ACCUCARE®

ONE STEP DENGUE IgG/IgM RAPID TEST

(Serum/Plasma)

One step rapid Card Test for detection of IgG and IgM antibodies against dengue virus in human Serum/Plasma

For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
10 Tests	DENC 10
25 Tests	DENC 25

CLINICAL SIGNIFICANCE

Dengue virus, a virus belonging to the Flavavirus group of viruses, is one of the most significant mosquito-borne diseases in the world in terms of morbidity and mortality. There are four known serotypes of dengue. Symptoms of dengue fever include high fever, headache, muscle pain and skin rash. The complications often associated with this infection are dengue hemorrhagic fever or dengue shock syndrome. The immune response to this virus includes the production of IgM antibodies by the 5th day of symptoms, which remain in the circulatory system for 30-60 days. IgG antibodies appear by the 14th day of infection and persist for life. A secondary infection often results in high fever and, in many cases, initiates hemorrhagic events and circulatory failure. A secondary infection also induces an IgM antibody response after 20 days of infection and IgG antibodies rise within 1-2 days after the onset of symptoms.

The ACCUCARE® DENGUE IgG/IgM RAPID TEST is a qualitative test for the detection of IgG and IgM antibodies to dengue virus in human serum or plasma. The test provides a differential detection of anti-dengue IgG and anti-dengue-IgM antibodies and can be used for the presumptive distinction between a primary and secondary dengue infection. This test is able to detect all 4 Dengue serotypes.

PRINCIPLE

ACCUCARE® ONE STEP DENGUE IgG/IgM RAPID TEST is a qualitative immunoassay for the detection of Dengue antibodies in human serum or plasma. The nitrocellulose membrane is pre-coated with Anti-human IgG and Anti-human IgM at Test region and separate control to assure assay flow and test performance. The recombinant antigen for Dengue IgG & IgM conjugated with colloidal gold particles and control antibodies. When specimen is added in sample well followed by assay buffer which will react with the recombinant antigen and this antigen-antibody complex move upward on the membrane via capillary action. If the specimen contains IgG antibodies to Dengue than pinkish purple color line will appear at pre-coated Anti-human IgG test region. If the specimen contains IgM antibodies to Dengue than pinkish purple color line will appear at pre-coated Anti-human IgM test region. The intensity of the test lines will vary depending upon the amount of antibodies present in the sample. The appearance of pinkish purple line in the test region should be considered as positive result. Test contains internal control (C line) which should exhibit a pinkish purple line of the immunocomplex of the control antibodies.

CONTENTS

Test Device
Assay Buffer
Instruction for Use (IFU)
Disposable (Dropper) 5 µl sampling device
Desiccant

STORAGE & STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed aluminum pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test device/strip, if the pouch is damaged or seal is broken.

PRECAUTIONS

1. For professional *In-vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens and tested device/strip.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Read the Instruction for use carefully before performing the test.

LIMITATIONS

1. ACCUCARE® ONE STEP DENGUE IgG/IgM RAPID TEST detects the presence of Dengue IgG & IgM antibodies and should not be used as the sole criteria for the diagnosis of Dengue virus infection.
2. Serological cross-reactivity across the Flavivirus group is common.
3. As with all diagnostic tests, all results must be correlated with other clinical findings. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of an early infection of Dengue virus.
4. This is only a screening test. Therefore, isolation of virus, antigen detection in fixed tissues, RT-PCR and more specific alternative diagnosis method must be used in order to obtain a confirmation of dengue virus infection.

SPECIMEN COLLECTION & PREPARATION

1. The ACCUCARE® ONE STEP DENGUE IgG/IgM RAPID TEST can be performed using either serum or plasma.
2. Separate the serum or plasma from whole blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, it should be packed in compliance with federal regulations for transportation of etiologic agents.

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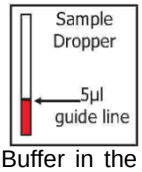
ONE STEP DENGUE IgG/IgM RAPID TEST

(Serum/Plasma)

PROCEDURE

1. Allow test device, Assay Buffer and specimen equilibrates to room temperature (15-30°C) prior to testing.
2. Remove the test device from the aluminum foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
3. Place the test device on a clean and flat surface. Carefully dispense 1 drop (5 µl) of Serum/Plasma in the sample well "S" using the dropper provided.
   - Take a sample dropper, and while gently squeezing the tube, immerse the open end in the blood drop and then gently release the pressure to draw blood into the sample dropper upto the mark line.

