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Date: 08/04/05

Ref: 186/MKT/Q/64

SUBJECT **BQA (quantex IgG, IgA, IgM, C3, C4) evaluation versus Beckman Immage in Wexham Park Hospital (UK)**



Please find attached the summary of an evaluation of the BQA (Biokit Quantex Analyzer) performed in the Immunology Department of Wexham Park Hospital in the UK.

The evaluation was carried out in comparison to the Beckman Immage under the supervision of the Laboratory Manager, Dr. Lynn Day.

The following parameters were checked: IgG, IgA, IgM, and C3, C4.

The evaluation compared both methods and studied the practicability of the BQA.

The correlation was found to be very good between the two methods. The summary of the results and all the graphics and tables are attached.

The laboratory people liked the instrument very much regarding either software, hardware and maintenance. Their opinion and remarks are written in the questionnaire attached.

Comparison of the Quantex immunoturbidimetric method from Biokit on the BQA (Biokit Quantex Analyzer) with the nephelometric IMAGE Immunochemistry System from Beckman Coulter for the determination of IgG, IgA, IgM, C3 and C4.

Objective

This study compared the performance of quantex turbidimetric reagents from Biokit on the BQA (Biokit Quantex Analyzer) with the corresponding nephelometric technique of Beckman Coulter on an IMAGE currently in routine use.

Material and Methods

The study included a total of 282 sera for IgA, 221 for IgG, 219 for IgM, 83 for C3 and 99 for C4 obtained from the daily laboratory routine and with values distributed throughout the whole clinical range. These samples have been analysed in parallel using both techniques. Within the samples there were several with monoclonal gammopathy. Beckman Coulter nephelometric reagents for the Image and Biokit turbidimetric reagents for the BQA were used. Applications used for both analysers were the ones supplied by the manufacturers and are attached in this summary. The calibrators and controls corresponding to each of the methods were used.

Results

The results obtained including all the cases analyzed are:

IgA:	r= 0.9954	slope= 0.9790
IgG:	r= 0.9841	slope= 0.9346
IgG*:	r= 0.9917	slope= 1.0297 (only sera < 40 G/L)
IgM:	r= 0.9760	slope= 0.9672
IgM*:	r= 0.9922	slope= 0.9115 (only sera < 10 G/L)
C3:	r= 0.9660	slope= 1.0170
C4:	r= 0.9762	slope= 1.0963

Tables with the results values and graphs are attached.

Conclusion

The correlation is very good between the two methods for all five parameters evaluated. The very few samples that gave a result with greater than 10% variation from the Image level were repeated, these differences were always resolved, and neither method was correct more often.

The BQA fitted the laboratory well, was fast, quiet and accommodated all sample tube types, no samples were rejected due to low volume. The software is very user friendly, re-run samples are easily identified and the status display is very useful.

The BQA allows continuous loading of samples and also reagents, standards and controls are easily identified. Additionally the system benefits from minimal, easy maintenance and a self start procedure.

To fully integrate the system we would recommend positioning on a low bench, plumbing in the distilled water and waste systems and interfacing to the Laboratory Information System. Other recommendations such as a well categorised easily accessed user manual, colour coded tubing and bar code reading we are reliable informed have been addressed by the manufacturer.

A handwritten signature in black ink, appearing to read 'Lynn Day', with a long horizontal flourish extending to the right.

Lynn Day
Laboratory Manager
Immunology Department
Wexham Park Hospital
October 2004

Our thanks to Sabrina Coelho for her hard work processing this large sample cohort.

BQA Evaluation Results IgG

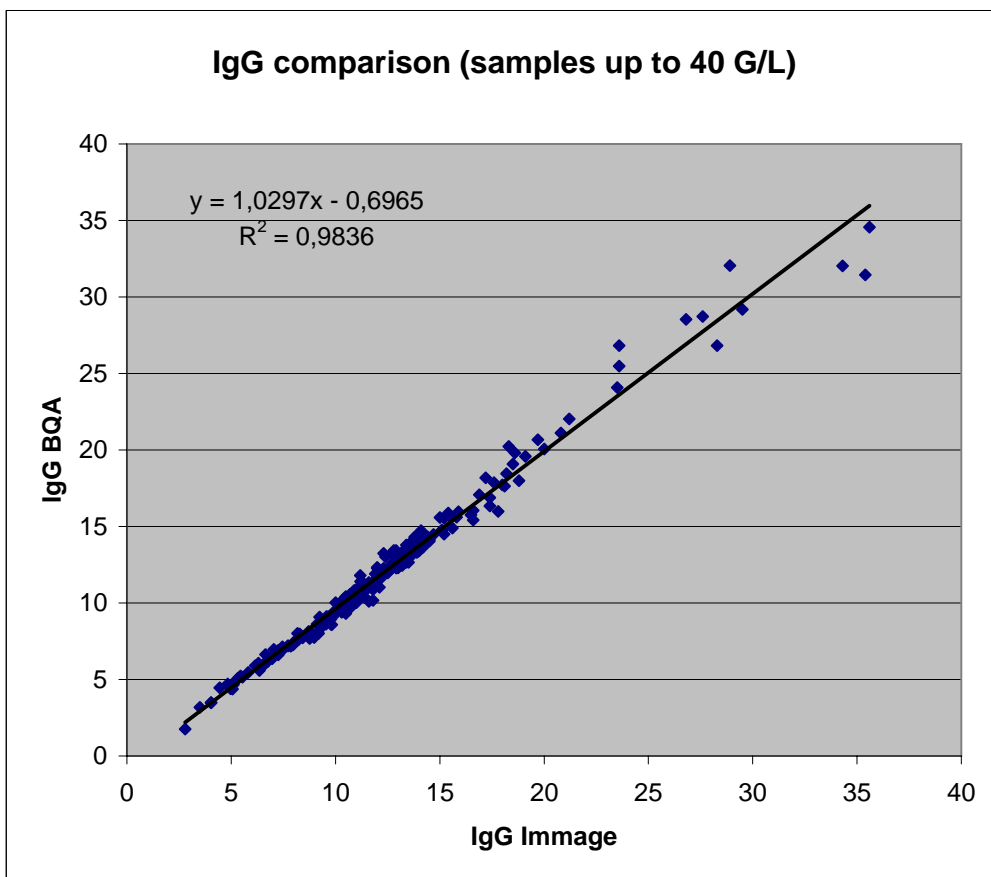
Sample Number	Laboratory Number	Immagine Result	BQA Result
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2	b302538j	10,5	10,42
3	b302562b	13,8	14,3
4	b302566g	12,7	13,16
5	b302774f	9,24	9,08
6	b302808l	18	17,73
7	b302857a	12,0	12,32
8	b303007y	12,9	13,31
9	b304447g	14,3	14,27
10	b305023a	11,0	10,83
11	b305142h	11,2	11,41
12	b305252s	12,4	13,01
13	b305525l	12,2	11,67
14	b305610y	11,2	10,45
15	b306072j	23,6	26,83
16	b306332y	9,61	8,82
17	b306647b	7,05	6,96
18	b306779l	10,8	10,58
19	b306836l	12,8	13,02
20	b306992f	11,1	11,01
21	b307116n	6,56	5,94
22	b317966j	12,8	12,55
23	b318134s	13	13,22
24	b318156j	12	11,38
25	b318175j	12,9	13,43
26	b318226y	7,85	7,17
27	b318251j	12,3	12,26
28	b318254p	14,1	14,72
29	b318287t	21,2	22,02
30	b318451k	7,96	7,25
31	b318511y	11,9	11,9
32	b318608a	6,65	6,63
33	b318705t	9,79	8,6
34	b318757v	18,2	18,45
35	b318807b	9,11	8,62
36	b325316s	5,06	4,37
37	b336375t	10,3	9,44
38	b336515b	13	12,67
39	b336788v	10,6	9,79
40	b336794n	9,55	8,64
41	b336883v	9,16	8,56
42	b337028b	9,67	9,11
43	b337092v	14	13,39
44	b338307q	6,35	5,89
45	b338120x	14,2	13,63
46	b338134g	14,7	14,48
47	b338144j	13,5	12,65
48	b338277j	18,1	17,64
49	b338307q	6,35	5,59
50	b338312s	12,9	12,28
51	b338326q	13	12,3
52	b338439k	8,05	7,45
53	b338551f	13	12,31
54	b338565p	10,2	9,67
55	b325316s	5,06	4,71
56	b337578l	11,6	10,11
57	b337586v	9,05	7,95
58	b337604q	8,43	7,82
59	b337670h	9,38	8,47
60	b337692l	10,5	9,31
61	b337695d	8,76	7,67
62	b337957p	28,3	26,82
63	b338028t	10,4	9,48
64	b338044x	12,1	11,02

