Dengue NS1 Antigen Rapid
(A rapid and sensitive test for the qualitative detection of NS1 antigen to the dengue virus in human serum, plasma or whole blood)

INTENDED USE
The Reszon Diagnostics Dengue NS1 Antigen Rapid Test device is a qualitative test for the detection of NS1 Antigen to dengue virus in human serum, plasma, or whole blood. This test is for In-Vitro Diagnostic use only. The results obtained should not be the sole determinant for clinical decision.

SUMMARY AND EXPLANATION OF THE TEST
Dengue virus, a virus belonging to the Flavivirus group of viruses, is one of the most significant mosquito-borne diseases in the world in terms of morbidity and mortality. It is transmitted principally by the mosquito types Aedes aegypti and Aedes albopictus. The virus is found commonly throughout the tropic and subtropic regions of the world. There are four known serotypes of Dengue. Symptoms of Dengue fever include high fever, headache, muscle pain and skin rash. Occasionally it develops into a potentially lethal complication called severe dengue (dengue hemorrhagic fever or dengue shock syndrome). There is no specific treatment for Dengue/ severe Dengue, but early detection and access to proper medical care lowers fatality rates to below 1%

Dengue NS1 (nonstructural protein 1) is a highly conserved glycoprotein that is circulating in patient sera during the early clinical phase of the disease. NS1 antigen is found in patient samples from the first day up to 9 days after onset of fever. The detection of NS1 antigen provides a tool for the early diagnosis of Dengue infection before serological antibodies are detectable.

The Reszon Diagnostics Dengue NS1 Antigen Rapid Test provides an excellent methodology for specifically detecting Dengue NS1 antigen. Additional advantages include:
- fast, simple and reliable
- simple to perform and no additional sample preparation required
- no special equipment is needed
- results are easy to interpret
- minimal sample volume used

PRINCIPLE OF THE TEST
The Dengue NS1 Antigen Rapid Test device is a qualitative test for the detection of NS1 antigen to dengue virus in human serum or plasma. Only serum, plasma, or whole blood samples may be used with this test.

First a specimen is dispensed into the sample well; the Gold antibody conjugate will bind to Dengue antigen in the specimen sample which in turn will bind with Anti-Dengue NS1 coated on the membrane. As the reagent moves across the membrane, the Dengue NS1 antibody on the membrane will bind to the antibody-antigen complex causing pale or dark pink-purple line to form at the test line region of the test membrane. The intensity of the lines will vary depending upon the amount of antigen present in the sample. The appearance of pink-purple line in the test region should be considered as positive result. A purplish-pink control line will always appear in the control region if the test has been performed properly.

REAGENTS AND MATERIALS SUPPLIED
1. Dengue NS1 Antigen Rapid cassette (25 pieces packed in individually sealed aluminium pouch)
2. One copy of instruction manual (product insert)

MATERIALS REQUIRED BUT NOT SUPPLIED
1. Lancets, sample collection capillaries and disinfecting sterile wipes
2. Sample dispensing apparatus such as pipette capable of delivering 20-100 µl sample volume
3. Clock or timer

STORAGE AND STABILITY
Store at 4-30 °C, do not freeze. Keep the test device sealed until used. Keep away from direct sunlight, moisture and heat.

The test is stable through the expiration date printed on the sealed pouch when stored between 4-30 °C. Do not use any test beyond its printed expiration date.

WARNINGS AND PRECAUTIONS
1. For professional In-Vitro Diagnostic use only.
2. This product insert must be strictly followed in order to produce accurate test results.
3. Keep the test device sealed until use. Once the device pouch has been opened, the test device must be used immediately.
4. All test devices and specimens must be at room temperature (15-30°C) before running the assay.
5. Do not use device if the sealed pouch is visibly damaged.
6. Do not use the kit contents beyond the expiration date.
7. Handle all specimens as being potentially infectious. Dispose all materials that come in contact with the specimen as infectious waste.
8. Wipe any spills of sera or plasma promptly with 1% sodium hypochlorite solution.
9. Do not reuse test device.

