WHO International Standard  
First WHO International Standard for anti-human papillomavirus  
type 6 serum  
NIBSC code: 19/298  
Instructions for use  
(Version 1.0, Dated 10/01/2023)  
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1. INTENDED USE  
This material will serve as the primary biological standard for  
antibodies to HPV type 6. The intended use of the International  
Standard is for the calibration and harmonisation of  
immunoassays detecting binding antibodies and pseudovirion-  
based neutralisation assays. The International Standard may be  
used for the calibration of secondary reference materials and the  
International Unit applied in the assessment of assay analytical  
sensitivity, specificity and variability.

2. CAUTION  
This preparation is not for administration to humans or animals  
in the human food chain. The donations used to make the  
standard were tested at NIBSC and found negative or nonreactive  
for HBsAg, antibodies to HIV and HCV RNA.  

As for 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 assigned potency of the First WHO International Standard  
for anti-HPV type 6 serum is 7 International Units(IU)/ampoule (i.e. 28  
IU/mL following reconstitution as detailed in Section 7).  

Uncertainty: the proposed unitage does not carry an uncertainty  
associated with its calibration. The only uncertainty is therefore  
derived from the variability of the dry fill weight of the ampoule  
content.

4. CONTENTS  
Country of origin of biological material: United Kingdom.  
Each ampoule contains the freeze-dried equivalent of 0.25 mL of  
pooled female human anti-serum

5. STORAGE  
Ampoules should be stored at -20°C or below until use.  
Please note because of the inherent stability of lyophilized  
material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING  
DIN ampoules have an ‘easy-open’ coloured stress point, where  
the narrow ampoule stem joins the wider ampoule body. Various  
types of ampoule breaker are available commercially. To open the  
ampoule, tap the ampoule gently to collect material at the bottom  
(labelled) end and follow manufactures instructions provided with  
the ampoule breaker.

7. USE OF MATERIAL  
No attempt should be made to weigh out any portion of the freeze-  
dried material prior to reconstitution  
The contents of each ampoule should be reconstituted in 0.25mL of  
distilled water. Following addition of the distilled water, the  
ampoules should be left at ambient temperature for approximately  
30 minutes until dissolved and then mixed thoroughly, avoiding the  
generation of excessive foam.

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.

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

It is the policy of WHO not to assign an expiry date to International  
Standards. They remain valid with the assigned potency and  
status until withdrawn or amended. Please note the stability of the  
International Standard when reconstituted has not been specifically determined. Therefore, it is recommended that the  
reconstituted material is for single use only. Should users wish to  
store reconstituted material, they should determine the stability of  
reconstituted material according to their own method of  
preparation, storage and use.

9. REFERENCES  
Kemp et al., WHO Collaborative Study to Evaluate Candidate 1st  
WHO International Standards  
for Antibodies to Human Papillomavirus Types 6, 11, 31, 33, 45, 52  
and 58. 2022 WHO Expert Committee on Biological Standardization.  
WHO/BS/2022.2435

10. ACKNOWLEDGEMENTS  
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NIBSC Standards Production and Development for the production of  
NIBSC 19/298 and distribution of the study materials.

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:
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

<table>
<thead>
<tr>
<th>Physical and Chemical properties</th>
<th>Toxicological properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance: Freeze-dried</td>
<td>Effects of inhalation: Not established, avoid inhalation</td>
</tr>
<tr>
<td>Stable: Yes Oxidising: No</td>
<td>Effects of ingestion: Not established, avoid ingestion</td>
</tr>
<tr>
<td>Hygroscopic: No Irritant: No</td>
<td>Effects of skin absorption: Not established, avoid contact with skin</td>
</tr>
<tr>
<td>Flammable: No Handling: See caution, Section 2</td>
<td>Suggested First Aid</td>
</tr>
<tr>
<td>Other (specify): Material of human origin</td>
<td>Inhalation: Seek medical advice</td>
</tr>
<tr>
<td></td>
<td>Ingestion: Seek medical advice</td>
</tr>
<tr>
<td></td>
<td>Contact with eyes: Wash with copious amounts of water. Seek medical advice</td>
</tr>
<tr>
<td></td>
<td>Contact with skin: Wash thoroughly with water.</td>
</tr>
</tbody>
</table>

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.

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: 0.25 g
Toxicity Statement: Toxicity not assessed
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 http://www.who.int/bloodproducts/publications/TRS932Annex2_Inter_biolefstandardsrev2004.pdf (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.

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.

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