

Instructions for Use

Version: 1.0.2

Revision date: 17-Jun-24

Dengue Virus IgG/IgM and NS1 Antigen Rapid Test Kit**Catalog No.:** abx092384**Size:** 100 tests / 400 tests / 1920 tests/ 10000 tests**Storage:** Store all reagents at 2-30°C. Keep dry.**Application:** For qualitative detection of Dengue Virus IgG/IgM and NS1 Antigen in Human serum, plasma, and whole blood samples.**Sensitivity:** 97.3 % (IgG), 96.9 % (IgM), 100 % (NS1 Antigen)**Specificity:** 99.3 % (IgG), 98.9 % (IgM), 99 % (NS1 Antigen)**Introduction and assay principle**

Abbexa's Dengue Virus IgG/IgM and NS1 Antigen Rapid Test Kit is based on the gold immunochromatography assay (GICA) principle. Separate test strips are included in each cassette for Dengue Virus IgG/IgM and NS1 Antigen testing.

Dengue Virus IgG/IgM: Any anti-Dengue Virus IgG/IgM antibodies present in the samples combines with colloidal gold particle-labelled recombinant Dengue antigen in the test well, and the complex travels to the test area. The test line contains anti-IgG and IgM antibodies. When the concentration of Dengue Virus IgG/IgM antibodies in the sample solution is higher than the detection limit, there is a color change and a line appears at the G/M detection line respectively, indicating a positive result.

Dengue NS1 Antigen: Any Dengue Virus NS1 Antigen present in the samples combines with colloidal gold particle-labelled anti-NS1 antibodies in the test well, and the complex travels to the test area. The test line contains anti-NS1 antibodies. When the concentration of Dengue Virus NS1 Antigen in the sample solution is higher than the detection limit, there is a color change and a line appears at the T detection line, indicating a positive result. This test is sensitive to all 4 NS1 Antigen serotypes (DEN1, 2, 3, and 4).

Kit Components

- Test cassettes: 100 (100 tests)
- Disposable pipettes: 100
- Sample diluent: 1 vial

Material Required But Not Provided

- High-precision pipette and sterile pipette tips
- Timer
- Lancet

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Sample preparation

- **Serum:** Samples should be collected by conventional methods, using no anticoagulants. Allow the blood to clot, then separate the serum by centrifugation. Samples may be stored at 2-8 °C for short-term storage (up to 5 days) or -20 °C for long-term storage.
- **Plasma:** Samples should be collected by conventional methods, using EDTA, Citrate, or Heparin as anticoagulant. Separate the plasma by centrifugation.
- **Whole Blood:** Samples should be collected by conventional methods, using EDTA, Citrate, or Heparin as anticoagulant. Avoid using hemolyzed samples. Test samples immediately, or store at 2-8 °C for short-term storage (up to 24 hours).

Assay procedure

Dengue Virus IgG/IgM

1. Take a test cassette and lay it flat on a clean table. Slowly and vertically add approximately 5 µl of sample to the sample well on the test cassette, then immediately add 3 drops (approximately 90-120 µl) of Sample Diluent to the well. Avoid foaming.
2. Leave at room temperature for 20-25 minutes, then analyze the result. Results read outside of the 20-25 minute time period are invalid. Negative result should be confirmed after 25 minutes.

Dengue Virus NS1 Antigen

1. Take a test cassette and lay it flat on a clean table. Using the provided disposable pipette, slowly and vertically add 2 drops of sample (approximately 60-70 µl) of sample to the sample well on the test cassette, then immediately add 1 drop (approximately 30-40 µl) of Sample Diluent to the well. Avoid Foaming.
2. Leave at room temperature for 20 minutes, then analyze the result. Results read outside of the 20-25 minute time period are invalid. Negative results should be confirmed after 25 minutes.

Results analysis

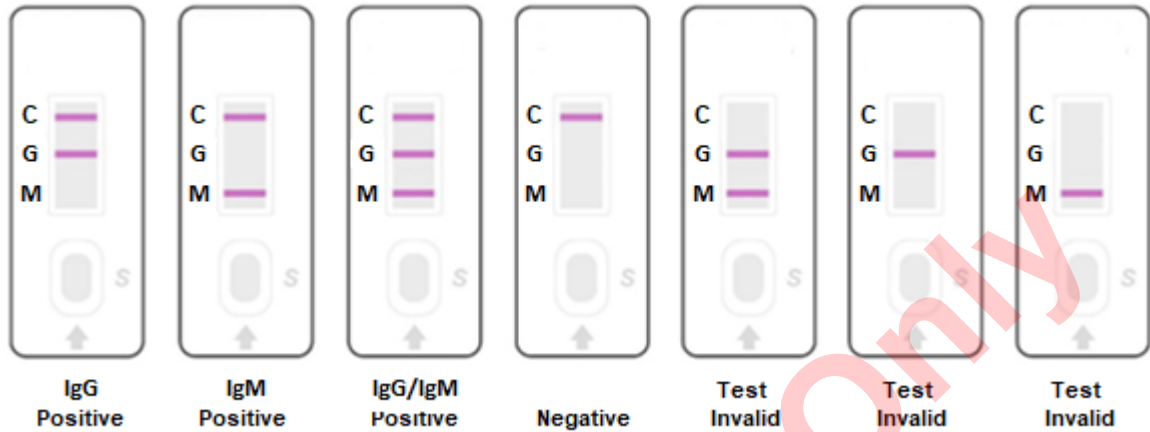
Dengue Virus IgG/IgM results:

- **Dengue IgG positive result:** A colored line is observed in both the control (C) section and the IgG test (G) section.
- **Dengue IgM positive result:** A colored line is observed in both the control (C) section and the IgM test (M) section.
- **IgG/IgM double positive result:** A colored line is observed in the control (C) section, the IgG test (G) section, and the IgM test (M) section.

