Paul-Ehrlich-Institut
Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

A WHO Collaborating Centre
for Quality Assurance of Blood Products and in vitro Diagnostic Devices

# WHO 1st International Standard for detection of IgG antibodies to Cytomegalovirus (anti-CMV IgG)
# Code number 136616/17

## Instructions for use
## (Version 2, October 2017)

### 1. INTENDED USE
The 1st International Standard for detection of IgG antibodies to human cytomegalovirus (anti-CMV IgG) was established for the calibration of anti-CMV IgG test kits with quantitative test interpretation. It may also be used for quality control and for the determination of the analytical sensitivity of anti-CMV IgG test kits.

### 2. UNITAGE
This material is assigned an unitage of 46.4 IU/ml.

### 3. CONTENTS
Each vial contains 1.0 ml freeze-dried anti-CMV-IgG-positive and anti-CMV-IgM-negative human plasma. For the preparation of the standard a pool of 3 plasma donations from Germany was used without additives.

### 4. CAUTION
**This preparation is not for administration to humans.**
The standard material has been tested negative for CMV DNA, HBV-DNA, HCV-RNA, HIV-1-RNA, HIV-2 RNA, Anti-HIV 1/2, Anti-HCV, HBsAg, Syphilis, and is positive for Anti-EBV and Anti-HHV-6. The preparation is derived from human plasma and should be regarded as potentially hazardous to health. It should be used and disposed of in accordance with the safety regulations of your own laboratory. These safety measures include the wearing of protective gloves and the avoidance of aerosol formation. Care should be exercised in opening the vials to avoid cuts.

### 5. USE OF MATERIAL
No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution.
Allow the ampoule to reach ambient temperature before opening and **reconstitute with 1.0 ml distilled water**.

### 6. CHARACTERISTICS
The suitability of the international standard candidate (code 136616/17) for diagnostic anti-CMV IgG test kits was evaluated in a WHO Collaborative Study organized by the Paul Ehrlich Institute (PEI). Sixteen laboratories from 9 different countries tested the standard described above with 16 different test kits. Potential limitations of the standard are:
The anti-CMV-IgG standard is suitable for anti-CMV-IgG assays only according to its intended use.
Anti-CMV total test kits do not provide anti-CMV IgG-specific results with anti-CMV IgG/IgM-positive samples.
There was low commutability in 4 anti-CMV IgG test kits of the collaborative study, due to low avidity of anti-CMV IgG in some additional study samples.

### 7. STABILITY
The standard is supplied lyophilized and should be stored at or below -20°C. It is the policy of WHO not to assign an expiry date to its international reference materials. They remain valid with the assigned potency and status until withdrawn or amended. Stability of the standard nevertheless is monitored by PEI at regular intervals. The results obtained so far indicate long-term stability at or below -20°C.

Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact PEI.

### 8. REFERENCES
The report of the collaborative study is available from WHO reference number WHO/BS/2017.2322: N. Wissel, K. Hanschmann, H. Scheiblauer; Report of the WHO collaborative study to establish the 1st International Standard for detection of anti-CMV IgG.

### 9. ACKNOWLEDGEMENTS
We thank the participants of the collaborative study for their expertise and contribution.

### 10. FURTHER INFORMATION
For further information to this material please contact: pei-ivd@pei.de or http://www.who.int/biologicals/en/.

### 11. 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 whoccivd@pei.de or pei-ivd@pei.de

### 12. CITATION
In any circumstance where the recipient publishes a reference to PEI materials, it is important that the correct name of the preparation, the code number, the name and the address of PEI are cited correctly.

### 13. MATERIAL SAFETY SHEET

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|---|---|
| **Physical properties (at room temperature)** | |
| Physical appearance: Lyophilized powder | |
| Fire hazard: None | |
| **Chemical properties** | |
| Stable: Yes | Corrosive: No |
| Hygroscopic: No | Oxidizing: No |
| Flammable: No | Irritant: No |
| **Other**: none | |
| Handling: See caution, section 4 | |
| **Toxicological properties** | |
| Not established - avoid inhalation, ingestion or skin contact. | |
| **Suggested First Aid** | |
| Inhalation and ingestion:<br>Seek medical advice.<br>Contact with eyes or skin:<br>Wash thoroughly with water. Seek medical advice. | |
| **Action on Spillage and Method of Disposal** | |
| Spillage of vial contents should be taken up with absorbent material wetted with an appropriate disinfectant. Rinse area with an appropriate disinfectant. Absorbent materials used to treat spillage should be treated as biological waste. | |

### 14. LIABILITY AND LOSS
Information provided by the Institute is given after the

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If any of the Goods supplied by the Institute should prove not to meet their specification when stored and used correctly (and provided that the Recipient has returned the Goods to the Institute together with written notification of such alleged defect within seven days of the time when the Recipient discovers or ought to have discovered the defect), the Institute shall either replace the Goods or, at its sole option, refund the handling charge provided that performance of either one of the above options shall constitute an entire discharge of the Institute's liability under this Condition.