Vamber

CANINE T&S IgE TEST KIT
INSTRUCTION MANUAL

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INTENDED USE

CANINE T&S IgE TEST KIT is designed to determine the levels of Total IgE (T IgE) and Specifıc IgE (S IgE) against different allergens in canine serum or plasma.

KIT CONTENTS

Contents	Quantity
Solid Array Unit	2
Solution Unit	2
Substrate	2
Result Card	2
Locator	1
Color Scale	1
Instruction Manual	1
Pet Label	2

DESIGN AND PRINCIPLE

For one sample testing, one Solid Array Unit, one Solution Unit and one Substrate should be used together. The Solid Array Unit, which contains an array composed of location markers, anti–canine IgE antibody, and allergens on a membrane and a protective cap, is packaged in one aluminum foil bag with a desiccant.

The Solution Unit contains all the necessary reagents for forming enzyme linked complex of antibody–antigen reaction that are deposited separately in the different compartments of a plastic cartridge and sealed with a protective aluminum foil.

The Substrate is deposited in a small substrate bottle.

Briefly, pull open the Solution Unit and deposit the serum sample in the compartment 1 of the Solution Unit and mix well. After tearing aluminum foil bag, take the Solid Array Unit out and pull off the protective cap. Immobilized location markers, anti–canine IgE antibody, and allergenic substances can be observed as pink spot array on the membrane in the window of the Solid Array Unit.

Then insert the Solid Array Unit into the compartment 1 and have it absorb the solution in the compartment 1 for a few minutes. After the absorption, the pink dye will disappear from the membrane in the window, which indicates successful specifıc antibody–antigen reaction finished.

Then the Solid Array Unit will be transferred to the remaining compartments at timed intervals step by step. The bound canine IgE antibodies on the spot array will be labeled with enzyme in the compartment 3, which contains anti–canine IgE–enzyme conjugate. For a satisfactory result, wash steps are introduced. In the compartment 2, the unbound canine IgE antibodies and other substances in the serum sample will be removed. In compartment 4 , 5and 6, the unbound or excess enzyme conjugate will be adequately removed. At the end, pipette substrate in the substrate bottle, and slowly drop the substrate on the membrane at the window center to develop purple–blue spots if there were enzyme bound there.

To confirm the validation of the performance, purple–blue color of the location markers on the membrane should be visible above a certain level after finishing a successful testing process.

The location markers will be always visible on the membrane in the window of the Solid Array Unit after successful testing. By placing the transparent Locator on the window of the Solid Array Unit in correct position, the Total IgE and Specifıc IgE spots can be located.

By comparing the visible spots with the Color Scale provided, the signal strength can

be obtained and the levels representing the clinical interpretation can be recorded by hand in the Result Card provided according to the INTERPRETING TEST RESULTS

TEST PROCEDURE

Preparation before performing the test:

1. Bring one Solid Array Unit, one Solution Unit and one Substrate to room temperature (20℃–30℃) for 30 minutes before using.

2. Prepare a dispenser and two pipette tips proper for 200μL and 1000μL.

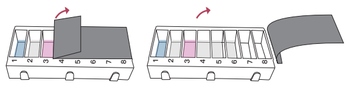
3. Stand upright the Solution Unit on a work bench and confirm that compartment numbers, from 1 to 8, can be seen in correct direction.

Stamp the Solution Unit slightly to make sure the solutions in the compartments,

from 1 to 6, turn back to the bottom.

Performing the test:

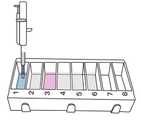
1. Hold tightly the solution cartridge with one hand and pull the protective foil along the horizontal direction carefully with another hand from the compartment 1 to 8 to remove whole the protective foil off.



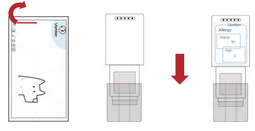
2. Obtain 200μL of the tested serum or plasma sample with a proper dispenser set with a pipette tip.

EDTA or heparin anticoagulant tubes are recommended for plasma sample collection.

3. Deposit the sample into the compartment 1. Then raise and lower dispenser plunger several times to achieve mixing



4. Tear open the aluminum foil bag, take the solid–state array unit out, and then remove the protective cap.



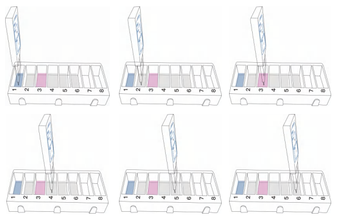
5. Insert the Solid Array Unit into the compartment 1 for 20 minutes.

