PATHKITS

# SIMPLE Dengue IgG IgM RAPID Test

Product Code : **PKRK004**
Kit Contents: **25 Kits**
Shelf Life: **24 months**


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

**Introduction**

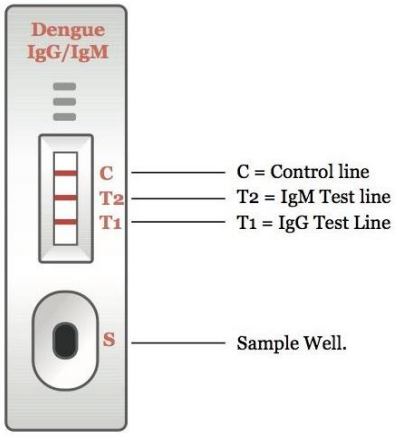
Dengue fever is an acute illness caused by an infection of dengue viruses (DENV 1 to 4). It is a mosquito-borne viral disease occurring in the areas of tropical Asia, Africa, Australia and the Americas. The virus is transmitted by mosquitoes of the daytime-biting Stegomyia family, principally female 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. Immune response includes IgM antibodies produced by 3rd-5th day of symptoms and persists for 30-60 days. IgGs appear the 14th day and persist for life. Secondary infections often result in high fever and in many cases with haemorrhagic events and circulatory failure. Secondary infections show that IgGs rise within 1-2 days after the onset of symptoms and induce IgM response after 20 days of infection. Therefore, patients with secondary infections will have a positive IgG result, usually with a positive IgM result as well. Thus, the use of a reliable and sensitive rapid serological test that can simultaneously detect the presence of antidengue IgG and IgM antibodies is of great clinical utility. The SIMPLE Dengue IgG IgM RAPID Test Kit provides an excellent methodology for specifically detecting anti-dengue IgG and IgM antibodies. The presence of high titers of IgG antibodies does not interfere with the detection of IgM antibodies in the sample. By using a mixture of highly purified dengue proteins, the test is able to detect all 4 Dengue serotypes.

**Intended Use**

The SIMPLE Dengue IgG IgM RAPID Test is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to dengue virus 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 IgG IgM RAPID Test Kit is a solid phase immunochromatographic assay for the detect and differentiate IgG and IgM antibodies to dengue virus in human serum, plasma or whole blood. Dengue IgG/IgM test device has 3 pre-coated lines, “G” (Dengue IgG Test Line), “M” (Dengue IgM Test Line) and “C” (Control Line) on the surface of the membrane. All three lines in the result window are not visible before applying any samples. The “Control Line” is used for procedural control. The control line should always appear if the test procedure is performed properly and the test reagents of the control line are working. Pink “G” and “M” lines will be visible in the result window if there are enough IgG and/or IgM antibodies to dengue virus in the sample. If IgG and/or IgM antibodies to dengue virus are not present in the sample, there will be no color appearance in “G” and/or “M”. When a specimen is added to the sample well, anti-dengue IgGs and IgMs in the specimen will react with recombinant dengue virus envelope proteins-colloidal gold conjugates and form a complex of antibodies-antigen. As this complex migrates along the length of the test device by capillary action, it will be captured by the relevant anti-human IgG and/or anti-human IgM immobilized in two test lines across the test device and generate a colored line.




**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**

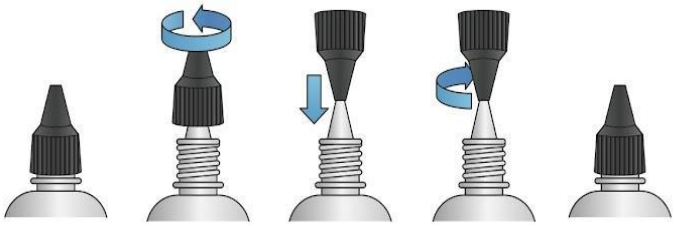
- Timer or Stopwatch.
- PPE and other consumables for collection and disposal of samples.

**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 IgG IgM RAPID Test is limited to the qualitative detection of IgG and IgM antibodies to dengue virus in human serum, plasma or whole blood. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
- In early infections and some secondary infections, detectable levels of IgM antibodies may be low. Some 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.
- Serological cross-reactivity across the flavi virus group (Dengue virus, St. Louis encephalitis, Japanese encephalitis, West Nile and yellow fever virus) is common.
- The use of icteric or lipemic samples should be avoided. This test should not be used on specimens from immunosuppressed individuals.
- This test cannot be used to monitor therapy or to estimate the relative antibody titer.

**Test Procedure**

1. Bring the kit components and specimen to be tested to room temperature before testing.
2. 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.
3. The test should be performed immediately after removing the test card from the pouch.
4. Label the patient's name or identification number on the test card.
5. Tighten the vial cap of the assay buffer provided along with the kit in the clockwise direction to pierce the nozzle of the dropper bottle.



