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SUMMARY OF SAFETY AND EFFECTIVENESS

Carbamazepine Method for Bayer Technicon Immuno 1® System

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

INTENDED USED

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

METHOD	**Immuno 1 Carbamazepine**	**Syva EMIT® 2000 (predicate Device)**
Part No.	Reagents T01-3677-51 Calibrators T03-3679-01	Reagents 4F019UL Calibrators 4F109UL
Minimum Detectable Conc.	0.2 µg/mL	0.5 µg/mL
Precision (Between-Run)	2.8 µg/mL 3.9% 9.6 µg/mL 4.2% 16.1 µg/mL 8.7%	4.0 µg/mL 7.3% 10.0 µg/mL 5.9% 16.3 µg/mL 5.6%
Correlation	$y = 1.07x - 0.13$ where y = Immuno 1 Carbamazepine method x = Syva EMIT® 2000 Carbamazepine Assay* n = 50 r =0.978 S_{yx} =0.89 µg/mL *This assay was performed on Roche COBAS FARA II® Instrument.	

Gabriel J. Murada, Jr.
Manager Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

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