

## Clinical Operator Study and Test Data

This clinical study was conducted between September 24 and October 3, 1996. To determine the between-operator variability of the Test-mate ChE Cholinesterase Test System, nine different operators at three geographically distinct testing sites were selected. The Laboratory Director supervised the study at each testing site. In addition, Dr. Magnotti of EQM Research, served as a tenth control operator. Each testing site used a separate Test-mate ChE Cholinesterase Test System and had no communications with the other testing sites.

### Veterans Administration Hospital Laboratory - Cincinnati, Ohio

Operator 1: Donna Dempsey, M.T.<sup>1</sup> (ASCP<sup>2</sup>)  
Operator 2: Ken Mescher, M.T. (ASCP)  
Operator 3: Alan Collier, M.T. (ASCP)  
Lab Director: Saad Ghosn, M.D. (Pathologist)

### Floyd Memorial Hospital Laboratory - New Albany, Indiana

Operator 4: Nicolette Stepro, M.T. (ASCP)  
Operator 5: Lynn-Marie Weber, M.T. (ASCP)  
Operator 6: Barbara Hinklin, M.T. (ASCP)  
Lab Director: Walter Mastropaolo, Ph.D., DABCC<sup>3</sup>

### University of Louisville Hospital Laboratory - Louisville, Kentucky

Operator 7: Nancy Johnson, M.T. (ASCP)  
Operator 8: Carolyn Tongate, M.T. (ASCP)  
Operator 9: David Hess, M.T. (ASCP)  
Lab Director: Roland Valdes, Ph.D., DABCC

### EQM Research, Inc. - Cincinnati, Ohio

Operator 10: Ralph Magnotti, Ph.D., DABCC

Each operator was instructed in the correct use of the Test-mate ChE Cholinesterase Test System by Dr. Magnotti. The initial operator training consisted of a hands-on session which included performing several AChE assays and several PChE assays. Each operator then performed ten AChE assays and ten PChE assays over a five day time period in a satisfactory fashion. During this five day time period, each operator analyzed a sample of the same blood that had been anticoagulated with EDTA.

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<sup>1</sup>Medical Technologist

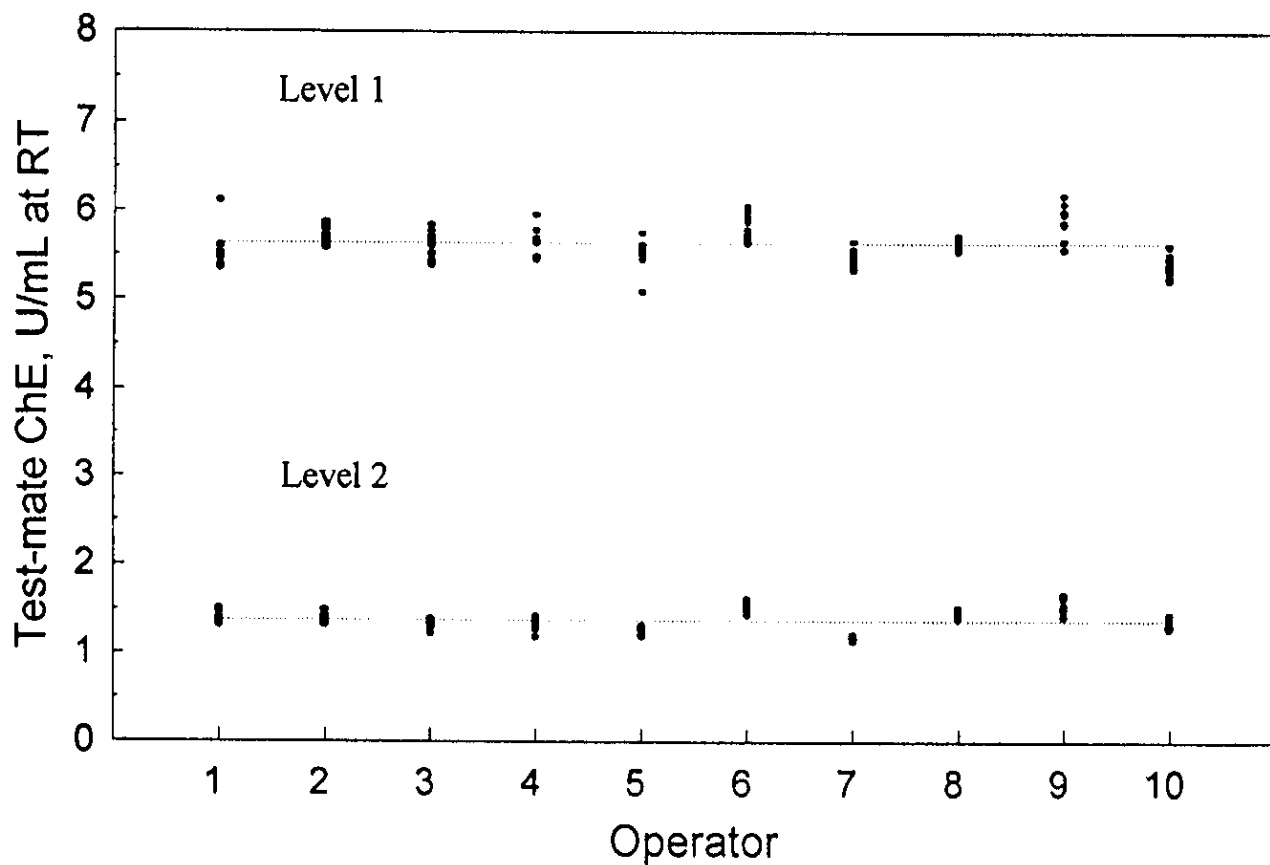
<sup>2</sup>American Society of Clinical Pathologists

