

JAN 13 1997

K964587

SUMMARY OF SAFETY AND EFFECTIVENESS

Vancomycin Method for Bayer Technicon Immuno 1[®] System

Listed below is a comparison of the performance between the Immuno 1 Vancomycin method and a similar device that was granted clearance of substantial equivalence (Syva EMIT[®] Vancomycin Assay, Behring Diagnostics Inc.). The information used in the Summary of Safety and Effectiveness was extracted from the Immuno 1 Vancomycin method sheet and the Syva EMIT[®] Vancomycin Assay Insert Sheet.

INTENDED USED

This *in vitro* method is intended to quantitatively measure vancomycin, an antibiotic, in human serum or plasma (heparin) using Syva EMIT[®] Vancomycin Assay on a *Technicon Immuno-1[®]* system. Measurements of vancomycin are used in the diagnosis and treatment of vancomycin overdose and in monitoring levels of vancomycin to ensure appropriate therapy.

METHOD	Immuno 1 Vancomycin	Syva EMIT [®] Vancomycin (predicate Device)
Part No.	Reagents T01-3705-01 Calibrators T03-3714-01	Reagents 6W419UL Calibrators 6W519UL
Minimum Detectable Conc.	0.2 µg/mL	Not Listed
Precision (Between-Run)	8.5 µg/mL 5.3% 39.5 µg/mL 6.6% 50.6 µg/mL 5.3%	7.2 µg/mL 10.3% 38.7 µg/mL 5.6% 39.5 µg/mL 6.2%

Correlation $y = 1.032 x - 0.006$

where

- y = Immuno 1 Vancomycin method
- x = Syva EMIT[®] Vancomycin Assay*
- n = 53
- r = 0.981
- S_{yx} = 1.779 µg/mL

*This assay was performed on Technicon RA-1000[®] Instrument using parameters and protocol specified in Behring Application Sheet.

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