

One Step House Dust Mite RAPID TEST

Anigen Rapid HDM Test Kit

■ Explanation of the Test

House Dust Mites (HDM) have been well established as the most significant indoor sensitizing agents that are important in the induction of asthma, allergic rhinitis and atopic rhinitis around the world. *Dermatophagoides farinae* and *Dermatophagoides pteronyssinus* are the most significant allergens among the HDM.

[Intended Use] Anigen Rapid HDM Test Kit is a solid phase immunochromatographic assay for the rapid, quantitative detection of house dust mite in the dust of a bed mattress, carpet, sofa or kennel. This test is intended for the presumptive detection of house dust mite levels.

[Principle] Anigen Rapid HDM Test Kit has two pre-coated lines, “C” (Control line), “T” (HDM Test Line) on the surface of the kit. Both lines in the result window are not visible before applying any samples. The “Control Line” is used for procedural control, and should always appear if the test procedure is performed properly and the test reagents of the control line are working. A purple “T” line will be visible in the result window if there are house dust mites in the sample. If the house dust mite is not present in the sample, no color will appear in the “T” line.

When a specimen is added to the test, house dust mite in the specimen sample reacts with anti-house dust mite antibody that is conjugated with colloidal gold. As this mixture migrates along the length of the test kit by capillary action, the house dust mite and anti-house dust mite complex is captured by the another anti-house dust mite antibody immobilized in the test “T” line, and generate a colored line.

■ Materials Provided

- 1) Ten test kits individually foil pouched with a desiccant
- 2) Dust collection swabs (10)
- 3) Ten(10) Specimen tubes containing assay diluent buffer
- 4) Ten(10) Disposable droppers
- 5) One(1) Instruction for use

■ Precautions

- 1) For best results, strict adherence to these instructions is required.
- 2) Do not open or remove the test kit from their individually sealed pouches until immediately before their use
- 3) Do not reuse the test kit.
- 4) All reagents must be at room temperature before running the assay.
- 5) Do not use reagents beyond the stated expiration date marked on the package label.
- 6) The components in this kit have been quality control tested as standard batch unit. Do not mix components from different lot numbers.

■ Storage and Stability

The kit can be stored at room temperature (2 ~ 30°C) or refrigerated. The test kit is stable through the expiration date marked on the package label. DO NOT FREEZE. Do not store the test kit in direct sunlight.

■ Dust Collection and Preparation

- 1) **House dust in the bed mattress, carpet, sofa, kennel. or suspected materials may be used with this test.**

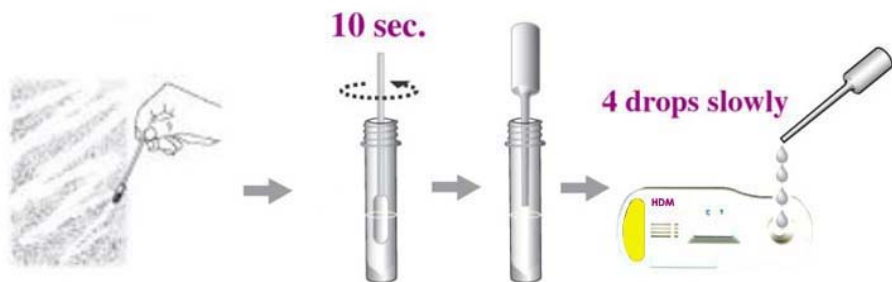


- 2) With the dust collection swab, collect the dust over a surface area of A4 paper size (30x24cm) in quick zigzag movement for 2 minutes.

■ Test Procedures

- 1) Allow all kit components and specimen to reach room temperature prior to testing.
- 2) Insert the swab into the specimen tube containing 300ul of assay diluent.
- 3) Mix the swab samples with assay diluent to extract well.
- 4) Remove the test device from the foil pouch, and place it on a flat and dry surface.
- 5) Add four (4) drops of the mixed sample into the sample hole using the dropper, drop by drop and slowly
- 6) As the test begins to work, you will see purple color move across the result window in the center of the test device. If the migration has not appeared after 1 minute, add one more drop of the mixed sample to the sample well.
- 7) Interpret test results at 10 minutes. Do not interpret after 10 minutes.

[Figure for test procedures]



■ Interpretation of the Test

Extremely high house dust mite level (Above 2 μ g of house dust mite per 1g of dust)

The strength of the T line is higher than that of the C line. This means a high house dust mite concentration is present which can be dangerous. The object should be cleaned or removed immediately



Very high house dust mite level (2 μ g of house dust mite per 1g of dust)

The strength of the T line is similar to the C line. This is indicative of a clinically relevant level. The object should be cleaned immediately.



Low house dust mite level (Below 2 μ g of house dust mite per 1g of dust)

The strength of the T line is lower than that of the C line. This means a slight amount of house dust mite. This level may occasionally cause the clinical signs.



Negative House Dust Mite level (No house dust mite)

The presence of only one purple color band on the C line indicates a negative result. This means no house dust mites are present in the sample.



Invalid

The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Repeat the test using a new test kit.




■ Limitation of the Test

- 1) This Test is for *in-vitro* diagnostic use only.
- 2) This test detects only the presence of HDM in the specimen.

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