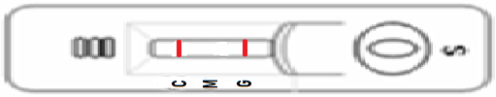


4. After that add 2 drop (appx. 60 µl) of Assay Buffer in the sample well "S".
5. Allow reaction to occur and read the results at 15 minutes. Do not interpret the results after 20 minutes.

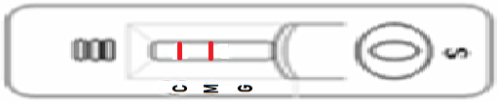
INTERPRETATION OF RESULTS

1. POSITIVE

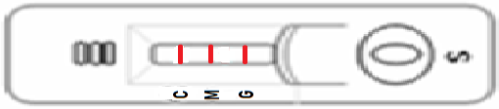
- If two color lines appear, one at control region 'C' and other at test region 'G', the specimen is positive for Dengue IgG.



- If two color lines appear, one at control region 'C' and other at test region 'M', the specimen is positive for Dengue IgM.

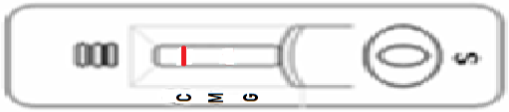


- If three color line appear, one at control line 'C', one at test region 'G' and one at test line 'M', the specimen is positive for both Dengue IgG & IgM.



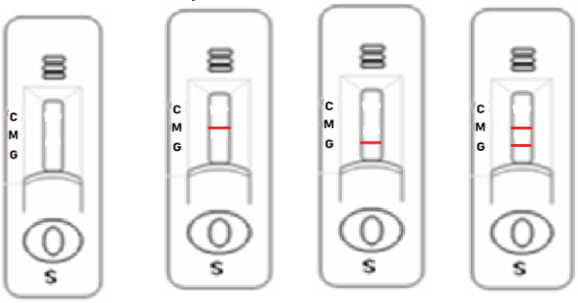
2. NEGATIVE

If only one color band appear at control line 'C' as the specimen is Negative for Dengue IgG & IgM infection.



3. INVALID

If no color band appear, at control line 'C' within the stipulated time th result is invalid. Repeat the test using a fresh Test Device.



PERFORMANCE CHARACTERISTICS

The ACCUCARE® ONE STEP DENGUE IgG/IgM RAPID TEST has been evaluated with positive and negative samples confirmed by ELISA examination.

1) Dengue IgG Test :

Specimen	Accucare® One Step Dengue Duo		
Reference test	**Positive**	**Negative**	**Total**
Positive	36	1	37
Negative	2	287	289
Total	38	288	326

Sensitivity : 97.30 % **Specificity : 99.30 %**

2) Dengue IgM Test :

Specimen	Accucare® One Step Dengue Duo		
Reference test	**Positive**	**Negative**	**Total**
Positive	31	1	32
Negative	3	279	282
Total	34	280	314

Sensitivity : 96.90 % **Specificity : 98.90 %**

BIBLIOGRAPHY

1. Sabin, AB and Schlesinger RW. Production of immunity to Dengue with virus modified by propagation in mice: Science (1945), 101:640.
2. Innis, BL, Nisalak, A., et.al. An enzyme-linked immunosorbent assay to characterize dengue infections where dengue and Japanese encephalitis co-circulate. Am. J. Trap. Med. Hygiene (1989), 40:418-427.
3. CDC/NIH Guidelines. Biosafety in Microbiological and Biomedical Laboratories. 2nd Edition, 1988.
4. Siti-Strong. Diagnosis, prevention, and trea®ent of tropical disease, 7th ed., Philadelphia, the Ablakiston Company.

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	*Catalog Number*		*Date of Manufacturing*
	Store between		Use By or Expiration Date
	Manufacturer		Do not reuse
IVD	For *in vitro* Diagnostic use only		Keep Dry
Σ	Tests per Kit		Do Not Use if Damaged

ISO 13485:2016

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