylated allergens. After specimens were added, the gold-conjugates move along the membrane chromatographically by capillary action and antibodies get to the test region. If sufficient cat/dog dander sIgE is present in the sample, it will react with biotinylated allergen in sample pad, the mixture then migrates through conjugate pad by capillary action and interact with colored anti-IgE antibody colloidal gold conjugates, form a complex. Then the complex moves to the membrane, and combine with streptavidin. As a result, a colored band will form at the test regions of the membrane. If no cat/dog dander sIgE is present in the sample, biotinylated allergen pre-coated on the sample pad will bind to streptavidin immediately, so there is no colored line at the test region of the membrane. Therefore, the colored band on the test regions indicates a positive result. And appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

WHO DOES USE THE TEST?

Pet Allergy Test is useful for people with typical allergic symptoms (itching and/or reddened skin, watery eyes and sneezing repeatedly) especially if they have a family history of allergies. More than 20% of allergic patients live in a state of severe debilitation because of their condition and struggle daily with the fear of a possible asthma attack or more serious situations caused by an allergic reaction..

WHAT SHOULD I DO IF THE RESULT IS NEGATIVE ?

A negative result means that the level of IgE class antibodies detected in the blood is lower than normal. If symptoms persist, consult your physician. If symptoms persist, seek medical advice.

WHAT SHOULD I DO IF THE RESULT IS POSITIVE ?

A positive result means that the level of specific IgE class antibodies detected in the blood is higher than normal. You should contact your family doctor so that he will decide which other tests to perform.

HOW ACCURATE IS THE TEST?

Accuracy (E1-Cat) = 98 % | Accuracy (E5-Dog) = 98 %

CONTENTS

1 device for the Allergy Test, 1 plastic pipette, 1 vial with dropper containing Test diluent required for 1 test, 1 pain-free, sterile lancing device for obtaining a blood sample (HTL-Strefa), 1 disinfecting gauze, 1 instruction for use leaflet

PRECAUTIONS

1) Read these instructions for use carefully before performing the test. The Test is reliable only if all the instructions are followed correctly.
2) Keep the test out of the reach of children.
3) Do not use the test after the expiry date or if the package has been damaged.
4) Follow the procedure exactly for the specified quantities of blood and diluent.
5) Store the test components at a temperature between +2°C and +30°C. Do not freeze it.
6) Use the test and lancing device once only.
7) Test for external use only. DO NOT SWALLOW.
8) In vitro diagnostic device for individual use.
9) Not recommended for people who take anti-coagulant medications (blood thinners) or people suffering from haemophilia.
10) After using, please dispose of all components according to your local waste.
11) Do not take any decision of medical revelance without first consulting your medical doctor.

INTERPRETATION OF RESULTS

E1 = Cat Dander
E5 = Dog Dander

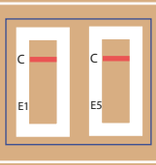
READ THE RESULTS AFTER EXACTLY 15 MINUTES.
DO NOT READ AFTER 20 MINUTES.

15 minutes

The intensity of the line colours is not relevant for the purposes of interpretation of the Test's results.
Do not take any decision of medical relevance without first consulting your medical doctor.

NEGATIVE RESULT

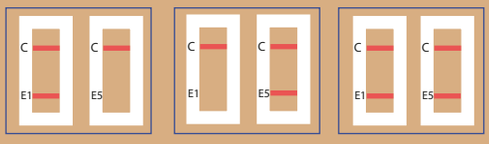
A coloured line appears only under the C (control) signs.



POSITIVE RESULT

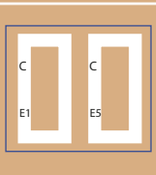
E1 : Cat Dander | E5 : Dog Dander

A red line next to each test field indicates that an elevated level of IgE allergy antibodies has been measured and indicates that sensitisation to the allergen is present and you may be allergic to it. A final diagnosis should be made by a physician in connection with the evaluation of clin-ical symptoms and other laboratory data.



RESULT NOT VALID

Control line (C) fails to appear.
Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new card.



