

Summary

The tables and graphs below show the data obtained from a study of 15 CueSee® CO-OX samples. Seven levels containing different clinically significant values for total hemoglobin (tHb), oxyhemoglobin (FO_2Hb), carboxyhemoglobin ($FCOHb$) and methemoglobin ($FMetHb$) were measured. The data was obtained utilizing 12 different CO-oximeter instruments across multiple facilities with an average number of data points equaling 833.

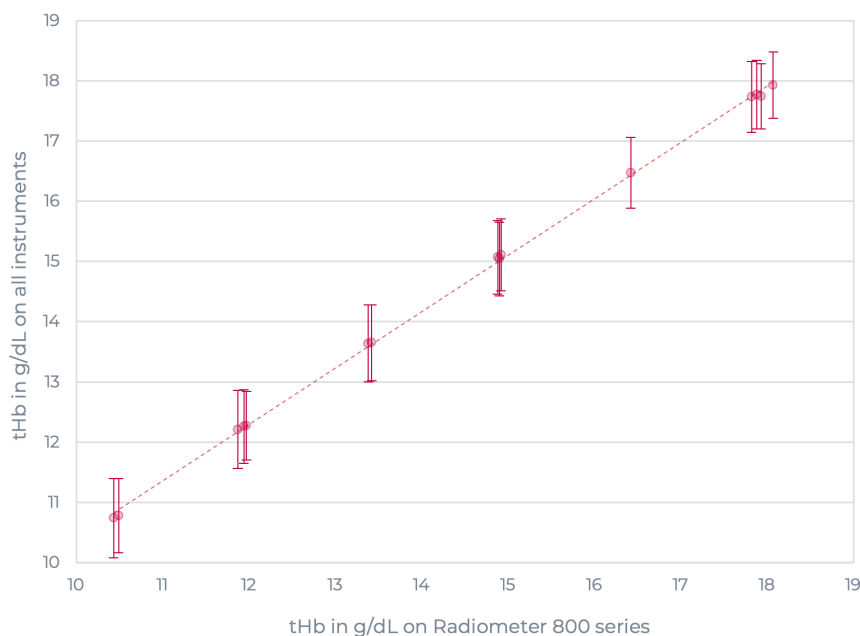
The plot graphs show that CueSee® CO-OX covers a clinically significant range for tHb and all Hb fractions. Evaluation of the graphs and SD values on all instruments demonstrate the reproducibility and reliability of the products. For individual instrument models the SDs are typical < 0.3 g/dL for tHb and < 0.5% for Hb fractions.

Complete coverage of AMR for all Hb fractions is currently not found in other products on the market. This along with the bloodlike product matrix of CueSee® CO-OX provides a superior product for Calibration Verification and Linearity Studies.

This performance of dependable measurements, increased open stability time and the added benefits of safety and ease of use make CueSee® CO-OX a cost-effective product for all QA/QC needs including quality control, method comparison and competency assessment.

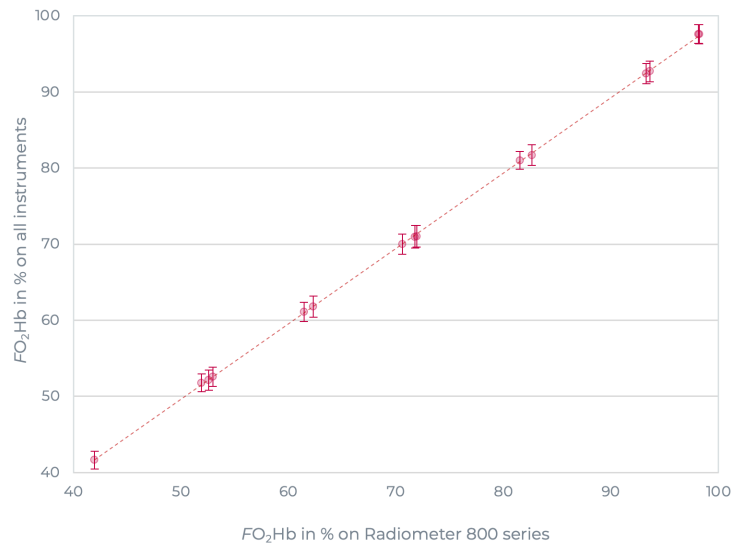
Sample	n	Mean	SD
1	779	10.8	0.62
2	775	12.3	0.57
3	772	15.0	0.61
4	789	17.7	0.54
5	765	16.5	0.59
6	788	17.8	0.57
7	768	15.1	0.60
8	772	12.3	0.61
9	792	17.9	0.55
10	771	13.7	0.63
11	807	17.7	0.59
12	785	13.6	0.64
13	806	10.7	0.66
14	789	12.2	0.65
15	789	15.1	0.61

