Nanopia® E Control

INTENDED USE
The Nanopia® E Control is used to monitor the accuracy and precision of the Nanopia® KL-6 assay. The Nanopia® KL-6 Control can only be used with the Nanopia® KL-6 Reagent.

SUMMARY AND PRINCIPLE
See the Nanopia® KL-6 Reagent package insert.

REAGENTS/COMPOSITION
The Nanopia® E Control contains 2 levels of controls. The Nanopia® E Controls are a lyophilized preparation of 2 control levels, Level 1 and Level 2. Each level has 3 vials at 1 mL each.

Precautions and Warnings
1. For In Vitro Diagnostic Use.
2. Do not use the controls beyond the expiration date printed on the labels.
3. Warning: All specimens used in the test should be considered potentially infectious. Universal precautions as they apply to your facility should be used for handling and disposal of materials during and after testing.
4. Disposal of all waste material should be in accordance with local guidelines.

Preparation of Controls
Add 1 mL of purified water to the vial. Mix gently to avoid the formation of foam. Invert to mix before use.

Storage and Stability
Unopened controls are stable until the expiration date shown on the label when stored at 2 - 8°C.

Once opened and capped, the controls are stable up to 4 weeks at 2-8°C.

DO NOT FREEZE

Indications of Deterioration
Presence of turbidity or microbial growth may indicate deterioration.

PROCEDURE
Materials Provided

<table>
<thead>
<tr>
<th>Description</th>
<th>Configuration</th>
<th>Catalog Number</th>
</tr>
</thead>
</table>
| Nanopia® E Control | Level 1 – 3 x 1 mL  
Level 2 – 3 x 1 mL | 516214          |

Materials Required but not Provided

<table>
<thead>
<tr>
<th>Description</th>
<th>Configuration</th>
<th>Catalog Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nanopia® KL-6 Reagent 1</td>
<td>2 x 24 mL</td>
<td>466175</td>
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<tr>
<td>Nanopia® KL-6 Reagent 2</td>
<td>2 x 8 mL</td>
<td>466199</td>
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</tbody>
</table>

• Analyzer capable of running two-reagent chemistries.

Procedure
When using this control, treat it in exactly the same manner as a patient specimen.

Refer to the instrument operator’s manual for analyzer specific control procedures and for guidance in determining the frequency of running controls.

Quality Control values should be within the expected ranges.

References
2. Data on file at Sekisui Medical.

Definitions for Symbols
REF
Catalog number
In vitro diagnostic medical device
IVD
Temperature limitation
Manufacturer
Use by
LOT
Batch code
Consult Instructions for use
Caution, consult accompanying documents
EC
Authorized representative in the European Community
REP
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