DEGREE OF HYDROXOCOBALAMIN INTERFERENCE WITH COMMON LABORATORY TESTS

Due to the intense red color of hydroxocobalamin (OHCob) and its absorbance at 352 and 525 nm, interference studies were performed on common Chemistry and Hematology tests at Legacy Laboratories. The following tables summarize these findings. If the test is not listed in the tables below, then the degree of interference is unknown. Delta is an estimate of the amount of change of that analyte at 1000 mg/L OHCob. Healthcare providers should interpret patient results with caution since these results are only an estimate of OHCob interference for each of the analytes. The actual *in vivo* concentration of OHCob in the patient's blood or urine is based on many factors including, but not limited to, dose, dose rate, and time since administration, and genetics. The tables are organized as described below:

TABLE	DEPARTMENT	MATRIX
1	Chemistry	Serum or plasma
2	Chemistry	Urine
3	Immunochemistry	Serum or plasma
4	Respiratory Therapy	Heparinized whole blood
5	Hematology	EDTA whole blood
6	Coagulation	Citrated plasma
7	Urinalysis	Urine

Table 1: OHCob Interference on Blood Chemistry Tests[1] – Various concentrations of OHCob was added to pooled Serum and Heparinized Plasma specimens.

INTERFERENCE	ASSAY	METHOD	DELTA
None	Albumin	Beckman AU	<6%
	Alkaline Phosphatase (ALP)	Beckman AU	<6%
	CO_2, Total (Bicarbonate)	Beckman AU	<6%
	Calcium (Ca)	Beckman AU	<6%
	Chloride (Cl)	Beckman AU	<6%
	GGT	Beckman AU	<6%
	Glucose	Beckman AU	<6%
	Lactate	Beckman AU	<6%
	Lactate Dehydrogenase (LDH)	Beckman AU	<6%
	Lipase	Beckman AU	<6%
	Potassium (K)	Beckman AU	<6%
	Protein, Total (TP)	Beckman AU	<6%
	Sodium (Na)	Beckman AU	<6%
	Urea Nitrogen (BUN)	Beckman AU	<6%
	Triglyceride	Beckman AU	<6%

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INTERFERENCE	ASSAY	METHOD	DELTA
Increase	Cholesterol, Total	Beckman AU	51.0%
	Ethanol	Beckman AU/ Siemens Syva Emit	11.0%
	Magnesium	Beckman AU	34.0%
	Phosphorus	Beckman AU	8.0%
	Prealbumin	Beckman AU	11.0%
Decrease	ALT	Beckman AU	-5 to -73%
	Amylase	Beckman AU	-32.0%
	AST	Beckman AU	-1 to -51%
	Bilirubin, Direct	Beckman AU	-0.1 to -0.2 mg/dL
	Bilirubin, Total	Beckman AU	-0.1 to -0.2 mg/dL
	Creatinine	Beckman AU	-0.1 to -0.2 mg/dL
	Creatine Kinase (CK)	Beckman AU	-15.0%
	Iron	Beckman AU	-8.0%
	Uric Acid	Beckman AU	-28.0%

Table 2: OHCob Interference on Urine Chemistry Tests[1] – Various concentrations of OHCob was added to pooled urine specimens.

INTERFERENCE	ASSAY	METHOD	DELTA
None	Calcium (U Ca)	Beckman AU	<6%
	Chloride (U Cl)	Beckman AU	<6%
	Creatinine	Beckman AU	<6%
	Glucose	Beckman AU	<6%
	Phosphorus	Beckman AU	<6%
	Potassium (U K)	Beckman AU	<6%
	Sodium (U Na)	Beckman AU	<6%
	Urea Nitrogen (UUN)	Beckman AU	<6%
	Uric Acid	Beckman AU	<6%
Increase	Magnesium (U Mg)	Beckman AU	0.6 mg/dL
	Protein, Total (UTP)	Beckman AU	8.0%

Table 3: OHCob Interference on Blood Immunochemistry Tests[1] – Various concentrations of OHCob was added to pooled Serum and Heparinized Plasma specimens.

