

g-Pet PLUS Veterinary Glucose Meter System Accuracy Evaluation Report – Rabbit

1. Introduction

The performance of the g-Pet PLUS Veterinary Glucose Meter is critical as the information provided by the meter assists veterinarians in making treatment decisions.

This study was intended to evaluate the system accuracy of the g-Pet PLUS Veterinary Glucose Meter by using fresh venous whole blood compared with YSI2900. The experiment was performed by veterinary professionals and conducted as specified in this report. All tested data was summarised following ISO 15197:2013 standards (harmonised as EN ISO 15197:2015).

2. Applicable Standards

- ISO 15197:2013: In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus.

3. Facilities and Materials

- x9 g-Pet PLUS Veterinary Glucose Meters
- x3 lots of g-Pet PLUS Veterinary Glucose Test Strips
- 21 gauge needle and syringe
- x10 rabbit blood samples
- Reference method, YSI2900
- Thermometer
- Haematocrit centrifuge
- HT tubes and tube closure

Table 1 Lot Numbers of Test Strips and Serial Numbers of Meters

Test Strip Lot No.	Lot 1: MSH028C108	Lot 2: MSH028C109	Lot 3: MSH028E130
Meter S/N	M17VA002331	M17VA002334	M17VA002337
	M17VA002332	M17VA002335	M17VA002338
	M17VA002333	M17VA002336	M17VA002339

4. Protocol

4.1 For Original Blood Samples

1. Make sure the ambient temperature is maintained at $+23^{\circ}\text{C} \pm 5^{\circ}\text{C}$ and the temperature changes during the experimental period should be within $\pm 2^{\circ}\text{C}$.
2. Prepare 9 meters and make sure they are in correct working order. Make sure the code shown on the meter is the same as the code on the test strip bottle label.
3. Record the “animals” information.
4. Take venous blood samples from the animal using a heparin tube. Samples should only be taken by veterinary professionals.
5. Take some of the blood samples and separate plasma by centrifuging. Measure the blood glucose concentration using YSI2900.
6. Take test strips from the vial and insert into the meters.
7. Measure the blood glucose concentration using the g-Pet PLUS Meter.
8. Measure the blood haematocrit (%) level using the Centrifugal method.

4.2 For Spiked Blood Samples

1. Make sure the ambient temperature is maintained at $+23^{\circ}\text{C} \pm 5^{\circ}\text{C}$ and the temperature changes during the experimental period should be within $\pm 2^{\circ}\text{C}$.
2. Prepare 9 meters and make sure they are in correct working order. Make sure the code shown on the meter is the same as the code on the test strip bottle label.
3. Record the “animals” information.
4. Take venous blood samples from the animal using a heparin tube. Samples should only be taken by veterinary professionals. Add 20% glucose solution for target glucose concentration with glycolysis blood samples* (shown in Table 2: Bin #1, Bin #2, Bin #5, Bin #6 and Bin #7).

*Glycolysis blood samples should be prepared according to the following instructions: After collecting the venous blood sample, keep some samples at $+37^{\circ}\text{C}$ in a water bath for several hours to promote glycolysis.

5. Take some of the spiked blood samples and separate plasma by centrifuging. Measure the blood glucose concentration by using YSI2900.
6. Take test strips from the vial and insert into the meters.
7. Measure the blood glucose concentration using the g-Pet PLUS Meter.
8. Measure the blood haematocrit (%) level using Centrifugal method.

Table 2 Recommended Ratio of Animal Blood Glucose Levels

Bin #	Glucose Concentration	Percentage of Samples	Note
1	≤ 50 mg/dL	5%	Manipulated blood sample is acceptable.
2	$>50 \sim 80$ mg/dL	15%	Manipulated blood sample is acceptable.
3	$>80 \sim 120$ mg/dL	20%	All samples should be unaltered.
4	$>120 \sim 200$ mg/dL	30%	Manipulated blood sample is acceptable.
5	$>200 \sim 300$ mg/dL	15%	Manipulated blood sample is acceptable.
6	$>300 \sim 400$ mg/dL	10%	Manipulated blood sample is acceptable.
7	>400 mg/dL	5%	Manipulated blood sample is acceptable.

