

Laboratory Medicine Bulletin

Change of Method: Insulin Like Growth Factor I

March 06, 2013

Recently Siemens Diagnostics suspended reagent for their Insulin Like Growth Factor I (IGF-I) for the Immulite series of instruments. This suspension was driven by technical problems with the manufacturing process which led to an upward shift in the median of patient results by approximately 20%. This problem was superimposed on a previous shift of 20% introduced by an assay reformulation that occurred in 2007.

For these reasons, as of March 06, 2013, there will be a province-wide change in the method used for IGF-I from the Siemens Immulite 2000 XPi to the Immunodiagnostic Systems iSYS method. This iSYS method is calibrated against the World Health Organization recombinant standardized IGF-I reference material (02/254). Like the former method, the iSYS method is a two-site chemiluminescent immunoassay. However, results between the two methods are not necessarily comparable. For results below 200 ug/L, the iSYS yields results on average 5% higher than the Immulite. However, in the high-normal to high range the iSYS reads, on average, 20-25% lower. At the extremes of concentration, the percent effects are larger still. The relationship between the new method and the most recently available lot of the old method can be estimated using the following quadratic equation:

$$\text{IGF-I}_{\text{New}} = 10.0 + 0.955 \times \text{IGF-I}_{\text{Old}} - 0.000273 \times \text{IGF-I}_{\text{Old}}^2$$

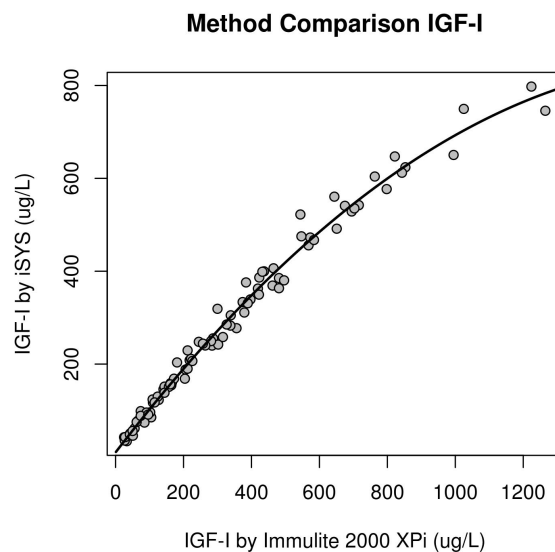


Figure 1: Relationship between IDS iSYS (New) IGF-I assay and the Immulite 2000 XPi (Old) IGF-I assay on 92 routine outpatient samples.

Correspondingly, the age and gender-dependent reference intervals will change substantially and are provided in Appendix I. The reference interval data is extremely robust having been developed on a cohort of over 9000 individuals. For a table of estimated conversions between the old and new methods, see Appendix II.

For patients being serially monitored with IGF-I measurements – those with known acromegaly or those receiving growth hormone replacement – it will be necessary to establish a new baseline level.

If you have any questions about this change, please do not hesitate to contact me.



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Appendix I: Age and gender specific normal ranges for IGF-I on the Immunodiagnostic Systems iSYS platform.

Age (y)	Male Reference Interval (ug/L)		Female Reference Interval (ug/L)	
	Lower	Upper	Lower	Upper
0	13	138	16	143
1	18	176	19	160
2	23	212	22	178
3	28	247	25	198
4	34	282	29	219
5	40	316	34	244
6	46	349	39	271
7	53	382	45	302
8	60	414	52	336
9	68	443	59	371
10	75	469	67	407
11	83	490	75	440
12	90	505	82	467
13	96	514	89	488
14	101	516	94	501
15	104	512	98	505
16	107	502	101	502
17	109	488	102	493
18	109	472	103	478
19	109	453	102	461
20	108	432	100	441
21	107	411	98	419
22	105	390	95	397
23	102	369	92	376
24	100	349	89	355
25	97	330	86	336
26	94	313	83	319
27	91	297	81	303
28	89	283	78	289
29	86	270	76	278
30	84	259	74	268
31	82	250	73	260
32	80	243	72	254
33	79	237	71	249
34	78	232	70	244
35	77	228	69	240
36	76	225	69	236
37	75	222	68	233
38	74	219	67	229
39	73	216	66	224
40	72	213	65	220
41	70	210	63	215
42	69	208	62	211
43	68	206	61	207
44	66	204	60	204

Age (y)	Male Reference Interval (ug/L)		Female Reference Interval (ug/L)	
	Lower	Upper	Lower	Upper
45	65	202	59	201
46	64	200	58	199
47	62	198	57	196
48	61	197	56	193
49	60	197	55	191
50	59	196	54	189
51	58	197	53	187
52	57	197	52	186
53	56	197	51	184
54	55	197	49	182
55	54	196	48	179
56	53	194	47	176
57	51	193	46	174
58	50	192	45	172
59	49	191	44	171
60	48	190	43	171
61	47	190	42	170
62	47	189	41	168
63	46	190	40	166
64	46	191	39	165
65	45	192	39	164
66	45	194	38	164
67	45	195	38	164
68	44	195	37	164
69	44	195	37	165
70	43	195	37	166
71	43	194	36	166
72	42	193	36	166
73	42	192	36	166
74	41	192	35	165
75	40	190	35	165
76	40	189	35	165
77	39	187	34	165
78	39	186	34	165
79	38	185	34	167
80	38	184	34	168
81	38	183	35	171
82	37	182	35	173
83	37	182	35	175
84	37	182	35	175
85	37	181	35	176
86	36	180	34	175
87	36	179	34	174
88	36	177	33	172
89	35	175	32	169
>89	35	173	31	166

Appendix II: Estimated conversions between the old IGF-I method (Siemens Immulite 2000 Xpi) and the new method (IDS iSYS).

Estimated Conversion (ug/L)	
Old Method Result (Immulite 2000 Xpi)	New Method Result (IDS iSYS)
50	57
100	103
150	147
200	190
250	232
300	272
350	311
400	348
450	384
500	419
550	453
600	485
650	515
700	545
750	573
800	599
850	625
900	648
950	671
1000	692
1050	712
1100	730
1150	747
1200	763
1250	777
1300	790
1350	802
1400	812
1450	821
1500	828
1550	834
1600	839