

On November 9, 2005, an office of the U.S. Food and Drug Administration (FDA) released the following advisory:<sup>1</sup>

*We recently received a report of a patient who suffered irreversible brain damage following an aggressive insulin treatment that was given for elevated glucose readings. Unfortunately, the elevated glucose readings were incorrect because the glucose monitoring device, which was unable to distinguish between glucose and maltose, was reacting to the maltose in the intravenous immunoglobulin solution that the patient was receiving.*

*Serious injuries and deaths from these false glucose readings continue to occur despite this problem being discussed widely in the literature and identified in the Clinical Laboratories Standards Institute document titled, Glucose Monitoring in Settings Without Laboratory Support; Approved Guideline (AST 4-A2).*

The Chemistry Resource Committee, believing that this problem may still not have received enough recognition in the clinical laboratory community, developed an exercise demonstrating the effect would be extremely useful.

Samples WB-11 and WB-12 in Survey WBG-C/WB2-B from November, 2008, had identical glucose concentrations. The only difference between them was that WB-11 had no maltose whereas WB-12 had 100 mg/dL maltose (a concentration that can be seen in clinical samples).

In the table below, the Survey results from the five largest participant groups are highlighted:

<b>Mean Glucose Concentration (mg/dL)</b>					
<b>Five Largest Peer Groups (Survey WBG-C/WB2-B, November, 2008)</b>					
<b>Code</b>	<b>Meters</b>	<b>Description</b>	<b>WB-11</b>	<b>WB-12</b>	<b>WB-12 – WB-11</b>
1091	~ 8,200	Abbott Precision PCx	119.6	121.4	1.8
1092	~ 1,180	Abbott Precision PCx	132.5	134.8	2.3
1411	~ 13,360	Roche Comf Curve	94.9	149.9	55.0
1412	~ 8,790	Roche Comf Curve	95.2	150.3	55.1
2093	~ 10,500	Lifescan Surestep	141.8	143.1	1.3

As shown, the mean measured glucose concentration was different between manufacturers (a known phenomenon, resulting from matrix issues, not the subject of this exercise). Focusing on the individual rows, there should be no difference between WB-11 and WB-12 as they had the same glucose concentration. Yet, for one manufacturer, the apparent glucose concentration was roughly 55 mg/dL (50%) higher in WB-12 than in WB-11.

This manufacturer highlights the interference in its package insert under "Limitations" and lists clinical scenarios in which maltose (and/or galactose, another potential interferent) may be present (e.g., some peritoneal dialysis solutions, some preparations of intravenous immunoglobulin (IVIG)).<sup>2</sup>

We hope that this explanation helps to broaden awareness of this laboratory medicine issue and that health care institutions where this could be a problem take steps to educate their testing personnel.

#### **References:**

1. <http://www.fda.gov/cdrh/oivd/news/glucosefalse.html>, last viewed 11/08/2008
2. Accu-Chek Comfort Curve package insert, 2007, Roche Diagnostics.

NOTE: Because this exercise was graded by peer group, even though WB-12 results were expected to be the same as WB-11 results, the established grading criteria of +/- 20% or +/-12 mg/dL or +/- 3 SD, whichever is greatest was applied to the peer group mean to establish the range of acceptability. This was truly an educational exercise, albeit a critically important one.

Gary L. Horowitz, MD, Chair  
Chemistry Resource Committee

WB-11	WBG-C/WB2-B 2008	No.					Low	High
	Method	Results	Mean	S.D.	C.V.	Median	Value	Value
	ABBOTT PRCSN PCX/1XXXXXX	1181	132.5	13.0	9.8	133	94	170
	ABBOTT PRCSN PCX/XCEED	8207	119.6	6.0	5.0	120	101	138
	ABBOTT PRCSN XTRA/4XXXXXX	107	145.3	11.9	8.2	147	116	168
	ABBOTT PRCSN XTRA/5XXXXXX	58	136.0	15.4	11.3	139	106	166
	ABBOTT PRECISION G	27	114.2	7.1	6.2	115	96	125
	BAYER ASCENSIA ELITE/XL	65	93.4	6.0	6.5	93	77	106
	BAYER CONTOUR 15 SEC	69	101.0	5.7	5.6	100	88	118
	BAYER CONTOUR 5 SEC	243	161.3	9.3	5.8	161	135	189
	LIFESCAN 1-T II HOS/WB	15	133.9	8.7	6.5	138	121	148
	LIFESCN SURESTP/PRO/FL	10506	141.8	7.4	5.2	141	120	164
	NOVA STATSTRIP	148	127.1	6.7	5.2	127	112	147
	ROCHE ACCU-CHEK AVIVA	40	138.5	30.8	22.2	154	68	169
	ROCHE ACCU-CHEK II	43	91.1	4.3	4.7	91	85	99
	ROCHE ADVANTAGE 52XXXXX	272	94.3	6.3	6.7	94	76	112
	ROCHE COMF CURV 53XXXXX	251	94.4	5.5	5.8	94	79	109
	ROCHE COMF CURV 54XXXXX	8779	95.2	5.0	5.2	95	80	110
	ROCHE COMF CURV 55XXXXX	13356	94.9	4.8	5.0	95	81	109

WB-12	WBG-C/WB2-B 2008	No.					Low	High
	Method	Results	Mean	S.D.	C.V.	Median	Value	Value
	ABBOTT PRCSN PCX/1XXXXXX	1180	134.8	13.2	9.8	135	100	175
	ABBOTT PRCSN PCX/XCEED	8177	121.4	6.0	4.9	121	103	139
	ABBOTT PRCSN XTRA/4XXXXXX	106	149.2	10.9	7.3	150	116	179
	ABBOTT PRCSN XTRA/5XXXXXX	57	138.8	15.5	11.2	140	107	163
	ABBOTT PRECISION G	29	116.0	14.3	12.3	118	85	148
	BAYER ASCENSIA ELITE/XL	64	95.3	6.4	6.7	95	80	110
	BAYER CONTOUR 15 SEC	69	102.1	5.2	5.1	101	90	116
	BAYER CONTOUR 5 SEC	241	162.6	9.2	5.7	162	138	189
	LIFESCAN 1-T II HOS/WB	15	136.1	8.7	6.4	136	124	148
	LIFESCN SURESTP/PRO/FL	10497	143.1	7.7	5.4	143	120	167
	NOVA STATSTRIP	146	127.6	6.7	5.3	128	107	147
	ROCHE ACCU-CHEK AVIVA	43	203.0	37.8	18.6	222	142	244
	ROCHE ACCU-CHEK II	43	143.3	8.5	6.0	145	128	161
	ROCHE ADVANTAGE 52XXXXX	273	147.6	9.7	6.6	148	123	170
	ROCHE COMF CURV 53XXXXX	253	148.9	7.7	5.1	149	132	166
	ROCHE COMF CURV 54XXXXX	8789	150.3	7.9	5.3	150	126	174
	ROCHE COMF CURV 55XXXXX	13363	149.9	7.7	5.2	150	127	173