NOTE:

Ratios may vary and concentration levels may be combined for different animal samples.

5. Data Analysis

Record the measured values of the reference methods (e.g., YSI2900), g-Pet PLUS Meter and the packed cell level (HCT%) for each sample. Then, calculate the deviation (Bias) between the meter value and YSI2900. Finally, determine the conformity rate based on the distribution of deviation as shown in Table 3 (Conformity rate = conformity number/total tested number).

The test results will be further analysed by CEG distribution. The CEG is divided into five zones, which represent the estimated risk to the patient if a result falls in a particular zone. All g-Pet PLUS test results were plotted on the CEG graph (as shown in Figure 1) and the percentage distribution of each zone was calculated.

Table 3 System Accuracy Results

System Accuracy Results for Tested Glucose Concentrations Bias Within ± 15 mg/dL or $\pm 15\%$ (Within ± 0.83 mmol/L or $\pm 15\%$)		
Bias within ± 5 mg/dL or $\pm 5\%$ (within ± 0.28 mmol/L)	Bias within ± 10 mg/dL or $\pm 10\%$ (within ± 0.56 mmol/L)	Bias within ± 15 mg/dL or $\pm 15\%$ (within ± 0.83 mmol/L)
Conformity rate %	Conformity rate %	Conformity rate %

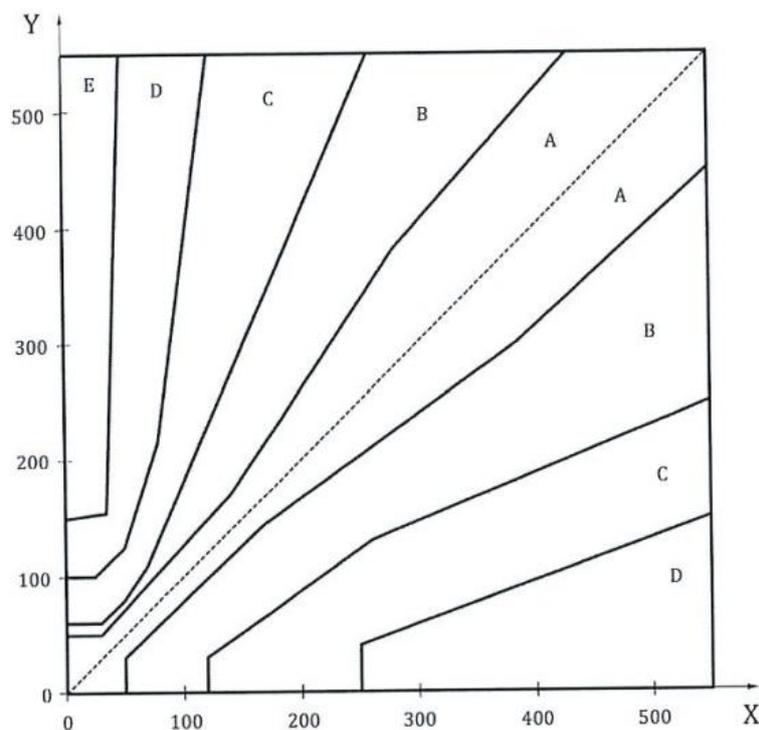


Figure 1 Consensus Error Grid (mg/dL)

6. Acceptance Criteria

- $\geq 95\%$ of the measured glucose values should fall within either ± 15 mg/dL (0.83 mmol/L) of the average comparison measurement result at glucose concentrations < 100 mg/dL (5.55 mmol/L) or within $\pm 15\%$ at glucose concentrations ≥ 100 mg/dL (5.55 mmol/L).
- $\geq 99\%$ of the measured glucose values should fall within zones A and zones B of CEG plot.

7. Results and Conclusion

7.1 Study Population

In principle, the distribution of blood glucose concentrations of at least 100 blood samples from different subjects should follow ISO 15197:2013. However, 10 subjects' testing data of rabbit were firstly collected to accelerate the g-Pet PLUS Meter accuracy evaluation in this short-term clinical study. The participants' age of rabbit ranged from 2 to 3 months. The detailed information of subjects are shown in Table 4 and Section 8.2.

