



INNOFLUOR® TEICOPLANIN CONTROL SET

Catalog No. 41032

**CAUTION: FOR EXPORT USE ONLY.
NOT AVAILABLE IN THE U.S.A.**

INTENDED USE

The INNOFLUOR® TEICOPLANIN Control Set is intended for use in the quality control of the INNOFLUOR® TEICOPLANIN Assay System.

PRINCIPLES OF THE PROCEDURE

The INNOFLUOR® TEICOPLANIN Assay System is intended for the quantitative determination of total teicoplanin in serum for therapeutic drug monitoring by fluorescence polarization immunoassay. The concentrations of the controls have been chosen to best monitor the quality and stability of a calibration curve. See the INNOFLUOR® TEICOPLANIN Assay System Product Insert, included in the reagent set, for a complete summary and explanation of the test.

REAGENTS

The INNOFLUOR® TEICOPLANIN Control Set consists of three vials of teicoplanin in human serum and <0.1% sodium azide as preservative with the following mean values and expected ranges for use:

See Values Sheet

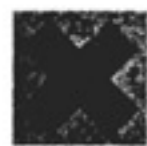
Each control vial contains 2 mL, sufficient for 25 determinations.

Warnings and Precautions:

For In Vitro Diagnostic Use

INNOFLUOR® controls contain human blood components. All human blood derivatives should be considered potentially infectious. It is recommended that these reagents and human samples be handled using established good laboratory practices since no test method can guarantee that products derived from human blood will not transmit infection.

Sodium azide preservative in diagnostic reagents may react with lead and copper in plumbing to form highly explosive compounds. Flush with liberal amounts of water upon disposal.



- R22 Harmful if swallowed
- R32 Contact with acids liberates very toxic gas
- S35 This material and its container must be disposed in a safe way.
- S36 Wear suitable protective clothing
- S46 If swallowed, seek medical advice immediately and show this container or label.

Preparation:

Controls are frozen. Thaw completely and mix thoroughly but gently to provide a homogeneous mixture. Before each use, mix thoroughly but gently to avoid the formation of bubbles.

Storage and Stability of Controls:

Controls must be stored frozen ($\leq -10^{\circ}\text{C}$) until first use. After first use, store controls tightly capped at 2° to 8°C (do not refreeze). Controls are stable at 2° to 8°C for sixteen weeks. Do not use the controls beyond the expiration date printed on the package and vial labels.

Do not allow the controls to remain at room temperature longer than is required to perform the assay.

Discard the control vials if increased turbidity, unusual odor or other indications of microbial contamination are present.

ASSAY PROCEDURE

The control results must be within established acceptable ranges before patient samples are assayed.

See the INNOFLUOR® TEICOPLANIN Assay System Product Insert, Assay Procedure and Quality Control Instructions, for directions concerning the use of teicoplanin controls.

Innofluor® Controls



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**Made in the U.S.A.
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