

QMS[®] Amikacin (AMIK) Calibrators

IVD For In Vitro Diagnostic Use Only

Rx Only

REF 0374157

This Quantitative Microsphere System (QMS) package insert must be read carefully prior to use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Intended Use

The QMS Amikacin Calibrator set is intended for use in calibration of the QMS Amikacin assay.

Contents

The QMS Amikacin Calibrator set consists of human serum and <0.1% sodium azide as preservative with the following concentrations of amikacin:

Vial	Concentration (µg/mL)	Quantity	Fill Volume
A	0.0	1	1.0 mL
B	3.0	1	1.0 mL
C	10.0	1	1.0 mL
D	20.0	1	1.0 mL
E	35.0	1	1.0 mL
F	50.0	1	1.0 mL


Standardization

The reference material used to verify the accuracy of the QMS Amikacin Calibrators is the United States Pharmacopeia (USP) reference standard for amikacin. Reference samples were prepared by gravimetric dilution of USP amikacin into human serum free of amikacin at concentrations across the calibration range of the assay. The calibrator set is prepared by gravimetric dilution of high purity amikacin into human serum free of amikacin.

Warnings and Precautions

Precautions for Users


- **For in vitro diagnostic use.**
- The calibrators in this set are designed for use as a unit. Do not substitute or mix calibrators with those from other lots.

 This product contains human sourced and/or potentially infectious components. Components sourced from human blood have been tested and found to be nonreactive for HBsAg, anti-HIV 1/2, and anti-HCV. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, it is recommended that all human sourced materials be considered potentially infectious and handled with appropriate biosafety practices.

WARNING: QMS Amikacin calibrator contains ≤0.1% sodium azide.
EUH032 - Contact with acids liberates very toxic gas.

Instructions For Use

- Refer to the QMS Amikacin assay package insert, included in the reagent kit, for a complete summary and explanation of the test.
- Calibrators may be used immediately upon removal from 2 to 8°C storage.
- Mix each calibrator by gentle inversion several times before dispensing.
- Carefully squeeze at least four (4) drops of each calibrator into the individual sample cups, avoiding the formation of bubbles.
- After each use, tightly close the caps and return calibrators to 2 to 8°C.

 **CAUTION:** Bubbles may interfere with proper detection of calibrator level in the sample cup, causing insufficient calibrator aspiration that could impact results.

Storage and Stability

- Do not allow the calibrators to remain at room temperature longer than is required to perform the assay.
- Do not expose the calibrators to temperatures above 32°C. Improper storage of calibrators can affect assay performance.
- After first use, the calibrators are stable until the expiration date when stored tightly capped at 2 to 8°C.
- Do not use the calibrators beyond the expiration date.

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.

Limitations of the Procedure

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

Quality Control

All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

Glossary:

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


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