Table 4 General Information of Subjects Represented

	Rabbit
Subjects	10
Gender	M (4) / F (6)
Age (Months)	Average: 2.4 months (Range: 2 – 3 months)
HCT (%)	Average: 39.4% (Range: 25% – 52%)
Glucose (mg/dL)	Average: 181.5 mg/dL (Range: 20.5 – 537 mg/dL)

7.2 System Accuracy Study

The independent system accuracy results of the rabbit test are shown in Table 5. The summary results from the three strip lots demonstrate that the performance meets the accuracy criteria set by ISO 15197:2013, thereby supporting the extension of the g-Pet PLUS Meter's intended use for rabbits. Additionally, the tested raw data including the bias plot and CEG plot are referred to in Section 8.2.

Table 5: Description of clinical study used as 159 blood samples of rabbit as adjusted to glucose concentrations from 20.5 mg/dL and 537 mg/dL in HCT 25% to 52%. Compare to YSI2900 the test results of three lots can meet the accuracy criteria of ISO 15197:2013.

ISO 15197:2013	System Accuracy Results for Tested Glucose Concentrations Bias Within ± 15 mg/dL or $\pm 15\%$ (Within ± 0.83 mmol/L or $\pm 15\%$)		
	± 5 mg/dL or %	± 10 mg/dL or %	± 15 mg/dL or %
Lot 1	51.2% (244/477)	87.2% (416/477)	99.0% (472/477)
Lot 2	60.6% (289/477)	88.5% (422/477)	98.5% (470/477)
Lot 3	50.5% (241/477)	86.2% (411/477)	98.1% (468/477)
3 Lots Pooled	54.1% (774/1431)	87.3% (1249/1431)	98.5% (1410/1431)

8. Supporting Information

8.1 Supporting Information of Rabbit Clinical Study Results with YSI2900

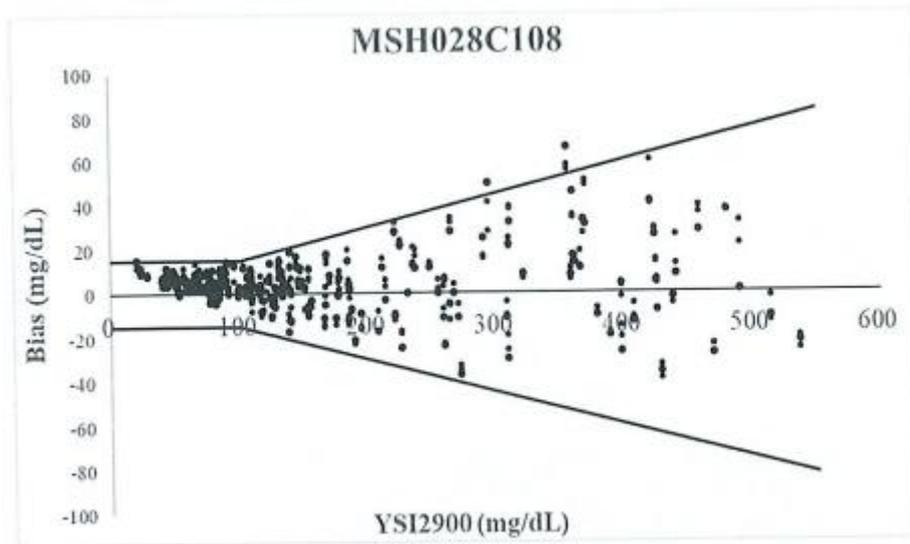
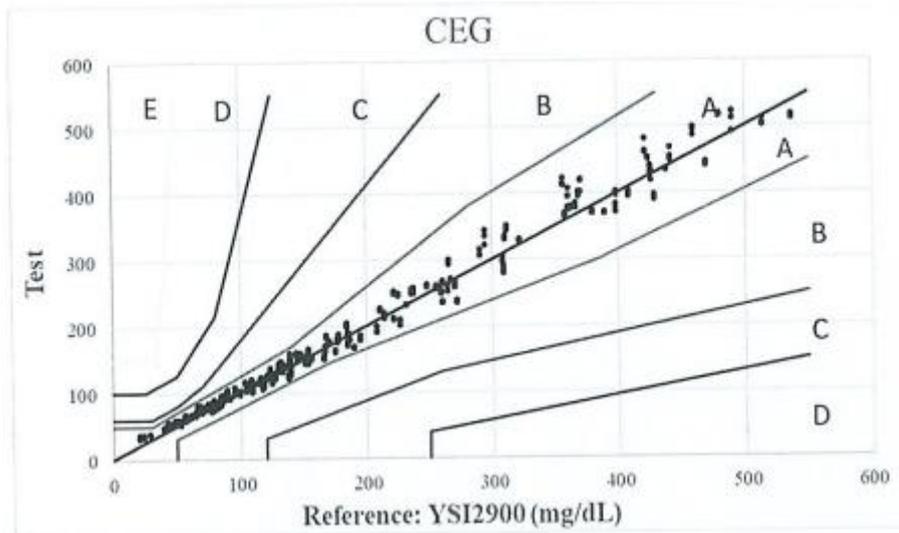


