



SD BIOSENSOR

# Claim Report(UK)

QC1



# Deviation Claim(UK)-Pre-meal capillary blood

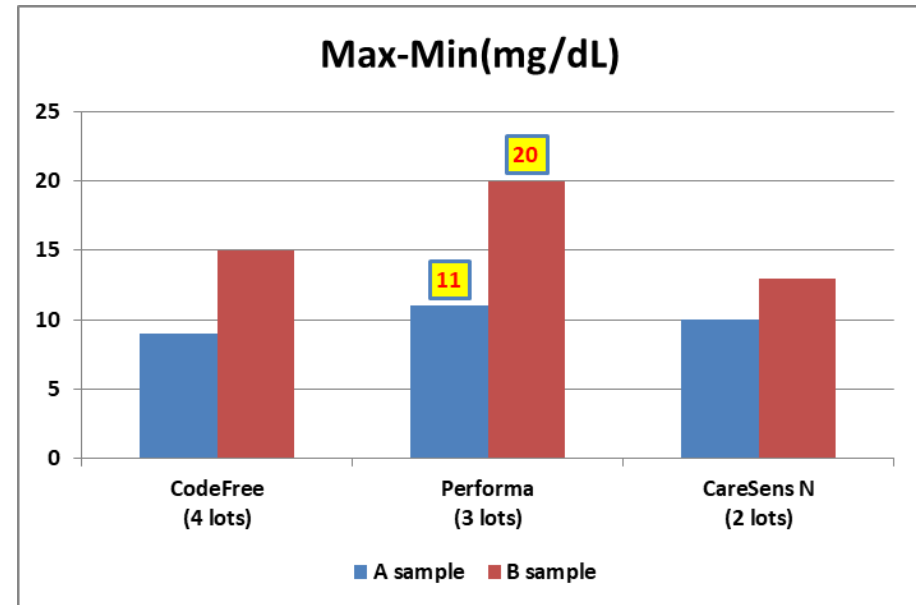
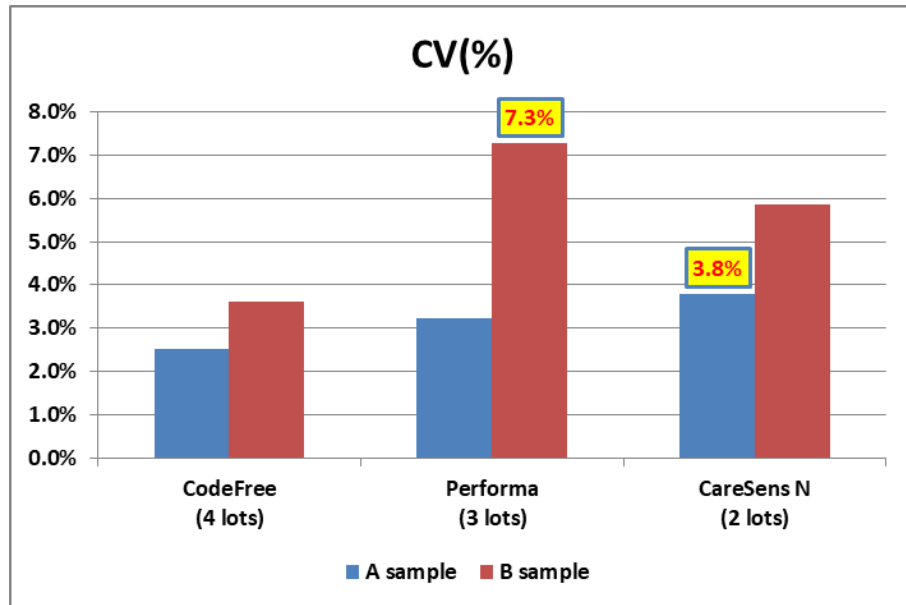
## Pre-meal capillary blood

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

\*. Result

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

- Analysis: Lots deviation of CodeFree is small.





