PATHKITS

SIMPLE Dengue NS1/IgG/IgM Combo RAPID Test

Product Code : **PKRK005**
Kit Contents: **25 Kits**
Shelf life: **24 months**

Kit Components	Quantity (Units)
Test Strips	25
Assay Buffer	1 x Bottles
Sample Dropper	25
IFU	1

Introduction

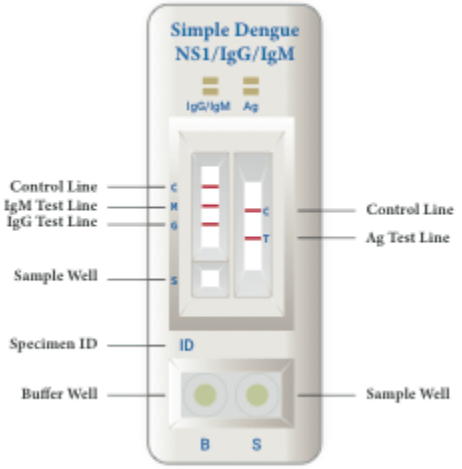
Dengue fever is an acute illness caused by an infection of dengue viruses (DENV 1 to 4). It is a mosquito-borne viral disease occurring in the areas of tropical Asia, Africa, Australia and the Americas. The virus is transmitted by mosquitoes of the daytime-biting Stegomyia family, principally female mosquito species *Aedes aegypti* and, less commonly, *Aedes albopictus*. An estimated 100 million cases of dengue fever and 250,000 cases of life-threatening dengue hemorrhagic fever occur annually on a worldwide basis. Rapid and reliable tests for primary and secondary infections of dengue are essential for patient management. Primary dengue infection is associated with mild to high fever, headache, muscle pain and skin rash. Serological detection is a common method for the diagnosis of infection with dengue viruses. Anti-dengue virus IgM starts to appear 3 days after initial exposure and remains in circulation for about 30-60 days. Anti-dengue virus IgG rises around 7 days, peaks at 2-3 weeks and persists for the duration of life4-6. Detection of antigens, such as dengue NS1, released during virus replication in the infected patient show very promising results; it enables diagnosis from the first day after the onset of fever up to day 9 once the clinical phase of the disease is over, thus, allowing early detection and prompt treatment. The SIMPLE Dengue NS1/IgG/IgM Combo RAPID Test detects anti-dengue virus IgG and IgM and circulating dengue NS1 antigen (DEN1, 2, 3, 4) in human serum, plasma or whole blood. It can be performed within 20-25 minutes by minimally skilled personnel and without the use of laboratory equipment.

Intended Use

The SIMPLE Dengue NS1/IgG/IgM Combo RAPID Test is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of NS1 antigen and IgG and IgM antibodies to dengue virus (DEN 1, DEN2, DEN3, and DEN4) in human serum, plasma or whole blood. The kit is intended for professional use and as a preliminary test result to aid in the diagnosis of infection with dengue virus. Any use or interpretation of this preliminary test result must also rely on other clinical findings and the professional judgment of health care providers. Alternative test methods should be considered to confirm the test result obtained by this device.

Test Principle

The SIMPLE Dengue NS1/IgG/IgM Combo RAPID Test is a solid phase immunochromatographic assay for the detection of NS1 antigen and IgG and IgM antibodies to dengue virus (DEN1, DEN2, DEN3, and DEN4) in human serum, plasma or whole blood.



[Dengue IgG/IgM test]

It is situated on the left-side is a lateral flow chromatographic immunoassay. The test strip consists of: 1) a colored conjugate pad containing recombinant dengue envelope antigens conjugated with colloidal gold (dengue Ag conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing two test lines (G and M lines) and a control line (C line). The G line is pre-coated with antibodies for the detection of anti-dengue virus IgG, the M line is pre-coated with antibodies for the detection of anti-dengue virus IgM, and the C line is pre- coated with a control line antibody.