Figure 1. Results for tHb



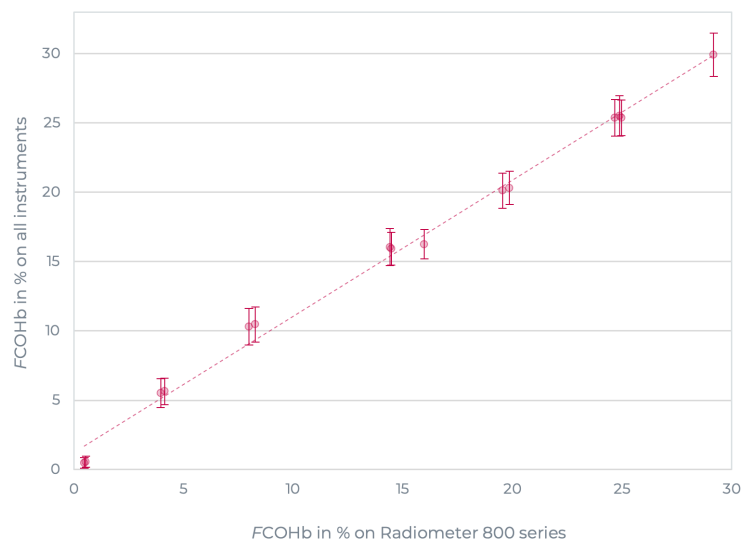
Sample	n	Mean	SD
1	855	81.7	1.35
2	851	71.0	1.44
3	848	52.6	1.26
4	867	92.7	1.36
5	841	41.6	1.15
6	862	97.6	1.26
7	848	52.1	1.31
8	853	71.0	1.47
9	874	92.4	1.34
10	852	61.8	1.38
11	884	97.6	1.23
12	868	61.1	1.27
13	889	81.0	1.17
14	872	70.0	1.34
15	872	51.8	1.16

Figure 2. Results for FO_2Hb



Sample	n	Mean	SD
1	929	10.3	1.32
2	925	15.9	1.18
3	917	25.4	1.32
4	940	5.5	1.04
5	907	29.9	1.56
6	863	0.5	0.38
7	908	25.5	1.46
8	915	16.0	1.33
9	939	5.6	0.96
10	914	20.1	1.27
11	888	0.6	0.41
12	937	20.3	1.20
13	960	10.5	1.26
14	942	16.3	1.05
15	939	25.4	1.28

Figure 3. Results for FCO_{Hb}



Sample	# Labs	Mean	SD
1	763	7.4	1.03
2	759	12.7	1.16
3	749	22.0	1.36
4	773	1.4	0.72
5	733	28.3	1.42
6	768	1.3	0.83
7	742	22.1	1.46
8	749	12.4	1.26
9	770	1.2	0.84
10	748	18.0	1.37
11	797	1.3	0.81
12	770	18.6	1.31
13	793	8.0	1.05
14	777	13.5	1.20
15	773	22.8	1.44

Figure 4. Results for $FMetHb$

