Clinical Precision Study and Test Data

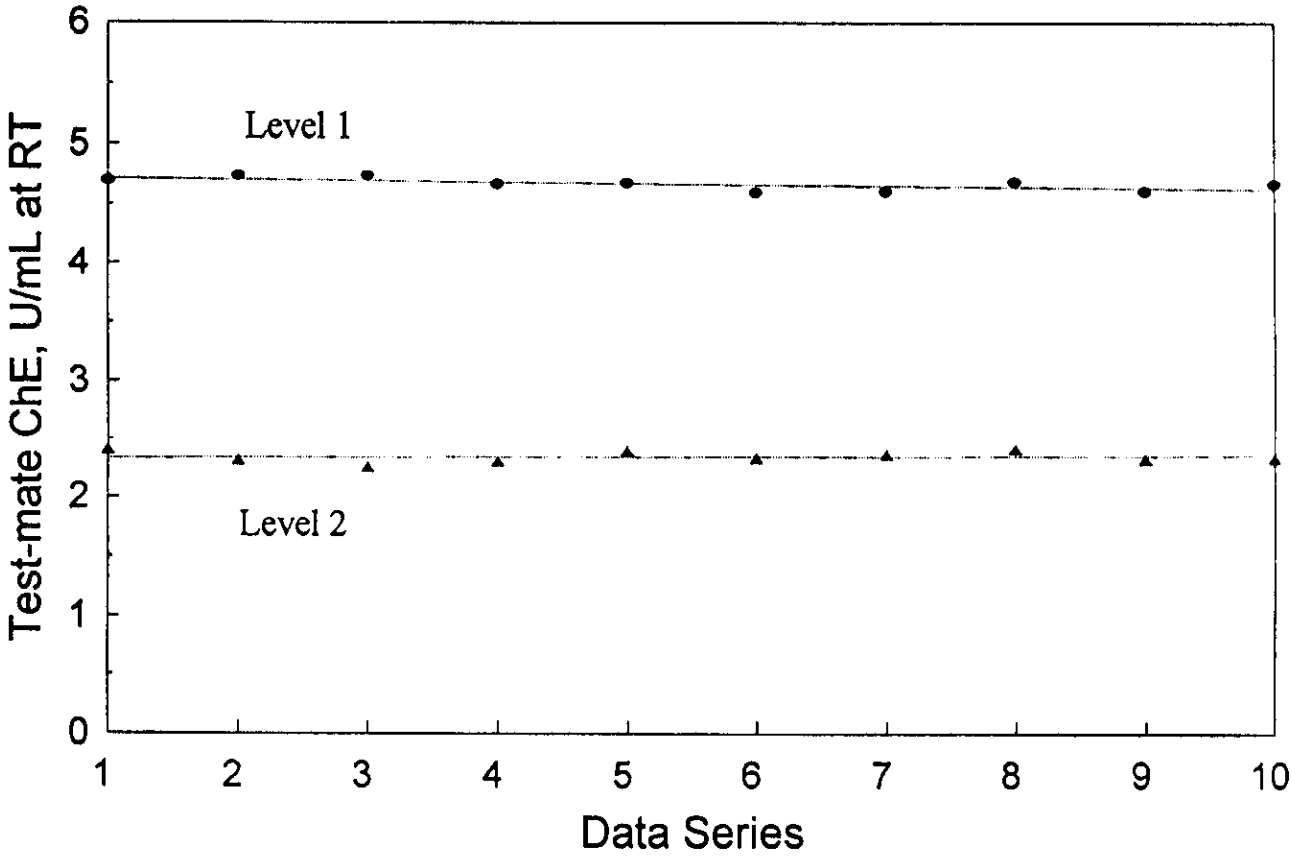
Within-Run Precision

Repeat tests were performed on January 3, 1996 using normal human donor blood (anticoagulated with EDTA) obtained from the Hoxworth Blood Center in Cincinnati, Ohio. Blood was gently inverted 20 times to insure thorough mixing, then transferred to a 0.5mL polypropylene microtube for sampling. Blood was sampled using both 10µL and 5µL capillaries, thereby producing two levels of cholinesterase activity. These two levels were chosen to correspond with normal (unpoisoned) and abnormal (poisoned) values that would be encountered when using the Test-mate ChE Cholinesterase Test System. Each of the levels was tested 10 times to determine both erythrocyte and plasma cholinesterase activity, resulting in a total of 40 tests that were performed over a three hour period. Temperature varied between 21°C and 22°C. The test data from this study was analyzed using Quattro Pro 6.0 to produce plotted graphs and provide statistical parameters [see fig. 15-A, fig. 15-B, fig. 15-C and fig. 15-D].