LANCET | PROCEDURE FOR USE

Lancetta/Lancet STERILE R

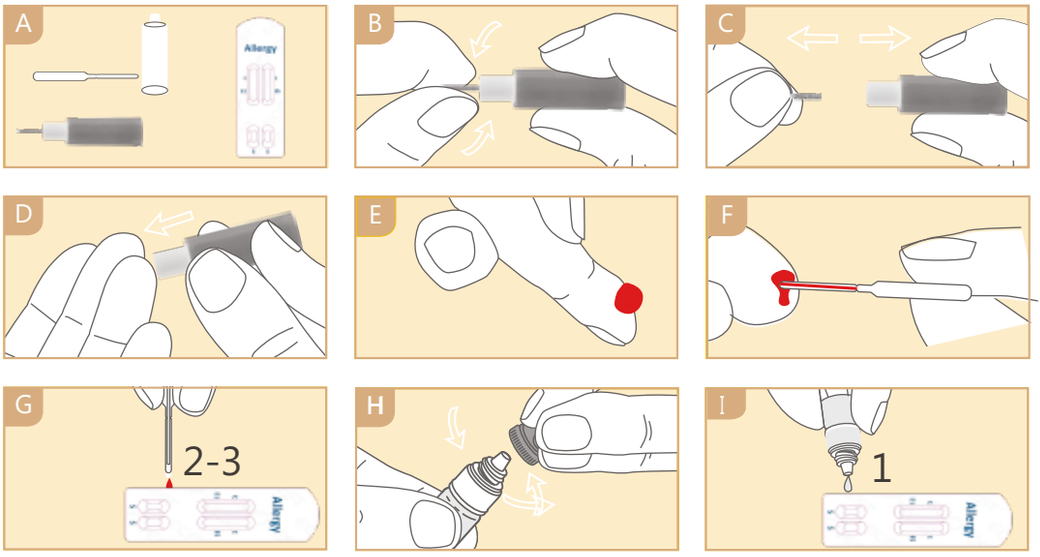
HTL-Strefa S.A.
ul. Adamowek 7
95035 Ozorkow
Poland
CE 0344

Twist off protective cap and then pull it straight out.

Press the Medlance® against the puncture site to activate the device. Dispose with your normal household waste.

Gently apply intermittent pressure near the puncture site to obtain the required blood volume.

TEST | PROCEDURE FOR USE



1) Wash your hands with soap and hot water, rinse with clean water and dry thoroughly with a clean towel.
2) Lay out the test components and take out the test cassette from the foil pouch. Discard the small desiccant bag - fig. A.
3) With care and without pulling, perform a 360° rotation of the lancing device's cap - fig. B
4) Now pull-off and discard the released cap - fig. C.
5) Press the lancet, on the side the cap was removed from, against your fingertip (the tip of the ring-finger recommended) - fig. D. The tip of the lancing device retracts automatically and safely after use and cannot be reused.
6) Keeping your hand pointing downwards, massage the tip of your finger until a large drop of blood forms - fig. E.
7) Collect blood using the plastic pipette. Keeping pression on the bulb, place the plastic pipette in contact with the drop of blood. Slowly release the bulb. Avoid moving the pipette away from the finger as much as you can, in order to prevent the formation of air bubbles - fig. F.
8) Add your blood sample to the first of the wells marked "S" - press the bulb of the pipette until 2-3 drops of blood are deposited - fig. G.
9) Repeat the operation "7" and "8" adding the blood sample in the second well "S".
11) Carefully twist-off the cap of the diluent vial (fig. H) and put 1 drop into both the 2 wells marked "S" - fig. I.
12) Wipe your finger with the antiseptic swab supplied.
13) Wait 15 minutes and read the result.

+2°C +30°C IVD

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	Consult instructions for use	IVD	In vitro diagnostics
	Use by date	REF	Catalog number
	Temperature limit		Manufacturer
CE	CE mark		Corrugated board
CE 0000	Certifying body number		Do not re-use
LOT	Batch code		