



# UNIVERSITY COLLEGE HOSPITAL, IBADAN

The pioneer Teaching Hospital in Nigeria.

P.M.B 5116, Ibadan Tel: +234 813 173 3447, +234 813 173 3398 E-mail: cmd@uch-ibadan.

Facebook: @UCHIBADAN Instagram: Universitycolleghospital Youtube: UCHIBADAN Twitter: @UchCmd Website: www.uch-ibadan.org.ng

## Title:

Validation of OnPoint Glucose Meter Conducted at the Department Of Chemical Pathology University College Hospital Ibadan

## Purpose:

1. To verify the manufacturer's claim for within-run and between-run precision
2. To estimate the bias and compare with CLSI standard

## Method:

- Within-run precision: Three heparinized whole blood samples (Hypo, Normo and Hyperglycaemic) were analysed ten times in one run.
- Between-run precision: Two quality control samples (Levels 2 and 3) were analysed daily for ten days.
- Estimation of bias: Fifty blood samples were analysed with the glucometer and in the central laboratory. The concentrations of the blood samples spanned the measurement range of the glucometer.

## Acceptability Criteria:

- Achievement of manufacturer's claim of a coefficient of variation of  $< 5\%$  for both within-run and between-run precision.
- 95% of the individual results from the glucose meter should agree within  $\pm 12\text{mg/dL}$  of the central laboratory values at glucose concentrations  $< 100\text{mg/dL}$  and within  $\pm 12.5\%$  of the central laboratory values at glucose concentrations  $\geq 100\text{mg/dL}$
- In addition, the sum of the number of individual results with 1) errors that exceed  $15\text{mg/dL}$  at glucose concentrations  $< 75\text{mg/dL}$  and 2) errors that exceed  $20\%$  at glucose concentrations  $\geq$  should not exceed 2% of all results

## Results:

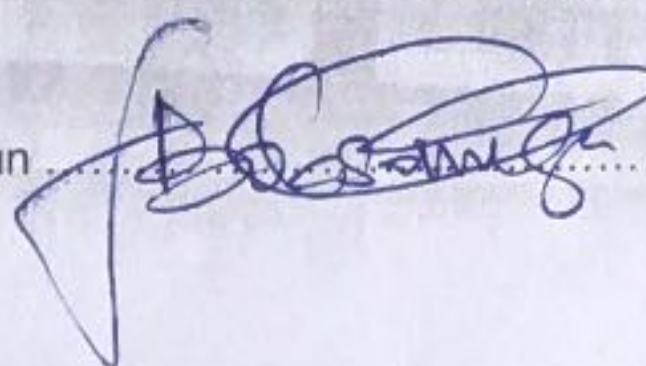
- **Within-run CV:** Hypo - 4.76%, Normo - 3.67%, Hyper- 3.14%
- **Between-run CV:** Level 2 CTRL - 3.03%, Level 3 CTRL - 2.41%
- **Bias estimate:** 96% of values were within acceptable limits of central laboratory values and 2% of all results had an error that exceeded  $20\%$  @ glucose conc above  $75\text{mg/dL}$ .

## Conclusion:

The OnPoint GH82 Blood Glucose Monitoring System has demonstrated acceptable performance and is therefore recommended for use in monitoring patient's glucose control.

Sign HOD

Dr O.M. Akinosun

 13/02/2024

Ibrahim Bako Shettima - Chairman, Board of Management

Prof. Jesse Abiodun Otegbayo - MBBS (Ib), Cert. Gastro. (Tel Aviv); Cert. Immunol (Ib); M.Sc. Chem. Path (Ib); Ph.D. Immunol (Ib); FWACP; FUICC (Switz); FACC (USA); FRCP (Glasg); MNIM; FCIPM, (UK), FPMA-UK, PPGD Mgt. Cons. & Org. trans; FIMCN **Chief Medical Director**

Dr. A.M. Adeoye- MBBS, Cert. Cardio(Chennai), M.Sc.(Epid), FWACP, FNCS, FESC, FACC (USA) -

**Chairman, Medical Advisory Committee; Director of Clinical Services, Research & Training**

Mr. S. O. Oladejo - MMP, B.Sc (Pol. Science), HND Banking & Finance, Cert. in PSLC (Kuru), FHAN, FNIM, FCIPM - **Director of Administration & Secretary to the Board**