Between-Day Precision

Repeat tests were performed between December 21, 1995 and January 2, 1996 using fingerstick blood samples obtained from the same healthy human subject. On each day of testing, blood was sampled using both 10µL and 5µL capillaries, thereby producing two levels of cholinesterase activity. These two levels were chosen to correspond with normal (unpoisoned) and abnormal (poisoned) values that would be encountered when using the Test-mate ChE Cholinesterase Test System. Each of the levels was tested 4 times to determine both erythrocyte and plasma cholinesterase activity, resulting in a total of 16 tests that were performed over a two hour period. Temperature varied between 20°C and 23°C. The test data from this study was analyzed using Quattro Pro 6.0 to produce plotted graphs and provide statistical parameters [see fig. 15-E, fig. 15-F, fig. 15-G and fig. 15-H].

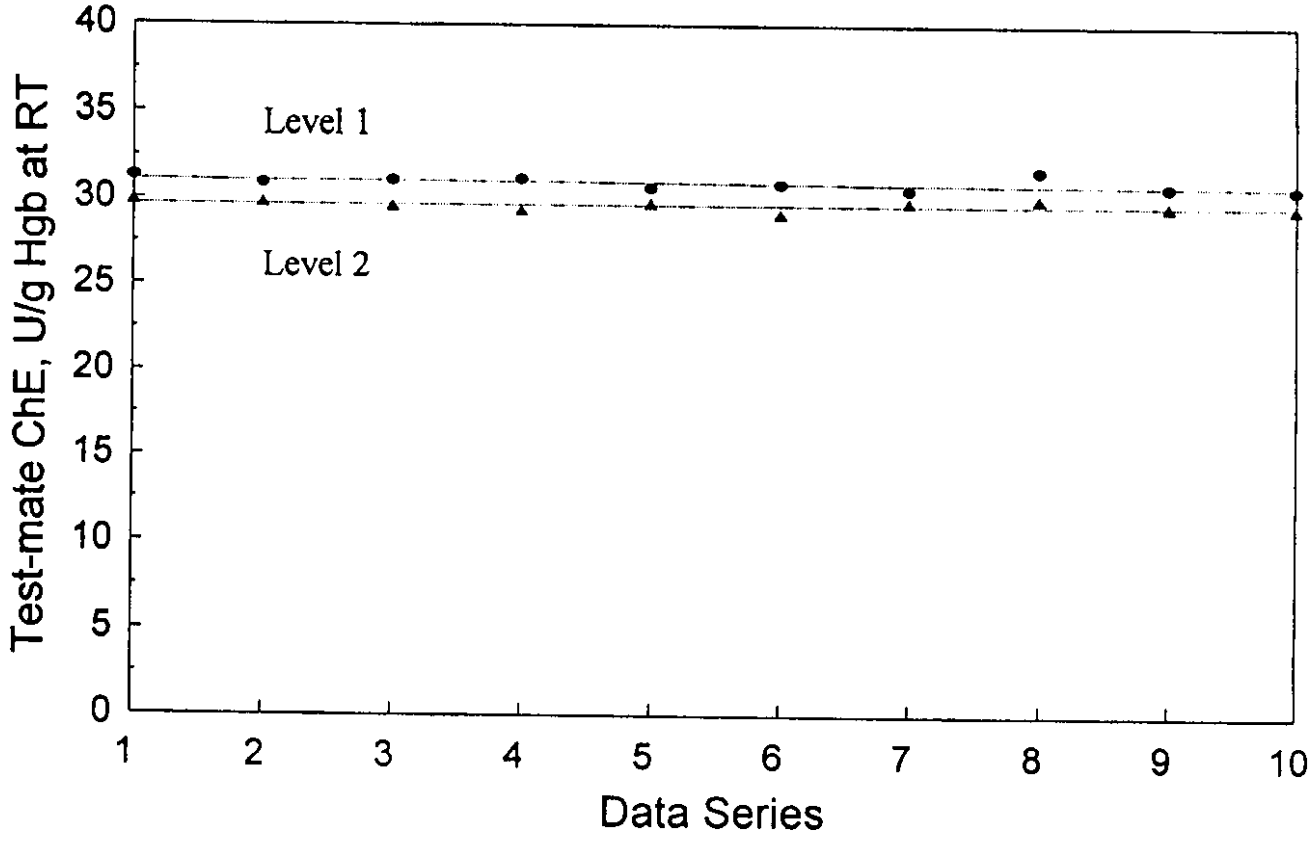
AChE: Within-Run Precision



Statistical Parameters:		
Level 1:	N	10
	Mean	4.671
	SD	0.05087
	%CV	1.1
Level 2:	N	10
	Mean	2.350
	SD	0.05011
	%CV	2.1