<sup>3</sup>Diplomate of the American Board of Clinical Chemistry

Five days prior to the beginning of the data collection phase of this test study, both a normal and an abnormal sample were prepared. These two levels were chosen to correspond with unpoisoned and poisoned values that would be encountered when using the Test-mate ChE. A normal sample was prepared by dividing 10mL of blood (anticoagulated with EDTA) from a healthy male donor into aliquots of 0.5mL. An abnormal sample was prepared by adding paraoxon to 10mL of blood (anticoagulated with EDTA) from a healthy male donor. To produce a similar depression of both AChE activity and PChE activity in a single abnormal sample, the following procedure was followed. Three milliliters of plasma was transferred from the 10mL settled blood sample to a 7mL glass vial and to it was added 100 $\mu$ L of 0.73 $\mu$ M paraoxon. To the remaining blood fraction of mostly packed erythrocytes was added 60 $\mu$ L of 7.3 $\mu$ M paraoxon. The blood and plasma were then incubated 12 hours at room temperature, recombined into a 20mL glass vial and divided into aliquots of 0.5mL. Both the normal and the abnormal samples were refrigerated prior to distribution to the testing sites.

Each operator performed 40 cholinesterase assays on a single day during the data collection phase of this study. Both the normal and the abnormal blood samples were analyzed ten times each for AChE activity and PChE activity. Temperature varied between 20°C and 26°C during this testing. The test data from this study was analyzed using Quattro Pro 6.0 to produce plotted graphs and provide statistical parameters [see fig. 17-A, fig. 17-B, fig. 17-C, fig. 17-D, fig. 17-E and fig. 17-F].

