

510(k) NOTIFICATION

Sigma Diagnostics
545 South Ewing Avenue
St. Louis, MO 63103

KC 4 A Micro
Coagulation Analyzer
December 15, 1995

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11/11/95

ATTACHMENT 1

Summary of Safety and Effectiveness

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510(k) Summary of Safety and Effectiveness

The Amelung KC 4 A Micro Coagulation Analyzer is a semi-automated mechanical clot detection system designed for the determination of prothrombin times (PT), activated partial thromboplastin times (APTT), fibrinogen concentrations and other clotting tests. Any clotting time test that has fibrin formation as its endpoint may be performed on the KC 4 A.

In beta sites performance studies, three physician office laboratories (POL) analyzed more than 45 samples using the KC 4 A. Split samples from the same specimens were also analyzed using the KC 4 A at Sigma Diagnostics, the study's reference laboratory. PT and APTT assays were performed at all sites. The correlation coefficient and the regression equation for these comparisons were as follows:

Site #1:	PT:	$r = 0.991$	$y = 0.981x + 0.492$
	APTT:	$r = 0.960$	$y = 1.066x + 0.379$
Site #2:	PT:	$r = 0.989$	$y = 1.019x - 0.248$
	APTT:	$r = 0.965$	$y = 1.029x + 1.021$
Site #3:	PT:	$r = 0.974$	$y = 1.012x + 0.326$
	APTT:	$r = 0.927$	$y = 0.786x + 9.470$

Precision studies were also performed at all sites. Results were within acceptable limits.

In in-house performance studies, PT and APTT were performed on more than one hundred samples using both the KC 4 A and the Fibrometer. The CA-5000 was used as the predicate device for Fibrinogen, Factor IX, and Factor X assays. The correlation coefficient and the regression equation were as follows:

PT:	$r = 0.988$	$y = 1.051x - 0.241$
APTT:	$r = 0.896$	$y = 1.235x + 0.873$
Fibrinogen:	$r = 0.930$	$y = 1.067x + 30.749$
Factor IX:	$r = 0.897$	$y = 0.958x + 3.403$
Factor X:	$r = 0.974$	$y = 1.010x - 0.166$

Precision studies were performed in-house. The coefficient of variation (CV) for all studies was less than 9%.

These data clearly demonstrate that the performance of the KC 4 A Micro Coagulation Analyzer is substantially equivalent to the performance of the predicate device.