65	b339866v	12,8	12,6
66	b339870s	29,5	29,19
67	b339925x	11,5	11,13
68	b339995f	11,2	10,75
69	b340108d	13,7	13,17
70	b340148g	6,88	6,38
71	b340280f	9,46	8,63
72	b340364s	17,4	16,88
73	b340367j	14,5	14,15
74	b340278q	13,6	13,14
75	b348110k	15,1	14,76
76	b348953t	7,03	6,57
77	b348990s	13,1	13,01
78	b349034p	8,22	7,6
79	b349065a	15,2	15,54
80	b349120y	16,9	17,08
81	b349130l	5,54	5,15
82	b349146h	14	14,05
83	b349164j	13,6	13,47
84	b349189w	9,86	9,11
85	b349387x	4,04	3,5
86	b349433p	4,04	3,48
87	b349629g	13,7	13,57
88	b349640h	7,26	6,9
89	b349839k	8,89	7,85
90	b349982h	8,42	7,71
91	b350011q	11,19	11,8
92	b350061l	10,9	10,43
93	b350189n	10,7	10,56
94	b350333k	8,41	7,79
95	b350485k	28,9	32,04
96	b357369s	11,8	10,17
97	b358398j	12,8	13,31
98	b358410v	10,9	10,81
99	b358659x	13,7	14,07
100	b358943y	9,55	8,61
101	b358949j	15,6	14,9
102	b358969h	17,4	16,34
103	b359134x	10,1	9,61
104	b359155s	9,58	9,13
105	b359298d	13,5	13,28
106	b359378q	15,8	15,61
107	b359396k	14,2	14,16
108	b359458a	11,3	10,49
109	b359635r	18,8	17,99
110	b359823j	11,2	10,34
111	b359913x	10,9	10,02
112	b360404q	7,74	7,19
113	b360445x	9,31	8,94
114	b360532w	8,18	8,02
115	b360664b	12,6	12,4
116	b360726k	9,55	8,91
117	b360770s	11,8	11,37
118	b361258k	13,7	13,48
119	b361189t	4,83	4,71
120	b354818q	13,8	13,55
121	b354819v	10	9,41
122	b359678d	27,6	28,73
123	b362222d	6,7	6,21
124	b362286v	4,97	4,39
125	b362352r	12,5	11,96
126	b362679w	13,9	13,99
127	b362760q	9,51	8,67
128	b362765s	7,25	6,62
129	b362965d	13,9	13,31
130	b363269d	23,6	25,49
131	b363632g	10,4	9,98
132	b363635v	8,97	7,75
133	b363643h	17,2	18,18
134	b363646l	6,96	6,37

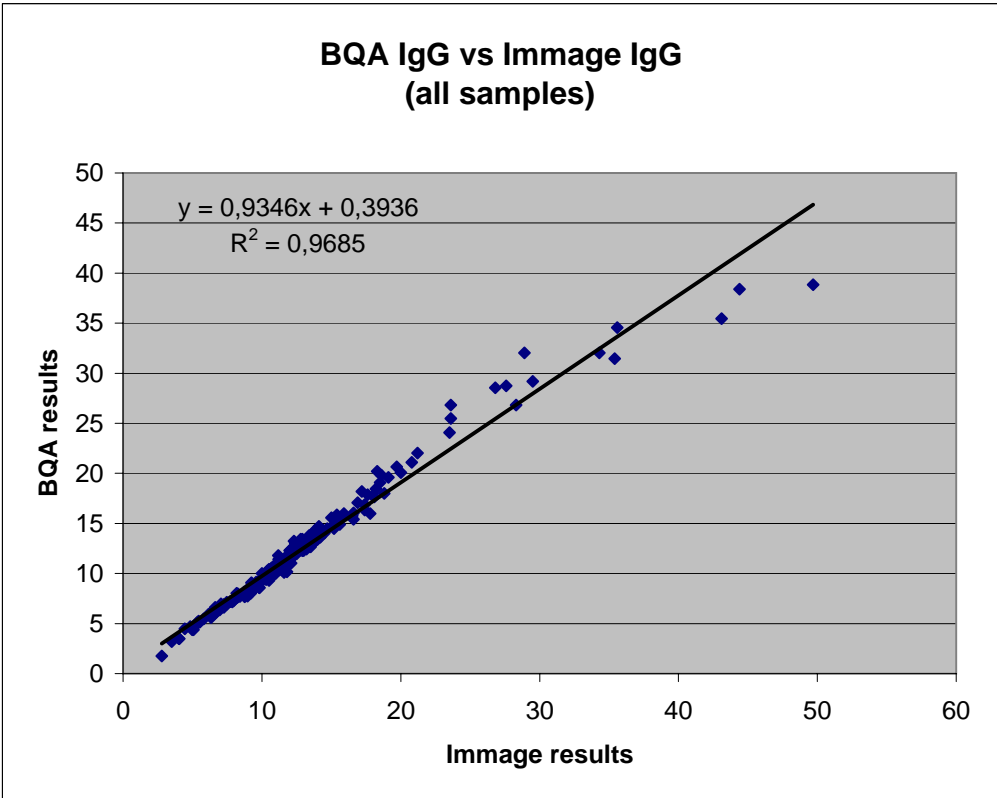
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137	b363676a	2,8	1,75
138	b363678t	7,72	7,19
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140	b364804p	10,7	9,67
141	b364905g	14,5	14,03
142	b364914n	16,5	15,75
143	b364988s	14,4	14,33
144	b365006a	15,2	14,49
145	b365068h	10,3	9,39
146	b365073w	11,3	10,8
147	b365076g	10,4	10,27
148	b365091b	9,77	8,93
149	b365132f	10,6	9,81
150	b365307v	18,3	20,22
151	b365410h	11	10,02
152	b365445t	10	10,02
153	b365553q	13,1	12,88
154	b365587d	9,89	9,37
155	b365619h	9,84	9,16
156	b365757w	12,9	12,72
157	b365778f	16,6	15,42
158	b365906p	13,4	13,6
159	b365973y	10,4	9,9
160	b366224t	13,2	12,44
161	b366573b	6,75	6,18
162	b350128x	10,2	9,78
163	b351955t	10,4	9,73
164	b352217y	10,7	10,29
165	b352223j	11,5	10,89
166	b352428a	11,3	11,36
167	b352500q	15,9	15,97
168	b353167y	12,1	11,9
169	b353170s	12,7	12,29
170	b353180d	10,9	10,3
171	b353191n	15	15,58
172	b353194r	10,3	9,54
173	b353331w	8,71	8,14
174	b353375v	13,5	13,37
175	b353451v	6,15	5,91
176	b353813y	6,3	6,06
177	b353986a	7,46	7,14
178	b354024a	12,8	13,43
179	b354087r	5,33	5,08
180	b367708j	15,4	15,87
181	b369259v	16,6	16,04
182	b369449v	5,81	5,47
183	b370128d	18,6	19,82
184	b370779v	12,3	13,24
185	b372087g	18,5	19,08
186	b372649h	9,82	8,57
187	b372650r	20	20,07
188	b372651p	19,7	20,66
189	b373243w	35,4	31,45
190	b373387t	5,45	5,23
191	b373397f	4,45	4,46
192	b380156p	11,4	10,35
193	b380358a	10,9	10,25
194	b380369d	19,1	19,59
195	b380390g	23,5	24,08
196	b380535r	13,4	13,79
197	b380548a	10,3	9,78
198	b380569t	12	11,68
199	b380603y	13,3	12,75
200	b380682s	12,3	11,79
201	b380692d	7,46	6,93
202	b381152q	17,6	17,87
203	b381159n	8,01	7,45
204	b381164l	9,19	8,01