6. Take 4µl anticoagulated blood sample and mix evenly by gently using the sample dropper.

**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.

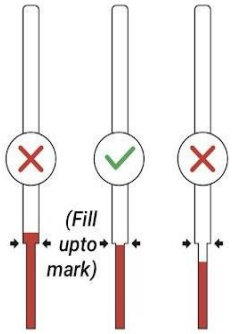



Fig (d) Fig (e) Fig (f)

**Use finger prick blood samples as described below.**

**Finger Prick Sample Collection:**

- Clean the patient's finger tip with the alcohol or spirit. Wait until the finger has completely dried.
- Prick the patient's finger with the lancet, perpendicular to the lines of the finger print. Make sure a well formed drop of blood is present on the tip of the finger.

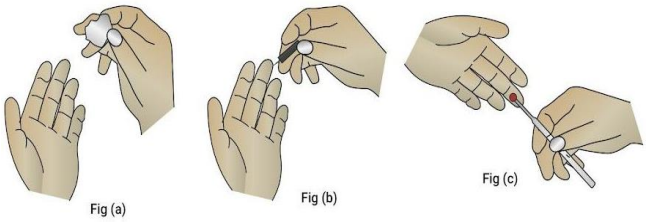


Fig (a) Fig (b) Fig (c)

- Take the sample dropper and collect 4µl of blood by dipping the tip of the sample dropper into the blood drop and immediately place the tip of the sample dropper in the sample well. Press the tip of the dropper onto the sample pad in the sample well to ensure that the complete volume of whole blood has been transferred to the strip.

7. Add 4 drops of the assay buffer in the buffer well. Screw cap the vial after use.

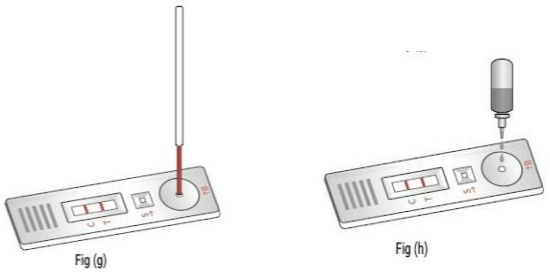


Fig (g) Fig (h)

8. Allow the reaction to occur for 20 minutes.
9. Observe the results in 20 minutes. Do not read the result after 20 minutes. Reading beyond prescribed time may give false results.
10. Discard the test card immediately after reading results at 20 minutes.

**Interpretation of results**

**Positive Results**

- The control line (C) and IgM line (M) are visible on the test device. This is positive for IgM antibodies to Dengue virus. This is indicative of a primary dengue infection.
- The control line (C) and IgG line (G) are visible on the test device. This is positive for IgG antibodies. This is indicative of secondary or previous dengue infection.
- The control line (C), IgM (M) and IgG line (G) are visible on the test device. This is positive for both IgM and IgG antibodies. This is indicative of a late primary or early secondary dengue infection.
- A difference of intensity in colour may occur between the test line & control line depending on the concentration of antibodies in the sample but this does not affect the interpretation of the results.
- Depending on the concentration of antibodies, positive results may be observed within 60 seconds. However, to confirm a negative result the test result should be read only at 20 minutes.

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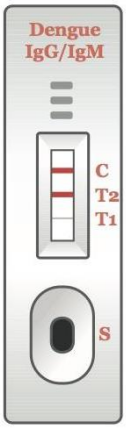
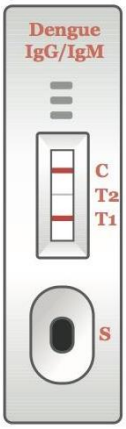
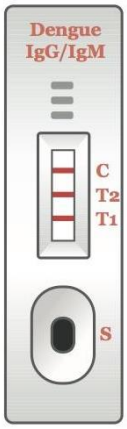
# SIMPLE Dengue IgG IgM RAPID Test




Positive for IgM



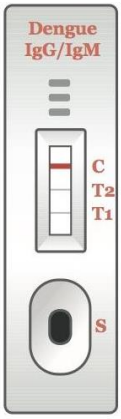

Positive For IgG




Positive For IgG & IgM

**Negative Result**

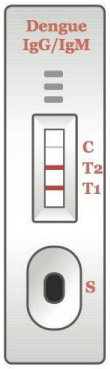
- The control line is only visible on the test device. No IgG and IgM antibodies were detected.
- Retest in 3-5 days if dengue infection is suspected.




Negative

**Invalid Results**

- Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure.
- Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

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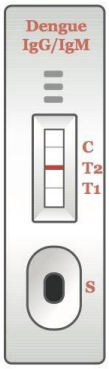


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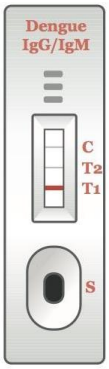


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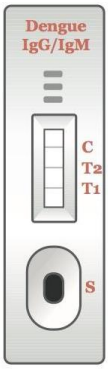


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**Technical Assistance**

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*
*Email: info@pathkits.com*

# 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
Fax: 23236973

**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<br>Model No.:PKRK005 - NA<br>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.<br>Class of medical device:Class C<br>Material of construction:NA<br>Dimension(if any):NA<br>Shelflife:24 Months<br>Sterile or Non sterile:Non-Sterilized<br>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<br>Model No.:PKRK003 - NA<br>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<br>Class of medical device:Class C<br>Material of construction:NA<br>Dimension(if any):NA<br>Shelflife:24 Months<br>Sterile or Non sterile:Non-Sterilized<br>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