6. Pick up the Solid Array Unit and insert it into the compartment 2 for 10 minutes.

7. Pick up the Solid Array Unit and insert it into the compartment 3 for 20 minutes.

8. Pick up the Solid Array Unit and insert it into the compartment 4 for 10 minutes.

9. Pick up the Solid Array Unit and insert it into the compartment 5 for 10 minutes.

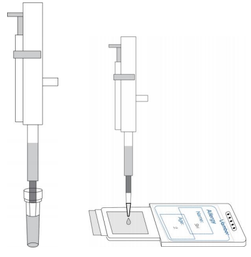


10. Pick up the Solid Array Unit and insert it into the compartment 6 for 10 minutes.

11. Pick up the Solid Array Unit and lay it flat on a work bench.

12. Pipette the Substrate from the substrate bottle, and add the Substrate on the membrane at window center.

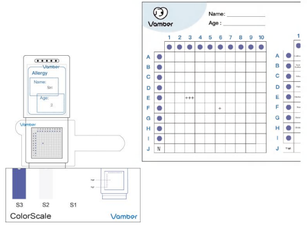
13. Wait for 15 minutes for developing purple blue color spots and record the result notation within 5 minutes.



14. Place the locator in the appropriate position on the Solid Array Unit window and locate the corresponding positions of the total IgE and specifnc IgE spots in the spot array.

15. Compare the visible spots with the Color Scale provided to determine the corres-ponding signal strength level.

16. Record the notation of the located visible spots representing Total IgE and Specifnc IgE in the Result Card provided by hand according to the illustration in the INTERPRETING TEST RESULTS tables.



Notes:

Use the Solid Array Unit as soon as possible when taking the protective cap off.

Do not touch the membrane or the pink spots immobilized on the membrane.

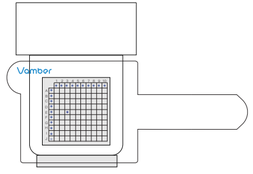
Hold the cartridge of the Solution Unit tightly when pulling, along horizontal direction, the protective foil off. Use different clean tips for transferring sample and Substrate.

It is not recommended to read the results 20 minutes after adding the substrate.

Find the location of various allergen substances on the array based on the Result Card.

If necessary, attach the provided Pet Labels for more than one sample testing.

INTERPRETING TEST RESULTS



Total IgE

Comparing with provided Color Scale, there are three conditions illustrated as the following table.

Interpretation	For Total IgE level	Notation
Abnormally low	Test spot≤ S2	AL
Normal	S2＜Test spot≤ S3	N
Abnormally High	S3＜Test spot	AH

The spot representing Total IgE level in serum sample is located on the far left and bottom.

Specific IgE

Comparing with provided Color Scale, there are four conditions illustrated as the following table.

Interpretation	For Total IgE level	Notation
Normal	Test spot≤ S1	–
Weak positive level	S1＜Test spot≤ S2	+
Positive level	S2＜Test spot≤ S3	++
High positive level	S3＜Test spot	+++

The Result Card lists the allergenic substances that may cause an increase in specifnc IgE levels and their locations in the spot array.

Invalid results

If spots of location markers do not develop color above S2, repeat the test.

QULITIY CONTROL

A procedural control spot is included in the test. It indicates a valid performance when a purple–blue color appears on the control spot （ the upper most spot on the Frosting Side of the Front End of the Key ） when finishing the whole process of the procedure. Control standards are not provided with this kit; however, it is recommended that positive and negative controls be involved as a good laboratory practice to confirm the test procedure and to verify proper testing performance.

STORAGE

1. Store the kit under normal refrigeration (2-8℃).

DO NOT FREEZE THE KIT.

2. The kit contains inactivated biological material. The kit must be handled and disposed of in accordance with local sanitary requirements.

LOT batch code

use by

manufacturer

contains suffcient for <n>tests

IVD in vitro diagnostic medical device

temperature limitation

REF catalogue number

consult instructions for use

EC REP authorized representative in the European Community

Do not reuse

Aoife Star International Limited 180 Temple Court, Northwood,Santry,Dublin 9

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