205	b381274j	15,5	15,64
206	b381363y	3,5	3,19
207	b381897a	8,8	8,12
208	b381982b	13,3	13,39
209	b382358h	26,8	28,54
210	b382558q	13,4	12,65
211	b382641n	12,2	12,09
212	b382691q	12	12,29
213	b382735t	8,28	7,97
214	b382741l	11,8	10,87
215	b382993g	12	11,62
216	b383142w	9,88	9,35
217	b446997r	17,8	15,98
218	b447985r	5,11	4,67
219	b4478973r	34,3	32,02
220	b449339d	35,6	34,57
221	b449450l	11,2	10,75

note: Results are in G/L



Regression
r 0,9917
*r*² 0,9836
N 218
slope 1,0297
Intercep. -0,6965



<i>Regresion</i>	
<i>r</i>	0,9841
<i>r</i> ²	0,9685
<i>N</i>	221
<i>slope</i>	0,9346
<i>Intercep.</i>	0,3936

BQA Evaluation Results IgA

Sample Number	Laboratory Number	Immune Result	BQA Result
1	b302267x	0,34	0,15
2	b302538j	2,14	1,99
3	b302562b	2,01	1,99
4	b302566g	1,61	1,62
5	b302774f	3,09	3,08
6	b302808l	5,69	5,73
7	b302857a	1,28	1,24
8	b303007y	4,67	4,54
9	b304447g	6,24	6,29
10	b305023a	2,26	2,26
11	b305142h	4,16	4,02
12	b305252s	4,04	3,87
13	b305525l	2,3	2,2
14	b305610y	1,66	1,64
15	b306072j	0,35	0,19
16	b306332y	1,49	1,41
17	b306647b	1,65	1,66
18	b306779l	8,28	8,8
19	b306828a	1,16	1,13
20	b306836l	1,52	1,54
21	b306992f	2,12	2,03
22	b307116n	0,18	0,05
23	b305217j	3,04	2,91
24	b307032k	1,14	1,09
25	b307155j	5,02	4,72
26	b307156h	0,44	0,25
27	b307476t	0,89	0,83
28	b317966j	1,87	1,74
29	b318134s	6,09	5,88
30	b318156j	3,05	2,72
31	b318168v	1,47	1,43
32	b318175j	1,21	1,19
33	b318226y	1,59	1,59
34	b318251j	3,07	2,99
35	b318254p	3,24	3,16
36	b318287t	8,37	8,59
37	b318451k	3,84	3,76
38	b318511y	1,45	1,39
39	b318608a	1,92	1,96
40	b318705t	1,7	1,55
41	b318757v	1,52	1,45
42	b318807b	2,7	2,6
43	b325316s	1,14	1
44	b336375t	1,42	1,32
45	b336515b	2,22	2,1
46	b336788v	2,36	2,18
47	b336794n	1,19	1,12
48	b336883v	1,35	1,32
49	b337028b	2,96	2,74
50	b337092v	2,21	2,05
51	b336647l	2,63	2,44
52	b337547q	2,7	2,59
53	b338307q	2,02	1,86
54	b338120x	2,5	2,27
55	b338134g	1,54	1,55
56	b338144j	2,15	2,1
57	b338277j	1,81	1,63
58	b338307q	2,02	1,86
59	b338312s	2,2	2,09

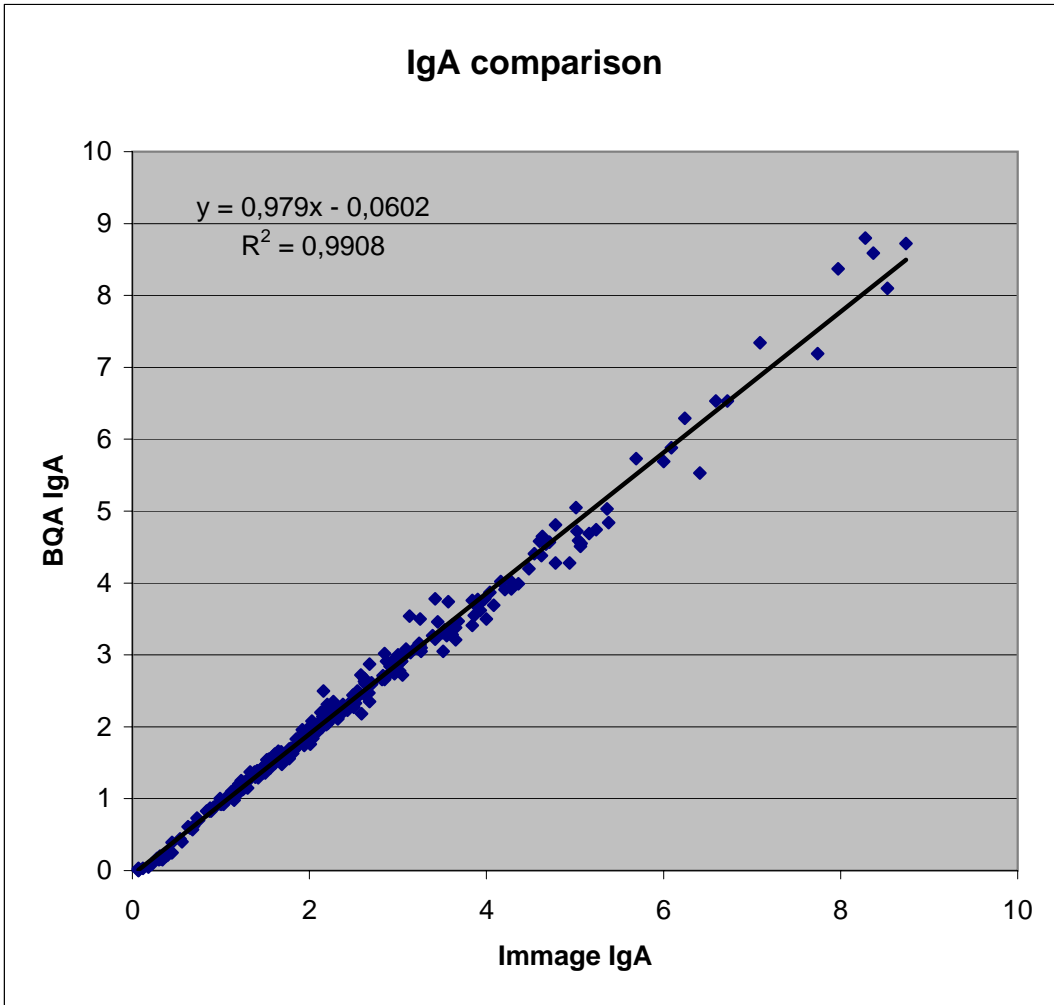
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65	b325316s	1,14	1
66	b337578l	4,28	3,92
67	b337586v	1,67	1,62
68	b337604q	0,87	0,83
69	b337670h	1,03	0,92
70	b337692l	1,74	1,64
71	b337695d	3,65	3,21
72	b337957p	8,53	8,1
73	b338028t	2,3	2,14
74	b338044x	3,02	2,78
75	b337701y	1,18	1,05
76	b338000f	2,43	2,28
77	b338106j	1,25	1,23
78	b339676v	2,45	2,33
79	b339779h	1,21	1,11
80	b339866v	3,55	3,27
81	b339870s	6,59	6,53
82	b339925x	2,95	2,78
83	b339995f	1,46	1,37
84	b340108d	1,87	1,74
85	b340148g	0,56	0,4
86	b340280f	2	1,87
87	b340364s	4,63	4,65
88	b340367j	2,24	2,1
89	b340278q	2,24	2,12
90	b339834n	2,43	2,23
91	b340448b	3,98	3,78
92	b344235q	3,84	3,41
93	b344326d	2,22	2,13
94	b348110k	4,21	3,91
95	b348953t	3,39	3,27
96	b348990s	2,63	2,6
97	b349034p	0,63	0,61
98	b349065a	4,62	4,38
99	b349120y	1,95	1,9
100	b349130l	1,03	0,97
101	b349146h	2,38	2,31
102	b347990l	3,86	3,55
103	b348631n	2,59	2,18
104	b349077f	1,61	1,49
105	b349164j	2,54	2,5
106	b349189w	3,25	3,14
107	b349387x	0,3	0,15
108	b349433p	0,22	0,09
109	b349629g	2,2	2,31
110	b349640h	1,55	1,49
111	b349839k	4,6	4,58
112	b349982h	2,85	2,66
113	b249296n	0,4	0,22
114	b349825a	1,65	1,6
115	b350011q	1,56	1,43
116	b350061l	2,27	2,2
117	b350189n	2,19	2,03
118	b350333k	2,87	2,91
119	b350485k	1,47	1,36
120	b350509a	2,16	2,5
121	b357369s	5,06	4,51
122	b358398j	1,28	1,23
123	b358410v	2,97	2,77
124	b358659x	1,91	1,84

