



TECHNICAL SPECIFICATION.

Product Name

First Response[®] Dengue (NS1) Card Test

**Manufacturer: Premier Medical Corporation Private
Limited**

**A1-302, GIDC, Sarigam-396155. Dist. Valsad,
Gujarat, INDIA.**

An ISO 13485 & EN ISO 13485 Certified Company

Product Details		
1	Product Name	First Response® Dengue (NS1) Card Test
2	Product Family	Rapid Diagnostic Tests
3	Product Code	PI22FRC

Intended Use:

The First Response® Dengue (NS1) Card Test is a lateral flow chromatographic immunoassay for the qualitative detection of dengue NS1 antigen (DEN1, 2, 3, 4) in human serum, plasma or whole blood. It is intended for use by healthcare professionals and qualified laboratory personnel. The test can be used as an aid in the diagnosis of Dengue infection. The test kit is not automated and does not require any additional instruments. The test is intended to be used at Point of care and/or laboratory settings. Reactive specimens should be confirmed by supplemental testing.

Assay Principle

The First Response® Dengue (NS1) Card Test is a lateral flow chromatographic immunoassay. The test strip in cassette device consists of 1) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with antibodies to dengue NS1 antigen, and the C line is pre-coated with a control line antibody, : 2) a red colored conjugate pad containing antibodies to dengue NS1 antigen conjugated with colloidal gold (dengue Ab conjugates) and a control antibody conjugated with colloidal gold. The antibodies to dengue NS1 recognize the antigens from all four dengue virus serotypes. When an adequate volume of specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. Dengue NS1 antigens, if present in the specimen, will bind to the Dengue Ab conjugates. The immunocomplex is then captured on the membrane by the pre-coated antibodies to dengue NS1 antigens forming a red colored T line, indicating a dengue Ag positive test result and suggesting an early acute primary or secondary infection. Absence of the T line suggests a negative result. The test contains an internal control (C line) which should exhibit a red colored line of the immunocomplex of the control antibodies, regardless of color development on the test line (T line). If the C line does not develop, the test result is invalid, and the specimen must be retested with another device.

Storage & Stability

First Response® Dengue (NS1) Card Test should be stored at 4-30°C. Do not freeze the kit or components. Test Device are stable until the expiry date printed on the label, when stored at room temperature 4-30° C. The test device is sensitive to humidity and heat. Perform the test immediately after removing the Test Device from the foil pouch. The shelf life of the kit is as indicated on the outer package. Do not use Test Device and Assay buffer beyond the date of expiry.

Shelf Life:

First Response® Dengue (NS1) Card Test has shelf life of 24 months.

Performance Characteristics:

First Response Dengue (NS1) Card Test has 100 % sensitivity and 100 % specificity.

Operational Characteristics:**Temperature range:**

- First Response Dengue (NS1) Card Test is stable at temperature range of 4-30°C.
- Operating Temperature range is room temperature.
- Test result interpretation time 15-20 minutes.

Kit components:

Each kit of First Response® Dengue (NS1) Card Test contains:

- Test devices packed in aluminum pouch with desiccant,
- Specimen Transfer Device.
- Sterile lancets.
- Alcohol swabs.
- Instruction for use in English language.
- Assay buffer bottle.

Certification:

First Response® Dengue (NS1) Card Test is manufactured by Premier Medical Corporation Pvt Ltd is ISO 13485 & EN ISO 13485 certified company.