Figure 1S Bias Plot of Lot 1 with ISO 15197:2013



Consensus Error Grid (CEG)							
Total	Region	A+B	A	B	C	D	E
477		477	477	0	0	0	0
	CEG (%)	100%	100%	0%	0%	0%	0%

Figure 2S CEG Plot of Lot 1 (Zone A + Zone B = 100%) with ISO 15197:2013

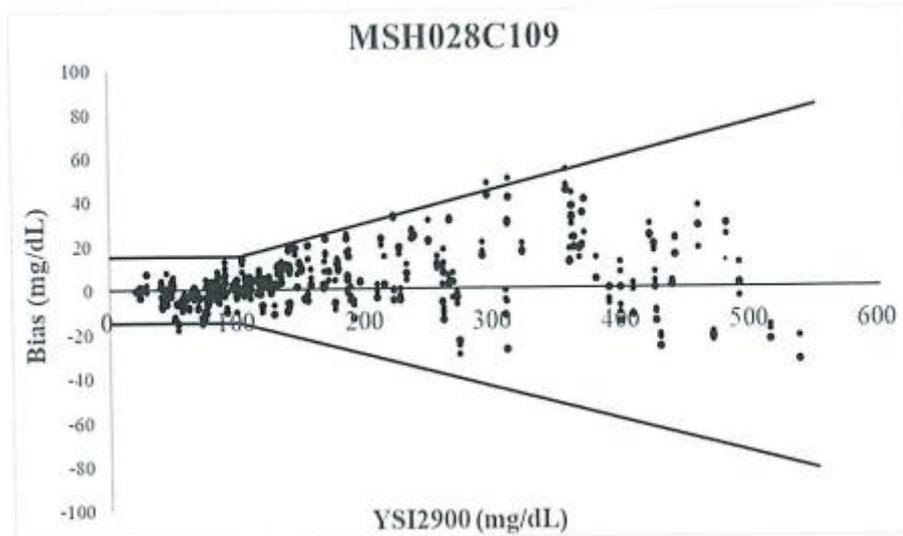
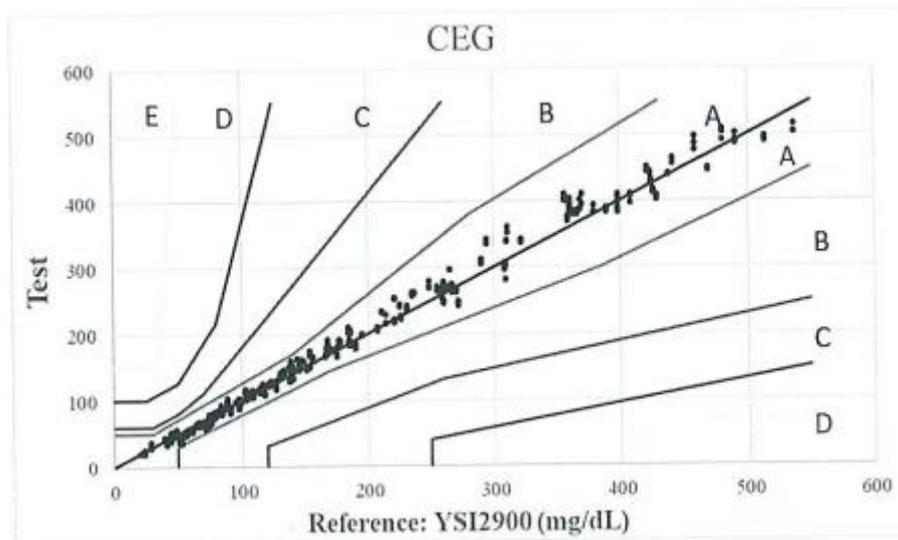