## APPENDIX 1

Assay : GLUCOSE		Desirable CV : Less than 5%	
Instrument : OnPoint GH82 Blood Glucose Monitoring System			
Laboratory: DEPARTMENT OF CHEMICAL PATHOLOGY, UCH IBADAN – Abott c4000 analyzer			
Sample Matrix:	Medisign GH Glucose Control Solution		
Date:	LEVEL 2 CTRL(INTERMEDIATE PRECISION)	LEVEL 3 CTRL(INTERMEDIATE PRECISION)	
1/9/2024	121	348	
1/10/2024	120	351	
1/11/2024	128	360	
1/12/2024	120	333	
1/13/2024	124	342	
1/14/2024	129	341	
1/15/2024	128	344	
1/16/2024	126	356	
1/17/2024	122	337	
1/18/2024	118	337	
GRAND MEAN	123.6	344.9	
BTW-RUN CV	3.03%	2.41%	
Sample Matrix:	Heparinized whole blood HYPO (REPEATABILITY)	Heparinized whole blood NORMO (REPEATABILITY)	Heparinized whole blood HYPER (REPEATABILITY)
Run1	22	99	272
Run2	20	98	254
Run3	20	105	268
Run4	21	101	261
Run5	23	97	277
Run6	20	97	286
Run7	22	103	272
Run8	21	106	278
Run9	20	100	275
Run10	21	108	270
GRAND MEAN	21	MEAN = 101.4	MEAN = 271.3
WITHIN-RUN CV	4.76%	3.67%	3.14%



APPENDIX 1

Assay : GLUCOSE		Desirable CV : Less than 5%	
Instrument : OnPoint GH82 Blood Glucose Monitoring System			
Laboratory: DEPARTMENT OF CHEMICAL PATHOLOGY, UCH IBADAN – Abott c4000 analyzer			
Sample Matrix:	Medisign GH Glucose Control Solution		
Date:	LEVEL 2 CTRL(INTERMEDIATE PRECISION)	LEVEL 3 CTRL(INTERMEDIATE PRECISION)	
1/9/2024	121	348	
1/10/2024	120	351	
1/11/2024	128	360	
1/12/2024	120	333	
1/13/2024	124	342	
1/14/2024	129	341	
1/15/2024	128	344	
1/16/2024	126	356	
1/17/2024	122	337	
1/18/2024	118	337	
GRAND MEAN	123.6	344.9	
BTW-RUN CV	3.03%	2.41%	
Sample Matrix:	Heparinized whole blood HYPO (REPEATABILITY)	Heparinized whole blood NORMO (REPEATABILITY)	Heparinized whole blood HYPER (REPEATABILITY)
Run1	22	99	272
Run2	20	98	254
Run3	20	105	268
Run4	21	101	261
Run5	23	97	277
Run6	20	97	286
Run7	22	103	272
Run8	21	106	278
Run9	20	100	275
Run10	21	108	270
GRAND MEAN	21	MEAN = 101.4	MEAN = 271.3
WITHIN-RUN CV	4.76%	3.67%	3.14%



