Dengue is a viral haemorrhagic fever endemic in countries with tropical and sub-tropical climates. The dengue virus is a member of the genus Flavivirus, Family Flaviviridae. The first dengue-like illness was described in South India in 1881 and was first named as Dengue in 1897. Dengue is a common infection and accounts for 500,000 hospitalizations and 20,000 deaths worldwide each year. The disease is characterized by abrupt onset of fever along with severe headache, muscle pain, joint pain, and sometimes vomiting and rash. The disease is transmitted by Aedes aegypti and Aedes albopictus mosquitoes. The virus is transmitted from an infected human to a mosquito in the fecundation stage of the mosquito's life cycle. It is a zoonotic disease and can be transmitted from human to human through blood or sexual contact.

**Explanation of the test**

Dengue viruses, transmitted by the mosquitoes, Aedes aegypti and Aedes albopictus mosquitoes, are predominantly distributed throughout the tropical and subtropical climate regions. There are four main genotypes of the dengue virus: DENV-1, DENV-2, DENV-3, and DENV-4. Dengue viruses are classified as positive-strand RNA viruses of the Flaviviridae family. The symptoms of dengue range from mild to severe, with an incubation period of 3-7 days. The disease can be classified into four stages: 1. The acute stage, 2. The febrile stage, 3. The critical stage, and 4. The convalescent stage.

**Limitations of the test**

1. A negative result does not exclude the possibility of dengue virus infection. If the symptoms persist, the patient should be retested.
2. A positive result does not confirm the presence of dengue virus. If the symptoms persist, the patient should be retested.
3. Cross-reactivity with other flaviviruses such as yellow fever virus, West Nile virus, and Japanese encephalitis virus should be considered.

**Internal control**

The SD BIOLINE Dengue NS1 Ag test device has "Test Line" and "Control Line" on the surface of the cassette. The SD BIOLINE Dengue NS1 Ag test device should be performed only after the control lines are visible. If the control lines are not visible, the test result cannot be used.

**Expected result**

The test is expected to be done 1 day after the onset of fever and up to 9 days after the end of primary dengue infection. If the NS1 Ag test result is negative, the patient should be monitored for at least 7 days after the onset of fever.

**Performance Characteristics**

The sensitivity and specificity of the test kit are provided in the package insert. The sensitivity and specificity of the test kit are determined by comparing the test results with the gold standard test.

**Factors affecting the test results**

The test results are affected by the concentration of the virus in the specimen and the time of collection. The sensitivity and specificity of the test kit are determined by comparing the test results with the gold standard test.

**Precautions**

1. The test kit should be used only for specimens collected within 5 days of the onset of fever.
2. The specimen should be collected in the morning while the patient is fasting.
3. The specimen should be collected from a venous puncture.
4. The specimen should be collected in a sterile container.
5. The specimen should be collected from a patient with a known history of dengue.
6. The specimen should be collected from a patient with a known history of dengue fever.
7. The specimen should be collected from a patient with a known history of dengue hemoglobinuria.
8. The specimen should be collected from a patient with a known history of dengue hemorrhagic fever.

**Negative Result**

1. The test result is negative.
2. The test result is negative.
3. The test result is negative.

**Positive Result**

1. The test result is positive.
2. The test result is positive.
3. The test result is positive.

**Reference**

The reference test is the gold standard test for the diagnosis of dengue fever. The reference test is the gold standard test for the diagnosis of dengue hemorrhagic fever. The reference test is the gold standard test for the diagnosis of dengue hemorrhagic fever.

**Kit Storage**

The SD BIOLINE Dengue test should be stored at room temperature. The test strip is sensitive to humidity and as a result, the test should be performed immediately after removing the test strip from the foil pack. Do not use beyond the expiration date.

**Stability of the test kit**

1. The test kit is stable at room temperature for 12 months after the expiration date.
2. The test kit is stable at room temperature for 12 months after the expiration date.
3. The test kit is stable at room temperature for 12 months after the expiration date.

**Expiration Date**

The expiration date of the test kit is the date when the test kit becomes unusable.

**Laboratory performance**

1. The laboratory performance of the test kit is determined by comparing the test results with the gold standard test.
2. The laboratory performance of the test kit is determined by comparing the test results with the gold standard test.
3. The laboratory performance of the test kit is determined by comparing the test results with the gold standard test.

**Quality control**

The quality control of the test kit is determined by comparing the test results with the gold standard test.

**Clinical performance**

The clinical performance of the test kit is determined by comparing the test results with the gold standard test.

**Interpretation of the test**

The interpretation of the test result is based on the comparison of the test result with the control line. The test result is considered positive if the control line is present.

**Conclusion**

The SD BIOLINE Dengue NS1 Ag test device has been evaluated for its sensitivity and specificity. The test kit has been found to be highly sensitive and specific for the diagnosis of dengue fever. The test kit is recommended for use in all laboratory settings.
SD BIOLINE Dengue NS1 Ag and IgG/IgM Test

[Dengue NS1 Ag]

Using disposable dropper provided, add 3 drops (about 100μL) of serum, plasma or whole blood into the sample well marked "S".

Interpret test results in 15~20 minutes.

[Dengue IgG / IgM]

Using capillary pipette provided, add 10μL of serum, plasma or whole blood into the sample well marked "S".

Put 4 drops of assay diluent into the assay diluent well round shaped.

Interpretation

[Dengue NS1 Ag]

**Negative**
The presence of only one color line within the result window indicates a negative result.

**Positive**
The presence of two color lines ("T" band and "C" line) within the result window in left-side, no matter which line appears first, indicates a positive result.

**Invalid**
- No control (C) line in result window.
- It is recommended that the specimen be re-tested.

[Dengue IgG / IgM]

**Positive**

1. **IgM positive** (Primary dengue infection)
   - Two lines "C" and "M" in result window.
   - It is positive even if "M" line is weak.

2. **IgG positive** (Secondary or past dengue infection)
   - Two lines "C" and "G" in result window.
   - It is positive even if "G" line is weak.

3. **IgG and IgM positive** (Late primary or early secondary dengue infection)
   - Three lines "C", "M" and "G" in result window.

**Negative**
(No dengue infection)
- One line "C" in result window at right

**Invalid**
- No control (C) line in result window.
- It is recommended that the specimen be re-tested.