



July 11, 2018

A review of our QC253, Full Range CO-Oximeter Control, lot# 74856, 74952, and 75047 with an expiration date of 2019-02, has prompted us to adjust our assigned value for the AVOXimeter® 1000E, AVOXimeter® 4000 and GEM OPL analyzers. Please see the chart below for the corrected values.

QC253 Expected Values - AVOX1000e			
Level 1 Lot 74856	Mean	Min	Max
THb	8	7.3	8.7
O2Hb	92.7	88.2	97.2
Level 2 Lot 74952	Mean	Min	Max
THb	13.1	12	14.2
O2Hb	83.8	79.5	88.1
Level 3 Lot 75047	Mean	Min	Max
THb	16.3	15	17.6
O2Hb	54.3	50	58.6

QC253 Expected Values - AVOX4000 / GEM OPL			
Level 1 Lot 74856	Mean	Min	Max
THb	7.9	7.2	8.6
O2Hb	93.7	89.2	98.2
COHb	6.1	2.1	10.1
MetHb	0.5	-2.4	3.4
Level 2 Lot 74952	Mean	Min	Max
THb	13.1	12	14.2
O2Hb	84.5	80.2	88.8
COHb	15.9	11.4	20.4
MetHb	0.2	-2.7	3.1
Level 3 Lot 75047	Mean	Min	Max
THb	16.2	14.9	17.5
O2Hb	53.6	49.3	57.9
COHb	47	41.7	52.3
MetHb	0.1	-2.8	3

RNA Medical has not reprinted the insert for this lot, so please use this letter as notification for this change. Keep this letter with your records as long as you have this lot in stock. This letter will also be available on our website.

Please do not hesitate to contact RNA Medical at 1-800-533-6162 or by email at [CustomerService@RNAMedical.com](mailto:CustomerService@RNAMedical.com) if you have any questions regarding this revision.

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