Reagent for research purpose use only

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.[1]
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

Description	Configuration	Catalog Number
Nanopia® E Control	Level 1 – 3 x 1 mL Level 2 – 3 x 1 mL	516214

Materials Required but not Provided

Description	Configuration	Catalog Number
Nanopia® KL-6 Reagent 1	2 x 24 mL	466175
Nanopia® KL-6 Reagent 2	2 x 8 mL	466199
Nanopia® KL-6 Calibrator	4 Levels x 0.5 mL	466458

• Analyzer capable of running two-reagent chemistries.

Procedure

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

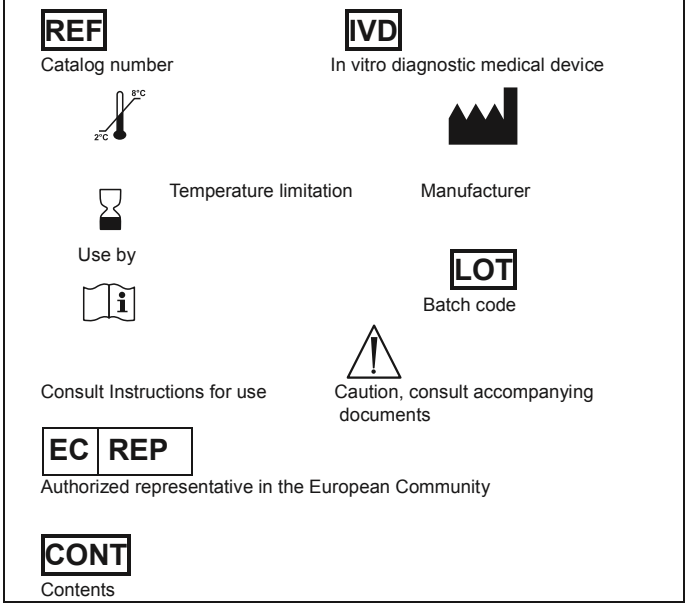
Refer to the instrument operator's manual for analyzer specific control procedures and for guidance in determining the frequency of running controls.

Quality Control values should be within the expected ranges.

References

1. Wilson DE and Chosewood LC, eds. Biosafety in Microbiological and Biomedical Laboratories. (5th Edition), U.S. Dept. of Health and Human Services, Public Health Service, HHS
   Publication No. (CDC) 21-1112, Washington, DC: 2009.
2. Data on file at Sekisui Medical.

Definitions for Symbols



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