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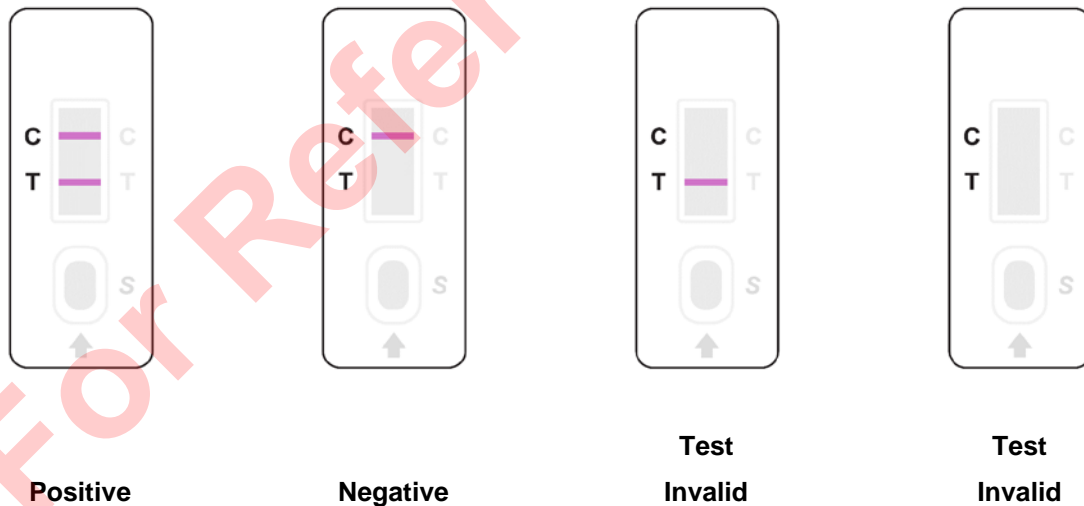
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- **Negative result:** A colored line is observed in the control (C) section only.
- **Invalid result:** No colored line is observed in the control (C) section.



Dengue NS1 Antigen results:

- Positive result: A colored line is observed in both the control (C) section and the test (T) section.
- Negative result: A colored line is observed in the control (C) section only.
- Invalid Result: No colored line is observed in the control (C) section.



Notes

1. The test cassettes should be brought to room temperature before use.
2. After opening the aluminum foil, use the test cassette as soon as possible.
3. Samples should be clear with no visible particles, turbidity or bacterial pollution.

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4. Do not mix or re-use the disposable pipettes to avoid cross-contamination.
5. Do not use water, PBS, or similar solutions as a negative control.
6. Avoid touching the cassette membrane through the sample well or test result window.
7. This kit is for qualitative detection of Dengue Virus IgG/IgM and NS1 Antigen in Human serum, plasma, and whole blood samples. For other sample types, a preliminary experiment is recommended to determine compatibility with this kit. Positive samples can be tested with another method (e.g. HPLC, LC/MS) for quantitative results.
8. The limit of detection for Dengue Virus NS1 antigen is 0.25 ng/ml
9. Cross-reactivity: No false positive IgG/IgM results were observed when testing 1-13 samples from HAV, HBV, HCV, HEV, HIV, *H.pylori*, CMV, Chagas, Chikunguna, hCG, Rubella, *T.gondii*, Typhi, *T.pallidum*, ANA, GAMA, or RF (up to 8400 IU/ml).
10. Cross Reactivity: No false positive Dengue NS1 Antigen results were observed when testing 6-10 positive samples from HAV, HBV, HCV, HIV, *H.pylori*, Malaria, Chikungunya, Zika, Leishmania, Typhoid, CMV, HSV-1, HSV-2, hCG, Rubella, *T.gondii*, TB, Typhoid, ANA, HAMA, or RF (up to 8400 IU/ml).

11. List of potentially interfering substances (IgG/IgM):

Albumin	60 g/L	Bilirubin	20 mg/dl
Acetaminophen	20 mg/dl	Creatinine	442 µmol/L
Atropine	20 mg/dl	Sodium citrate	3.80 %
Aspirin	20 mg/dl	Caffeine	20 mg/dl
Ascorbic acid	20 mg/dl	EDTA	3.4 µmol/L
Hemoglobin	2 g/L	IgG	1000 mg/dl
Heparin	3000 U/L	Glucose	55 mmol/L
Salicylic acid	4.34 mmol/L		

12. List of potentially interfering substances (Dengue NS1 Antigen):

Albumin	60 d/L	Bilirubin	20 mg/dl
Creatinine	442 µmol/L	EDTA	3.4 µmol/L
Glucose	55 mmol/L	Heparin	3000 U/L
Salicylic acid	4.34 mmol/L	Sodium citrate	3.80 %
IgG	1000 mg/dl		

13. This kit is for research use only and the results are for reference only. It is recommended to use this kit in conjunction with another detection method.
14. All waste should be disposed of appropriately. Please note that you may need to follow special waste disposal procedures for infectious samples. Please check local disposal regulations.