# APPENDIX 2

X ✓ fx

A	B	C	D	E	F
Heparinized whole blood	LABORATORY PLASMA VALUES		BIAS	COMMENT	
76	75	BIN2 -1/6	-1	Acceptable for use within the hospital agrees within+/-12	
137	122	BIN4-1/12	-15	Acceptable for use within the hospital agrees within+/-12.5%	
114	128	BIN3-1/8	14	Acceptable for use within the hospital agrees within+/-12.5%	
81	85	BIN3-2/8	4	Acceptable for use within the hospital agrees within+/-12	
121	109	BIN3-3/8	-12	Acceptable for use within the hospital agrees within+/-12.5%	
69	79	BIN2-2/6	10	Acceptable for use within the hospital agrees within+/-12	
133	130	BIN4-2/12	-3	Acceptable for use within the hospital agrees within+/-12.5%	
104	95	BIN3-4/8	-9	Acceptable for use within the hospital agrees within+/-12	
92	89	BIN3-5/8	-3	Acceptable for use within the hospital agrees within+/-12	
115	99	BIN3-6/8	-16	UNACCEPTABLE	
50	59	BIN2-3/6	9	Acceptable for use within the hospital agrees within+/-12	
75	74	BIN2-4/6	-1	Acceptable for use within the hospital agrees within+/-12	
33	37	BIN1-1/2	4	Acceptable for use within the hospital agrees within+/-12	
55	54	BIN2-5/6	-1	Acceptable for use within the hospital agrees within+/-12	
69	88	BIN2-6/6	19	UNACCEPTABLE	
137	155	BIN4-3/12	18	Acceptable for use within the hospital agrees within+/-12.5%	
117	116	BIN3-7/8	-1	Acceptable for use within the hospital agrees within+/-12.5%	
66	78	BIN2-7/6	12	Acceptable for use within the hospital agrees within+/-12	
121	115	BIN3-8/8	-6	Acceptable for use within the hospital agrees within+/-12.5%	
277	281	BIN5-1/6	4	Acceptable for use within the hospital agrees within+/-12.5%	
254	247	BIN5-2/6	-7	Acceptable for use within the hospital agrees within+/-12.5%	
116	106	BIN3-9/8	-10	Acceptable for use within the hospital agrees within+/-12.5%	
110	99	BIN3-10/8	-11	Acceptable for use within the hospital agrees within+/-12	
98	89	BIN3-11/8	-9	Acceptable for use within the hospital agrees within+/-12	
178	181	BIN4-4/12	3	Acceptable for use within the hospital agrees within+/-12.5%	
136	126	BIN4-5/12	-10	Acceptable for use within the hospital agrees within+/-12.5%	
111	99	BIN3-12/8	-12	Acceptable for use within the hospital agrees within+/-12	
124	123	BIN4-6/12	-1	Acceptable for use within the hospital agrees within+/-12.5%	
141	157	BIN4-7/12	16	Acceptable for use within the hospital agrees within+/-12.5%	
134	139	BIN4-8/12	5	Acceptable for use within the hospital agrees within+/-12.5%	
23	26	BIN1-2/2	3	Acceptable for use within the hospital agrees within+/-12	
23	21	BIN1-3/2	-2	Acceptable for use within the hospital agrees within+/-12	
172	187	BIN4-9/12	15	Acceptable for use within the hospital agrees within+/-12.5%	
103	105	BIN3-13/8	2	Acceptable for use within the hospital agrees within+/-12.5%	
137	140	BIN4-10/12	3	Acceptable for use within the hospital agrees within+/-12.5%	
95	103	BIN3-14/8	8	Acceptable for use within the hospital agrees within+/-12.5%	
252	270	BIN5-3/6	18	Acceptable for use within the hospital agrees within+/-12.5%	
105	112	BIN3-15/8	7	Acceptable for use within the hospital agrees within+/-12.5%	
153	164	BIN4-11/12	11	Acceptable for use within the hospital agrees within+/-12.5%	
102	111	BIN3-16/8	9	Acceptable for use within the hospital agrees within+/-12.5%	
127	134	BIN4-12/12	7	Acceptable for use within the hospital agrees within+/-12.5%	
283	271	BIN5-4/6	-12	Acceptable for use within the hospital agrees within+/-12.5%	

