



SD BIOSENSOR

Claim Report(UK)

QC1



Deviation Claim(UK)-Pre-meal capillary blood

Pre-meal capillary blood

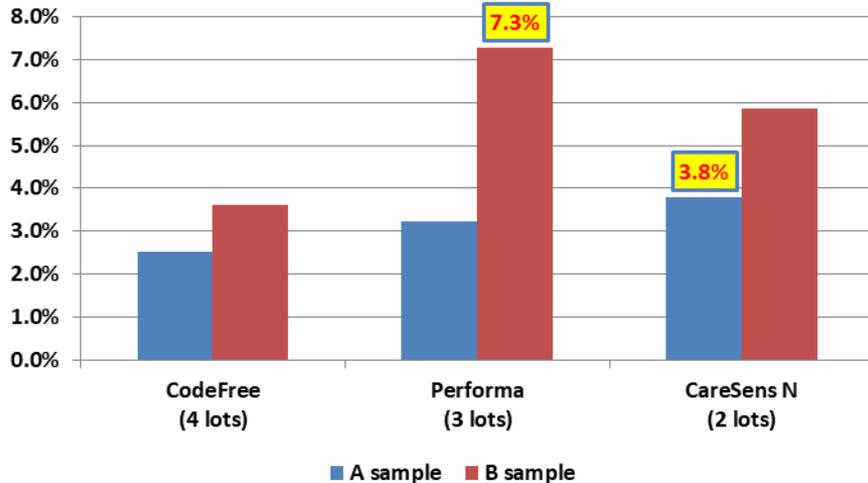
Samples	Results	CodeFree (4 lots)	Performa (3 lots)	CareSens N (2 lots)
A	Total CV(%)	2.5%	3.2%	3.8%
	Min	88	92	94
	Max	97	103	104
	Max-Min	9	11	10
B	Total CV(%)	3.6%	7.3%	5.9%
	Min	99	96	95
	Max	114	116	108
	Max-Min	15	20	13

*. Result

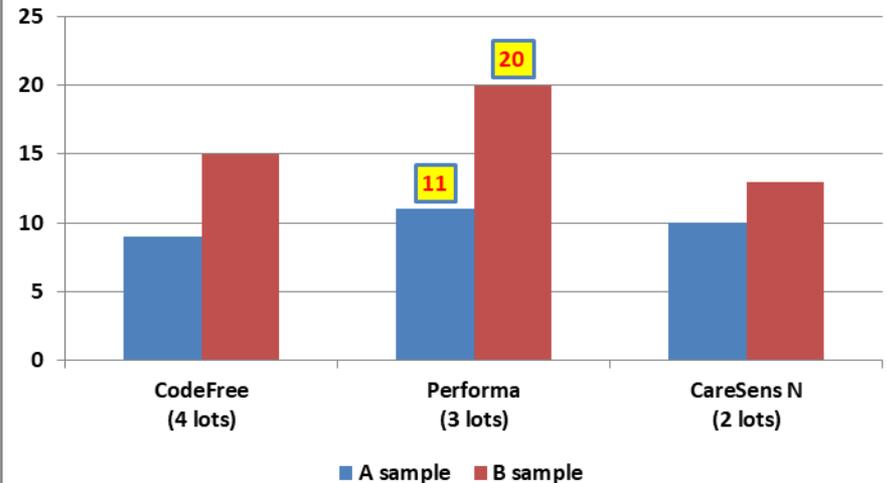
- The CV(%) & Max-Min(mg/dL) of CodeFree is low compared to other companies.

- Analysis: Lots deviation of CodeFree is small.

CV(%)



Max-Min(mg/dL)





