# QMS® Vancomycin (VANCO) Calibrators

Thermo SCIENTIFIC

**IVD** **For In Vitro Diagnostic Use Only**

**Rx Only**

**REF** **0373597**

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

### Contents
The QMS Vancomycin Calibrator set consists of human serum and <0.1% sodium azide as preservative with the following concentrations of vancomycin:

| Vial | Concentration (µg/mL) | Quantity | Fill Volume |
|---|---|---|---|
| A | 0.0 | 1 | 1.0 mL |
| B | 5.0 | 1 | 1.0 mL |
| C | 10.0 | 1 | 1.0 mL |
| D | 25.0 | 1 | 1.0 mL |
| E | 50.0 | 1 | 1.0 mL |
| F | 100.0 | 1 | 1.0 mL |

### Standardization
The reference material used to verify the accuracy of the QMS Vancomycin Calibrators is the United States Pharmacopeia (USP) reference standard for vancomycin. Reference samples were prepared by gravimetric dilution of USP vancomycin into human serum free of vancomycin at concentrations across the calibration range of the assay. The calibrator set is prepared by gravimetric dilution of high purity vancomycin into human serum free of vancomycin at concentrations of 0.0, 5.0, 10.0, 25.0, 50.0 and 100.0 µg/mL.

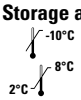
### Warnings and Precautions
Precautions for Users
- **For in vitro diagnostic use.**
- Do not use components beyond the expiration date.
- The calibrators in this set are designed for use as a unit. Do not substitute or mix calibrators with those from other lots.

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-HIV1/2, 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 Vancomycin calibrator contains ≤0.1% sodium azide.
EUH032 - Contact with acids liberates very toxic gas.

### Instructions For Use
- Refer to the QMS Vancomycin assay package insert, included in the reagent kit, for a complete summary and explanation of the test.
- Calibrators are frozen. Thaw completely before use.
- 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



- Calibrators must be stored frozen (< -10°C) until first use.
- After first use, store calibrators tightly capped at 2 to 8°C. Do not refreeze.
- Do not expose to temperatures above 32°C. Improper storage of calibrators can affect assay performance.
- After first use, calibrators are stable for six (6) weeks when stored tightly capped at 2 to 8°C.
- Do not allow the calibrators to remain at room temperature longer than is required to perform the assay.
- 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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For insert updates go to:
www.thermoscientific.com/diagnostics

**Other countries:**
Please contact your local Thermo Fisher Scientific representative.



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