Humasis

Dengue Combo Test

Please read the instructions carefully before use!

IVD For professional use

[INTENDED USE]

Humasis Dengue Combo Test is an in vitro diagnostic test based on immunochromatographic assay. It is designed for qualitative detection of Dengue NS1 antigen and IgG/IgM antibody in whole blood and plasma/serum.

[SUMMARY AND EXPLANATION]

Dengue is one of the worldwide diseases known as a mosquito (Aedes aegypti)-borne infectious disease. The incidence of dengue fever has increased dramatically over the last 50 years, with around 50~100 million people infected yearly. Dengue is currently endemic in more than 110 countries. It is accompanied by the symptom such as high sudden-onset fever, headache (typically behind the eyes), muscle and joint pains, and a rash and etc. There are four strains of the virus, which are called serotypes, and these are referred to as DENV-1, DENV-2, DENV-3 and DENV4. All four serotypes can cause the full spectrum of disease. Infection with one serotype is believed to produce lifelong immunity to that serotype but only short term protection against the others.

The severe complications on secondary infection seen to occur particularly if someone previously exposed to serotype DENV-1 then contracts serotype DENV-2 or serotype DENV-3, or if someone previously exposed to type DENV-3 then acquires DENV-2.

[PRINCIPLE OF THE TEST]

Humasis Dengue Combo Test is an in vitro immunochromatographic, one step assay designed to detect both dengue virus NS1 antigen and differential IgG/IgM antibodies to dengue virus in human serum, plasma or whole blood. Humasis Dengue Combo rapid test contains two test devices (left side; Dengue NS1 Ag Test, right side; Dengue IgG/IgM Test). The Dengue NS1 Ag rapid test in the left side is one step assay designed for the qualitative determination of Dengue NS1 antigen in human blood for the diagnosis of early acute dengue infection. The Dengue IgG/IgM rapid test is one step assay designed for the qualitative and differential detection of IgG and IgM antibodies to dengue virus in human blood, plasma and serum. The Dengue IgG/IgM rapid test is intended for professional use to aid in the presumptive diagnosis between primary and secondary dengue infection.

[CONTENTS]

Humasis Dengue Combo Test kit contains the following items:

1. Humasis Dengue Combo test
2. Buffer for Dengue IgG/IgM test
3. 10uL capillary pipette for Dengue IgG/IgM test
4. Disposable dropper for Dengue NS1 Antigen test
5. Instruction for use

[STORAGE AND SHELF-LIFE]

1. Store the test device packaged in a sealed foil pouch at 1 to 30˚C(34~86˚F). Do not freeze.
2. Shelf-life : 24 months from manufacturing date.

[PRECAUTIONS]

1. For in vitro dignostic use only.
2. Do not use the test device beyond the expiration date.
3. Do not use the test device if the pouch is damaged or the seal is broken.
4. The test result should be used in conjunction with other clinical information such as clinical signs and symptoms and other test results to diagnose Dengue virus.
5. Specimen Handling and Storage
   1) Test the whole blood specimen within an hour after sampling.
   2) Handle all specimens as potentially infectious.
   3) Specimens with high level of hemolyic should be avoided as it can give inaccurate result.
   4) If the specimen is kept in the fridge before, it should be left in room temperature for fifteen minutes before testing it.
6. Keep it sealed until usage, and once opened use it quickly.
7. Do not re-use the device that has already been used.

[TEST METHODS]

Specimen collection, storage and preparation

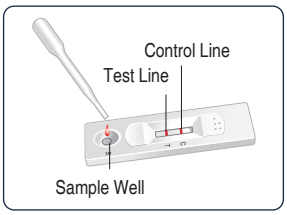
1. Whole blood
   1) Collect venipuncture whole blood in a tube with anticoagulant (heparin, EDTA or socium citrate).
   2) The collected specimen should be used immediately after collection, otherwise should be refrigerated at 2-8˚C.
   3) Collected sample can be stored at 2-8˚C up to 3 days, and refrigerated sample should be left in room temperature (15-30˚C) for 15-30 ,minutes prior to testing.
   4) Collected samples stored longer than 3 days may provide inaccurate test results.
2. Plasma
   1) Use tube containing EDTA, heparin or sodium citrate to collect venipuncture whole blood. Separate plasma by centrifugation.
   2) If plasma specimens are not immediately tested, they should be stored at 2-8˚C up to 2 weeks. For storage longer than 2 weeks, specimens should be frozen and stored at below -20˚C.
3. Serum
   1) Collect venipuncture whole blood in a tube containing NO anticoagulant.
   2) Leave the sample in room temperature for 30 minutes for it to clot, and centrifuge to separate serum.
   3) If specimens are not immediately tested, they should be stored at 2-8˚C and used within 2 weeks. For storage longer than 2 weeks, specimens should be frozen and stored at below -20˚C.

Test Preparation

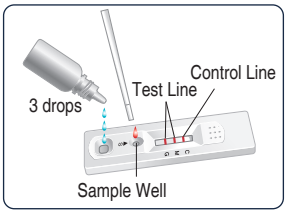
1. Pull out the specimen and device, and leave it on room temperature(15-30˚C) for 15-30 minutes before the test and let them reach the room temperature prior to testing.
2. If there is precipitate in the plasma or serum samples, it may affect the results, so centrifuge the sample again before testing.

