



Non WHO Reference Material
NIBSC Immunodeficiency Multiplex NAT Reagent
NIBSC code: 24/202-xxx
Instructions for use
(Version 2.0, Dated 13/03/2025)

This material is not for in vitro diagnostic use

1. INTENDED USE

This reagent is intended for performance monitoring of NAT assays detecting AdV-2, BKV, HCMV, EBV, HSV-1, HSV-2, HHV-6A, HHV-6B, JCV, B19 and VZV. The reagent is intended to give a low positive result for each analyte.

When tested using an in-house NAT assay (Roche MagNA Pure 24 extraction platform with Roche LightCycler 480 II amplification instrument) Ct values of approximately 30 are obtained for each viral target. Different extraction and amplification instruments and different PCR assays may yield different results. It is therefore suggested that each user verifies the performance of this reagent in their own instruments and assays. Due to the potential for batch-to-batch variation, users are advised to verify the performance of each new batch of this reagent in their assay.

The reagent is not intended to be used for assay calibration purposes, or for in vitro diagnostic use.

2. CAUTION

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

This reagent contains low concentrations of the following viruses and should be considered infectious:

Adenovirus serotype 2 (AdV-2)
BK virus (BKV)
Human Cytomegalovirus (HCMV)
Epstein Barr Virus (EBV)
Human herpes Simplex Virus type 1 (HSV-1)
Human herpes Simplex Virus type 2 (HSV-2)
Human herpes Virus type 6A (HHV-6A)
Human herpes Virus type 6B (HHV-6B)
JC virus (JCV)
Parvovirus B19 (B19V)
Varicella Zoster Virus (Type B) (VZV)

The Parvovirus B19 stock used to prepare the product is comprised of human plasma which has been tested and found negative for anti-HIV, HIV RNA, anti-HCV, HCV RNA, HBsAg, HBV DNA and HAV RNA.

The reagent also contains foetal calf serum.

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 ampoules or vials, to avoid cuts.

3. UNITAGE

No unitage is assigned to any component of this multiplex reagent.

4. CONTENTS

Country of origin of biological material: United Kingdom.

Each vial coded 24/202-xxx contains 1.0 mL of PBS-A with 2% fetal calf serum consisting of the following whole viruses:

Adenovirus serotype 2 (AdV-2)
BK virus (BKV)
Human Cytomegalovirus (HCMV)
Epstein Barr Virus (EBV)
Human herpes Simplex Virus type 1 (HSV-1)
Human herpes Simplex Virus type 2 (HSV-2)
Human herpes Virus type 6A (HHV-6A)
Human herpes Virus type 6B (HHV-6B)
JC virus (JCV)
Parvovirus B19 (B19V)
Varicella Zoster Virus (Type B) (VZV)

5. STORAGE

On receipt this reagent should be stored at -70°C until use.

Material type: Liquid – will be shipped according to the storage and shipping conditions of the product

6. DIRECTIONS FOR OPENING

Vials have a screw cap; an internal stopper may also be present. The cap should be removed by turning anti-clockwise. Care should be taken to prevent loss of the contents. Please note: If a stopper is present on removal of the cap, the stopper should remain in the vial or be removed with the cap.

7. USE OF MATERIAL

Thaw and mix thoroughly before use. The reagent should then be used directly without further dilution.

After use, any excess material can be stored at or below 2-8°C and must be used within seven days, after which the material should be discarded.

Users are encouraged to provide information on the performance of the reagent in their assay(s), either by e-mail (refer to section 12) or via the Result Reporting System (RRS), a tool developed by NIBSC for the data monitoring of its serology and NAT reagents. Users are encouraged to sign up here: <https://nibsc.org/products/rrs>.

8. STABILITY

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label.

This reagent has a shelf-life of 48 months from the date of manufacture.

9. REFERENCES

None.

10. ACKNOWLEDGEMENTS

None.

11. FURTHER INFORMATION

Further information can be obtained as follows;
This material: enquiries@nibsc.org



WHO Biological Standards:

<http://www.who.int/biologicals/en/>

JCTLM Higher order reference materials:

<http://www.bipm.org/en/committees/jc/jctlm/>

Derivation of International Units:

http://www.nibsc.org/standardisation/international_standards.aspx

Ordering standards from NIBSC:

<http://www.nibsc.org/products/ordering.aspx>

NIBSC Terms & Conditions:

http://www.nibsc.org/terms_and_conditions.aspx

12. CUSTOMER FEEDBACK

Customers 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 enquiries@nibsc.org

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 NIBSC code number, and the name and address of NIBSC are cited and cited correctly.

14. MATERIAL SAFETY SHEET

Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified

Physical and Chemical properties	
Physical appearance: white solid	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify):	Contains animal material as well infectious viruses.
Toxicological properties	
Effects of inhalation:	Contains infectious viruses, avoid inhalation
Effects of ingestion:	Contains infectious viruses, avoid ingestion
Effects of skin absorption:	Contains infectious viruses, 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 ampoule contents should be taken up with absorbent material wetted with an appropriate disinfectant. Rinse 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 by NIBSC, NIBSC's Standard Terms and Conditions for the Supply of Materials (available at http://www.nibsc.org/About_Us/Terms_and_Conditions.aspx or upon request by the Recipient) ("Conditions") apply to the exclusion of all other terms and are hereby incorporated into this document by reference. The Recipient's attention is drawn in particular to the provisions of clause 11 of the Conditions.

16. INFORMATION FOR CUSTOMS USE ONLY

Country of origin for customs purposes*: United Kingdom
* Defined as the country where the goods have been produced and/or sufficiently processed to be classed as originating from the country of supply, for example a change of state such as freeze-drying.
Net weight: 1.0 g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable.
Attached: No