This Quantitative Microsphere System (QMS) instructions for use must be read carefully prior to use. Instructions must be followed accordingly.

**Intended Use**

The QMSTM Plazomicin Immunoassay Controls, when used in conjunction with QMS Plazomicin Immunoassay and QMS Plazomicin Immunoassay Calibrators, are intended for quality control of QMS Plazomicin Immunoassay.

**Materials Provided**

Each control kit contains three controls with the following concentrations of plazomicin:

<table>
<thead>
<tr>
<th>Control</th>
<th>Concentration (µg/mL)</th>
<th>Quantity</th>
<th>Fill Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2.5</td>
<td>1</td>
<td>1.5 mL</td>
</tr>
<tr>
<td>2</td>
<td>8.0</td>
<td>1</td>
<td>1.5 mL</td>
</tr>
<tr>
<td>3</td>
<td>30.0</td>
<td>1</td>
<td>1.5 mL</td>
</tr>
</tbody>
</table>

Each control kit may be used with any reagent lot. The controls contain human serum matrix and plazomicin with sodium azide as a preservative.

**Storage and Stability**

Store controls at 2-8 °C. The controls are stable until the expiration date printed on the label.

**Standardization**

The purity and composition of the QMS Plazomicin Immunoassay Controls were confirmed by LC-MS/MS. The controls were prepared by gravimetric addition of plazomicin to a human serum matrix.

**Instruction For Use**

QMS Plazomicin Immunoassay Controls should be treated the same as patient specimens and should be handled and used in accordance with the instructions accompanying the instrument, kit, or reagents being used.

- Refer to the QMS Plazomicin Immunoassay package insert, included in the reagent kit, for a complete summary and explanation of the test.
- The QMS Plazomicin Immunoassay Controls are for use with the QMS Plazomicin Immunoassay only.
- Controls are shipped at 2-8 °C. Mix each control thoroughly by gentle inversion using a rocker for 15-20 minutes. Avoid the formation of bubbles. After each use, tightly close the caps and return controls to 2-8 °C storage.

**Limitations**

Accurate and reproducible results are dependent upon properly functioning instruments, reagents, calibrators and controls, storage of product as directed, and good laboratory technique.

**Warnings and Precautions**

- **Precautions for Users**
  Exercise the standard precautions required for handling all laboratory reagents.

- **CAUTION:** Materials of human origin were tested for HIV1 and 2, Hepatitis B and Hepatitis C by an FDA-approved method. The findings were negative. No test method can rule out the potential risk of infection with absolute certainty; therefore, the material must be handled with universal precautions. In the event of exposure, the directives of the responsible health authorities should be followed.

- **WARNING:** QMS Plazomicin Immunoassay Controls contains ≤0.1% sodium azide. EUH032 - Contact with acids liberates very toxic gas.

- **CAUTION:** The controls contain less than 0.1% sodium azide. Avoid contact with skin and mucous membranes. Flush affected areas with copious amounts of water. Seek immediate medical attention if controls are ingested or come into contact with eyes. Sodium azide may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such controls, always flush with large amounts of water to prevent accumulation of azide. Clean exposed metal surfaces with a 10% solution of sodium hydroxide.

**Indications of Instability or Deterioration**

Instability or deterioration should be suspected if there are visible signs of leakage, turbidity, microbial growth, or if the assay does not meet the reagent package insert and/or instrument-specific operations manual criteria.

**Glossary:**

http://www.thermofisher.com/symbols-glossary

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