125	b358943y	0,12	0,03
126	b358949j	5,07	4,55
127	b358969h	4,78	4,28
128	b359134x	2,46	2,33
129	b359155s	3,26	3,05
130	b358667p	2,57	2,45
131	b358946s	5,16	4,69
132	b359298d	4,08	3,69
133	b359378q	2,7	2,61
134	b359396k	3,68	3,47
135	b359458a	2,03	1,9
136	b359635r	1,93	1,93
137	b359823j	1,79	1,7
138	b359913x	1,77	1,56
139	b360404q	7,74	7,19
140	b359233n	3,21	3,11
141	b359411w	1,5	1,41
142	b359536t	3,65	3,38
143	b359558h	2,07	1,98
144	b360445x	4,71	4,57
145	b360486t	0,28	0,17
146	b360532w	0,73	0,73
147	b360664b	2,26	2,26
148	b360726k	3,42	3,22
149	b360770s	0,92	0,88
150	b361258k	5,04	4,59
151	b361189t	2,52	2,33
152	b360438d	1,15	0,98
153	b360774h	2,18	2,23
154	b361074s	0,54	0,44
155	b359678d	0,31	0,2
156	b362222d	2,91	2,84
157	b362286v	1,21	1,1
158	b362352r	1,83	1,68
159	b359277b	1,98	1,85
160	b362679w	3,62	3,42
161	b362760q	3,61	3,28
162	b362765s	0,65	0,59
163	b362965d	1,29	1,23
164	b363269d	8,74	8,72
165	b363632g	1,85	1,75
166	b363635v	1,68	1,65
167	b362654j	2,04	1,84
168	b362815g	1,26	1,22
169	b363497d	2,7	2,61
170	b363643h	3,91	3,7
171	b363646l	3,88	3,69
172	b363657a	3,14	3,03
173	b363669f	0,96	0,92
174	b363676a	0,07	0,02
175	b363678t	1,02	0,93
176	b364713d	4,27	4,03
177	b364804p	0,38	0,2
178	b364905g	2,49	2,35
179	b364914n	5,36	5,03
180	b364988s	2,9	2,74
181	b365006a	3,26	3,1
182	b365068h	2,68	2,35
183	b365073w	1,2	1,1
184	b365076g	2,67	2,47
185	b365091b	1,69	1,48
186	b365132f	3,53	3,35
187	b365307v	0,69	0,62
188	b365410h	1,07	0,98
189	b365445t	0,75	0,7

190	b365553q	2,15	2,14
191	b365300v	2,82	2,66
192	b365542j	1,44	1,37
193	b365619h	1,42	1,29
194	b365757w	1,64	1,54
195	b365778f	5,24	4,74
196	b365906p	3,65	3,44
197	b365973y	2,11	1,98
198	b366224t	5,38	4,84
199	b366573b	1	0,92
200	b365987f	7,97	8,37
201	b366120f	1,94	1,74
202	b366317a	1,85	1,74
203	b366721h	4	3,5
204	b350128x	2,83	2,71
205	b351955t	1,39	1,3
206	b351938j	2,51	2,4
207	b352204j	2,49	2,44
208	b352217y	0,32	0,16
209	b352223j	3,5	3,31
210	b352428a	1,23	1,25
211	b352500q	0,98	0,93
212	b353167y	3,45	3,46
213	b353170s	3,93	3,62
214	b353180d	2,57	2,46
215	b353191n	1,31	1,27
216	b353194r	3	3
217	b352308g	0,84	0,83
218	b353183k	1,23	1,17
219	b353331w	1,54	1,49
220	b353375v	4,36	3,99
221	b353451v	1,77	1,69
222	b353813y	1,54	1,43
223	b353986a	1,92	1,78
224	b354024a	2,18	2,12
225	b353207a	2,09	1,93
226	b353622v	1,3	1,15
227	b353737y	1,08	1,04
228	b353896h	1,57	1,46
229	b353929a	3,9	3,77
230	b354011r	2,37	2,28
231	b354087r	2,1	2,05
232	b354087r	3,04	2,91
233	b367708j	2,94	2,92
234	b369259v	3,42	3,78
235	b369449v	0,99	1
236	b370128d	1,33	1,37
237	b370779v	6	5,69
238	b372087g	1,72	1,61
239	b372649h	1,04	0,96
240	b372650r	7,09	7,34
241	b372651p	2,64	2,64
242	b369650l	0,07	0,03
243	b371743d	0,07	0
244	b380156p	4,54	4,41
245	b380358a	1,85	1,83
246	b380369d	3,22	3,09
247	b380390g	3,13	3,54
248	b380535r	1,38	1,35
249	b380548a	2,58	2,72
250	b380569t	5,01	5,05
251	b380603y	2,85	3,02
252	b380682s	1,64	1,57
253	b380383r	1,97	1,96
254	b380508y	1,38	1,37

255	b380685j	2,24	2,29
256	b380692d	1,12	1,1
257	b381152q	4,78	4,81
258	b381159n	2,13	2,2
259	b381164l	2,03	2,08
260	b381274j	2,62	2,67
261	b381363y	0,45	0,25
262	b381897a	0,68	0,57
263	b381040y	6,72	6,53
264	b381393b	3,25	3,5
265	b381557t	1,47	1,44
266	b381885p	2,27	2,35
267	b381928f	1,72	1,62
268	b381982b	2,62	2,63
269	b382358h	0,45	0,39
270	b382558q	3,57	3,74
271	b382641n	1,37	1,35
272	b382346f	0,88	0,87
273	b382735t	1,71	1,58
274	b382741l	1,41	1,39
275	b382993g	1,94	1,83
276	b383142w	0,07	0,01
277	b382552b	2,68	2,87
278	b446997r	4,94	4,28
279	b447985r	1,5	1,36
280	b4478973r	1,2	1,2
281	b449339d	2,32	2,11
282	b449450l	4,48	4,2

note: Results are in G/L



Regression	
<i>r</i>	0,9954
<i>r</i> ²	0,9908
<i>N</i>	282
<i>slope</i>	0,979
<i>Intercep.</i>	-0,060

