

Nanopia® KL-6 Calibrator

INTENDED USE

For the calibration of the Nanopia® KL-6 assay. The Nanopia® KL-6 Calibrator 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® KL-6 calibrators are liquid preparations of sialylated carbohydrate antigen KL-6.

Precautions and Warnings

1. Do not use the calibrators beyond the expiration date printed on the label.
2. **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
3. Nanopia® KL-6 Reagents must be used with the Nanopia® KL-6 Calibrator.
4. **Caution** : Avoid freezing reagents.
5. **Caution** : KL-6 Calibrator contain less than 0.1% sodium azide as a preservative. Sodium azide may react with lead and copper plumbing to form potentially explosive metal azide buildup. Flush with copious amounts of water when discarding material.
6. Disposal of all waste material should be in accordance with local guidelines.
7. **Caution** : Do not store below 2°C.

Preparation of Calibrator

Calibrators: Liquid, ready-to-use.

Unopened, the calibrators are stable until the expiration date shown on the label when stored at 2 - 8°C.

Once opened, and capped, the calibrators are stable for 10 weeks at 2 - 8°C.

Invert to mix before use. Avoid the formation of foam.

Storage and Stability

Unopened calibrator is stable until the expiration date shown on the label when stored at 2 - 8°C.

Indications of Deterioration

Presence of turbidity or microbial growth may indicate deterioration.

PROCEDURE

Materials Provided

Description	Configuration	Catalog Number
Nanopia® KL-6 Calibrator	4 Levels x 1.0 mL	536519

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® E Control (Level 1, 2)	Level 1 – 3 x 1 mL Level 2 – 3 x 1 mL	516214

- Physiological saline (0.9% w/v NaCl) to be used as zero calibrator.
- Volumetric pipette or calibrated single channel pipette.
- Analyzer capable of running two-reagent chemistries.

Calibration

When using this calibrator, treat it in exactly the same manner as a patient sample.

The Nanopia® KL-6 assay requires a multipoint calibration curve. The values of the Nanopia® KL-6 Calibrator, which can be found on the calibrator vial labels, are traceable to an in-house standard.

Refer to the instrument operator's manual for analyzer specific calibration procedures and for guidance in determining calibration frequency.

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

REF

Catalog number



Temperature limitation



Manufacturer



Use by



Consult Instructions for use

LOT

Batch code



Caution, consult accompanying documents

EC REP

Authorized representative in the European Community

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