

EzDx™ Dengue IgM/IgG Test Procedure

- FIRST, read carefully the Product Insert on how to use the EzDx™ Dengue IgM/IgG kit.
- Now open the kit and look for the following.

1) Test device individually foil pouched with a desiccant



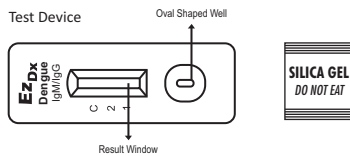
2) Buffer Solution



3) Sample Dropper

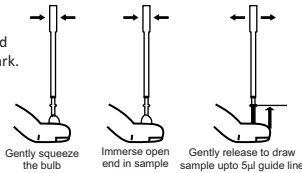
4) Product Insert

Open the pouch and look for the following.

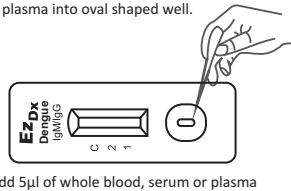


- Next, look at the expiry date at the back of the pouch. Use another kit, if expiry date has passed.

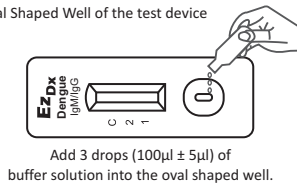
- With the help of Sample Dropper provided draw 5µl of sample upto the indicated mark.



- Add 5µl of whole blood, serum or plasma into oval shaped well.



- Add Buffer Solution into the Oval Shaped Well of the test device

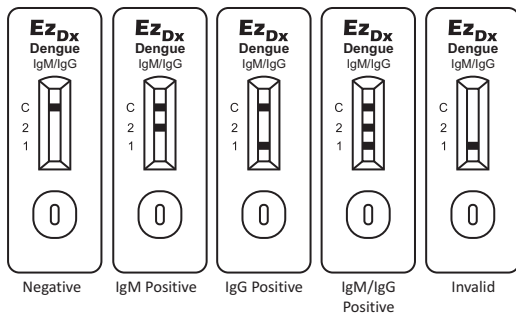


- INTERPRET TEST RESULTS AT THE END OF 20 MINUTES.

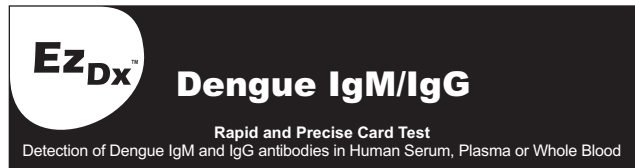
CAUTION : Do not read test after 20 minutes, since it may give incorrect results.



- Interpretation of Test Results.



(4)



Ref: 001RDE010KI-1

Product Code: RK DEN 001

INTRODUCTION

EzDx™ Dengue IgM/IgG test is rapid immunochromatography assay for the simultaneous detection of IgM and IgG antibodies to Dengue virus in human Whole Blood, Serum or Plasma. The assay is used as screening test for Dengue viral infection and as an aid for differential diagnosis of primary and secondary infections in conjunction with other criteria.

PRINCIPLE

EzDx™ Dengue IgM/IgG test utilizes the principle of Immuno-chromatography. Mouse anti-human IgM and IgG antibodies are immobilized on the nitrocellulose membrane respectively, as two individual test lines (IgM line and IgG line) in the test window of the test device. The IgG line in the test window is closer to the sample well and followed by IgM line. As the test samples flows through the membrane within the test device, the colored Dengue specific recombinant antigen-colloidal gold conjugate complexes with specific antibodies (IgM and/or IgG) of dengue virus, if present in the sample. This complex moves further on the membrane to the test region where it is captured by the anti-human IgM and/or IgG antibodies coated on the membrane leading to formation of colored band, which indicates a positive test results. Absence of this colored band in the test window indicates a negative test result. A built-in control line will always appear in the test window when the test has performed properly, regardless of the presence or absence of anti-dengue virus antibodies in the specimen. This test is intended for professional use and must be used by trained personnel.

MATERIAL PROVIDED

EzDx™ Dengue IgM/IgG test kit contains the following items to perform the assay:

- EzDx™ Dengue IgM/IgG** devices individually pouched with desiccant
- Sample Dropper.
- Buffer Solution
- Product Insert

WARNING AND PRECAUTION

- For *in-vitro diagnostic* use only.
- For best results, strict adherence to these instructions is required. Anyone performing an assay with this product must be trained in its use and must be experienced in laboratory procedures.
- The **EzDx™ Dengue IgM/IgG** test device should remain in its sealed pouch until ready for use since the test devices are sensitive to humidity as well as heat.
- Use separate syringe or clean pipette tips/ sample Droppers for different samples to avoid cross-contamination of samples which could cause erroneous results. Do not pipette by mouth.
- Do not smoke, eat or drink in areas where specimens or kits are handled.
- Wear disposable gloves while handling specimens and performing the tests, and thoroughly wash hands afterwards.
- As known relevant interference, haemolytic samples, rheumatoid factors contained samples and lipaemic, icteric samples can lead to impair the test results.
- All patients samples should be handled as if they are capable of transmitting diseases. Follow established GLP for proper disposal of samples, used dropper/ pipette tips or syringes and used test devices.
- Do not reuse test devices.
- All reagents must be at room temperature before performing the test.
- Do not use reagents beyond the stated expiration date marked on the package label.
- The components in this kit have been quality control tested as standard batch unit. Do

(1)

not mix components from different lots.

