RAPIDPoint® 405/500 Systems
RAPIDLab® 1245/65 Systems

Siemens Healthcare Diagnostics Inc.

Customer Bulletin
2018-08

Hydroxocobalamin Interference with CO-oximetry on the RAPIDPoint® 405/500 and RAPIDLab® 1245/65 Blood Gas Systems

The purpose of this Customer Bulletin is to supplement the recently released Urgent Field Safety Notice (POC 18-010_UFSN OUS) which refers to the hydroxocobalamin interference with specific CO-oximeter parameters on the Siemens RAPIDPoint 405/500 and RAPIDLab 1245/65 Blood Gas Systems.

We believe this information should be useful in providing a more detailed understanding of the hydroxocobalamin interference.

Clinical Usefulness of Hydroxocobalamin

Hydroxocobalamin (Vitamin B12a) is a precursor to cyanocobalamin (Vitamin B12) and is recognized as both a cyanide poisoning antidote and a Vitamin B12a supplement. As a cyanide antidote, hydroxocobalamin may be given immediately, via infusion, to patients exposed to smoke inhalation and with known or suspected cyanide poisoning. As a supplement, it may be taken either orally or intramuscularly, to treat vitamin B12 deficiency.

Hydroxocobalamin Dosage

Cyanide Poisoning

Hydroxocobalamin can be administered as an antidote for patients with known or suspected cyanide poisoning. The initial hydroxocobalamin dose is 5000 mg administered intravenously. A second 5000 mg hydroxocobalamin dose may be administered as clinically indicated. The 5000 mg dose equates to approximately 1 mg of hydroxocobalamin per ml of blood. A second dosage would equate to approximately 2 mg of hydroxocobalamin per ml of blood. These are the levels listed in the Urgent Field Safety Notice and represent the hydroxocobalamin concentration that will interfere with the CO-oximeter results.

Vitamin B12 Deficiency

Hydroxocobalamin and cyanocobalamin may also be given as a therapeutic treatment for Vitamin B12 deficiency. The standard dose for Vitamin B12 deficiency treatment is up to a 1 mg dose, administered either orally or by intramuscular injection. This treatment dose is *5000 times lower* than the dose that is listed in the UFSN and equates to a significantly lower blood concentration (up to 0.0002 mg of hydroxocobalamin per ml of blood) since oral and injected hydroxocobalamin is not fully absorbed into the blood. Standard hydroxocobalamin and cyanocobalamin doses administered to patients for Vitamin B12 deficiency therapy do not interfere with the CO-oximeter results.

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Hydroxocobalamin Interference on CO-oximeter Parameters: RAPIDPoint 405/500 Systems

Parameter Level	Magnitude of interference with 1 mg hydroxocobalamin per 1 ml blood	Magnitude of interference with 2 mg hydroxocobalamin per 1 ml blood
*f*COHb @ 2.0%	NA *	NA *
*f*COHb @ 20%	-4.8%	-9.5%
*f*MetHb @ 5%	-2.0%	-4.0%
*f*MetHb @ 20%	- 3.3%	-6.6%
fO_2Hb @ 80%	+4.0%	+8.0%
fO_2Hb @ 95%	+2.9%	NA*
*f*HHb @ 1.0%	-0.7%	NA*
*t*Hb @ 12 g/dL	-0.6 g/dL	-1.2 g/dL
*t*Hb @ 18 g/dL	-0.6 g/dL	-1.3 g/dL

*The data suggests this measurement would be outside the detection limit.

Hydroxocobalamin Interference on CO-oximeter Parameters – RAPIDLab 1245/65 Systems

Parameter Level	Magnitude of interference with 1 mg hydroxocobalamin per 1 ml blood	Magnitude of interference with 2 mg hydroxocobalamin per 1 ml blood
*f*COHb @ 2.0%	NA*	NA*
*f*COHb @ 20%	-5.3%	-10.5%
*f*MetHb @ 5%	-1.7%	-3.4%
*f*MetHb @ 20%	-3.7%	-7.5%
fO_2Hb @ 80%	+4.6%	+9.1%
fO_2Hb @ 95%	+2.4%	+4.7%
*f*HHb @ 0.8%	-0.5%	NA*
*t*Hb @ 12 g/dL	-0.7 g/dL	-1.3 g/dL
*t*Hb @ 18 g/dL	-0.3 g/dL	-0.6 g/dL

*The data suggests this measurement would be outside the detection limit.

Notes:

- Percentages are reported as absolute percentages.
- The tables in the UFSN provided the observed recovery with the interfering substance present. The tables above show the same dataset expressed as the magnitude of the bias found with the interfering substance present.
- The bias values are not meant to correct for sample results with interfering substance present.
- The test protocol was performed in accordance to CLSI guidelines using contrived whole blood samples.
- This interference is not unique to Siemens CO-oximetry. Due to the red color of the hydroxocobalamin, the material interferes with other spectrophotometric methods that measure in the visible range (400-700 nm).
- Refer to the Cyanokit® manufacturers website for additional information on hydroxocobalamin half-life:https://www.cyanokit.com/sites/default/files/Single_5-g_Vial_PI.pdf https://www.cyanokit.com/

Technical Assistance

If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

Trademark Information

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