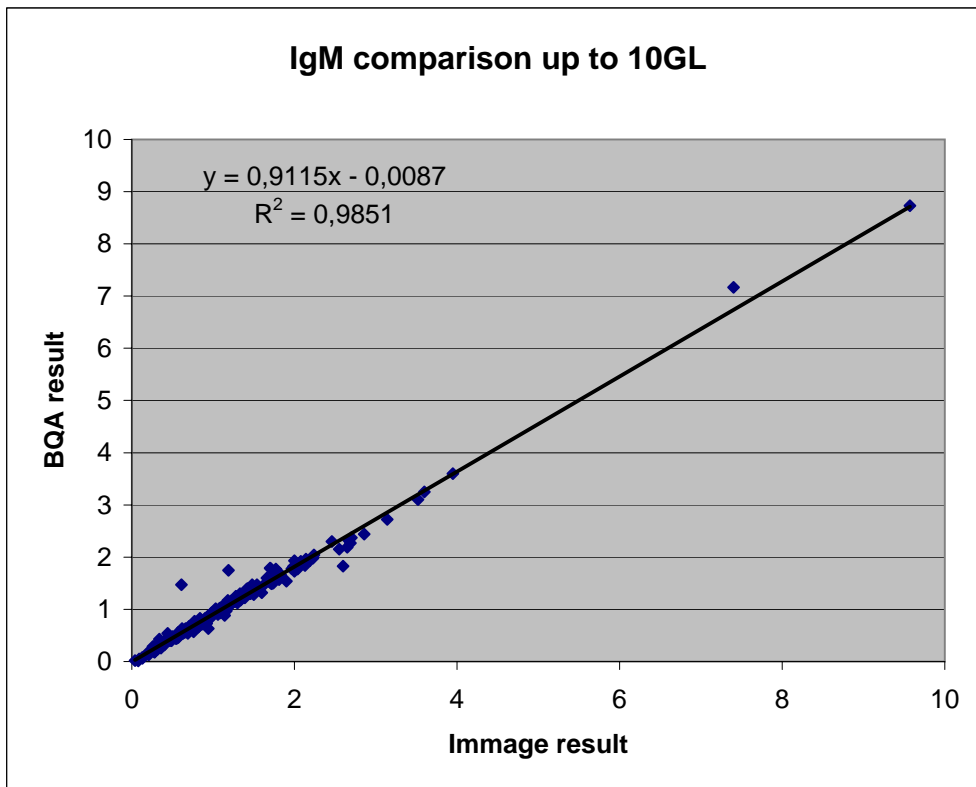
BQA Evaluation Results IgM

Sample Number	Laboratory Number	Image	BQA Result
1	b302267x	0,69	0,54
2	b302538j	2,08	1,92
3	b302562b	1,16	0,99
4	b302566g	0,57	0,46
5	b302774f	0,49	0,4
6	b302808l	1,3	1,12
7	b302857a	2,65	2,19
8	b303007y	0,89	0,73
9	b304447g	1,09	0,93
10	b305023a	0,7	0,59
11	b305142h	0,65	0,56
12	b305252s	1,36	1,22
13	b305525l	1,13	0,95
14	b305610y	2,55	2,15
15	b306072j	0,13	0,06
16	b306332y	0,75	0,61
17	b306647b	0,76	0,69
18	b306779l	1,45	1,3
19	b306828a	1,16	0,97
20	b306836l	1,75	1,61
21	b306992f	0,87	0,72
22	b307116n	0,61	1,47
23	b305217j	1,81	1,57
24	b317966j	1,9	1,54
25	b318134s	2,69	2,27
26	b318156j	1,6	1,32
27	b318175j	1,18	1,04
28	b318226y	0,82	0,66
29	b318251j	1,13	0,96
30	b318254p	0,41	0,35
31	b318287t	2,86	2,44
32	b318451k	1,52	1,35
33	b318511y	0,9	0,75
34	b318608a	0,34	0,3
35	b318705t	0,32	0,24
36	b318757v	2	1,73
37	b318807b	0,94	0,63
38	b325316s	0,28	0,19
39	b336375t	2,7	2,37
40	b336515b	1,26	1,15
41	b336788v	0,84	0,72
42	b336794n	0,39	0,33
43	b336883v	0,98	0,85
44	b337028b	1,2	1,07
45	b337092v	0,75	0,62
46	b338307q	0,54	0,44
47	b338120x	0,92	0,8
48	b338134g	0,88	0,78
49	b338144j	1,19	1,75
50	b338277j	1,72	1,49
51	b338307q	0,44	0,54
52	b338312s	2,19	1,93
53	b338326q	1,53	1,38
54	b338439k	0,36	0,26
55	b338551f	1,78	1,6
56	b338565p	1,14	0,88
57	b338644w	0,28	0,18
58	b325316s	0,28	0,19
59	b337578l	1,36	1,25
60	b337586v	0,57	0,49
61	b337604q	1,26	1,15
62	b337670h	3,14	2,72
63	b337692l	1,5	1,28

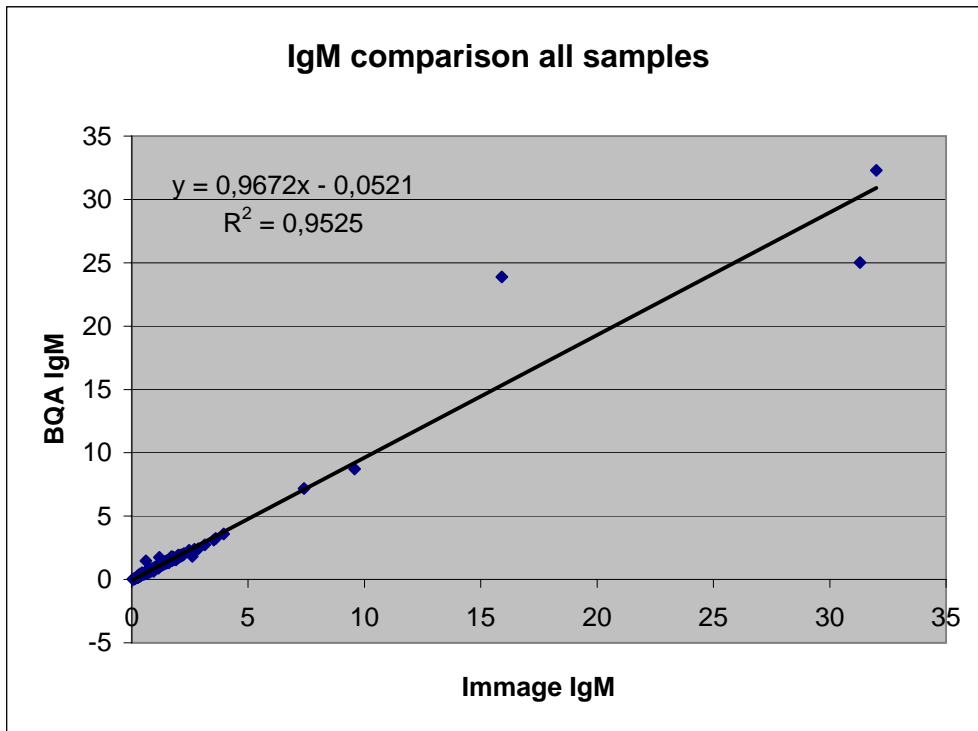
64	b337695d	0,21	0,13
65	b337957p	0,67	0,61
66	b338028t	1,14	1,02
67	b338044x	0,53	0,47
68	b339866v	1,06	0,9
69	b339870s	1,09	0,97
70	b339925x	2,24	2,04
71	b339995f	1,81	1,6
72	b340108d	0,84	0,69
73	b340148g	0,92	0,73
74	b340280f	0,55	0,44
75	b340364s	1,11	1,01
76	b340367j	0,76	0,57
77	b340278q	1,72	1,51
78	b344296a	0,7	0,6
79	b348953t	0,44	0,41
80	b348990s	2,12	1,88
81	b349034p	0,26	0,29
82	b349065a	1,08	0,97
83	b349120y	0,66	0,63
84	b349130l	0,9	0,83
85	b349146h	2,14	1,96
86	b349164j	1,32	1,21
87	b349189w	1,22	1,16
88	b349629g	0,34	0,33
89	b349640h	0,76	0,7
90	b349839k	0,27	0,22
91	b349982h	1,39	1,22
92	b350011q	1,81	1,7
93	b350061l	0,5	0,48
94	b350189n	2,67	2,32
95	b350333k	1,68	1,54
96	b350485k	1,17	1,12
97	b357369s	0,53	0,46
98	b358398j	0,85	0,8
99	b358410v	0,39	0,35
100	b358659x	1,36	1,29
101	b358943y	0,08	0,01
102	b358949j	1,29	1,24
103	b358969h	3,95	3,6
104	b359134x	1,14	1,04
105	b359155s	0,71	0,67
106	b359298d	1,76	1,58
107	b359378q	0,77	0,77
108	b359396k	0,97	0,9
109	b359458a	0,84	0,83
110	b359635r	1,19	1,06
111	b359823j	0,57	0,56
112	b359913x	0,68	0,58
113	b360404q	0,82	0,76
114	b360445x	0,32	0,31
115	b360486t	0,24	0,2
116	b360532w	1,13	1,05
117	b360664b	0,43	0,4
118	b360726k	2,23	1,98
119	b360770s	1,15	1,02
120	b361258k	0,21	0,19
121	b361189t	1,27	1,15
122	b359678d	0,2	0,16
123	b362222d	0,62	0,56
124	b362286v	1,62	1,46
125	b362352r	2,04	1,77
126	b362679w	0,77	0,67
127	b362760q	0,34	0,36
128	b362765s	0,24	0,21
129	b362965d	0,71	0,61
130	b363269d	0,98	0,93
131	b363632g	1,13	1,08

