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SUMMARY OF SAFETY AND EFFECTIVENESS

Quinidine Method for Bayer Technicon Immuno 1® System

Listed below is a comparison of the performance between the Immuno 1 Quinidine method and a similar device that was granted clearance of substantial equivalence (Syva EMIT® 2000 Quindine Assay, Behring Diagnostics Inc.). The information used in the Summary of Safety and Effectiveness was extracted from the Immuno 1 Quinidine method sheet and the Syva EMIT® 2000 Quinidine Assay insert.

INTENDED USED

This *in vitro* method is intended to quantitatively measure Quinidine, an anti-arrhythmic drug, in human serum or plasma (heparin) using Syva EMIT® 2000 Assay on a *Technicon Immuno-1®* system. Measurements of quinidine are used in the diagnosis and treatment of quinidine overdose and in monitoring serum levels of quinidine to ensure appropriate therapy.

METHOD	**Immuno 1 Quinidine**	**Syva EMIT® 2000** (predicate Device)
Part No.	Reagents T01-3678-51 Calibrators T03-3680-01	Reagents 4Q019UL Calibrators 4Q109UL
Minimum Detectable Conc.	0.06 µg/mL	0.25 µg/mL
Precision (Between-Run)	1.2 µg/mL 5.5% 3.5 µg/mL 4.8% 6.0 µg/mL 5.3%	1.5 µg/mL 6.5% 3.4 µg/mL 5.2% 5.7 µg/mL 5.6%
Correlation	y = 1.02x - 0.16 where y = Immuno 1 Quinidine method x = Syva EMIT® 2000 Quinidine Assay* n = 25 r =0.991 S_{yx} =0.148 µg/mL *This assay was performed on Roche COBAS FARA II® Instrument.	

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* Please Note: Additional # patients requested. DATA provided in 11/26/96 memo. No significant change in correlation. RDB.

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