[Dengue NS1 Ag test]

It is situated on the right-side and the test strip consists of: 1) a colored conjugate pad containing antibodies to dengue NS1 antigen, conjugated with colloidal gold (dengue Ab conjugates) and a control antibody conjugated with colloidal gold, 2) 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, and the C line is pre-coated with a control line antibody. The antibodies to dengue NS1 recognize the NS1 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

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capillary action across the cassette. Dengue NS1 antigen, 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 antigen forming a colored T line. Anti-dengue virus IgG and/or IgM, if present in the specimen, will bind to the dengue Ag conjugates. The immunocomplex is then captured by the pre-coated reagent forming a colored G and/or M line, respectively.

Dengue Ag positive result suggests an active infection. Dengue IgM positive result suggests a primary infection. Dengue IgG positive result suggests a secondary or past infection, and Dengue IgG and IgM positive result suggests late primary or early secondary infection. The results obtained with this test should be used in conjunction with other diagnostic procedures and clinical findings.

Absence of any G, M or T lines suggests a negative result. Each test contains an internal control (C line) which should exhibit a colored line of the immunocomplex of the control antibodies in each the left and right panels, regardless of color development on any of the test lines. If the C line does not develop in a panel, the test result is invalid and the specimen must be retested with another device. An invalid result in one panel does not invalidate the test result in the other panel.

Warnings and Precautions

- For professional in vitro diagnostic use only. Do not use it after the expiration date.
- Do not eat,drink or smoke in the area where the specimens or kits are handled.
- Handle all the specimens as if they contain infectious agents.
- Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- Do not open the sealed pouch, unless ready to conduct the assay.
- Do not use the components in any other type of test kit as a substitute for the components in this kit.
- Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
- Handle the negative and positive controls in the same manner as the patient specimens.
- Do not reuse the test device.
- Use separate sample dropper or pipette tips for each sample in order to avoid cross contamination of samples which could cause erroneous results.

Sample collection and Storage Instructions

- Collect the whole blood in a collection tube (containing EDTA, citrate or heparin or oxalate or Tri-sodium Citrate as suitable anticoagulants) by venipuncture.
- If samples are not immediately tested, they should be stored at 2- 8 ℃. For storage periods more than 3 days, freezing is recommended. They should be brought to room temperature prior to use.
- Fresh blood from finger prick may also be used as a test sample.
- Clotted contaminated blood samples should not be used lor perlorminq the test. Fresh blood from finger prick or puncture may also be used as a test specimen.

Storage and Stability

- This kit can be stored between 1-30 ℃. Do not freeze the kit.
- The kit is stable upto expiration date as printed on the pouch.
- Do not use it beyond the expiry date.

Materials Required but not provided

- Timer or Stopwatch.
- PPE and other consumables for collection and disposal of samples.

Limitations of Test

- As with all the diagnostic tests, the interpretation of assay results must always be correlated with clinical findings.
- Any modifications to the given procedure or use of other reagents will invalidate the test procedure.
- It is intended for screening use only, not for use in diagnostic procedures.
- The SIMPLE Dengue NS1/IgG/IgM Combo RAPID Test is limited to the qualitative detection of NS1 antigen and IgG and IgM antibodies to dengue virus (DEN 1, DEN2, DEN3, and DEN4) in human serum, plasma or whole blood. The intensity of the test band does not have linear correlation with the antigen/ antibody titer in the specimen.
- A negative result for an individual subject indicates absence of detectable dengue NS1 antigens. However, a negative test result does not preclude the possibility of exposure to dengue NS1.
- A negative result can occur if the quantity of dengue NS1 antigens present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
- In early infections and some secondary infections, detectable levels of IgM antibodies may be low. Some

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patients may not produce detectable levels of antibody within the first seven to ten days after infection. If clinical symptoms persist, patients should be re-tested in 3-4 days with the first specimen.

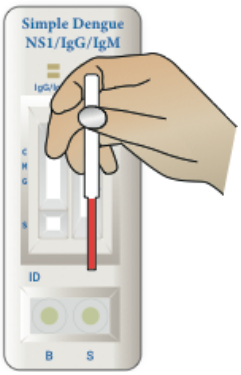
- This test cannot be used to monitor therapy or to estimate the relative antibody titer.