Fig. 15-A

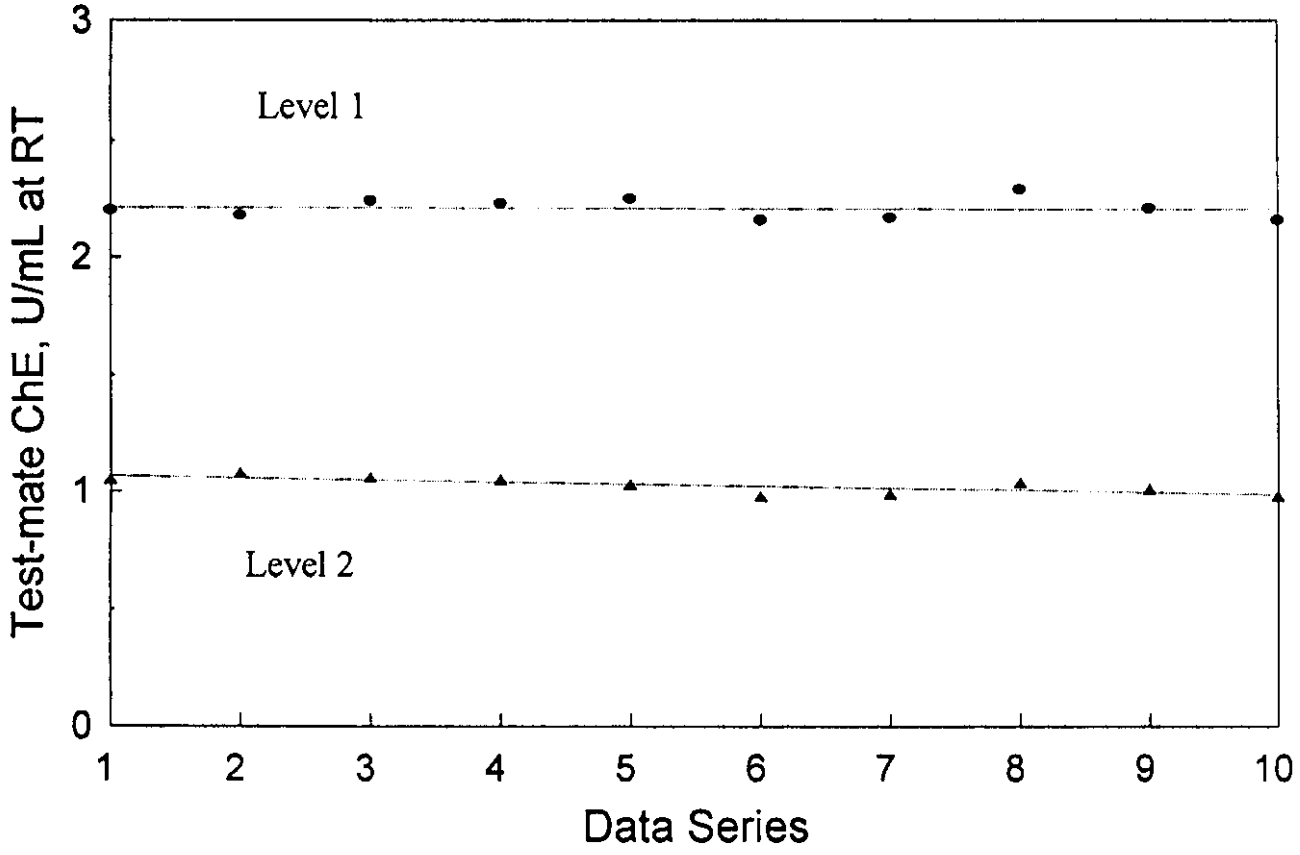
AChE: Within-Run Precision



Statistical Parameters:		
Level 1:	N	10
	Mean	30.99
	SD	0.3381
	%CV	1.1