# Deviation Claim(UK)-Post-meal capillary blood

## Post-meal capillary blood

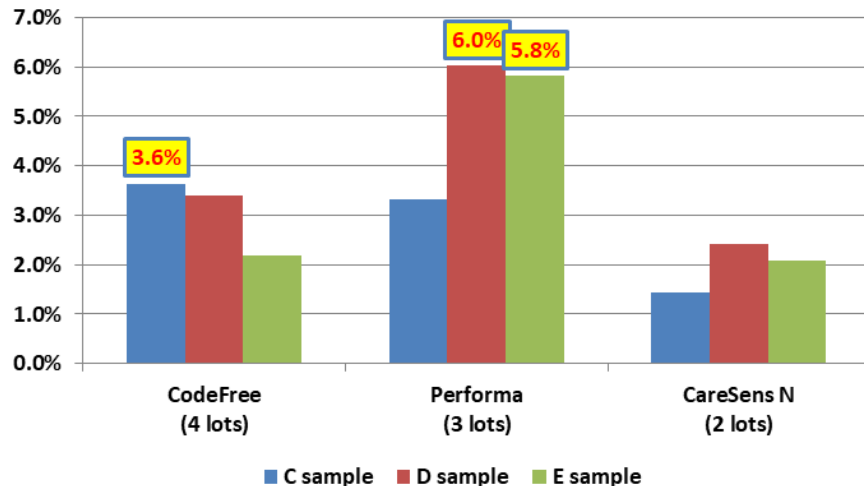
Samples	Results	CodeFree (4 lots)	Performa (3 lots)	CareSens N (2 lots)
C	Total CV(%)	3.6%	3.3%	1.4%
	Min	353	376	451
	Max	400	426	467
	Max-Min	47	50	16
D	Total CV(%)	3.4%	6.0%	2.4%
	Min	112	109	116
	Max	125	130	124
	Max-Min	13	21	8
E	Total CV(%)	2.2%	5.8%	2.1%
	Min	140	142	148
	Max	152	170	155
	Max-Min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

### \*. Result

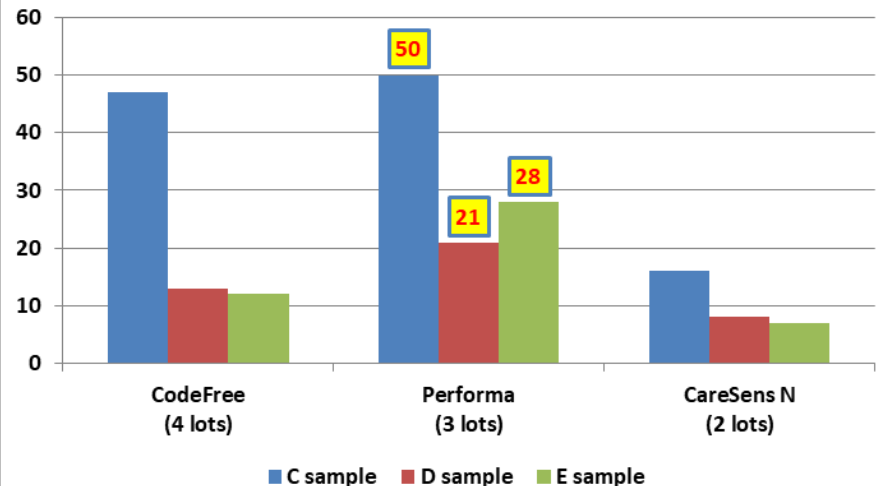
- The CV(%) & Max-Min(mg/dL) of CodeFree is low or equal compared to other companies.

- 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(%)		<b>-4.1%</b>	<b>-0.1%</b>	<b>3.3%</b>
	Bias CareSens N(%)		<b>-7.1%</b>	-3.3%	
B	Avg(mg/dL)	93.2	104.9	103.3	100.8
	Bias YSI(%)		<b>12.6%</b>	<b>10.8%</b>	<b>8.2%</b>
	Bias CareSens N(%)		<b>4.0%</b>	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(%)		<b>-9.9%</b>	<b>-3.4%</b>	<b>11.1%</b>
	Bias CareSens N(%)		<b>-18.9%</b>	-13.0%	
D	Avg(mg/dL)	115.4	117.4	116.6	120.8
	Bias YSI(%)		<b>1.8%</b>	<b>1.0%</b>	<b>4.7%</b>
	Bias CareSens N(%)		<b>-2.8%</b>	-3.5%	
E	Avg(mg/dL)	151.2	146.4	155.7	151.5
	Bias YSI(%)		<b>-3.2%</b>	<b>3.0%</b>	<b>0.2%</b>
	Bias CareSens N(%)		<b>-3.4%</b>	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**

Head office : C-4th&5th, 16, Deogyong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA  
Manufacturing site : 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA  
sales@sdbiosensor.com | www.sdbiosensor.com