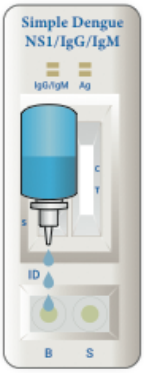
Test Procedure

- Bring the kit components and specimen to be tested to room temperature before testing.
- Open the test card and desiccant from the pouch prior to use and place it on a flat and dry surface. Check the color of the desiccant, it should be blue. Note: Do not use the card if desiccant is pink in color.
- The test should be performed immediately after removing the test card from the pouch.
- Label the patient's name or identification number on the test card.
- Remove the dengue combo test device from the sealed pouch, and place it on a clean and flat surface.

For Dengue IgG/IgM test

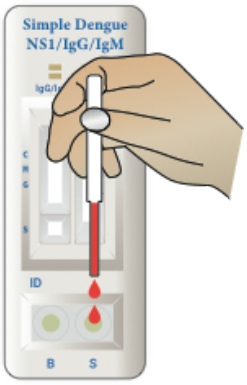
- Transfer 10µl of serum, plasma or whole blood in the sample well (S) of the Dengue IgG/IgM device using disposable capillary tube provided in the kit.
- Add 3-4 drops (about 120µl) of sample diluent into the diluent well of the test device.
- Read the test result at 15-20 minutes. Do not read the test result after 20 minutes.





For Dengue NS1 Ag

- Apply 4 drops (about 100 µl) of serum(or plasma) or whole blood specimens into the sample well (S) of the Dengue NS1 Ag device using disposable dropper provided in the kit.
- Read the test result at 15~20 minutes. Do not read the result after 20 minutes.

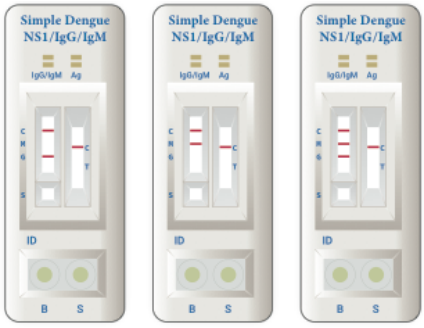


Note: Sample should be taken as per the marking and sample taken below or above the mark is wrong and will lead to erratic results.

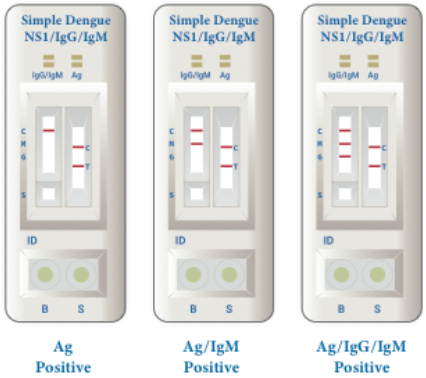
Interpretation of results

Positive Results

For Dengue IgG/IgM test, the presence of Test band ('G' and/or 'M') with Control (C) band indicates a positive result.



For Dengue NS1 Ag, the presence of Test band (T) with Control (C) band indicates a positive result and presence of both IgG/IgM and Ag represents positivity for both Dengue antigen and antibody.



Negative Result

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The presence of only the Control (C) band indicates a negative result.

Negative

Invalid Results

If control (C) band is not appeared in the result window after performing the test, the result is considered invalid.

Invalid

Technical Assistance

For customer support, please contact our Technical Support:
PathKits Healthcare Pvt Ltd, Plot 28, 29 Sector 18(P), Gurgaon- 122015, India Customer care No.: +91-7303429198
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Central Drugs Standard Control Organisation

Directorate General of Health Services

Ministry of Health & Family Welfare

(Medical Device & Diagnostic Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Phone No-011-23236965
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File No. : NZ/MD/2021/000155

Dated : 15-MAR-2022

M/s PATHKITS HEALTHCARE PRIVATE LIMITED,
Plot No-28-29, Sector-18
Gurgaon, Gurgaon, Haryana (India) - 122001
Telephone No.: 8802872273 FAX: 8802872273

Sub:- Licence to manufacture for Sale or for Distribution of Class C or Class D medical devices in Form MD-9 under Medical Device Rules, 2017- regarding.

