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BEHRING

SUMMARY OF SAFETY AND EFFECTIVENESS

Emit® 2000 Gentamicin Assay and Emit® 2000 Gentamicin Calibrators

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

Behring Diagnostics Inc. is submitting this Premarket Notification, 510(k) to convey our intention to commercially distribute a modified Emit® 2000 Gentamicin Assay, an in vitro diagnostic reagent test kit for the quantitative analysis of gentamicin in human serum or plasma. The modified Emit 2000 Gentamicin Assay has been found to be substantially equivalent to the Abbott TDx Gentamicin Assay (K904226) with regard to intended use, assay sample, and overall performance characteristics.

I. PERFORMANCE STUDIES

A. Within-Run and Total Precision

Within-run and total precision for the Emit 2000 Gentamicin Assay were calculated in a manner consistent with the NCCLS EP5-T2 protocol. Precision was evaluated using three levels (subtherapeutic, therapeutic, and upper therapeutic) of commercially available controls. The results of these studies are summarized below:

Within-run precision CVs: 1.6 to 5.6%.
Total precision CVs: 2.7 to 6.7%

B. Accuracy

One-hundred and four patient samples were evaluated using the Emit 2000 Gentamicin Assay on the Syva 30R Analyzer. The analysis demonstrate excellent correlation with the Abbott TDx Gentamicin Assay (FPIA). The accuracy results are summarized below:

Slope	0.94
Intercept (ng/mL)	0.10
Mean (ng/mL)	
Emit 2000 Assay	2.706
FPIA Method	2.544
Standard Error of the Estimate (ng/mL)	0.18
Correlation	0.995
Number of Samples	104

In conclusion, Behring Diagnostics considers the Emit 2000 Gentamicin Assay to be substantially equivalent to the Abbott TDx Gentamicin Assay.