Level 2:	N	10
	Mean	29.70
	SD	0.2625
	%CV	0.9

Fig. 15-B

PChE: Within-Run Precision

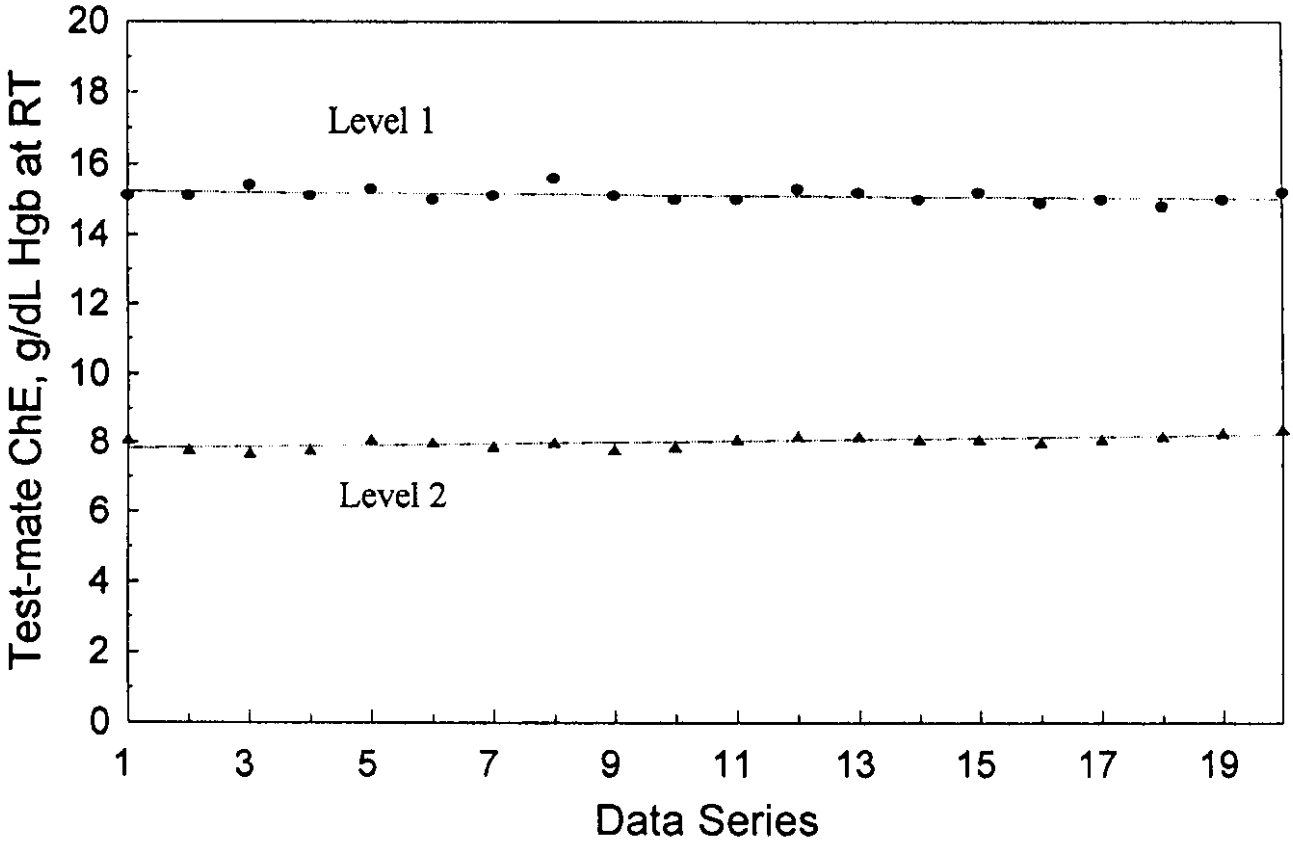


Statistical Parameters:

Level 1:	N	10
	Mean	2.209
	SD	0.04332
	%CV	2.0
Level 2:	N	10
	Mean	1.027
	SD	0.03529
	%CV	3.4

Fig 15-C

Hgb: Within-Run Precision

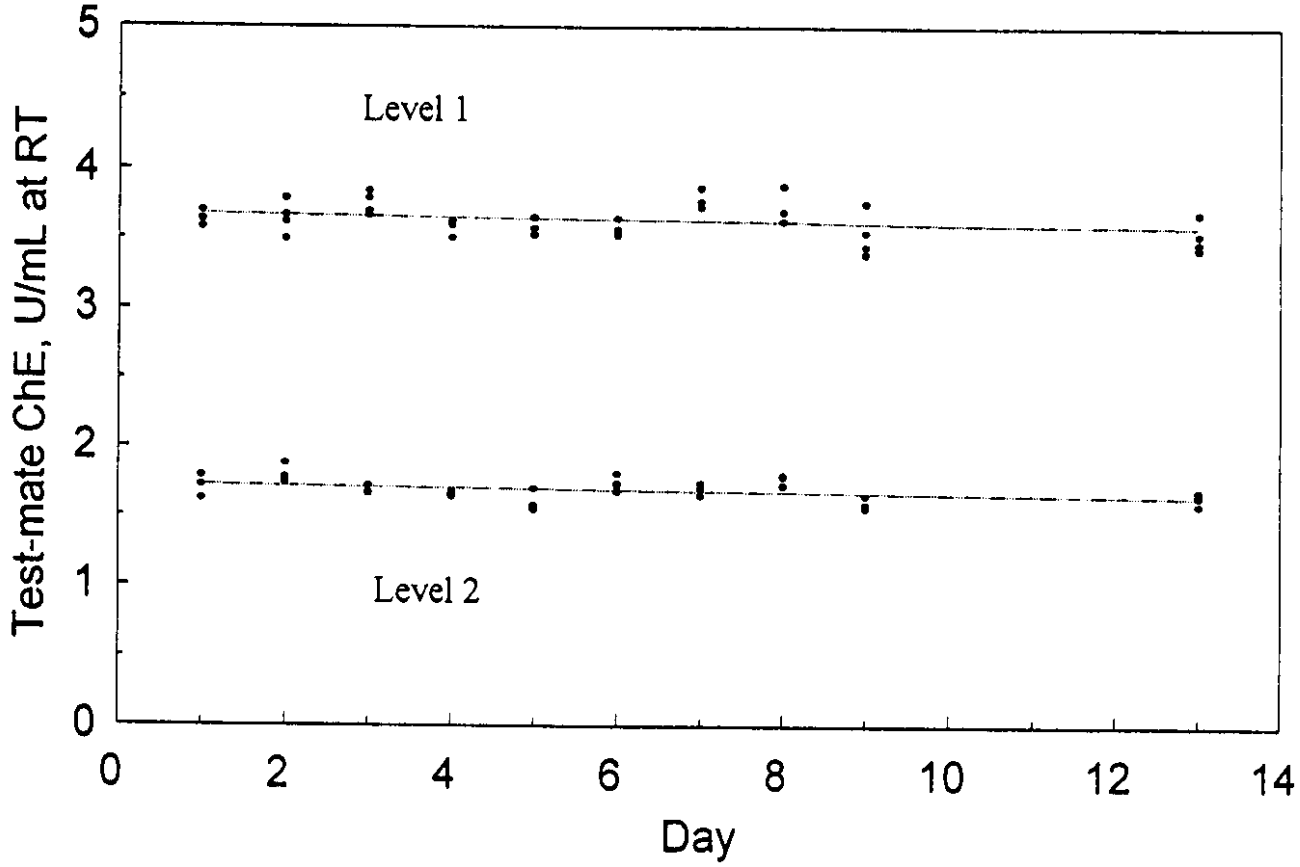


Statistical Parameters:

Level 1:	N	20
	Mean	15.12
	SD	0.1824
	%CV	1.2
Level 2:	N	20
	Mean	8.04
	SD	0.1818
	%CV	2.3

Fig. 15-D

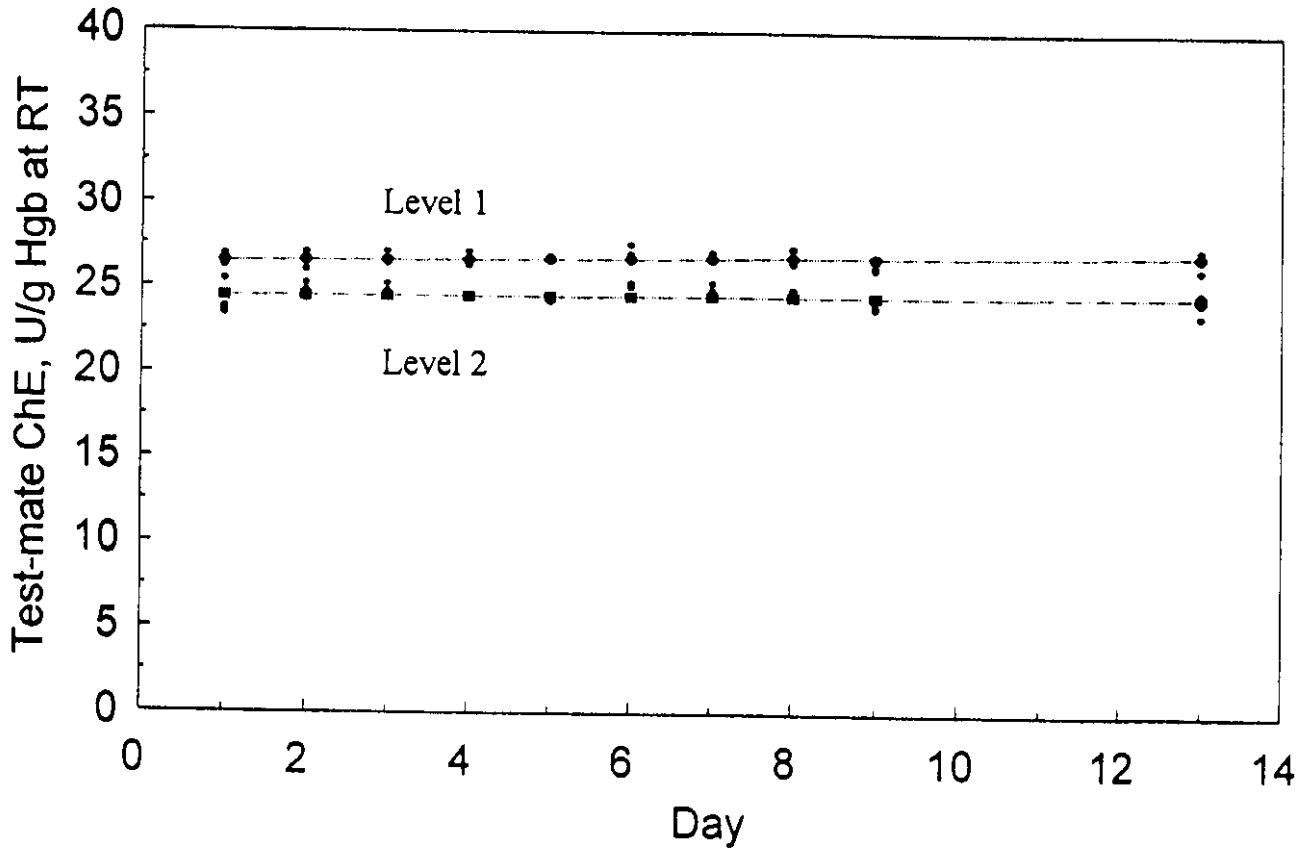
AChE: Between-Day Precision



Statistical Parameters:		
Level 1:	N	40
	Mean	3.642
	SD	0.1205
	%CV	3.3
Level 2:	N	40
	Mean	1.690
	SD	0.07694
	%CV	4.6