LIMITATION OF THE TEST
1. This product is designed for use with human serum, plasma or whole blood only.
2. This test detects the presence of Dengue NS1 antigens in human serum/plasma and should not be used as the sole criterion for the diagnosis of a Dengue Fever infection.
3. Strict adherence to the test procedure is required. Optimal assay performance requires strict adherence to the assay procedure described in this Instruction sheet and any deviations from the procedure may lead to aberrant results.
4. Do not re-use negative devices.
5. The test is a qualitative assay and cannot be used to monitor therapy or to estimate the titer of the infection.
6. The results obtained should only be interpreted in conjunction with other diagnostic results and clinical information. If the test result is negative and Dengue Fever infection suspicion still exists, additional follow-up testing using other clinical methods is recommended.
7. A negative result at any time does not preclude the possibility of an early infection.
8. A final diagnosis should be based on these test results in conjunction with other clinical and laboratory findings.

WARRANTY AND LIMITED LIABILITY
The performance characteristics stated were obtained by using the assay procedure in this insert. Failure to follow the assay procedure may derive inaccurate results. In such event, the manufacturer disclaims all warranties expressed, implied or statutory, including the implied warranty of merchantability and the fitness for use. The manufacturer will not be liable for any damage caused by misuse, improper handling and storage, non-compliance with warnings and procedures, damage caused by events occurring after the product is released, failure to ensure the product is in proper condition before use, or any warranty given by independent distributor.

SAMPLE COLLECTION AND PREPARATION
1. Handle all specimens as capable of transmitting infectious diseases. Dispose of all materials that come in contact with the specimen as infectious waste.
2. Specimens should be collected aseptically by fingerstick or venipuncture according to standard methods. The use of grossly lipemic or turbid samples should be avoided.
3. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used. Whole blood samples should be used immediately, if possible.
4. 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.
5. 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.
**ASSAY PROCEDURE**

1. Bring test cassette, specimen and/or buffer to room temperature (15-30°C) before testing.
2. Gently tear open the pouch and remove the test cassette, use it as soon as possible. Lay the test device on a clean, flat work surface. Label the test cassette with the sample name.
3. Pipette 70 µl of serum, plasma, or whole blood into the sample well.
4. Wait for the pink-purplish line(s) to appear. The test result should be read at between 15 and 20 minutes. Result may be read up to 30 minutes.

**NOTE:** Do not interpret the result after 30 minutes.

**QUALITY CONTROL**

1. Positive and negative standard controls are not included and are optional. However, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.
2. A procedural control is included in the test. If the control line at position C does not become visible, the test is invalid and the test must be repeated. Positive samples will have additional coloured band at position T.

**INTERPRETATION OF RESULTS**

The background of the strip should be pinkish-white, not red, prior to confirming a negative result. Positive results may appear as early as 5 minutes. Negative results must be confirmed after 15 minutes, or at 30 minutes. Results should not be read after 30 minutes.

1. **Positive:**
   Coloured bands appear at the control line (C) and test line (T), indicate a positive result for Dengue NS1 antigen.
2. **Negative:**
   Only control line (C) is visible. No NS1 antigen was detected.
3. **Invalid:**
   Control line (C) is absent. If this occurs, the assay should be repeated using a new test cassette.

**REFERENCES**


**ORDER INFORMATION**

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Description</th>
<th>Packing Size</th>
</tr>
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<tbody>
<tr>
<td>RDG-RD0202</td>
<td>Dengue NS1 Antigen Rapid</td>
<td>25 tests / kit</td>
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**MANUFACTURER**

Revongen Corporation Center, No. 12A, Jalan TP5, Taman Perindustrian UEP, 47600 Subang Jaya, Selangor, Malaysia
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NOTE: The intensity of the color in the test line region will vary depending on the concentration of NS1 antigen present in the specimen. However, neither the quantitative value nor the rate of increase in NS1 antigen can be determined by this qualitative test. The diagnosis of Dengue fever should be made using the results of this test together with the other clinical and laboratory findings.