Figure 3S Bias Plot of Lot 2 with ISO 15197:2013



Consensus Error Grid (CEG)							
Total	Region	A+B	A	B	C	D	E
477		477	477	0	0	0	0
	CEG (%)	100%	100%	0%	0%	0%	0%

Figure 3S CEG Plot of Lot 2 (Zone A + Zone B = 100%) with ISO 15197:2013

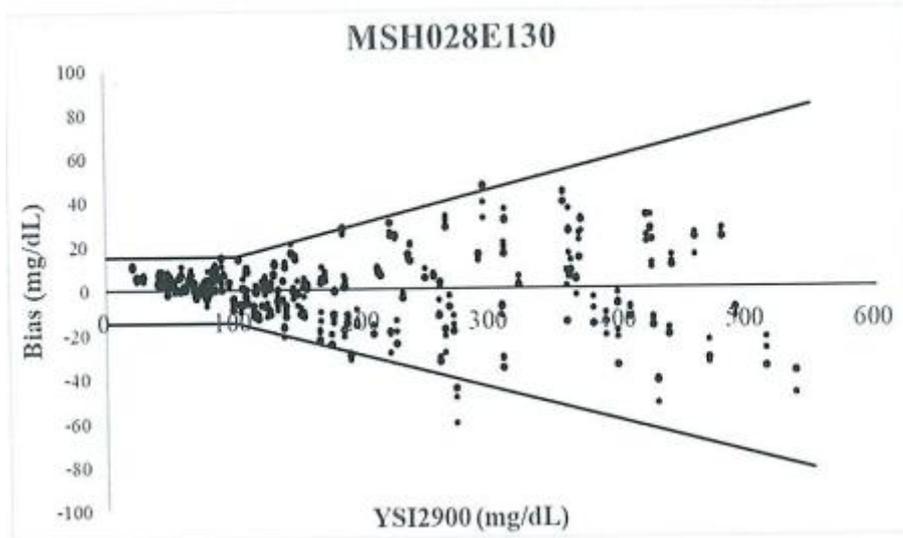
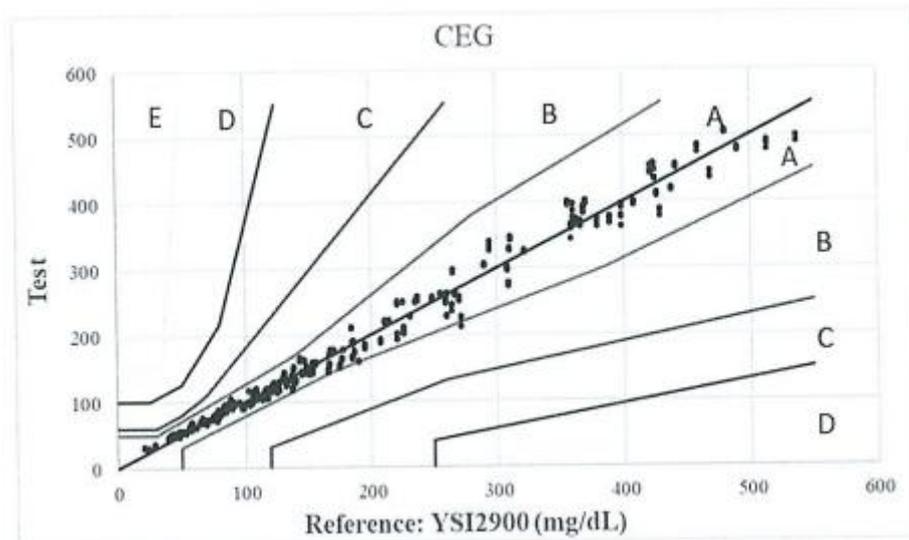


