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 Specific IgE (S IgE) against different allergens in canine serum or plasma.

KIT CONTENTS

Contents	Quantity
Solid Array Unit with a protective cap and a desiccant packaged in an aluminum foil bag	2
Solution Unit	2
Substrate	2
Manual Interpretation package, containing Guide, Locator, and Color Scale	1
Result Card	2
Instruction Manual	1

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 are 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, open the Solution Unit and deposit the sample in the compartment 1 of the Solution Unit and mix well. Take the Solid Array Unit out and pull off the protective cap.

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 specific antibody-antigen reaction finished.

Then transfer the Solid Array Unit to the remaining compartments at timed intervals step by step. The bound canine IgE antibodies on the spot array will be labeled with enzyme through biotin-streptavidin reaction. The anti-canine IgE-biotin conjugate is deposited in compartment 3, and the streptavidin-enzyme conjugate is deposited in compartment 5.

For a satisfactory result, wash steps are introduced. In the compartment 2, the unbound canine IgE antibodies in the sample will be removed. In compartment 4 , the unbound anti-canine IgE-biotin conjugate will be removed. In the compartment 6, 7 and 8, the unbound streptavidin-enzyme conjugate will be adequately removed.

At the end, pipette Substrate in the substrate bottle, and add it 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.

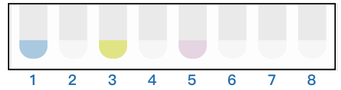
TEST PROCEDURE

Preparation before performing the test:

1. Bring one Solid Array Unit package, one Solution Unit and one Substrate to room temperature (20°C-30°C) for 30 minutes before using.

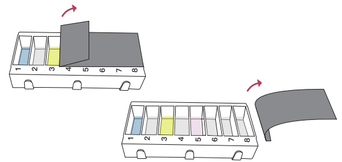
2. Prepare proper dispensers and pipette tips. 200μL and 1000μL are recommended.

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 all the reagents in the compartments, from 1 to 8, turn back to the bottom.



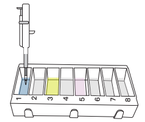
Performing the test:

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 150μL of the tested serum or plasma sample with a dispenser of 200μL. 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. Open the aluminum foil bag, and take the Solid Array Unit out. Write dog' s name and age on Solid Array Unit. Remove the protective cap.

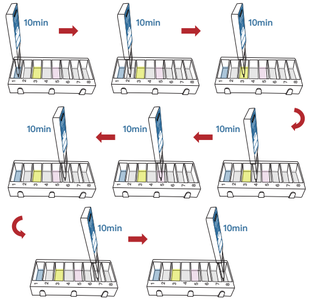
5. Insert the Solid Array Unit into the compartment 1, and let it stand there for 10 minutes.

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

7. Pick up the Solid Array Unit and insert it into the compartment 3, and let it stand there for 10 minutes.

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

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



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

11. Pick up the Solid Array Unit and insert it into the compartment 7, and let it stand there

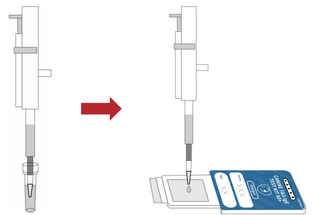
for 10 minutes.

12. Pick up the Solid Array Unit and insert it into the compartment 8, and let it stand there for 10 minutes.

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

14. Pipette the Substrate from the substrate bottle, and drop it slowly on the membrane at the window center.

15. Wait for 15 minutes for developing purple blue color spots and interpret the result within 5 minutes.



NOTES:

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

2. 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, and do not touch the membrane during the operation.

3. Hold the cartridge of the Solution Unit tightly when pulling, along horizontal direction, the protective foil off.

4. The tested sample should be clear. Whole blood, hemolysis or visible turbid sample is not proper for this test.

5. The freshly collected sample should be tested in time. If timely testing is not available, store the sample in refrigerator no more than 3 days.

6. Use different clean tips for transferring sample and Substrate.

7. The reagents in the compartments of the cartridge should disappear when it reaches the standing time.

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

9. If location markers on the membrane do not develop color when the whole operation finished, repeat the test.

10. Refer to the Result Card for the information of allergens and their positions on the protein array in the Solid Array Unit.

INTERPRETATION OF TEST RESULTS

There three methods for interpreting the test results.

Vamber AI System

You may enter the Vamber AI System via intelligent mobile phone and get the final test interpretation quickly and automatically. Briefly, enter the Vamber AI System and take photo of the protein array result developed in the Solid Array Unit. Then you can get the final interpretation in digital report form. You can also print the report though connecting general office equipments.

For detailed information, please refer to the Guide of Vamber AI System.

VI System

VI is an equipment that can obtain high quality image of the protein array result developed in the Solid Array Unit. Briefly, enter the Solid Array Unit into the equipment and obtain the final interpretation in digital form or paper form.

For detailed information, please refer to the Guide of VI System.

Manual Interpretation

In the Manual Interpretation package provided, there are Guide of Manual Interpretation,

Locator and Color Scale. Briefly, find the visible spot other than the location markers, and compare it with the Color Scale to obtain the signal intensity. Compare it with the Locator to obtain it' s position on the protein array, and record the results in the corresponding Result Card.

For detailed information, please refer to the Guide of Manual Interpretation

QULITIY CONTROL

The visible purple-blue location markers on the membrane indicate a qualified testing performance.

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 in 2°C-8°C.

DO NOT FREEZE THE KIT.

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

LOT	batch code
	manufacturer
IVD	in vitro diagnostic medical device
REF	catalogue number
EC REP	authorized representative in the European Community
Σ	contains sufficient for <n> tests
	temperature limitation
	consult instructions for use
	do not reuse
	keep dry; guard against damp
	keep away from heat
	recyclable

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

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Version 1.0