Article number and Product Name
P0043 HIV-RNA quantification panel.

Intended Use
The HIV-RNA quantification panel provides a consistent standard across NAT methods, enabling blood screening laboratories and diagnostic manufacturers to assess the linearity and accuracy of quantitative molecular diagnostic test procedures for the detection of Hepatitis C virus (HIV) in blood samples. This product can be used with (real time) amplification and hybridisation methods. It also can be used as a calibration panel in quantification of secondary HIV-RNA standards. This product is not for diagnostic use.

Summary and Explanation
Testing Human immunodeficiency viral load is imperative to monitor success of patient treatment and clinical research on Human immunodeficiency virus. The quantification panel provide standardised sample with a known viral load which can be used to compare, adjust assays. The panel consist of a standard dilution series in negative human plasma. Multiple testing of standard dilutions in the Bayer Versant bDNA 3.0 assay enabled us to calibrate in copies/ml thereby relating to SI units. The quantification is confirmed by limiting dilution analysis using blood screening assays. A standard dilution was also included in the WHO collaborative studies for the first WHO HIV-RNA standard. It was found one bDNA copy was equivalent to 2.38 IU. The HIV-RNA quantification panel is designed for testing the accuracy of different NAT methods, batches or secondary standards. The quantification panel ensures NAT procedures for HIV-RNA are properly validated, and that test results across manufacturers, testing laboratories, operators, platforms and assay formats are commutable. The concentrations of HIV-RNA quantification panel members are primarily expressed in bDNA copies/ml and secondarily in IU/ml. The HIV standard was diluted in a pool of plasma units that tested negative for viral markers in individual donation NAT and serology testing. The viral concentrations in the plasma pool are ensured by gravimetrically recorded dilutions from calibrated viral stock solutions stored at −70°C.

Principles of the Evaluation Procedure
HIV-RNA quantification panel members have been carefully formulated to mimic human plasma specimens containing relevant concentrations of HIV-RNA. Accuracy and linearity can be evaluated by plotting the given log (concentration) against the log (measured concentration). The linearity is evaluated by calculating the correlation coefficient for different concentration ranges. The slope of the line can be used to relate the measured concentration to the given concentration in copies/ml, IU/ml. The accuracy is estimated for each sample by applying descriptive statistics on log (measured concentrations). Determination of sensitivity should be testing multiple times sensitivity panels and probit analysis.

HIV-RNA quantification panel reagents

<table>
<thead>
<tr>
<th>Panel member</th>
<th>HIV-RNA concentration (copies/ml)</th>
<th>HIV-RNA concentration (IU/ml)*</th>
<th>Quantity (ml per vial)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>250.000</td>
<td>595.238</td>
<td>1 x 1.0 ml</td>
</tr>
<tr>
<td>2</td>
<td>25.000</td>
<td>59.524</td>
<td>1 x 1.0 ml</td>
</tr>
<tr>
<td>3</td>
<td>10.000</td>
<td>23.810</td>
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</tr>
<tr>
<td>4</td>
<td>2.500</td>
<td>5.952</td>
<td>1 x 1.0 ml</td>
</tr>
<tr>
<td>5</td>
<td>1.000</td>
<td>2.381</td>
<td>1 x 1.0 ml</td>
</tr>
<tr>
<td>6</td>
<td>250</td>
<td>595</td>
<td>1 x 1.0 ml</td>
</tr>
<tr>
<td>7</td>
<td>50</td>
<td>119</td>
<td>1 x 1.0 ml</td>
</tr>
</tbody>
</table>

* As calibrated against the first WHO HIV-RNA standard only using bDNA 2.0 results

Precautions
Warning: The HIV-RNA quantification panel members contain infectious HIV particles and are potentially biohazardous. Observe the universal precautions for prevention of transmission of infectious agents when handling these materials. Although the normal human plasma used in the production of this panel was negative for infectious disease markers the quantification panel members should be handled as if capable of transmitting (unknown) infectious agents. Do not pipette by mouth. Use personal protective equipment, including lab coats, gloves and safety glasses. Do not eat, drink or smoke in areas where the members are handled. Disinfect liquids, materials or spills with a 0.5% sodium hypochlorite solution or equivalent. Dispose of all materials and liquids used in procedure as if they contained pathogenic agents.
**Storage Instructions**

It is necessary to store the panel at –70°C or lower to ensure no degradation can occur and the given quantification is correct. Discard any unused material after the first use. Any panel members that appear cloudy or contain precipitates after thawing should be discarded.

**Instructions for Use**

Thaw the panel members quickly in a water bath at 37°C to avoid formation of cryo-precipitates, mix gently during thawing until ice clot just has disappeared. Immediately after thawing, vortex briefly, and give a short spin before releasing screw cap from the vials. The panel members are now ready use.

The panel members should be handled and tested in a manner identical to that required for clinical specimens run in the test procedure being evaluated. Follow the manufacturers or testing laboratory instructions and recommendations for the handling and testing of clinical specimens.

After thawing the samples should be used within 24 hours, for a short period you can store at 2-8°C. In case you want to aliquot members for multiple use samples must be snap frozen using liquid nitrogen.

**Limitations**

HIV-RNA quantification panel members are not intended to replace the internal calibrators integral to in vitro diagnostic (IVD) test kits, but may be used as external, independent standardised samples for the assessment of the performance of quantitative NAT assays.

**Key to Symbols Used**

<table>
<thead>
<tr>
<th>Date of manufacturing</th>
<th>Manufacturer</th>
<th>Lot number</th>
<th>Catalogue number</th>
<th>Store at -70°C or lower</th>
<th>Biological substance Category B</th>
</tr>
</thead>
</table>

**Quantifications**


**Technical Support:**

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