132	b363635v	0,72	0,68
133	b363643h	1,09	1,03
134	b363646l	0,83	0,79
135	b363657a	0,63	0,59
136	b363669f	1,17	1,06
137	b363676a	0,04	0,02
138	b363678t	1,83	1,66
139	b364713d	1,74	1,58
140	b364804p	0,69	0,62
141	b364905g	0,63	0,54
142	b364914n	0,62	0,63
143	b364988s	0,42	0,41
144	b365006a	1,71	1,5
145	b365068h	2,13	1,84
146	b365073w	0,78	0,68
147	b365076g	0,4	0,32
148	b365091b	0,47	0,4
149	b365132f	1,99	1,82
150	b365307v	0,4	0,37
151	b365410h	1,54	1,47
152	b365445t	0,93	0,86
153	b365553q	1,26	1,15
154	b365587d	1,34	1,18
155	b365619h	0,27	0,29
156	b365757w	0,31	0,32
157	b365778f	0,7	0,67
158	b365906p	1,46	1,3
159	b365973y	0,81	0,69
160	b366224t	1,23	1,11
161	b366573b	1,97	1,78
162	b350128x	7,4	7,17
163	b351955t	0,79	0,73
164	b352217y	1,1	0,96
165	b352223j	1,14	0,96
166	b352428a	0,63	0,58
167	b352500q	1,37	1,25
168	b353167y	1,17	1,06
169	b353170s	0,95	0,88
170	b353180d	0,29	0,26
171	b353191n	1,74	1,5
172	b353194r	1,46	1,33
173	b353331w	1,54	1,39
174	b353375v	1,2	1,07
175	b353451v	0,49	0,43
176	b353813y	0,4	0,39
177	b353986a	0,84	0,76
178	b354024a	1,27	1,19
179	b354087r	0,73	0,69
180	b367708j	3,52	3,1
181	b369259v	0,94	0,85
182	b369449v	0,42	0,43
183	b370128d	0,33	0,29
184	b370779v	1,71	1,78
185	b372087g	0,2	0,14
186	b372650r	2,6	1,83
187	b372651p	1,66	1,6
188	b373243w	0,66	0,57
189	b373387t	0,44	0,43
190	b380156p	1,32	1,2
191	b380358a	1,33	1,3
192	b380369d	1,09	0,99
193	b380390g	2	1,93
194	b380535r	1,08	1,02
195	b380548a	0,59	0,56
196	b380569t	1,17	1,12
197	b380603y	1,77	1,77
198	b380682s	1,18	1,17
199	b380692d	0,82	0,74

200	b381152q	1,01	0,97
201	b381159n	3,6	3,25
202	b381164l	0,8	0,69
203	b381274j	0,78	0,63
204	b381363y	0,34	0,43
205	b381897a	1,7	1,79
206	b381982b	1,42	1,4
207	b382358h	0,13	0,08
208	b382558q	0,82	0,74
209	b382641n	1,48	1,47
210	b382691q	1,03	1,01
211	b382735t	2,46	2,3
212	b382741l	1,41	1,38
213	b382993g	1,28	1,25
214	b383142w	0,09	0,05
215	b446997r	0,6	0,53
216	b447985r	1,16	1,04
217	b4478973r	0,89	0,78
218	b449339d	9,57	8,73
219	b449450l	1,37	1,25



Regression
r 0,9922
*r*² 0,9851
N 216
slope 0,9115
Intercep. -0,0087



Regression	
<i>r</i>	0,9760
<i>r</i> ²	0,9525
<i>N</i>	219
<i>slope</i>	0,9672
<i>Intercep.</i>	-0,0521

note: We can see that there are some differences in the reported values of 3 IgM myeloma samples. All these samples are reporting between 15 G/L and 33 G/L. We like to remark here that samples reporting higher than 32 G/L in the BQA have to be postdiluted by hand to obtain the real result. If not the result have to be reported as >32 g/L. This can explain, at least in part, these differences.

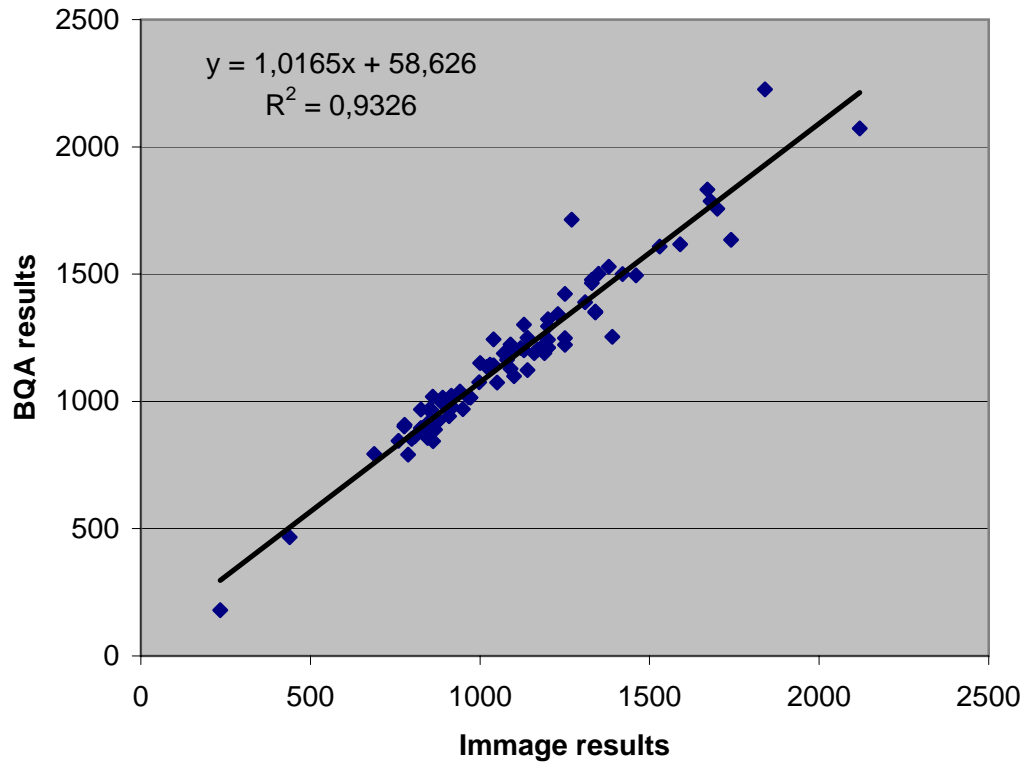
BQA Evaluation Results C3

Sample Number	Laboratory Number	Immage	BQA Result
1	b302538j	1000	1150,23
2	b302566g	966	1016,11
3	b304395x	1190	1189,85
4	b305525l	1100	1099,1
5	b306647b	439	465,94
6	b318156j	1250	1222,3
7	b318226y	1190	1223,5
8	b318451k	1340	1352,8
9	b318597l	1170	1203,98
10	b330755r	909	942,04
11	b330864s	1120	1209,8
12	b338307q	1200	1211,52
13	b338307q	1200	1211,52
14	b338312s	808	862,09
15	b338326q	896	986,74
16	b339232s	998	1075,06
17	b339253d	1080	1163,56
18	b339870s	1230	1343,44
19	b340364s	897	988,18
20	b340378q	1250	1248,9
21	b346963p	1070	1188,45
22	b348110k	845	913,12
23	b348953t	1310	1389,65
24	b348990s	1160	1189,63
25	b349157v	890	1015,02
26	b349164j	1200	1322,79
27	b349259j	1040	1142,26
28	b349624l	1020	1135,65
29	b350498l	1100	1197,08
30	b350759n	1330	1465,42
31	b353180d	883	1001,26
32	b353187x	1200	1242,73
33	b353194r	941	1039,03
34	b353451v	1420	1499,65
35	b354011r	842	896,73
36	b358628r	862	844,33
37	b358949j	826	968,87
38	b358969h	1460	1495,2
39	b359396k	1190	1221,43
40	b370779v	1090	1223,89
41	b372938b	1680	1786,51
42	b373492f	778	908,27
43	b380358a	849	966,59
44	b380603y	856	967,13
45	b380682s	861	1018,17
46	b381152q	1200	1295,01
47	b429944q	915	1022,84
48	b430064t	1040	1244,27
49	b432635l	234	180,03
50	b432794q	867	889,07
51	b433032r	1390	1253,75

