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SUMMARY OF SAFETY AND EFFECTIVENESS

Valproic Acid Method for Bayer Technicon Immuno 1® System

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

INTENDED USED

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

METHOD	**Immuno 1 Valproic Acid Method Set**	**Syva EMIT® Valproic Acid Assay** (predicate Device)
Part No.	T01-3698-01	6G009UL
Minimum Detectable Conc.	0.9 µg/mL	Not listed
Precision (Between-Run)	3.4% @ 50.4 µg/mL 2.6% @ 115.4 µg/mL 2.9% @ 132.2 µg/mL	4.6% @ 76 µg/mL
Correlation	$y = 0.94x - 0.22$	

where
- y = Immuno 1 Valproic Acid method
- x = Syva EMIT® Valproic Acid Assay*
- n = 50
- r = 0.996
- S_{yx} = 3.16 µg/mL

*This assay was performed on COBAS FARA II® Instrument using parameters and protocol specified in Behring Application Sheet.

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