

A collaborative study under Indigenization of Diagnostic (InDx) program by Centre for Cellular and Molecular Platforms (C-CAMP) in collaboration with National Centre for Biological Sciences (NCBS)

Indian National Standard
Secondary Reference Standard for DENV RNA
Code: XXXX/XX/XX-XXXXX
Instructions for use
(Version 1.0, Dated dd/mm/yy)

1. INTENDED USE

The Indian Standard for DENV RNA for Nucleic acid Amplification Technique (NAT)-based assays consists of an acid-heat inactivated isolate of various DENV serotypes. The preparation has been evaluated at the National Centre for Biological Sciences through collaborative studies. The intended use of the national standard is for the calibration and harmonisation of NAT-based assays or secondary reference reagents for the detection of DENV RNA.

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.

The preparation contains material of human origin. As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation of aerosols. Care should be exercised in opening vials or vials, to avoid cuts.

3. UNITAGE

The assigned potency of the Standard, XXXX/XX/XX-XXXXX, is ____ **Log₁₀ IU/ml**. Each vial contains 0.5 or 1 mL of the reference material.

4. CONTENTS

Country of origin of biological material: India.

Each vial of XXXX/XX/XX-XXXXX contains 0.5 or 1 mL of non-infectious isolate of a specified DENV serotype. The virus has been inactivated at 60°C. The inactivation has been validated by serial passage on permissive C6/36 cells. The material is formulated in a universal buffer comprising 10 mM Tris-HCl (pH 7.4), 0.5% human serum albumin and 1% D-(+)- Trehalose dehydrate. This matrix shows commutability with human serum samples. The larger volumes of the clean matrix can be purchased separately.

5. STORAGE

The vials should be stored at -60°C or below until use. Aliquoted contents do not show any significant changes in IU/ml (tested via RT-qPCR) when stored at -20°C up to a month.

6. DIRECTIONS FOR OPENING

The frozen material is packed in conventional screw cap vials. Thaw the vial at 4°C or on ice. Centrifuge briefly before opening the vials.

7. USE OF MATERIAL

The material can be diluted in the matrix appropriate to the material/assay being calibrated and requires extraction prior to DENV RNA measurement.

8. STABILITY

Reference materials are held at NCBS biorepository within assured, temperature-controlled -80°C storage facilities. Reference Materials should be stored on receipt at -60°C or below. In line with WHO policy, no expiry date has been assigned to the reference materials. When stored at indicated temperature, they remain valid with the assigned potency and status until withdrawn or amended.

9. REFERENCES

Following study was used as a reference:

[1] Collaborative Study to Establish a WHO International Reference Panel for Dengue Virus types 1 to 4 RNA for Nucleic Acid Amplification Technology (NAT)-Based Assays [WHO/BS/2016.2299].

10. ACKNOWLEDGEMENTS

Core grants of C-CAMP and NCBS.

Collaborating institutes: Tata Institute for Genetics and Society (TIGS), Shiv Nadar Institute of Eminence (SNIE)

11. FURTHER INFORMATION

Further information can be obtained via e-mail: indx-support@ccamp.res.in

cc: tanaynb@ncbs.res.in, lalithkj@ccamp.res.in

Ordering standards: indx-support@ccamp.res.in

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12. CUSTOMER FEEDBACK

Users are encouraged to provide feedback on the suitability or use of the material provided or other aspects of our service. Please send any comments to indx-support@ccamp.res.in

13. CITATION

In all publications, including data sheets, in which this material is referenced, it is important that the preparation's title, its status, the reference number **XXXX/XX/XX-XXXX**, and the name and address of NCBS are cited correctly.

14. MATERIAL SAFETY SHEET

Physical and Chemical properties	
Physical appearance: Transparent liquid at 25°C	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify):	
Toxicological properties	
Effects of inhalation:	Not established, avoid inhalation
Effects of ingestion:	Not established, avoid ingestion
Effects of skin absorption:	Not established, avoid contact with skin
Suggested First Aid	
Inhalation:	Seek medical advice
Ingestion:	Seek medical advice
Contact with eyes:	Wash with copious amounts of water. Seek medical advice
Contact with skin:	Wash thoroughly with water.
Action on Spillage and Method of Disposal	
Spillage of vial contents should be taken up with absorbent material wetted with an appropriate disinfectant. Rinse the area with an appropriate disinfectant followed by water. Absorbent materials used to treat spillage should be treated as biological waste.	

15. LIABILITY AND LOSS

In the event that this document is translated into another language, the English language version shall prevail in the event of any inconsistencies between the documents. Unless expressly stated otherwise, NCBS and C-CAMP's Standard Terms and Conditions for the Supply of Materials (available upon request by the Recipient) ("Conditions") apply to the exclusion of all other terms and are hereby incorporated into this document by reference.

INFORMATION FOR CUSTOMS USE ONLY

Country of origin for customs purposes*: India
* Defined as the country where the goods have been produced and/or sufficiently processed to be classed as originating from the country of supply
Net weight: 0.5 or 1 gm
Toxicity Statement: Toxicity not assessed

16. CERTIFICATE OF ANALYSIS

NCBS and C-CAMP can generate a Certificate of Analysis for the current Reference Material on request. This material is officially endorsed by the NCBS and C-CAMP based on the report of the internal study, which established their suitability for the intended use.