INTERFERENCE	ASSAY	METHOD	DELTA
Decreased	CK-MB, Blood	Beckman Access 2	-15.0%
Unpredictable*	Myoglobin, Blood	Beckman Access 2	na

*Unpredictable = the concentration fluxuated in the both the positive and negative direction

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Table 4: OHCob Interference on Respiratory Therapy Tests, Blood Gases, and Co-Oximetry Tests[1,2] - Various concentrations of OHCob was added to pooled venous whole blood.

INTERFERENCE	ASSAY	METHOD	DELTA
None	Base Excess	Siemens RapidPoint	<6%[1]
	Calcium, Ionized	Siemens RapidPoint	<6%[1]
	Chloride	Siemens RapidPoint	<6%[1]
	$HCO3^-$	Siemens RapidPoint	<6%[1]
	Glucose	Siemens RapidPoint	<6%[1]
	Sodium	Siemens RapidPoint	<6%[1]
	pH	Siemens RapidPoint	<6%[1]
	Potassium	Siemens RapidPoint	<6%[1]
Decrease	pO_2	Siemens RapidPoint	-7.0%[1]
	Carboxyhemoglobin (COHb)	Siemens RapidPoint	Up to -10%[2]
	Methemoglobin (MetHb)	Siemens RapidPoint	Up to -7%[2]
	Total Hemoglobin	Siemens RapidPoint	Up to -4%[2]
	Deoxyhemoglobin	Siemens RapidPoint	Up to -1%[2]
Increase	Oxyhemoglobin	Siemens RapidPoint	Up to 8%[2]
Unpredictable*	pCO2	Siemens RapidPoint	na[1]

*Unpredictable = the concentration fluxuated in the both the positive and negative direction

Table 5: OHCob Interference on Hematology Tests[1] - Various concentrations of OHCob was added to EDTA whole blood.

INTERFERENCE	ASSAY	METHOD	DELTA
None	WBC	Sysmex	<2%
	RBC	Sysmex	<1%
	Hematocrit	Sysmex	<1%
	MCV	Sysmex	<1%
	RDW-CV	Sysmex	<1%
	Platelets	Sysmex	<2%
	MPV	Sysmex	<1%
	Neutrophils %	Sysmex	<1%
	Neutrophils #	Sysmex	<2%
	Lymphocytes %	Sysmex	<1%
	Lymphocytes #	Sysmex	<3%
	Monocytes %	Sysmex	<2%
	Monocytes #	Sysmex	<1%
	Eosinophils %	Sysmex	<4%
	Eosinophils #	Sysmex	<1%
	Basophils %	Sysmex	<5%
	Basophils #	Sysmex	<1%

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INTERFERENCE	ASSAY	METHOD	DELTA
Increase	Hemoglobin	Sysmex	6.0%
	Reticulocytes %	Sysmex	5% to 15%

Table 6: OHCob Interference on Coagulation Tests[1] – Interference studies were not determined using Legacy's current instrumentation. Based on previous studies using a different method, OHCob causes significant changes in PT-INR, PTT, and Fibrinogen results.[1] Coagulation testing is not recommended on patients who have been administered this drug.

INTERFERENCE	ASSAY
Results change significantly. Coagulation testing not recommended while the patient is taking this drug.	PT-INR
	PTT
	Fibrinogen

Table 7: OHCob Interference on Urinalysis[3] - Various concentrations of OHCob was added to Urine.

INTERFERENCE	ASSAY	DELTA
Increase	pH	>10%
	Glucose	>10%
	Protein	>10%
	Erythrocytes	>10%
	Leukocytes	>10%
	Ketones	>10%
	Bilirubin	>10%
	Urobilinogen	>10%
	Nitrate	>10%

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2. *Urgent Field Safety Notice - Hydroxocobalamin Interference,* Siemens Healthcare Diagnostics, Inc., POC 18-010.A.US, July 2018.

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