52	b433335h	918	977,28
53	b433340w	1140	1122,97
54	b433954v	878	924,2
55	b434075j	1740	1635,36
56	b435119n	788	791,08
57	b435125b	846	855,96
58	b435263k	798	852,95
59	b437926y	1140	1249,65
60	b438033w	1130	1201,01
61	b438333r	1270	1713,58
62	b438516x	1330	1477,68
63	b438526b	1350	1500,95
64	b438596n	1090	1127,66
65	b438599r	1840	2226,43
66	b439014n	1250	1422,31
67	b439763d	1670	1832,65
68	b439907n	777	902,13
69	b440180w	1590	1617,21
70	b442442d	949	969,86
71	b443759y	1380	1529,52
72	b444296n	1340	1349,68
73	b444767x	1530	1608,76
74	b446069b	826	895,72
75	b446384s	1030	1129,96
76	b446394d	1050	1073,67
77	b447192d	688	793,29
78	b447212f	2120	2072,52
79	b447685w	1030	1144,1
80	b448009d	760	845,19
81	b448041h	1130	1301,05
82	b448380t	972	1014,71
83	b449000k	1700	1757,34

note: results in G/dL

C3 comparison



Regresion

<i>r</i>	0,9660
<i>r</i>²	0,9326
<i>N</i>	83
<i>slope</i>	1,017
<i>Intercep.</i>	58,626

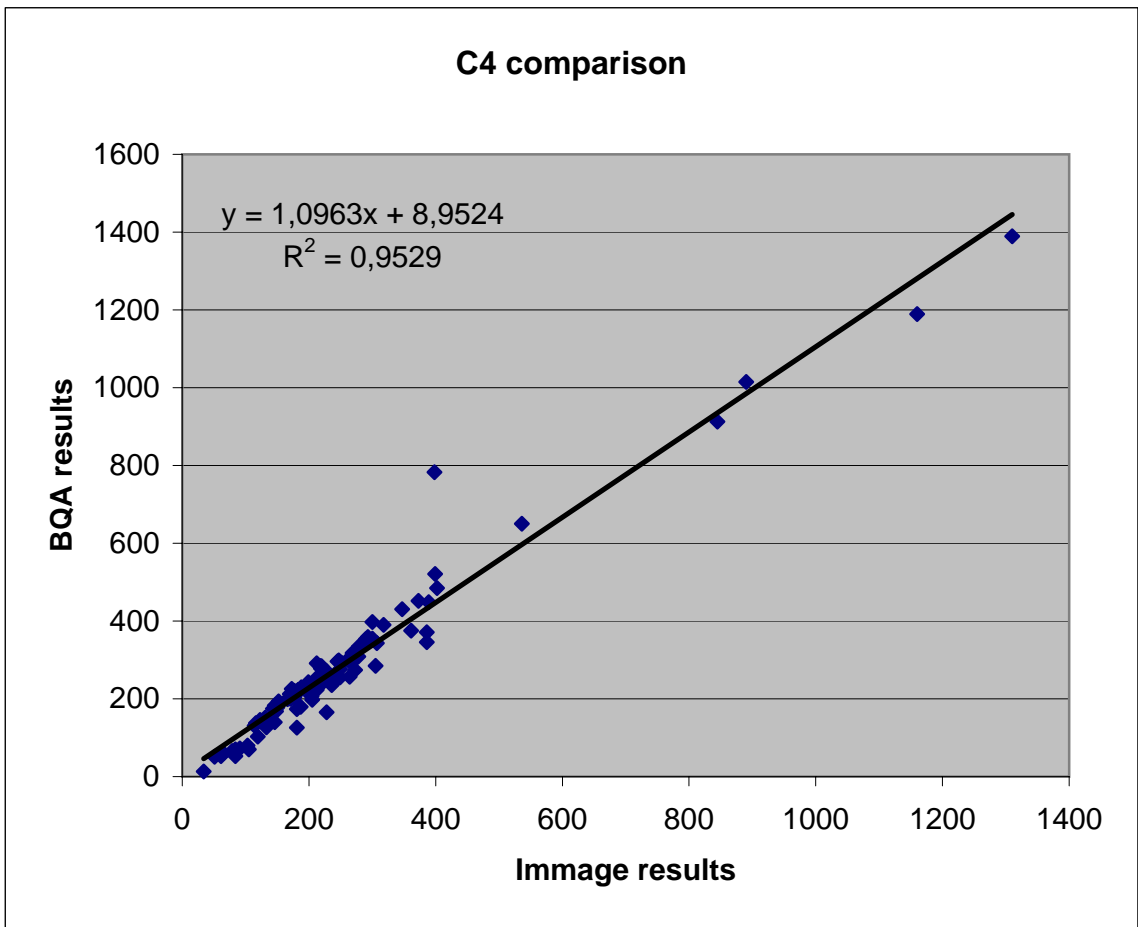
BQA Evaluation Results C4

Sample Number	Laboratory Number	Immagine	BQA Result
1	b302538j	79	65,89
2	b302566g	199	224,86
3	b304395x	123	145,79
4	b305525l	267	292,47
5	b306647b	65	60,41
6	b318156j	150	178,17
7	b318226y	143	174,12
8	b318451k	217	284,92
9	b318597l	194	229,02
10	b330755r	181	125,77
11	b330864s	389	448,21
12	b338307q	280	331,46
13	b338307q	280	331,46
14	b338312s	91	72,1
15	b338326q	173	207,35
16	b339232s	269	318,1
17	b339253d	152	190,15
18	b339870s	204	206,85
19	b340364s	114	130,56
20	b340378q	287	345,47
21	b346963p	191	225,95
22	b348110k	845	913,12
23	b348953t	1310	1389,65
24	b348990s	1160	1189,63
25	b349157v	890	1015,02
26	b349164j	173	225,71
27	b349259j	188	229,74
28	b349624l	149	180,78
29	b350498l	347	430,54
30	b350759n	290	353,53
31	b353180d	220	283,99
32	b353187x	227	272,13
33	b353194r	211	251,54
34	b353451v	198	230,39
35	b354011r	152	193,1
36	b354818q	386	371,33
37	b354819v	305	285,09
38	b358628r	84	52,74
39	b358949j	307	343,59
40	b358969h	84	69,55
41	b359155s	245	296,06
42	b359396k	199	242,48
43	b360532w	264	256,84
44	b362368n	293	358,52
45	b362601l	196	233,23
46	b362998r	51	51,41
47	b363635v	219	278,19
48	b363669f	177	220,58
49	b364713d	170	212,35
50	b364846d	247	298,92
51	b365068h	210	241,54

52	b365410h	61	52,54
53	b365587d	146	182,66
54	b365778f	116	137,38
55	b366129t	251	293,27
56	b370779v	178	208,75
57	b372938b	536	650,45
58	b373492f	131	151,2
59	b380358a	171	200,02
60	b380603y	300	397,91
61	b380682s	131	148,19
62	b381152q	205	197,37
63	b429944q	105	69,89
64	b430064t	103	79,68
65	b432635l	34	13,06
66	b432794q	146	140,26
67	b433032r	361	375,54
68	b433335h	249	255,25
69	b433340w	187	179,74
70	b433954v	181	173,93
71	b434075j	386	345,97
72	b435119n	236	235,66
73	b435125b	183	222,73
74	b435263k	228	165,82
75	b437926y	133	126,74
76	b438033w	212	222,86
77	b438333r	119	103,17
78	b438516x	278	308,95
79	b438526b	373	451,93
80	b438596n	249	276,81
81	b438599r	398	782,92
82	b439014n	318	389,77
83	b439763d	276	322,64
84	b439907n	223	243,47
85	b440180w	242	263,17
86	b442442d	223	264,02
87	b443759y	273	274,44
88	b444296n	279	335,22
89	b444767x	402	484,46
90	b446069b	177	204,01
91	b446384s	148	168,12
92	b446394d	261	300,07
93	b447192d	166	198,97
94	b447212f	300	354,6
95	b447685w	212	291,2
96	b448009d	171	204,04
97	b448041h	236	258
98	b448380t	206	225,27
99	b449000k	399	520,68

note: results in G/dL

C4 comparison



<i>Regresion</i>	
<i>r</i>	0,9762
<i>r</i> ²	0,9529
<i>N</i>	99
<i>slope</i>	1,096
<i>Intercep.</i>	8,952

**DRAFT PROTOCOL FOR THE EVALUATION OF THE BIOKIT QUANTEX
ANALYSER (BQA) WITHIN IMMUNOLOGY**

**Department of Immunology
Wexham Park Hospital**

Lynn Day Laboratory Manager

INSTALLATION AND TRAINING

1. *Installation of the instrument*
2. *Introduction and demonstration of both the Hardware and Software aspects of the BQA*
3. *User familiarisation*
 - 3.1. *Biokit Quantex test assays*
 - 3.2. *Calibration and validation with controls*
 - 3.3. *Serum sample testing*
4. *Analysis and discussion of results, regards the validation of both the BQA and the Quantex range, toward the introduction to, and routine use within the UK Immunology market*

EVALUATION

An incident log to be maintained throughout the evaluation process, to record any apparent errors and issues by date, together with a description and actions taken to reach resolution

Immunoglobulins IgA, IgG, IgM

NEQAS Samples

Permission sort and gained from Peter White Director, MDA Sheffield 08/07/03, for the inclusion of previously circulated UK NEQAS samples within the serum panel for testing, as deemed appropriate for evaluation purposes

Comparison

To run approximately 200 samples on both the BQA and Beckman Image. The sample panel to encompass a range of concentrations but weighted towards strongly positive sera.

