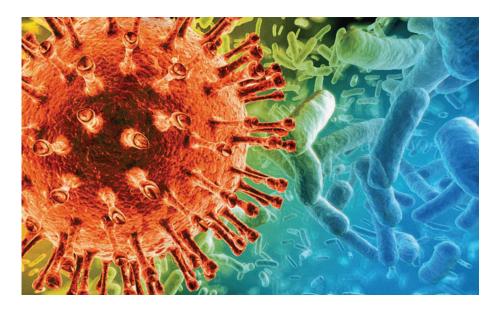
PRODUCT SPECIFICATION

Thermo Scientific

QMS Teicoplanin Immunoassay

- Liquid, stable, and ready-to-use reagents
- Excellent correlation to the Innofluor Teicoplanin assay
- Optimal sensitivity (LOQ is ≤ 3.0 µg/ mL), dynamic range (3 – 50 µg/mL) and total precision (< 6%)
- Exceptional on-board reagent stability 30 days
- Calibration curve stability > 7 days
- No measurable interference with endogenous substances and prescription drugs
- Applicable on a variety of clinical chemistry analysers



Thermo Scientifc[™] QMS[™] Teicoplanin Immunoassay

The QMS Teicoplanin Immunoassay is intended for the quantitative determination of Teicoplanin in human serum or plasma on automated clinical chemistry analysers, such as the Thermo Scientific[™] Indiko[™] and Indiko Plus[™] Clinical Chemistry analysers, as an aid in the management of patients receiving teicoplanin therapy.

Teicoplanin - The Drug

Teicoplanin (Targocid) is a bactericidal glycopeptide antibiotic, produced by fermentation of Actinoplanes teichomyceticus. Similar to Vancomycin, Teicoplanin is active against both aerobic and anaerobic Gram-positive bacteria. It is used for the treatment of moderate to severe infections (including MRSA infections). Determination of teicoplanin concentration may optimise therapy. Teicoplanin trough concentrations that are at least 10 µg/mL may optimize therapy in cases of severe infection.

CE Not for sale in USA





QMS Teicoplanin Assay: The field of drug monitoring is constantly changing. With our many years of experience in developing assays, we are able to anticipate future drug monitoring needs by providing a broad range of innovative drug monitoring solutions. Offering the most extensive menu in the industry, we continue helping our customers meet their distinct drug monitoring requirements.

QMS - The Technology

The Quantitative Microshpere System (QMS) technology uses stable and reproducible microparticles. This particle-enhanced turbidimetric technology is suitable for the measurement of blood levels of therapeutic drugs (TDM) in areas such as infection, epilepsy, cardiology, pain management, and organ transplantation.

Performance Characteristics

Representative performance results obtained on a commercially available automated clinical chemistry analyser that employs the turbidimetric quantitative analysis are shown below.

Sensitivity / Limit of Quantitation (LOQ)

The LOQ of the QMS Teicoplanin assay is defined as the lowest concentration for which acceptable inter-assay precision and recovery is observed. The LOQ was determined to be $< 3.0 \mu g/mL$.

Assay Range

The assay range is 3 to 50 µg/mL.

Accuracy / Recovery

Accuracy by recovery was determined by spiking Teicoplanin into human serum. A mean of the replicates for each sample was determined and percent recovery calculated. All samples within the assay range passed specifications of $100 \pm 10\%$.

Precision

A tri-level human serum based control containing Teicoplanin was used in the study. Each level of control was assayed in duplicate twice a day for 20 days. The results of the precision study demonstrate exceptional precision.

| Sample | Target Value (µg/mL) | N | Mean (µg/mL) | Within Run %CV | Between Run %CV | Between Day %CV | Total %CV |
|-----------------|-------------------------|----|-----------------|-------------------|--------------------|--------------------|-----------|
| Control Level 1 | 10 | 80 | 9.8 | 1.7 | 1.6 | 3.7 | 4.4 |
| Control Level 2 | 35 | 80 | 37.4 | 1.9 | 0.4 | 2.7 | 3.4 |
| Control Level 3 | 75 | 80 | 75.2 | 4.2 | 0.9 | 2.0 | 4.7 |

Method Comparison

Correlation results were obtained by measuring 100 clinical patient samples with the QMS Teicoplanin Assay and Innofluor Teicoplanin Assay. The results demonstrate excellent correlation between the two technologies.

| | Methods | N | Deming (95% CI) | | Passing-Bab | R |
|-------------------|---------|---------------------|----------------------|---------------------|----------------------|------|
| QMS vs. Innofluor | 100 | Slope | Intercept | Slope | Intercept | 0.98 |
| | | 0.93 (0.89 to 0.96) | 0.29 (-0.60 to 1.17) | 0.94 (0.90 to 0.97) | 0.17 (-0.50 to 0.76) | 0.90 |

Ordering Information

| Part Number | Product | Description | | |
|-------------|--------------------------------|---|--|--|
| 0374645 | QMS Teicoplanin | Reagent 1: 21 mL (Antibody Reagent) | | |
| | | Reagent 2: 9 mL (Microparticle Reagent) | | |
| 0374652 | QMS Teicoplanin Calibrator Set | Level A 1 x 2 mL ea | | |
| | | Levels B-F1x1mL ea | | |
| 0374660 | QMS Teicoplanin Control Set | Tri-level - 3 x 2.0 mL | | |

Clinical Diagnostics

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