Figure 5S Bias Plot of Lot 3 with ISO 15197:2013



Consensus Error Grid (CEG)							
Total	Region	A+B	A	B	C	D	E
477		477	475	0	0	0	0
	CEG (%)	100%	99.6%	0%	0%	0%	0%

Figure 6S CEG Plot of Lot 3 (Zone A + Zone B = 100%) with ISO 15197:2013

8.2 Raw Data

No.	Sex	Age	HT	YSI	MSH028C108			MSH028C109			MSH028E130		
1	M	2.5M	42	185	173	171	175	189	184	183	167	167	164
2	M	2.5M	42	208	191	191	200	204	210	207	188	192	192
3	M	2.5M	42	270	259	265	259	266	263	268	251	258	254
4	M	2.5M	42	366	377	378	385	384	385	380	370	371	363
5	M	2.5M	42	398	402	401	396	398	405	410	391	396	392
6	M	2.5M	49	166	155	151	152	168	166	168	143	148	147
7	M	2.5M	49	226	201	209	208	221	226	223	201	207	212
8	M	2.5M	49	309	279	283	290	281	303	303	273	277	278
9	M	2.5M	49	389	370	370	371	389	384	382	374	378	368
10	M	2.5M	49	469	441	445	445	447	449	445	437	445	435
11	M	2.5M	30	170	178	175	177	178	178	174	174	176	178
12	M	2.5M	30	225	247	246	249	244	241	243	249	250	248
13	M	2.5M	30	308	297	304	298	296	307	303	300	301	296
14	M	2.5M	30	421	462	461	481	445	444	450	454	442	445
15	M	2.5M	30	480	517	518	517	509	492	504	503	505	507
16	M	2.5M	38	89.9	96	93	93	93	88	87	90	90	93
17	M	2.5M	38	116	120	120	124	122	125	124	115	118	118
18	M	2.5M	38	185	189	191	186	191	185	185	186	186	191
19	M	2.5M	38	424	450	452	453	444	441	442	451	450	457
20	M	2.5M	38	248	260	262	259	270	279	269	253	257	253
21	M	2.5M	25	91.1	91	92	94	81	83	90	98	99	98
22	M	2.5M	25	131	142	141	140	142	134	133	142	142	142
23	M	2.5M	25	147	159	157	158	159	159	160	161	163	162
24	M	2.5M	25	184	199	204	199	207	209	201	212	210	209
25	M	2.5M	25	265	293	297	299	296	297	296	293	298	296
26	M	2.5M	35	82.8	86	87	85	85	86	86	92	90	89
27	M	2.5M	35	127	130	126	129	129	129	130	130	127	128
28	M	2.5M	35	156	153	150	152	158	161	165	158	159	156
29	M	2.5M	35	214	211	220	217	216	229	215	220	221	221
30	M	2.5M	35	255	255	261	257	266	270	264	261	262	260
31	M	2.5M	46	81.3	77	77	79	80	84	82	81	86	81
32	M	2.5M	46	125	115	114	120	124	124	123	117	119	113
33	M	2.5M	46	154	144	146	149	149	152	152	142	151	144
34	M	2.5M	46	195	186	179	180	198	198	199	179	186	181
35	M	2.5M	46	264	259	252	252	266	270	267	246	235	243
36	M	2.5M	52	78.1	77	74	76	81	79	78	74	76	71
37	M	2.5M	52	117	109	107	109	115	119	115	106	107	104
38	M	2.5M	52	138	121	126	129	128	132	129	121	122	117
39	M	2.5M	52	190	169	167	167	177	185	183	160	158	161
40	M	2.5M	52	260	236	236	237	246	251	249	227	229	229
41	M	2.5M	25	59.7	66	66	62	56	57	55	60	62	61
42	M	2.5M	25	84	86	90	87	84	86	92	92	94	94
43	M	2.5M	46	28.7	37	38	38	36	28	31	35	36	33
44	M	2.5M	46	48.5	59	57	54	52	48	48	53	51	50
45	M	2.5M	35	41.3	45	48	48	34	36	33	46	47	45
46	M	2.5M	35	65.3	70	71	71	63	61	66	69	69	68
47	M	2.5M	52	39.9	46	46	47	41	43	44	43	47	42