Fig. 15-E

AChE: Between-Day Precision

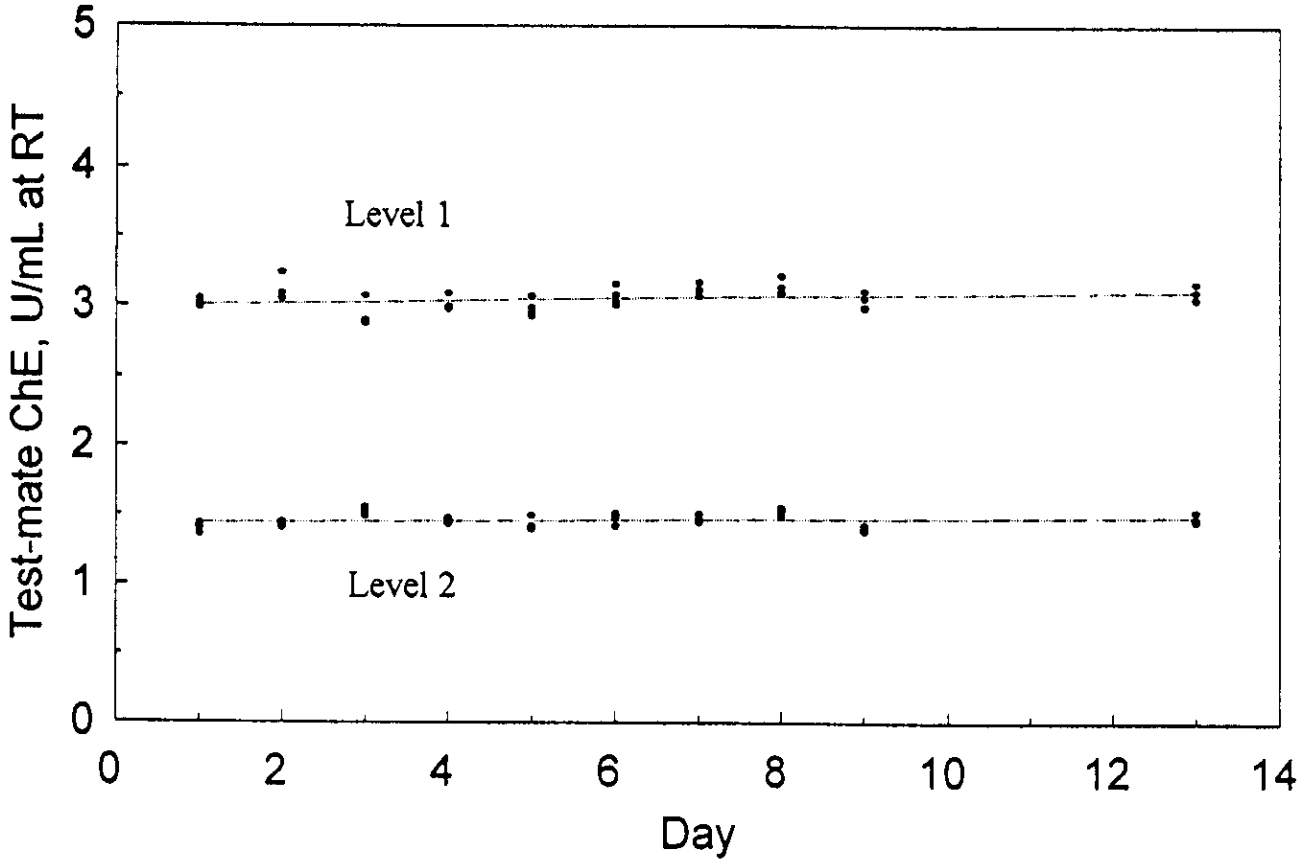


Statistical Parameters:

Level 1:	N	40
	Mean	26.72
	SD	0.4425
	%CV	1.7
Level 2:	N	40
	Mean	24.50
	SD	0.4877
	%CV	2.0