To resolve discrepant results by means of consensus, after repeat testing

Results

Record the results on the spreadsheet provided

Complement:- C3 & C4

NEQAS Samples

Permission sort and gained from Peter White Director, MDA Sheffield 08/07/03, for the inclusion of previously circulated UK NEQAS samples within the serum panel for testing, as deemed appropriate for evaluation purposes

Comparison

To run approximately 200 samples on both the BQA and Beckman Image. The sample panel to encompass a range of concentrations but weighted towards strongly positive sera.

To resolve discrepant results by means of consensus, after repeat testing

Results

Record the results on the spreadsheet provided

POST EVALUATION

- 1. Review and discuss the results achieved during the evaluation, together with the BQA questionnaire*
- 2. To work in collaboration with both Wexham Park Hospital and Biokit UK Limited, with regard to any publication potential*

QUESTIONNAIRE AND REMARKS

Questionnaire on the BQA and its use:

<p>1. Hardware</p>	<p>1.1. <i>Size of the instrument. Do you think it is suitable?</i> <i>The instrument fitted easily onto a standard lab bench. As it was a temporary installation there were some issues with trailing drainage tubes. However these would be overcome if the equipment were permanently installed in a department.</i></p> <p>1.2. <i>Any Safety Concerns?</i></p> <p>1.3. <i>Appearance. Attractive? How would you improve it?</i> <i>The overall appearance was in keeping with the department. The member of staff using the equipment was quite short and seeing to the bottom of the sample and reagent compartments was slightly difficult. Mainly only a problem when clean/decontamination</i></p> <p>1.4. <i>What kind of customer would you think appropriate, with the Tests/hour in mind?</i> <i>The work we carried out on the BQA was around protein assay. Immunoglobulins, complements etc It produced results very quickly and efficiently. They compared well with the majority of the results produced from our current equipment.</i></p> <p>1.5. <i>Any Noise?</i> <i>The machine was very quite. It made very little noise when in standby or when processing samples.</i> <i>Please comment on the following-</i></p> <p>1.6. <i>Size of rack for reagents</i> <i>Using the machine</i></p> <p>1.7. <i>Size of rack for samples</i> <i>Racking size was not as large as the current analyser in the department. It held 40 samples at a time which often meant worksheets had to be split over a couple of runs. Interfacing allowing continuous load would solve this drawback.</i></p> <p>1.8. <i>Adjustment for tubes and vials</i> <i>All tubes that were used in the lab, fitted well into the racks. Although the samples fitted, there was not much room for adjustment.</i></p> <p>1.9. <i>Safety of rack covers</i></p>
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	<p><i>The magnetic covers worked safely.</i></p> <p><i>1.10. Reagent bar code system</i></p> <p><i>1.11. Sample bar code system</i> <i>We were unable to use the barcodes, which are attached to our samples, as the BQA was unable to read them. We have been informed by the manufacturer that the problem has already been addressed.</i></p> <p><i>1.12. Dead volumes (reagents / samples)</i> <i>There were no samples rejected due to insufficient sample. Several were short volume samples.</i></p> <p><i>1.13. Connections (tubes for liquid, to PC, to network, etc.)</i> <i>There were several external connections, tubes which lead to different waste containers. The tubes should be colour identified to ensure no confusion. We have been informed by the manufacturer that this modification has already been implemented.</i></p> <p><i>1.14. Washing line</i></p> <p><i>1.15. Needle washing</i></p>
<p><i>2. Software-programming</i></p>	<p><i>2.1. Ease of programming</i> <i>The visual display unit was very user friendly. The colour coding of the sample positions allowed the high/low level re-runs to be identified quickly.</i></p> <p><i>2.2. Programming Reagents</i> <i>The programming of the reagents was practically all automated as long as the bar codes met correctly and the volume of reagent left was sufficient for the run.</i></p> <p><i>2.3. Programming concentrations for Std and Controls</i> <i>Once it had been programmed, all that was needed to do when running the controls was to highlight the control in the menu.</i></p> <p><i>2.4. Programming multi-standard</i> <i>Same as above.</i></p> <p><i>2.5. Programming channels</i></p> <p><i>2.6. Programming washing at the start of the day</i> <i>It was preset and remained to commence priming at 0830 Monday to Friday.</i></p> <p><i>2.7. Number of applications available</i> <i>Good.</i></p>

<p>3. Software – Routine use</p>	<p>3.1. Overall ease of use. Comments on screen <i>The whole system was easy to maintain apart from the amount of water the system required. It allowed easy recognition of the samples that were running and the ability to add samples whilst the machine was in motion.</i></p> <p>3.2. Ease of use of the sample bar codes <i>N/A</i></p> <p>3.3. Ease of use of the reagent bar codes <i>The bar code on the reagents read without any manual input.</i></p> <p>3.4. Request for calibrations and controls</p> <p>3.5. Request for samples <i>The start up menu allowed any requesting of samples to be quick.</i></p> <p>3.6. Management of errors <i>The flashing error menu highlighted any errors within the machine, calibration or control error, insufficient water or waste disposal problems. This allowed me to locate the problem quickly.</i></p> <p>3.7. Information available while working <i>All of the samples, their positions and what stage of processing on one page became useful.</i></p> <p>3.8. Information available on calibrations</p> <p>3.9. Information available on the controls (graph for values reported, etc.)</p> <p>3.10. Information about the analyses performed. Amount of results that may be stored <i>Analysis was very straightforward. Retrieval of the results was easy. Data base able to store sufficient results for longterm retrieval of data.</i></p> <p>3.11. Type of report on results. Appended information (high, low readings, outside of range, etc.)</p> <p>3.12. Information on screen available after sample processing</p> <p>3.13. Alarms. Are they self-explanatory? <i>Yes</i></p>
<p>4. Reagents –</p>	<p>4.1. General comparison of results with those obtained</p>

<p><i>Quality of results</i></p>	<p><i>with your usual instrument</i></p> <p><i>Results suggest good comparison. Initial minor inconsistencies were resolved with repeat runs.</i></p> <p>4.2. <i>Size of kits (No. of tests) compared to the size of the instrument</i></p> <p>4.3. <i>Ease of handling dedicated kits</i> <i>Small and easy to load on the reagent carousel.</i></p> <p>4.4. <i>Calibrations (stability)</i> <i>For one analyte we found the calibration drifted earlier than expected.</i></p> <p>4.5. <i>Accuracy</i></p> <p>4.6. <i>Stability of the reagents</i> <i>The reagents remained stable as long as they were refrigerated.</i></p> <p>4.7. <i>Working ranges</i></p> <p>4.8. <i>Re-run</i> <i>The automatic re-run of high/low level results saved time.</i></p>
<p><i>5. Maintenance</i></p>	<p>5.1. <i>Water management</i> <i>The BQA uses a large amount of water. This required the daily top-up of the distilled water. If the container was more than half full then the weight exceeded that permitted to be moved by female staff (16Kg) This was also true when discarding the waste. We would recommend plumbing in the distilled water and waste systems.</i></p> <p>5.2. <i>Size of containers for water and waste</i> <i>See above</i></p> <p>5.3. <i>Consumption of water and water with detergent</i> <i>Large</i> <i>The consumption of detergent was minimal; I only prepared the solution 2 times in the 2 month period of using the instrument.</i></p> <p>5.4. <i>Preparing water with detergent</i> <i>Easy</i></p> <p>5.5. <i>Switch off, sleep and wake-up functions</i> <i>Once set up this function was very useful. It meant the machine was ready to process as soon as samples had arrived. Requiring only QC to run to prepare for the days work.</i></p> <p>5.6. <i>System bleeding</i></p>

	<i>5.7. Reaction wells washing</i>
<i>Any further comments/ Summary</i>	