Sir,

Manufacturing licence No. MFG/IVD/2021/000068 in Form MD-9 is hereby forwarded to you. This licence is subject to following conditions:

1. Licence shall be produced when requested by the Medical Device Officer or any other senior officer under the control of Central Licensing Authority.
2. The licence holder shall inform the Central Licensing Authority of the occurrence of any suspected unexpected serious adverse event and action taken thereon including any recall within fifteen days of such event coming to the notice of licence holder
3. The licence holder shall obtain prior approval from the Central Licensing Authority, before any major change as specified in the Sixth Schedule is carried out and the Central Licensing Authority shall indicate its approval or rejection within forty five days and in case where no communication is received within the stipulated time from such Authority, such change shall be deemed to have been approved
4. The licence holder shall inform any minor change as specified in the Sixth Schedule to the Central Licensing Authority within a period of thirty days after such minor change take place
5. The licence holder shall carry out test of each batch of product manufactured prior to its release for compliance with specifications either in his own laboratory or in any other laboratory registered under sub-rule (3) of rule 83;

6. The licence holder shall, on being informed by the Central Licensing Authority that any part of any lot of the medical device has been found not conforming with the provisions specified under the Act and these rules, and on being directed so to do by such licensing authority, withdraw the remainder of that lot from sale and, so far as may, in the particular circumstances of the case, be practicable, recall the issues already made from that lot;
7. The licence holder shall maintain an audit or inspection book in Form MD-11 to enable the Notified Body or Medical Device Officer to record his observations and non-conformity, if any;
8. The licence holder shall maintain at least one unit of sample from each batch of invasive medical device and in vitro diagnostic medical device manufactured for reference purpose for a period of one hundred and eighty days after the date of expiry of such batch;
9. The licence holder shall maintain records of manufacturing and sales which shall be open to inspection by a Medical Device Officer;
10. The medical device, when offered for sale, shall be accompanied by either its package insert or user manual, wherever applicable;
11. The manufacturing or testing activity of medical device shall be undertaken only under the direction and supervision of the competent technical staff;
12. If the manufacturer has stopped manufacturing activity or closed the manufacturing site for a period of thirty days or more, the same shall be intimated to the Central Licensing Authority.

13. This licence is being issued with the conditions that 1.the firm shall submit real time stability data for three lots for all the proposed product up to claimed shelf life i.e 24 months as on when the studies completed. 2. Firm shall evaluate the three lots of proposed products at the laboratory specified in guidance of PER of IVDMD dated 24/02/2020 with in 90 days from date of issuance of this licence.

Yours faithfully

Licensing Authority
Seal/Stamp

सत्यमेव जयते

FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/IVD/2021/000068

Endorsement No. 3

1. M/s PATHKITS HEALTHCARE PRIVATE LIMITED, Plot No-28-29, Sector-18Gurgaon, Gurgaon, Haryana (India) - 122001 Telephone No.: 8802872273 FAX: 8802872273 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s PATHKITS HEALTHCARE PRIVATE LIMITED, 28, 29 Electronic City, Sector -18, Gurgaon, Haryana (India) - 122001 Telephone No.: 8588869343 FAX: 8588869343

2. Details of medical device(s) [Annexed]

3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer

4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:Dengue NS1/IgG/IgM Combo RAPID Test Kit Model No.:PKRK005 - NA Intended Use:It is a solid phase immuno chromatographic assay for the rapid, qualitative and differential detection of NS1 antigen and IgG and IgM antibodies to dengue virus (DEN 1, DEN2, DEN3, and DEN4) in human serum, plasma or whole blood. Class of medical device:Class C Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Simple Dengue IgG/IgM/NS1 Combo detect kit; Dengue at Home IgG/IgM/NS1 Combo detect kit
2	Generic Name:Dengue NS1 Antigen RAPID Test Kit Model No.:PKRK003 - NA Intended Use:It is an immunoassay for the simultaneous and qualitative detection of dengue NS1 antigen (DEN 1, 2, 3, 4) in human serum, plasma or whole blood Class of medical device:Class C Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Simple Dengue NS1 Antigen detect kit; Dengue at home NS1 Antigen detect kit

VENUGOPAL G SOMANI

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA), pseudonym=112046a34e21727bacb255748732c456d249073e55e953d9cb5b58748ee3113c, postalCode=110002, st=DELHI, serialNumber=e97f241aa0c0bba41522525ffca0705074b4997e6b2f4b5c8d81cf282adeaf5d, cn=VENUGOPAL G SOMANI
Date: 2022.03.15 14:36:25 +05'30'

Place:

Date:15-Mar-22

Central Licensing Authority