WHO Biological Reference Standards

*In vitro* diagnostic devices

- Summary of the 2nd Meeting of the WHO CC -

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World Health Organization
WHO is mandated by its Member States to "...develop, establish and promote international standards for biological products."

In practice, biological products cover:
- Vaccines
- Blood and blood products
- *In vitro* biological diagnostic devices
- Other biological products

(*) Expert Committee for Biological Standardization
WHO Biological Reference Standards


WHO Biological Reference Preparations (www.who.int/bloodproducts*)

- Nucleic Acid Technology:
  - HBV/HCV/HIV/Parvovirus/HAV (IS)
  - HIV genotype reference panel

- Immunoassays:
  - HBsAg; Anti-HBs; Anti-HBc
  - HIV p24 antigen
  - Anti-HIV subtype reference panel

- vCJD reference materials

- Blood grouping reagents

- Platelets immunology

- Blood Coagulation disorders

(*) WHO Catalogue of Biological Reference Preparations
Follow-up from the WHO CC Meeting in 2007

- Coordinate needs/priorities with WHO programs
- Discuss priority projects: WHO Biological Reference Preparations to optimally support global public health
- Update the strategic plan established in 2007
- Strengthen collaboration (WHO CC-Network model)

*WHO CCs for Biological Standards & Standardization: CBER/FDA, USA; NIBSC, UK; PEI, Germany*
# Priority Projects – Parasites

<table>
<thead>
<tr>
<th>Preparation</th>
<th>Proposed Standard</th>
<th>Coordinator</th>
<th>Next steps &amp; Decisions</th>
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<tbody>
<tr>
<td><strong>Anti-</strong> <em>Plasmodium</em> spec.</td>
<td>New Ref. Panel (new proposal)</td>
<td>S. Kumar, CBER P. Corran, NIBSC</td>
<td>Reference panel (falciparum, malariae, vivax) to validate blood donor screening assays (aiming to detect multi-species infections)</td>
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<tr>
<td><strong>Anti-</strong> <em>Toxoplasma</em> (IgM)</td>
<td>Replacement of current IS (TOXM)</td>
<td>S. Rijpkema, NIBSC</td>
<td>Current standard does not distinguish between IgG and IgM. Influence on the IU values. Effort to make an IgM-purified material</td>
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<tr>
<td>HIV-1 RNA genotype panel</td>
<td>2nd Ref Panel; under development</td>
<td>H. Holmes, NIBSC/ I. Hewlett, CBER</td>
<td>Major pandemic strains (A, C), unusual subtypes (G, H, J, K, group O) and wider range of CRFs; max. 12 panel members; heat inactivation; lyophilization; collaborative study in process; report to ECBS 2010</td>
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<tr>
<td>HIV-2 RNA</td>
<td>1st IS, Proposal for establishment at ECBS 2009</td>
<td>C. Morris, H. Holmes, NIBSC; I. Hewlett, CBER</td>
<td>Collaborative study completed; Report to ECBS 2009</td>
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## Priority Projects – Hepatitis viruses

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<td><strong>HBV genotype panel: NAT tests</strong></td>
<td>Reference Panel, proposed for establishment</td>
<td>M. Chudy, PEI; M. Nübling, PEI</td>
<td>NAT panel: 15 member; genotypes A-G; collaborative study in process; report to ECBS 2009</td>
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<tr>
<td><strong>HBV genotype panel: HBsAg tests</strong></td>
<td>Reference Panel under development</td>
<td>M. Chudy, PEI; M. Nübling, PEI</td>
<td>HBsAg panel: 15 member; genotypes A-H; pilot study (lyo); collaborative study 2009/2010</td>
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<tr>
<td><strong>HCV core Ag</strong></td>
<td>New proposal for development to ECBS 2009</td>
<td>PEI</td>
<td>Two candidate materials available; genotype 1 and 3 preparations (first one to calibrate in IU, the other show commutability)</td>
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### Priority Projects – Parvovirus and Dengue

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<td>B19V DNA genotype</td>
<td>Reference Panel, proposed for establishment</td>
<td>P. Minor, NIBSC</td>
<td>Four-member panel: genotypes 1, 2, 3 and negative plasma pool; collaborative study completed (33 labs); report to ECBS 2009</td>
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<td>panel</td>
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<td>S. Baylis, PEI Mei-ying Yu, CBER</td>
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<td>DENV RNA</td>
<td>DENV 1-4 NAT Ref Panel; New proposal for development to ECBS 2009</td>
<td>M. Rios, CBER</td>
<td>Selection of candidate materials: access to viral isolates acquired from infected humans;</td>
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<td>CMV DNA</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; IS: proposed study report ECBS 2010</td>
<td>J. Fryer, NIBSC</td>
<td>CMV strain Merlin propagated in cell culture; collaborative study will evaluate the material in parallel with strain AD169 and purified Merlin DNA;</td>
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<tr>
<td>EBV DNA</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; IS: proposed study report ECBS 2010</td>
<td>J. Fryer, NIBSC</td>
<td>EBV strain B95-8 propagated in cell culture; collaborative study in parallel with two other EBV-positive cells;</td>
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Other projects discussed (further consultation or information needed)

- Anti-HTLV-1/2 antibody panel
- Anti-HHV-8 antibodies and HHV-8 DNA
- Anti-CMV antibody standards (IgG, IgM)
- Blood-borne bacteria reference panel
- FLAVI, ARTHROPOD-BORNE HEMORRHAGIC VIRUSES: WNV RNA panel; Anti-DENV (IgM); Chikungunya virus; Japanese Encephalitis
- HEPATITIS VIRUSES: HDV RNA; HEV RNA; Anti-HCV mono-specific antibodies
- PARASITES: Anti-\textit{T. brucei} spec. (African trypanosomiasis); Anti-Babesia spec. antibody panel;
- POLYOMA/PAPILLOMA VIRUSES: BK DNA and JC DNA
- TSE BLOOD REFERENCE MATERIALS
WHO Biological Reference Preparations
WHO Catalogue

Web site address:

http://www.who.int/bloodproducts