13. Do not use the test kit if the pouch is damaged or the seal is broken.

KIT STORAGE AND STABILITY

- (1) The test device should be stored at 4 - 30°C (39°-86°F). DO NOT FREEZE
- (2) The test device is sensitive to humidity as well as to heat.
- (3) Do not use the test device beyond the expiration date. Expiration date of this Kit is as indicated on the kit cartons as well as on individual pouches.
- (4) Do not use the test kit if the pouch is damaged or the seal is broken.
- (5) Do not re-use the test device

SPECIMEN COLLECTION, STORAGE & PRECAUTION

1) Whole blood

- (1) Collect the whole blood into the collection tube (containing anticoagulants such as EDTA, Heparin or Oxalate) by venipuncture. Guidelines as recommended by the National Committee for Clinical Laboratory Standard (NCCLS) should be followed when collecting, transporting and processing patient samples.
- (2) Optimal results were obtained when patient samples were tested immediately after collection. Whole blood samples should be used within 24 hours after collection.

2) Plasma or Serum

- (1) [Plasma] Collect the whole blood into the collection tube (containing anticoagulants such as EDTA or Heparin or Oxalate) by venipuncture and then centrifuge blood to get plasma specimen.
- (2) [Serum] Collect the whole blood into the collection tube (NOT containing anticoagulants) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum.

Note:

- If plasma or serum specimens are not tested immediately, they should be refrigerated at 2-8°. (For storage period longer than 2 weeks, freezing is recommended. Samples be brought to room temperature (15 - 30°C) prior to use.

- Plasma or serum specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

TEST PROCEDURE

1. Collect specimen according to instruction in specimen collection and storage.
2. Allow the **EzDx™ Dengue IgM/IgG** kit components and specimens to attain room temperature prior to testing. Open the pouch just before performing the assay.
3. Remove the test device from the sealed pouch.
4. Load 5µl of Whole Blood, Serum or Plasma into the Oval Shaped well.
5. Add 3 Drops (100 µl ± 5µl) of Buffer Solution into the Oval Shaped well.
6. Read the result at the end of 20 minutes.
7. Interpret the result. Refer figure for interpretation of test results.

CAUTION :

Do not read the test after 20 Minutes, since it may give incorrect results.

INTERPRETATION OF THE RESULTS

Whole blood samples may cause red background to appear in the viewing window. If this is not masking the test line, the result remains valid.

NEGATIVE

Only the control band appears. Negative result indicates no Dengue antibodies are present in the Blood sample, indicating no Dengue infection in patient from whom the Blood was collected or the concentration of Dengue IgM/IgG antibodies present in the blood sample is below the detectable range.

POSITIVE

IgG Positive: Along with Control band, if IgG band alone appears it indicates the test is positive for IgG antibodies. This is indicative of Past Dengue infection.

IgM Positive: Along with Control band, if IgM band alone appears it indicates the test is positive for IgM antibodies. This is indicative of Primary dengue infection.

IgM and IgG Positive: Along with Control band, if IgM and IgG both bands appears it indicates the test is positive for both IgM and IgG antibodies. This is indicative of secondary dengue infection.

The shade of colour / intensity of band may vary, but it should be considered positive whenever there is even a faint line.

INVALID

If control band does not appear, the test is Invalid. In this case, please repeat the test using a fresh Device, and follow the test procedure exactly.

LIMITATIONS OF THE TEST

1. **EzDx™ Dengue IgM/IgG** test is for qualitative detection of anti-dengue antibody in human serum, plasma or Whole Blood and does not indicate the quantity of the antibodies.
2. The test is for *In Vitro* diagnostic use only. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

REFERENCES

- 1) Dengue hemorrhagic fever: Diagnosis, treatment, prevention and control. WHO 2nd Edition 1997.
- 2) Lam, SK. Dengue Haemorrhagic fever. Rev. Med. Micro. (1995), 6: 39-48.
- 3) Centres for Disease Control and Prevention and National Institutes of Health (1999). Guidelines: Biosafety in Microbiological and Biomedical Laboratories 4th Edition U.S.G.P.O. Washington.

DISCLAIMER:

While every precaution has been taken to ensure the diagnostic ability and accuracy of this product, this product is used outside of the control of the manufacturer and the distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

WARNING:

The Manufacturers and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

For any complaint/query and suggestions: **Customer Care No.: +91 22 25830326**

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