One Step
Dengue Ab-IgG/IgM Rapid Test Kit
(Serum/Plasma/Whole Blood)

Package Insert

A rapid, one step test for the qualitative detection of antibodies IgG/IgM to Dengue in human serum, plasma and whole blood.

For in vitro diagnostic use only.

PRODUCT NAME

One Step Dengue Ab-IgG/IgM Rapid Test Kit (Serum/Plasma/Whole Blood)

INTENDED USE

The Dengue Ab-IgG/IgM Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to dengue virus in serum/plasma/whole blood to aid in the diagnosis of Dengue viral infection.

PRINCIPLE

For IgG/IgM Test : The test device consists of: 1) a burgundy colored conjugate pad containing dengue recombinant envelope antigens conjugated with Colloid gold (dengue conjugates), 2) a nitrocellulose membrane strip containing two test lines (C and T lines) and a control line (C line). When an adequate volume of test sample is dispensed into the sample well of the test cassette, the sample migrates by capillary action across the cassette. IgG/M anti-dengue, if present in the sample, will bind to the dengue conjugates. The immunocomplex is then captured by the reagent pre-coated on the T band, forming a burgundy colored T line, indicating a dengue IgG/M positive test result and suggesting a recent or repeat infection. Absence of any T lines suggests a negative result.

MAIN COMPONENTS

Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent pad, PVC board

STORAGE AND EXPIRY

Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw.

SAMPLE REQUIREMENTS

1. To collect serum/plasma/whole blood samples following regular clinical laboratory procedures.
2. A serum/plasma/whole blood sample must be collected in a clean and dry container. EDTA, sodium citrate, sodium oxalate, heparin can be used as the anticoagulants. Detect immediately after collecting blood. If blood coagulation occurs, serum samples are suggested to use.
3. Do not leave the samples at room temperature for prolonged periods. Serum and plasma samples can be kept below -20℃ for 2 years, 2-8℃ for 3 days. Whole blood sample cannot be frozen. Whole blood with anticoagulants should be stored at 2-8℃ for 24 hour. Samples should not be frozen and thawed repeatedly.
4. Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing.

TEST METHODS

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20℃-30℃) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity: 20%~90%, Temp: 10℃-50℃)

1. Take off the outer packing, put the cassette onto the desk with the sample window up.
2. Drop 1 drop (25μl) of serum/plasma/whole blood vertically into the sample hole of cassette. Add about 2 drops (100μl) of sample buffer into the sample hole of cassette.
3. Read the test result from the 10th minute onwards, the result is invalid over 20 minutes.

INTERPRETATION OF RESULTS

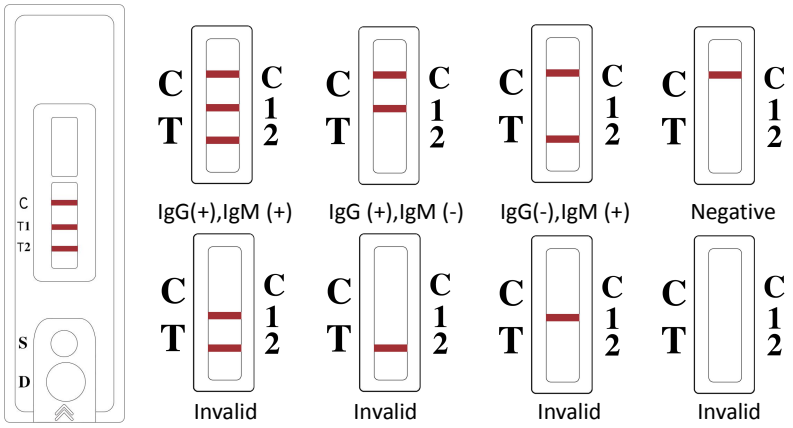
POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the IgG test region (T1), indicating the Dengue IgG positive.

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the IgM test region (T2), indicating the Dengue IgM positive.

POSITIVE: Three distinct red lines appear in the control region (C), the IgG test region (T1) and the IgM test region (T2), indicating the Dengue IgG and Dengue IgM positive.

NEGATIVE: One red line appears in the control region(C). No apparent red or pink line appears in the test region (T1 and T2).

INVALID: No red bands appear or control line fails to appear, indicating that the operator error or reagent failure.



LIMITATIONS

1. The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment.
2. Negative result may occur when detecting short-term infected samples or some second time infected samples, indicating that the specific antibodies of Dengue IgM does not exist or

the concentration is below the detection limit. Some patients may not produce enough antibodies to be detected in their body within 7 - 10 days, it may show negative results. For some patients, if the Dengue infection is still suspected, they need to do a new Dengue rapid test 3-4 days later.

3. It is common to have serological cross-reactions with Flaviviruses (ie, between dengue types 1, 2, 3, 4 and St. Louis encephalitis, West Nile, Japanese encephalitis, yellow fever virus, etc.).

4. Samples with high concentrations of Rheumatoid factor or Heterophilic antibodies may cause false positive results

5. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.

6. Cannot be used for screening the general population, but can only be used for the screening of patients with clinical symptoms or when there is suspicious exposure.

7. The continued existed or not existed of antibodies cannot be used to determine if the treatment is succeeded or not.

8. The best time for dengue testing is 6 ~ 14 days after the symptom of fever.

9. Do not use other kinds of quality control sample to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results.

PERFORMANCE CHARACTERISTICS

Dengue IgG Ab Reference Method

Method		ELISA		Total Results
IgG Rapid Test	Results	Positive	Negative	
	Positive	101	3	104
	Negative	4	192	196
Total Results		105	195	300

Sensitivity: 96.19% (101/105) Specificity: 98.46% (192/195) Accuracy: 97.67% (293/300)

Dengue IgM Ab Reference Method

Method		ELISA		Total Results
IgM Rapid Test	Results	Positive	Negative	
	Positive	103	3	106
	Negative	5	189	194
Total Results		108	192	300

Sensitivity: 95.37% (103/108) Specificity: 98.44% (189/192) Accuracy: 97.33% (292/300)

PRECAUTIONS

1. For IN VITRO diagnose only.

2. Do not use after the expiration date.

3. The test result is invalid over 20 minutes.

4. The strength of the quality control line doesn't indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.

5. All samples and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use.

6. Do not use other kinds of quality control sample to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results.

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