Fig. 15-F

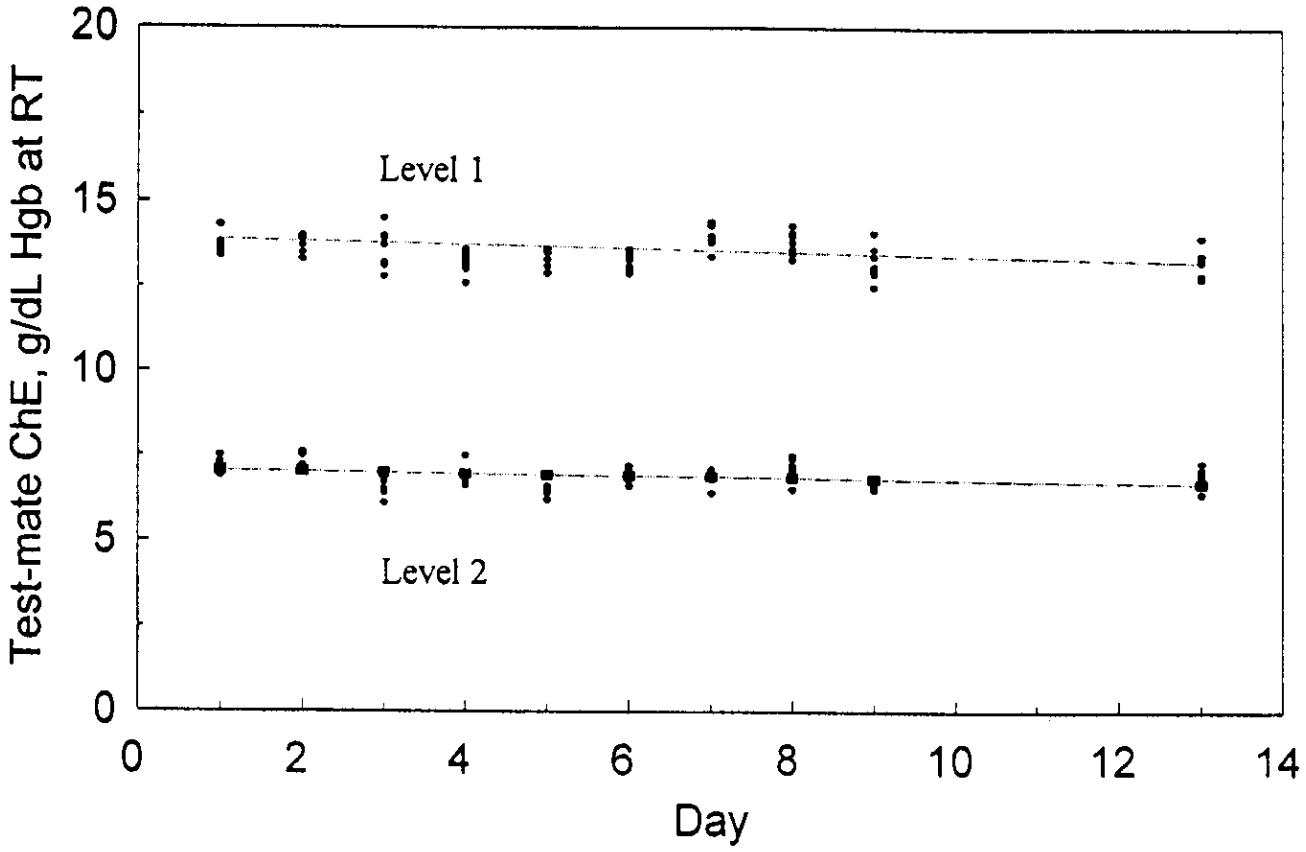
PChE: Between-Day Precision



Statistical Parameters:		
Level 1:	N	40
	Mean	3.052
	SD	0.08359
	%CV	2.7
Level 2:	N	40
	Mean	1.462
	SD	0.04917
	%CV	3.4

Fig. 15-G

Hgb: Between-Day Precision



Statistical Parameters:		
Level 1:	N	80
	Mean	13.51
	SD	0.4224
	%CV	3.1
Level 2:	N	80
	Mean	6.90
	SD	0.3329
	%CV	4.8

Fig. 15-H