Test procedure

1. Dengue NS1 Antigen Test
   1) Open the sealed pouch and take out the test device and put it on a level surface.
   2) Take 100uL (3 drops) of specimen and drop the specimen in sample insertion hole.
   3) Wait for 15-20 minutes and then read the results. Do not interpret the test results after 20 minutes.



2. Dengue IgG/IgM Test
   1) Open the sealed pouch and take out the test device and put it on a level surface.
   2) Take 10uL of specimen and drop the specimen in sample insertion hole.
   3) Add 3 drops of assay buffer (90-120uL) in buffer hole.
   4) Wait for 15-20 minutes and then read the results. Do not interpret the test results after 20 minutes.



[INTERPRETATION OF RESULTS]

Dengue NS1 Antigen test

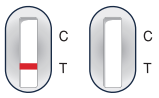
1. Negative

A colored band is visible only in the control region(C).

2. Positive

Two colored band are visible in the test region(T) and control region(C).

3. Invalid



If there is no color line in the control region(C), the result is invalid. This is due to deterioration of the test device or improper test procedure. Repeat the test with a new test kit.

Dengue IgG/IgM test

1. Negative

A colored line (C) is only visible on the test device. If dengue infection is highly suspected, retest within 3~5 days.

2. Positive

1) IgG Positive :

Two colored bands are visible in the Test region (G) and Control region (C). This is indicative of secondary or past dengue infection.

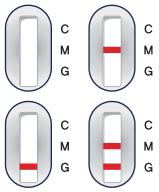
2) IgM Positive :

Two colored bands are visible in the Test region (M) and Control region (C). This is indicative of primary dengue infection.

3) IgG and IgM Positive :

Three colored bands are visible in the Test regions (G and M) and Control region (C). This is indicative of late primary or secondary dengue infection.

3. Invalid



If there is no color line in Control region (C), the result is invalid. This is due to deterioration of the test device or improper test procedure. Repeat the test with a new test device.

[QUALITY CONTROL]

The visible control line indicated that all reagents in the test device are working properly. The absence of the control line may indiate that insufficient sample added or the test device is inactivated.

[LIMITATIONS OF THE TEST]

1. A negative test result can occur if the quantity of Dengue NS1 antigen present in the sample is below the limit of detection of the assay, or the antigens that are detected are not present during the stage of disease when a sample is collected.
2. This test can provide fast and easy way to get a result but do not completely exclude the possibility of a false positive or a false negative result caused by various factors. Therefore, test result must be evaluated in conjunction with other clinical data available to the physician.
3. Most blood samples migrate within the running time of the test, however, in a few fresh samples and especially in stored samples, the background clearance may be delayed for 10-15 minutes longer.
4. In early infections and some secondary infections, detectable levels of IgM antibodies may be low. Some patients may not produce detectable levels of antibody within the first 7 to 10 days after infection. When symptoms persist, patients should be re-tested after 3-4 days.
5. Serological cross-reactivity across the Flavivirus group (Dengue, Japanese Encephalitis, West Nile and Yellow fever) commonly occurs.

[PERFORMANCE CHARACTERISTICS]

1. Dengue NS1 Antigen Test

NS1		RT-PCR		Total
		Positive	Negative	
Humasis Dengue NS1 Antigen Test	Positive	78	1	79
	Negative	22	160	182
Total		100	161	261

- Clinical sensitivity : 78% (78/100) (95% CI : 68.61% - 85.67%)
- Clinical specificity : 99.38% (160/161) (95% CI : 96.59% - 99.98%)

1. Clinical performance

1) Dengue IgG

IgG		ELISA		Total
		Positive	Negative	
Humasis Dengue IgG/IgM Antigen Test	Positive	92	19	111
	Negative	8	142	150
Total		100	161	261

- Clinical sensitivity : 92% (92/100) (95% CI : 84.84% - 96.48%)
- Clinical specificity : 88.2% (142/161) (95% CI : 82.19% - 92.74%)

2) Dengue IgM

IgM		ELISA		Total
		Positive	Negative	
Humasis Dengue IgG/IgM Antigen Test	Positive	77	6	83
	Negative	23	155	178
Total		100	161	261

- Clinical sensitivity : 77% (77/100) (95% CI : 67.51% - 84.83%)
- Clinical specificity : 96.27%(155/161) (95% CI : 92.07% - 98.62%)

[REFERENCES]

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: Manufacturer	: Do not reuse	: Consult instructions for use
REF : Catalogue number	LOT : Lot number	IVD : *In vitro* diagnostic medical device
: Temperature limit	: Use by	: Contains sufficient for <n> tests
: Keep away from sunlight	: Keep dry	: Do not use if package is damaged
CE : This product fulfills the requirements for Directive 98/79/EC on *in vitro* diagnostic medical devices		EC REP : Authorized representative

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Rev. 05/2023-01-06
SA / PI-2044HU00E