

2.2 Summary of Studies

Ref. No.

AM-HTF-G8-02

Rev. No.

0

Blood Glucose Monitoring System

Issue Date

2012. 03. 27

2.2.16. Evaluation of Arterial blood

Evaluation of arterial blood accuracy on Embrace PRO, AGM-4000

2012. 03. 27

Prepared by Bae, Man-Ho *Researcher*

Reviewed by Jung, Hye Sook *Manager*

Approved by Oh, Byung Do *Director*

2.2 Summary of Studies

Ref. No.
AM-HTF-G8-02
Rev. No.
0
Blood Glucose Monitoring System
Issue Date
2012. 03. 27

2.2.16 Evaluation of Arterial blood accuracy

Test Period		2008. 09. 22 ~ 2008. 09. 26	Investigator	Bae, Man-Ho						
Measurement Condition		24.2±1 °C, 43±10%(RH)	Coordinator	Jung, Hye Sook						
No.	Step	Description								
1	General	To validate the accuracy of the Embrace PRO system in arterial blood according to ISO 15197(2003) and CLSI Guidelines EP9-A2.								
2	Samples	Clinical evaluation is performed for validating arterial blood effects of Embrace PRO system. Total 70 fresh arterial blood samples are collected from diabetes clinic center at the Anyang Hospital.								
3	Reagent System	One hundred twenty five reagent system units (Embrace PRO test strips) are prepared from 5 vials (containing 25 test strips) from 2 lots (A8F13202, A8F14202)								
4	Meters	Two Embrace PRO meters are prepared.								
4	Evaluation procedure	<p>The evaluation procedure is following.</p> <ul style="list-style-type: none"> a) Confirm the code of Embrace PRO meter to test strip. b) Obtain a sample of arterial blood (lithium heparin tube). c) Take a test strip out of each Lot. (2 Lots) d) Measure the glucose concentration in the sample using meters. e) Record the result. f) Measure the glucose concentration in the sample using laboratory reference instrument. g) Record the result. 								
5	Acceptance criteria	<p>Ninety-five percent (95%) of the individual glucose results shall fall within ±15mg/dL of the results at glucose concentrations <75mg/dL and within ±20% at glucose concentrations ≥75mg/dL.</p> <ul style="list-style-type: none"> a) For glucose concentrations <75mg/dL, result shall be expressed as the percentage of values falling within the following intervals : ±5 mg/dL, ±10 mg/dL, ±15mg/dL. b) For glucose concentrations ≥75mg/dL, results shall be expressed as the percentage of values falling within the following intervals : ±5%, ±10%, ±15%, ±20%. <p style="text-align: center;">Table 1. Example of presentation of results for glucose concentration < 75 mg/dL</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <td>Within ± 5mg/dL</td> <td>Within ± 10 mg/dL</td> <td>Within ± 15 mg/dL</td> </tr> <tr> <td style="text-align: center;">45%</td> <td style="text-align: center;">70%</td> <td style="text-align: center;">95%</td> </tr> </table>			Within ± 5mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	45%	70%	95%
Within ± 5mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL								
45%	70%	95%								

2.2 Summary of Studies

Ref. No.
AM-HTF-G8-02
Rev. No.
0
Blood Glucose Monitoring System
Issue Date
2012. 03. 27

Table 2. Example of presentation of results for glucose concentration ≥ 75 mg/dL

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
22%	49%	85%	97%

Table 3. The arterial evaluation results for glucose concentration <75 mg/dL

	Result 1	Result 2	Total (Result 1+2)
Within ± 5 mg/dL	6/9(66.7%)	5/9(55.6%)	10/18(55.6%)
Within ± 10 mg/dL	9/9(100%)	9/9(100%)	18/18(100%)
Within ± 15 mg/dL	9/9(100%)	9/9(100%)	18/18(100%)

Table 4. The arterial evaluation results for glucose concentration ≥ 75 mg/dL

	Result 1	Result 2	Total (Result 1+2)
Within $\pm 5\%$	58/61(95%)	58/61(95%)	116/122(95%)
Within $\pm 10\%$	61/61(100%)	60/61(98.4%)	121/122(99%)
Within $\pm 15\%$	61/61(100%)	61/61(100%)	122/122(100%)
Within $\pm 20\%$	61/61(100%)	61/61(100%)	122/122(100%)

Table 5. Raw data of arterial blood evaluation

Samples	Site	YSI	Result 1 (Lot 1)	Result 2 (Lot 2)	Total	Site	YSI	Result 1 (Lot 1)	Result 2 (Lot 2)	Total
1	09/22 (Site 1)	62	59	60	59.5	09/24 (Site 2)	136	140	135	137.5
2		96	85	88	86.5		328	335	339	337
3		146	132	135	133.5		234	229	225	227
4		185	179	176	177.5		135	128	130	129

6

Data analysis and presentation



2.2 Summary of Studies

Ref. No.

AM-HTF-G8-02

Rev. No.

0

Blood Glucose Monitoring System

Issue Date

2012. 03. 27

		5		133	121	128	124.5		71	73	68	70.5
		6		66	64	68	66		93	86	89	87.5
		7		398	374	375	374.5		120	115	112	113.5
		8		219	229	235	232		148	145	146	145.5
		9		106	100	101	100.5		74	80	78	79
		10		141	141	140	140.5		187	181	185	183
		11		72	77	79	78		106	100	103	101.5
		12		100	91	93	92		196	187	185	186
		13		105	110	114	112		378	369	373	371
		14		176	167	169	168		93	85	81	83
		15		207	196	201	198.5		129	125	122	123.5
		16		93	82	85	83.5		129	121	125	123
		17		187	180	184	182		185	185	183	184
		18		126	121	124	122.5		173	169	168	168.5
		19		122	113	114	113.5		91	85	81	83
		20		161	147	151	149		186	182	182	182
		21		230	217	229	223		234	229	235	232
		22		57	59	62	60.5		69	76	74	75
		23		99	92	99	95.5		93	95	96	95.5
		24							123	118	119	118.5
		25							58	57	56	56.5
		26							135	143	138	140.5
		27							56	59	61	60
		28							119	112	116	114
		1	09/25 (Site 3)	138	133	134	133.5					
		2		127	122	124	123					
		3		119	117	118	117.5					
		4		90	86	89	87.5					
		5		151	162	167	164.5					
		6		125	133	130	131.5					
		7		210	191	194	192.5					

2.2 Summary of Studies

Ref. No.
AM-HTF-G8-02
Rev. No.
0

Blood Glucose Monitoring System

Issue Date
2012. 03. 27

8	179	172	173	172.5
9	117	105	112	108.5
10	152	145	145	145
11	91	81	85	83
12	121	118	120	119
13	132	129	128	128.5
14	114	104	108	106
15	122	123	121	122
16	133	128	130	129
17	120	117	113	115
18	145	140	138	139
19	106	100	101	100.5

7

Conclusion

According to test results, there is no significant difference or tendency arterial blood testing by Embrace PRO system. Therefore, Embrace PRO system is found to be suitable for arterial blood.