### AChE: Within-Run Precision



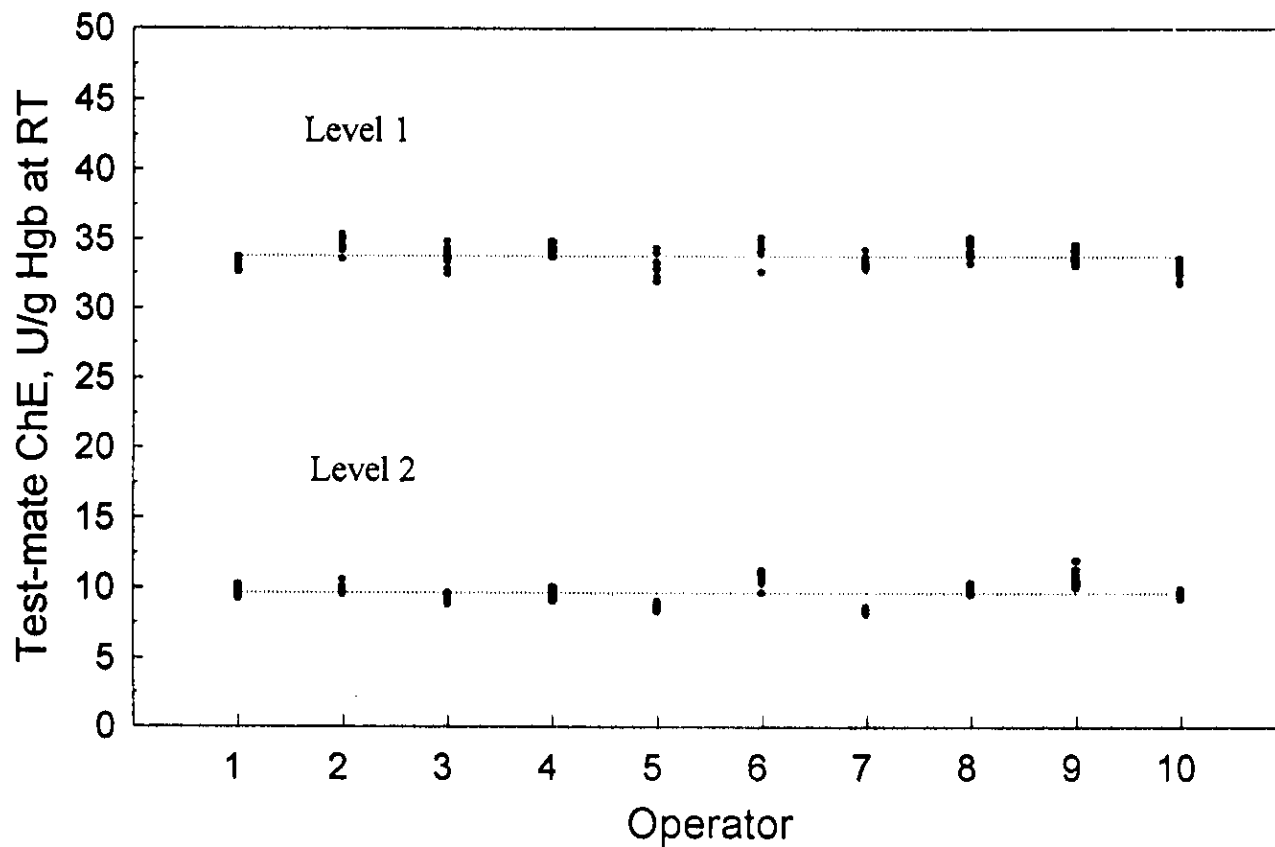
Statistical Parameters:

Level 1: N 100  
Mean 5.632  
SD 0.20566  
%CV 3.7

Level 2: N 100  
Mean 1.381  
SD 0.12415  
%CV 9.0

*Fig. 17-A*

### AChE: Within-Run Precision



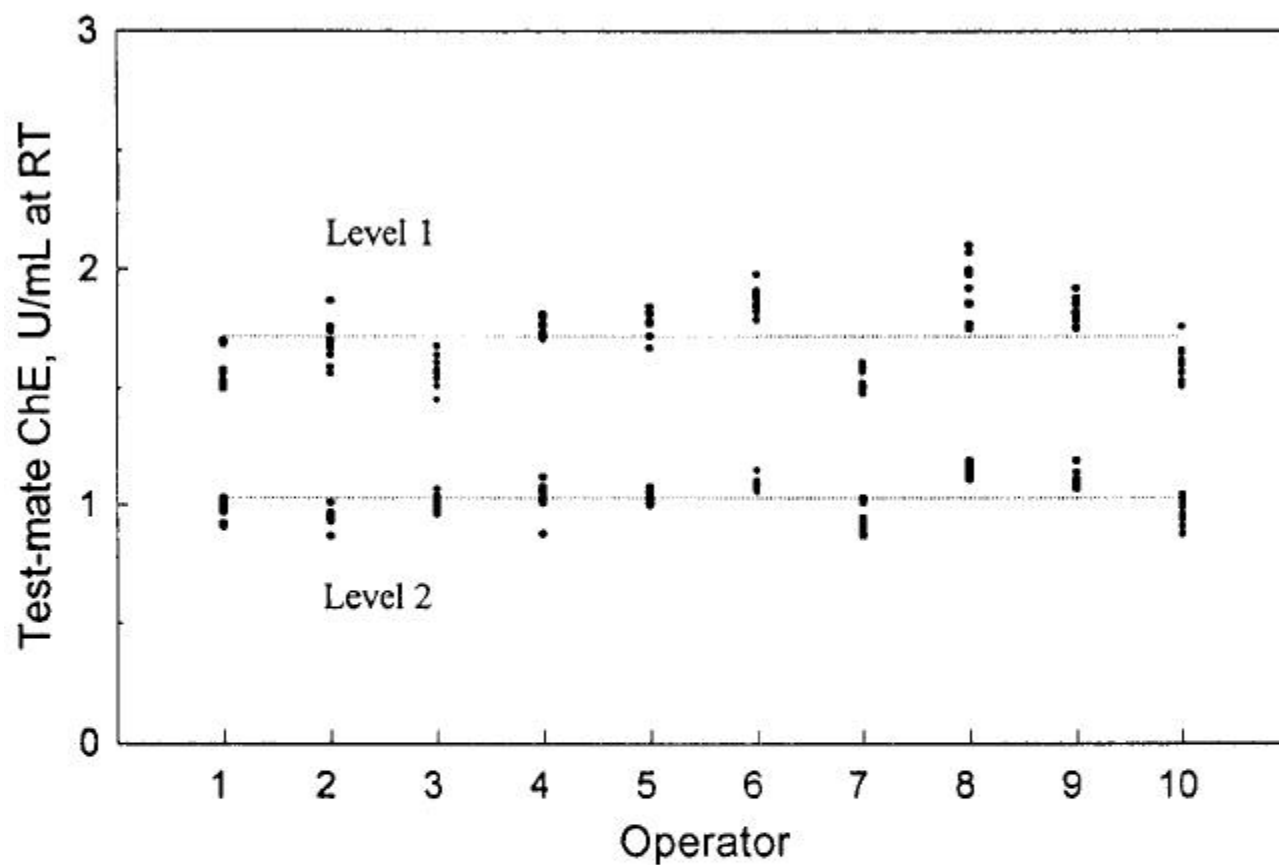
#### Statistical Parameters:

Level 1: N 100  
Mean 33.80  
SD 0.81582  
%CV 2.4

Level 2: N 100  
Mean 9.694  
SD 0.76605  
%CV 7.9

*Fig. 17-B*

PChE: Within-Run Precision



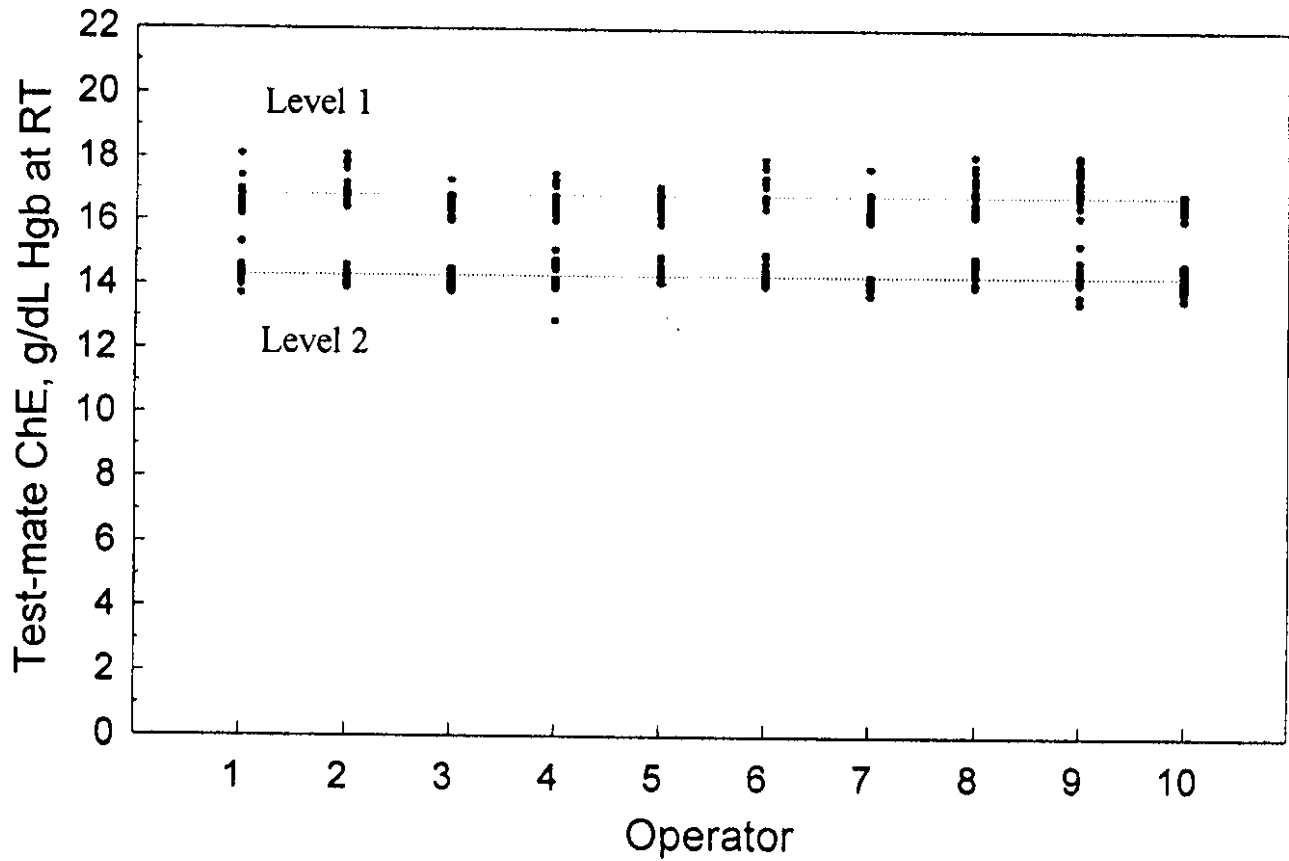
Statistical Parameters:

Level 1: N 100  
Mean 1.716  
SD 0.14662  
%CV 8.5

Level 2: N 100  
Mean 1.028  
SD 0.07712  
%CV 7.5

*Fig 17-C*

### Hgb: Within-Run Precision



Statistical Parameters:

Level 1: N 200  
Mean 16.81  
SD 0.45527  
%CV 2.7

Level 2: N 200  
Mean 14.30  
SD 0.30557  
%CV 2.2

*Fig. 17-D*

**Between Operator Variability - Normal Sample**

<b>Operator</b>		<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>Total</b>
<b>AChE U/mL</b>	Mean	5.55	5.74	5.61	5.67	5.52	5.81	5.47	5.65	5.92	5.40	5.63
	SD	0.22	0.10	0.15	0.14	0.17	0.15	0.10	0.06	0.19	0.12	0.21
	%CV	4.0	1.8	2.6	2.5	3.1	2.6	1.7	1.1	3.1	2.2	3.7
<b>A-Hgb g/dL</b>	Mean	16.7	16.6	16.6	16.5	16.7	16.9	16.3	16.5	17.4	16.5	16.7
	SD	0.52	0.20	0.39	0.40	0.37	0.34	0.22	0.20	0.51	0.22	0.45
	%CV	3.1	1.2	2.3	2.4	2.2	2.0	1.3	1.2	3.0	1.3	2.7
<b>AChE U/g Hgb</b>	Mean	33.3	34.7	33.8	34.4	33.1	34.3	33.4	34.3	33.9	32.8	33.8
	SD	0.37	0.56	0.72	0.35	0.77	0.66	0.42	0.61	0.46	0.57	0.82
	%CV	1.1	1.6	2.1	1.0	2.3	1.9	1.3	1.8	1.3	1.7	2.4
<b>PChE U/mL</b>	Mean	1.59	1.70	1.58	1.75	1.78	1.87	1.54	1.92	1.84	1.61	1.72
	SD	0.08	0.09	0.07	0.04	0.05	0.05	0.05	0.12	0.06	0.07	0.15
	%CV	5.0	5.3	4.2	2.1	3.0	2.8	2.9	6.1	3.3	4.5	8.5
<b>P-Hgb g/dL</b>	Mean	16.8	17.3	16.5	17.0	16.6	17.5	16.7	17.4	17.0	16.7	16.9
	SD	0.31	0.54	0.17	0.39	0.26	0.29	0.39	0.38	0.49	0.14	0.46
	%CV	1.8	3.1	1.0	2.3	1.6	1.7	2.3	2.2	2.9	0.8	2.7

Note: N = 10 for each operator, N = 100 for the total of all operators combined.

*Fig. 17-E*

### Between Operator Variability - Abnormal Sample

		Operator	1	2	3	4	5	6	7	8	9	10	Total
<b>AChE U/mL</b>	Mean		1.39	1.40	1.32	1.33	1.26	1.55	1.19	1.48	1.55	1.35	1.38
	SD		0.07	0.04	0.04	0.06	0.03	0.06	0.02	0.04	0.09	0.05	0.12
	%CV		5.2	3.1	3.4	4.8	2.7	3.6	1.9	2.9	5.7	3.4	9.0
<b>A-Hgb g/dL</b>	Mean		14.3	14.2	14.1	14.0	14.4	14.6	14.0	14.6	14.4	14.0	14.2
	SD		0.44	0.15	0.20	0.39	0.18	0.25	0.46	0.24	0.52	0.26	0.36
	%CV		3.0	1.0	1.4	2.8	1.3	1.7	1.1	1.6	3.6	1.8	2.5
<b>AChE U/g Hgb</b>	Mean		9.8	9.9	9.4	9.6	8.8	10.7	8.5	10.1	10.8	9.6	9.7
	SD		0.32	0.30	0.23	0.31	0.21	0.45	0.16	0.25	0.57	0.22	0.77
	%CV		3.3	3.0	2.5	3.2	2.3	4.2	1.9	2.4	5.2	2.3	7.9
<b>PChE U/mL</b>	Mean		0.99	0.96	1.02	1.03	1.03	1.09	0.94	1.15	1.11	0.98	1.03
	SD		0.04	0.04	0.03	0.06	0.03	0.02	0.06	0.03	0.04	0.05	0.08
	%CV		4.3	4.5	3.1	6.1	2.5	2.2	6.8	2.6	3.2	4.1	7.5
<b>P-Hgb g/dL</b>	Mean		14.4	14.4	14.1	14.7	14.6	14.1	14.1	14.4	14.5	14.4	14.4
	SD		0.15	0.14	0.20	0.29	0.22	0.13	0.16	0.16	0.12	0.20	0.25
	%CV		1.1	1.0	1.4	2.0	1.5	1.0	1.1	1.1	0.8	1.4	1.8

Note: N = 10 for each operator, N = 100 for the total of all operators combined.

*Fig. 17-F*