

ACS180PLUS Validation Results

Date of analysis: 14th September, 1999

Analyst: Daisuke Mukai

Quality Control Results

	LIG1		LIG2		LIG3	
	Measured	Result	Measured	Result	Measured	Result
Testosterone	104.76	Passed	419.63	Passed	953.76	Passed
	109.76	Passed	432.04	Passed	936.11	Passed
Progesterone	1.72	Passed	9.00	Passed	25.09	Passed
	1.75	Passed	10.05	Passed	25.06	Passed
Estradiol-6	90.58	Passed	314.15	Passed	773.96	Passed
	80.51	Passed	304.93	Passed	670.72	Passed
T3	0.77	Passed	2.04	Passed	3.28	Passed
	0.8	Passed	1.89	Passed	3.19	Passed
T4	2.63	Passed	7.88	Passed	13.32	Passed
	2.6	Passed	7.73	Passed	12.36	Passed

The upper items are the value before the measurement of the test samples and the lower items are the value after the measurement of the test samples.

Reference Range

	LIG1		LIG2		LIG3	
Testosterone	82 ~	153	303 ~	511	677 ~	1120
Progesterone	1.1 ~	2.6	6.1 ~	11.5	15.4 ~	29.7
Estradiol-6	50 ~	126	227 ~	396	447 ~	851
T3	0.67 ~	1.15	1.40 ~	2.30	2.41 ~	3.91
T4	2.5 ~	5.1	5.3 ~	8.9	10.3 ~	16.7

Ligand Plus

	Lot.No	Exp.Date
LIG1	9861071	Feb.00
LIG2	9862071	Feb.00
LIG3	9863071	Feb.00

Conclusion: All the measured results were confirmed within the allowable range.

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Repeatability Results

	Testosterone	Progesterone	T ₄	T ₃	Estradiol-6
1	18.44	93.05	2.10	0.50	83.56
2	19.08	90.71	1.78	0.48	89.56
3	18.93	75.60	2.03	0.50	85.83
4	18.80	78.77	1.99	0.52	88.53
5	19.00	92.61	2.09	0.52	86.88
6	17.79	89.39	1.83	0.52	84.70
7	19.87	70.71	1.93	0.49	92.90
8	19.11	111.04	1.95	0.51	68.70
9	19.11	111.82	1.93	0.52	62.86
10	19.33	75.95	1.94	0.53	105.31
11	18.28	113.27	2.03	0.53	86.52
12	19.02	85.59	1.89	0.51	94.83
13	20.40	82.69	1.93	0.54	79.19
14	20.07	77.16	2.08	0.53	95.96
15	18.90	72.10	2.2	0.53	80.81
16	19.40	75.88	2.17	0.52	76.26
17	18.58	83.99	2.05	0.53	78.21
18	20.69	83.58	1.94	0.52	78.40
19	19.15	113.44	2.13	0.51	81.15
20	18.08	83.85	1.90	0.53	86.06

Mean	19.10	88.06	1.99	0.52	84.31
SD	0.73	14.01	0.11	0.02	9.50
CV	3.84	15.90	5.61	2.95	11.26

Conclusion: The repeatability for the determination of Progesterone, Testosterone, T₄, T₃ and Estradiol-6 in the rat plasma was tested by performing 20 replicate determinations and the CV was 3.84, 15.9, 5.61, 2.95 and 11.26, respectively, which was acceptable.

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Result of linearity of detections with dilutions

Concentration (%)	Progesterone	Testosterone	T4	T3	Estradiol-6
100	26.14	964.81	13.40	3.24	710.50
100	24.79	915.25	13.17	3.21	715.61
75	19.66	725.40	9.59	2.48	540.64
75	20.23	753.08	9.97	2.44	545.71
50	13.11	473.37	6.19	1.69	403.9
50	14.19	456.14	6.60	1.69	412.18
25	6.55	200.63	2.76	0.81	260.43
25	7.00	229.87	2.97	0.80	250.61
0	0.00	0.00	0.00	0.12	0.00
0	0.00	0.00	0.00	0.16	0.00