48	M	2.5M	34	23.7	33	34	33	20	20	20	30	30	28
49	M	2.5M	34	52.1	54	57	58	46	46	45	56	55	55
50	M	2.5M	34	79.3	79	81	78	80	80	76	84	81	82
51	M	2.5M	34	109	114	117	116	114	114	112	117	119	118
52	M	2.5M	46	23.7	34	36	33	25	25	23	29	30	30
53	M	2.5M	46	44.3	54	51	51	45	52	44	46	52	50
54	M	2.5M	46	79.5	83	82	84	79	83	77	80	80	77
55	M	2.5M	46	109	107	101	105	112	105	109	103	105	105
56	M	2.5M	44	20.5	36	32	35	20	20	20	31	30	32
57	M	2.5M	44	43.3	55	52	52	41	43	41	51	48	52
58	M	2.5M	44	78.5	89	82	83	75	76	74	83	79	87
59	M	2.5M	44	108	111	112	112	107	105	109	105	104	103
60	M	2.5M	29	56.4	64	65	68	52	48	47	62	63	62
61	M	2.5M	29	85	94	88	95	82	87	79	92	94	90
62	M	2.5M	29	108	118	119	120	112	113	111	116	118	118
63	M	2.5M	29	131	146	147	143	138	140	139	143	142	144
64	M	2.5M	35	44.6	48	50	51	38	42	39	49	51	50
65	M	2.5M	35	74.6	85	79	75	71	79	76	77	75	74
66	M	2.5M	35	95.2	108	108	101	96	97	98	99	98	97
67	M	2.5M	35	123	137	131	137	126	129	126	125	129	128
68	M	2.5M	39	41.2	49	48	47	38	33	33	45	50	45
69	M	2.5M	39	68.4	73	75	79	66	65	67	72	72	70
70	M	2.5M	39	84.6	90	90	83	82	82	84	85	84	85
71	M	2.5M	39	123	121	129	128	126	124	128	123	123	121
72	M	2.5M	34	368	401	401	395	402	388	387	382	393	390
73	M	2.5M	46	438	436	436	433	439	441	441	417	420	420
74	M	2.5M	29	356	422	414	412	400	410	403	395	399	400
75	M	2.5M	35	360	406	394	395	397	403	393	386	387	396
76	F	2M	39	121	127	127	122	126	125	122	114	125	122
77	F	2M	39	109	112	112	108	109	111	111	103	106	105
78	F	2M	39	133	140	141	135	143	139	143	133	132	133
79	F	2M	39	187	180	179	179	182	188	184	172	174	176
80	F	2M	39	149	152	154	155	158	159	157	147	142	153
81	F	2M	39	168	186	184	182	191	185	184	173	178	178
82	F	2M	42	114	117	115	114	118	112	118	107	102	104
83	F	2M	42	137	140	141	142	148	148	146	141	132	133
84	F	2M	42	177	176	177	182	189	188	191	166	164	162
85	F	2M	41	105	108	112	113	110	111	110	98	98	98
86	F	2M	41	133	132	143	138	142	143	146	128	126	124
87	F	2M	41	154	165	161	160	174	168	168	155	159	157
88	F	2M	46	108	110	109	112	112	114	108	108	107	103
89	F	2M	46	140	140	142	147	149	147	151	128	131	131
90	F	2M	46	167	162	170	166	169	175	180	170	153	157
91	F	2M	45	98.2	100	101	101	103	96	88	89	92	91
92	F	2M	45	127	121	124	122	116	116	120	116	118	117
93	F	2M	45	151	144	153	154	147	146	147	140	143	140
94	F	2M	39	51	59	54	55	38	37	39	54	53	52
95	F	2M	46	57.3	63	63	59	53	49	51	57	58	57
96	F	2M	42	68.7	72	76	80	60	61	61	68	70	69
97	F	2M	39	76.5	84	81	84	70	66	69	78	80	81