Deviation Claim(UK)-Post-meal capillary blood

Post-meal capillary blood

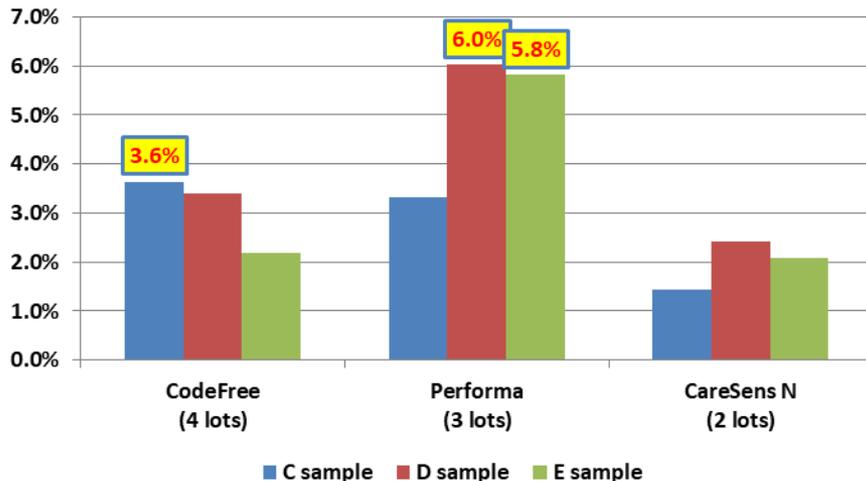
Samples	Results	CodeFree (4 lots)	Performa (3 lots)	CareSens N (2 lots)
C	Total CV(%)	3.6%	3.3%	1.4%
	Min	353	376	451
	Max	400	426	467
	Max-Min	47	50	16
D	Total CV(%)	3.4%	6.0%	2.4%
	Min	112	109	116
	Max	125	130	124
	Max-Min	13	21	8
E	Total CV(%)	2.2%	5.8%	2.1%
	Min	140	142	148
	Max	152	170	155
	Max-Min	12	28	7

*. Result

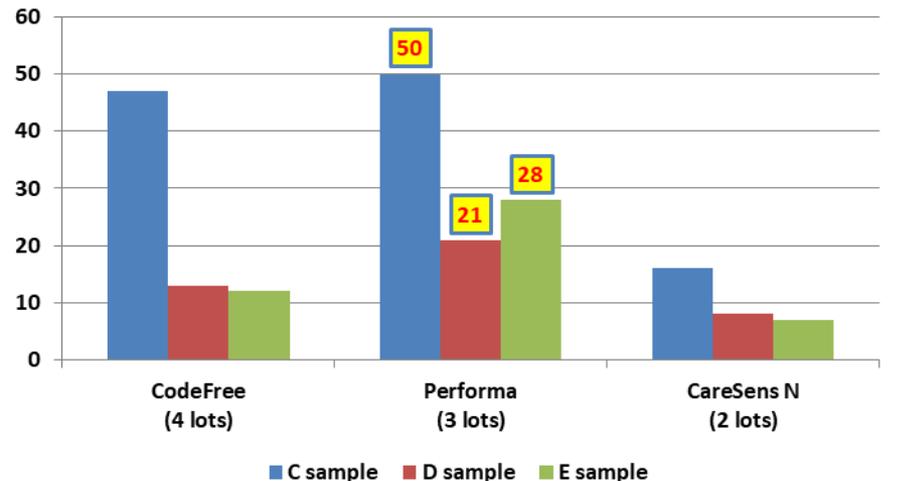
- The CV(%) & Max-Min(mg/dL) of CodeFree is low or equal compared to other companies.

- Analysis: Lots deviation of CodeFree are comparable to those of other companies.

CV(%)



Max-Min(mg/dL)





Deviation Claim(UK)-Accuracy analysis

Pre-meal capillary blood					
Samples	Results	Reference (YSI)	CodeFree (4 lots)	Performa (3 lots)	CareSens N (2 lots)
A	Avg(mg/dL)	96.0	92.1	95.9	99.2
	Bias YSI(%)		-4.1%	-0.1%	3.3%
	Bias CareSens N(%)		-7.1%	-3.3%	
B	Avg(mg/dL)	93.2	104.9	103.3	100.8
	Bias YSI(%)		12.6%	10.8%	8.2%
	Bias CareSens N(%)		4.0%	2.4%	
Post-meal capillary blood					
Samples	Results	Reference (YSI)	CodeFree (4 lots)	Performa (3 lots)	CareSens N (2 lots)
C	Avg(mg/dL)	415.5	374.6	401.4	461.7
	Bias YSI(%)		-9.9%	-3.4%	11.1%
	Bias CareSens N(%)		-18.9%	-13.0%	
D	Avg(mg/dL)	115.4	117.4	116.6	120.8
	Bias YSI(%)		1.8%	1.0%	4.7%
	Bias CareSens N(%)		-2.8%	-3.5%	
E	Avg(mg/dL)	151.2	146.4	155.7	151.5
	Bias YSI(%)		-3.2%	3.0%	0.2%
	Bias CareSens N(%)		-3.4%	2.8%	

*. Accuracy result

- Criteria: Bias reference within $\pm 15\%$ (ISO 15197:2015)

- All are within criteria.

- However, the results may vary depending on the coding policy of each manufacturer.

Thank You

SD BIOSENSOR, Ltd.



SD BIOSENSOR

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