WHO International Standard
First WHO International Standard for anti-human papillomavirus
type 11 serum
NIBSC code: 20/174
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 11. 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 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 assigned potency of the First WHO International Standard for
anti-HPV type 11 serum is 6 International Units(U)/ampoule (i.e.
24 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 that the stability
of 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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and Emma Summersgill, Division of Virology at NIBSC, for assisting
in the processing of the source materials and the NIBSC Standards
Production and Development for the production of NIBSC 20/174 and
distribution of the study materials.

11. FURTHER INFORMATION
This material encountered a freeze-drying failure resulting in
dehydration instead of lyophilisation. Evaluation of the long-term
stability of the freeze-dried product is in-progress and if necessary,
end users will be contacted to advise of notable findings.

The international collaborative study confirmed reactivity to
HPV11 in antibody binding assays and pseudovirion-based
neutralization assays. Reactivity to HPV6, HPV33, HPV52, and
HPV58 was also observed.

Further information can be obtained as follows;
This material: enquiries@nibsc.org
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 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>
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</thead>
<tbody>
<tr>
<td>Physical appearance: Freeze-dried</td>
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<tr>
<td>Stable: Yes</td>
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<tr>
<td>Hygroscopic: No</td>
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<tr>
<td>Flammable: No</td>
</tr>
<tr>
<td>Other (specify): Material of human origin</td>
</tr>
</tbody>
</table>

**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.

16. INFORMATION FOR CUSTOMS USE ONLY

| Country of origin for customs purposes*: United Kingdom |
| Net weight: 0.25g |
| 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_International_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.