98	F	2M	45	61.2	64	67	64	53	52	53	62	62	61
99	F	2M	41	75	77	79	84	65	62	66	75	73	74
100	F	2M	33	83.5	84	85	81	79	81	80	88	88	88
101	F	2M	33	130	132	137	143	140	137	140	137	136	136
102	F	2M	33	237	248	257	254	261	261	262	250	257	258
103	F	2M	33	310	332	331	335	340	339	341	326	329	331
104	F	2M	41	77.1	73	74	75	77	77	77	77	77	74
105	F	2M	41	140	128	127	134	134	132	134	133	131	130
106	F	2M	41	260	266	267	266	267	272	278	263	261	262
107	F	2M	41	362	376	379	376	385	380	381	370	367	375
108	F	2M	39	87.8	99	96	95	89	90	88	93	94	94
109	F	2M	39	139	158	152	151	157	157	159	149	151	152
110	F	2M	39	235	248	249	256	258	261	262	251	249	251
111	F	2M	39	290	315	307	306	305	307	311	306	304	303
112	F	2M	46	104	107	103	104	105	102	101	97	94	98
113	F	2M	46	145	151	150	148	146	152	146	144	146	141
114	F	2M	46	259	248	252	262	253	269	261	247	254	248
115	F	2M	46	267	267	267	271	270	247	263	259	264	264
116	F	2M	33	370	401	419	421	410	395	410	401	396	402
117	F	2M	33	459	487	495	498	487	477	496	482	474	484
118	F	2M	41	425	430	440	439	425	432	428	447	434	436
119	F	2M	41	514	503	512	501	490	497	495	478	491	486
120	F	2M	39	426	418	430	432	411	416	415	409	413	412
121	F	2M	39	490	491	512	522	492	486	501	481	477	480
122	F	2M	46	408	395	397	403	396	407	410	395	399	400
123	F	2M	46	537	515	511	517	504	504	515	499	489	489
124	F	3M	40	53.1	53	52	53	38	38	35	54	52	52
125	F	3M	40	72.5	81	75	76	60	60	57	73	73	73
126	F	3M	40	99.4	100	100	103	98	97	101	94	96	94
127	F	3M	40	133.1	134	136	137	136	136	137	128	130	127
128	F	3M	40	177.8	185	180	188	187	186	190	177	178	177
129	F	3M	40	230.9	231	231	231	238	235	242	227	229	229
130	F	3M	40	321.4	330	328	328	338	337	342	323	324	327
131	F	3M	40	441.0	449	454	467	456	463	464	451	453	456
132	F	3M	48	47.9	55	56	54	45	46	46	46	49	56
133	F	3M	48	69.8	72	71	74	66	67	67	67	67	66
134	F	3M	48	98.8	98	99	98	96	99	95	95	91	90
135	F	3M	48	118	115	110	111	111	109	108	105	106	107
136	F	3M	48	175	164	161	164	169	179	166	150	155	155
137	F	3M	48	221	211	212	209	216	221	220	202	192	201
138	F	3M	48	272	235	239	237	248	246	242	227	223	211
139	F	3M	48	429	393	390	396	402	406	408	387	377	388
140	F	3M	39	49.1	59	53	55	51	55	50	55	56	56
141	F	3M	39	64.3	66	71	69	63	61	64	69	70	68
142	F	3M	39	79.6	84	81	86	83	78	81	82	84	85
143	F	3M	39	106	109	110	109	111	107	109	107	111	106
144	F	3M	39	117	119	114	115	120	121	118	116	119	117
145	F	3M	39	186	188	190	184	201	204	201	187	189	191
146	F	3M	39	211	223	227	223	234	231	234	220	218	221
147	F	3M	39	360	377	374	377	392	383	389	367	376	365

148	F	3M	27	66	75	75	80	67	63	64	73	75	72
149	F	3M	27	58.2	60	63	64	55	56	56	65	69	66
150	F	3M	27	84.2	94	96	95	90	86	87	95	93	96
151	F	3M	27	89.1	103	99	104	96	99	102	104	100	103
152	F	3M	27	103	115	116	116	117	111	115	117	117	117
153	F	3M	27	144	161	158	156	163	163	160	161	165	160
154	F	3M	27	221	249	253	248	254	253	254	251	247	245
155	F	3M	27	294	344	335	322	336	342	336	341	326	333
156	F	3M	40	379	369	369	372	383	383	393	363	370	375
157	F	3M	48	398	371	378	383	383	390	387	363	376	379
158	F	3M	39	358	366	369	364	370	376	371	343	359	366
159	F	3M	27	311	343	350	349	352	361	352	342	347	343