Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO Reference Panel
1st WHO International Reference Panel for HIV-1 p24 Antigen
NIBSC code: 16/210
Instructions for use
(Version 3.0, Dated 23/09/2024)

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1. INTENDED USE

The 1st International Reference Panel for HIV-1 p24 Antigen (NIBSC code 16/210), contains a diverse collection of HIV-1 p24 Virus Like Particles (VLPs) derived from clinical isolates [1]; representing subtypes A1, B, C, D, G, H, circulating recombinant forms (CRFs): F1/CRF12_BF/BFrec, CRF20_BG, CRF01_AE, CRF02_AG, and a group O. Panel members were diluted in citrated negative human plasma and lyophilized in 1 mL aliquots and stored at -20 °C

The panel was evaluated in a worldwide collaborative study involving 15 laboratories performing a range of HIV immunoassays [2].

This panel is intended for the use with 4th generation combination/antigen only immunoassays and rapid tests to evaluate/validate the sensitivity and specificity to detect HIV-1 p24 antigen.

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.
The preparation contains material of human origin, and either the final product or the source materials, from which it is derived, have been tested and found negative for HBsAg, anti-HIV and HCV RNA. 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

The WHO Expert Committee has **not** formally assigned a unitage to any of the panel members [2]. However, the calibrated values relative to the 1st IRR (90/636) obtained in the study are shown below in International Units (IU) when reconstituted in 1mL of nuclease-free water, based on the results of a worldwide collaborative study [3].

NIBSC Code:	Subtype	(IU/mL)
16/212	A1	8.8
16/214	B	7.9
16/216	B	8.4
16/218	C	11.5
16/220	D	9.0
16/222	F1/CRF12_BF/BFrec	12.7
16/224	G	8.0
16/226	CRF20_BG	9.9
16/228	CRF01_AE	10.3
16/230	CRF02_AG	4.0
16/232	H	6.0
16/234	group O	11.3

4. CONTENTS

Country of origin of biological material: United Kingdom.
The final material was formulated and produced in the UK, diluent plasma was from a UK source; However, Virus Like particles contained within the panel originate from Switzerland.

5. STORAGE

This panel should be stored at -20 C upon receipt
Please note because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

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

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution
The materials should be reconstituted with 1 mL of deionized, nuclease-free molecular-grade water and left for a minimum of 20 minutes with occasional agitation before use.

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. It is the policy of WHO not to assign an expiry date to their international reference materials. Accelerated degradation studies have indicated that the material is suitably stable, when stored at -20 C until the material is withdrawn or replaced. These studies have also shown that the material is suitably stable for shipment at ambient temperatures without loss of performance.

NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES

[1] Vetter et al (2014) Generation of a Recombinant Gag Virus-Like-Particle Panel for the Evaluation of p24 Antigen Detection by Diagnostic HIV Tests. PLOS ONE V9: Issue 10
[2] WHO Expert Committee on Biological Standardization - Sixty-ninth report, Section 7.1.2
[3] Prescott G, Hockley J, Atkinson E, Morris C. International Collaborative Study to Establish the 1st WHO International Reference Panel for HIV-1 p24 antigen and HIV-2 p26 antigen. WHO ECBS Report 2018. WHO/BS/2018.2334.

10. ACKNOWLEDGEMENTS

Not applicable

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:

National Institute for Biological Standards and Control,
Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

World Health Organization

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: Lyophilised		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	No	Irritant:	No
Flammable:	No	Handling:	See caution, Section 2
Other (specify):	Contains citrated human plasma		

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 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: 1g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable. **Attached:** No

17. CERTIFICATE OF ANALYSIS

NIBSC does not provide a Certificate of Analysis for WHO Biological Reference Materials because they are internationally recognised primary reference materials fully described in the instructions for use. The reference materials are established according to the WHO Recommendations for the preparation, characterization and establishment of international and other biological reference standards https://www.who.int/publications/m/item/annex2-trs932(revised 2004). They are officially endorsed by the WHO Expert Committee on Biological Standardization (ECBS) based on the report of the international collaborative study which established their suitability for the intended use.