Sheet1

Sheet2

Sheet3

+

1



# APPENDIX 2

A		B	C	D	E	F
Heparinized whole blood		LABORATORY PLASMA VALUES		BIAS	COMMENT	
2		76	75 BIN2 -1/6	-1	Acceptable for use within the hospital agrees within+/-12	
3		137	122 BIN4-1/12	-15	Acceptable for use within the hospital agrees within+/-12.5%	
4		114	128 BIN3-1/8	14	Acceptable for use within the hospital agrees within+/-12.5%	
5		81	85 BIN3-2/8	4	Acceptable for use within the hospital agrees within+/-12	
6		121	109 BIN3-3/8	-12	Acceptable for use within the hospital agrees within+/-12.5%	
7		69	79 BIN2-2/6	10	Acceptable for use within the hospital agrees within+/-12	
8		133	130 BIN4-2/12	-3	Acceptable for use within the hospital agrees within+/-12.5%	
9		104	95 BIN3-4/8	-9	Acceptable for use within the hospital agrees within+/-12	
10		92	89 BIN3-5/8	-3	Acceptable for use within the hospital agrees within+/-12	
11		115	99 BIN3-6/8	-16	UNACCEPTABLE	
12		50	59 BIN2-3/6	9	Acceptable for use within the hospital agrees within+/-12	
13		75	74 BIN2-4/6	-1	Acceptable for use within the hospital agrees within+/-12	
14		33	37 BIN1-1/2	4	Acceptable for use within the hospital agrees within+/-12	
15		55	54 BIN2-5/6	-1	Acceptable for use within the hospital agrees within+/-12	
16		69	88 BIN2-6/6	19	UNACCEPTABLE	
17		137	155 BIN4-3/12	18	Acceptable for use within the hospital agrees within+/-12.5%	
18		117	116 BIN3-7/8	-1	Acceptable for use within the hospital agrees within+/-12.5%	
19		66	78 BIN2-7/6	12	Acceptable for use within the hospital agrees within+/-12	
20		121	115 BIN3-8/8	-6	Acceptable for use within the hospital agrees within+/-12.5%	
21		277	281 BIN5-1/6	4	Acceptable for use within the hospital agrees within+/-12.5%	
22		254	247 BIN5-2/6	-7	Acceptable for use within the hospital agrees within+/-12.5%	
23		116	106 BIN3-9/8	-10	Acceptable for use within the hospital agrees within+/-12.5%	
24		110	99 BIN3-10/8	-11	Acceptable for use within the hospital agrees within+/-12	
25		98	89 BIN3-11/8	-9	Acceptable for use within the hospital agrees within+/-12	
26		178	181 BIN4-4/12	3	Acceptable for use within the hospital agrees within+/-12.5%	
27		136	126 BIN4-5/12	-10	Acceptable for use within the hospital agrees within+/-12.5%	
28		111	99 BIN3-12/8	-12	Acceptable for use within the hospital agrees within+/-12	
29		124	123 BIN4-6/12	-1	Acceptable for use within the hospital agrees within+/-12.5%	
30		141	157 BIN4-7/12	16	Acceptable for use within the hospital agrees within+/-12.5%	
31		134	139 BIN4-8/12	5	Acceptable for use within the hospital agrees within+/-12.5%	
32		23	26 BIN1-2/2	3	Acceptable for use within the hospital agrees within+/-12	
33		23	21 BIN1-3/2	-2	Acceptable for use within the hospital agrees within+/-12	
34		172	187 BIN4-9/12	15	Acceptable for use within the hospital agrees within+/-12.5%	
35		103	105 BIN3-13/8	2	Acceptable for use within the hospital agrees within+/-12.5%	
36		137	140 BIN4-10/12	3	Acceptable for use within the hospital agrees within+/-12.5%	
37		95	103 BIN3-14/8	8	Acceptable for use within the hospital agrees within+/-12.5%	
38		252	270 BIN5-3/6	18	Acceptable for use within the hospital agrees within+/-12.5%	
39		105	112 BIN3-15/8	7	Acceptable for use within the hospital agrees within+/-12.5%	
40		153	164 BIN4-11/12	11	Acceptable for use within the hospital agrees within+/-12.5%	
41		102	111 BIN3-16/8	9	Acceptable for use within the hospital agrees within+/-12.5%	
42		127	134 BIN4-12/12	7	Acceptable for use within the hospital agrees within+/-12.5%	
43		283	271 BIN5-4/6	-12	Acceptable for use within the hospital agrees within+/-12.5%	

Sheet1

Sheet2

Sheet3





283	271	BIN5-4/6	-12	Acceptable for use within the hospital agrees within+/-12.5%
267	282	BIN5-5/6	15	Acceptable for use within the hospital agrees within+/-12.5%
283	271	BIN5-6/6	-12	Acceptable for use within the hospital agrees within+/-12.5%
388	362	BIN6-1/4	-26	Acceptable for use within the hospital agrees within+/-12.5%
518	578	BIN7-1/2	60	Acceptable for use within the hospital agrees within+/-12.5%
321	327	BIN6-2/4	6	Acceptable for use within the hospital agrees within+/-12.5%
476	454	BIN 7-2/2	-22	Acceptable for use within the hospital agrees within+/-12.5%
433	450	BIN7-3/2	17	Acceptable for use within the hospital agrees within+/-12.5%
488	504	BIN7-4/2	16	Acceptable for use within the hospital agrees within+/-12.5%
52				
53				4% FELL BELOW THE CLSI CRITERIA AS INDICATED ABOVE
54				(1) 2% OF ALL RESULTS HAD AN ERROR THAT EXCEEDED 20% @ GLUCOSE CONC ABOVE 75mg/dl
55	LOT NUMBERS OF THE STRIPS	HXB28Y1D1		
56		HXB27H1D1		
57	GLUCOMETER SERIAL NUMBER	H82X00970 (MANUFACTURED 29-8-2023		