

## **Interference Testing of HBOC-201, an Oxygen Based Therapeutic, with Dade Behring Chemistry Assays Performed on the Dimension® Clinical Chemistry System**

**Topic:** Factors Affecting Test Results

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### **Background**

HBOC-201 is a hemoglobin based oxygen therapeutic, manufactured by Biopure Corporation (Cambridge Massachusetts), that may interfere with photometric assays. Twenty-eight methods were evaluated on the Dade Behring Dimension® chemistry analyzer systems (RxL Max®, Xpand®) to determine if there was any interference in these methods from HBOC-201. The assays chosen were considered to be of importance to physicians treating patients who may have received HBOC-201.

### **Methods**

Testing was performed, in triplicate, for twenty-eight methods using a plasma pool and two levels of Bio-Rad Multiquant™ quality control. The final concentration of HBOC-201 in the test samples ranged from 0.1 to 6.4 g/dL. The samples were prepared with the addition of HBOC-201 only (the plasma pool and quality control samples were not spiked with additional analyte). The challenge concentrations of HBOC-201 were chosen to simulate what may be found in clinical samples. Acceptable performance in the presence of HBOC-201 was set at: +/-5% for electrolytes, +/-10% for general chemistry and cardiac methods and, +/-20% for enzyme methods, to aid in the interpretation of results.

### **Results**

Several criteria were employed in the analysis of results: linear regression limits, absolute limits using a percentage change, limits using an absolute value, and observation of error codes. No discernable, consistent difference in results was noted between the two Dimension systems for any of the methods. In addition, no evidence of degraded within-run precision was observed as a function of HBOC-201 concentration nor was there evidence of difference due to sample types tested (quality control or plasma).

Using the criteria stated above, the only method that could not be used at any concentration of HBOC-201 was direct bilirubin.

Results remained within the established limits for the following analytes, at or below, the concentrations of HBOC-201 indicated:

6.4 g/dL- sodium, potassium, blood urea nitrogen, magnesium, myoglobin

5.0 g/dL- creatine kinase MB (mass)

4.0 g/dL- cardiac troponin I

3.3 g/dL- chloride

2.5 g/dL- albumin

2.0 g/dL- calcium, phosphorus, lactic acid dehydrogenase

1.3 g/dL- cholesterol

1.0 g/dL- alkaline phosphatase, amylase, creatine kinase

0.8 g/dL- glucose

0.7 g/dL- automated high density lipoprotein

0.5 g/dL- total protein, uric acid, aspartate aminotransferase, alanine aminotransferase, gamma glutamyl transferase

0.4 g/dL- total bilirubin

0.3 g/dL- creatinine

0.2 g/dL- triglyceride

0.1 g/dL- carbon dioxide (colorimetric)

In conclusion, because HBOC-201 is a colored substance, it would be expected to interfere with colorimetric assays. Because of the variety of methodologies used for chemistry assays, the effect can vary depending upon wavelength used for the primary or secondary reading, chemical interference and a host of other factors. HBOC-201 material used in this study was provided by Biopure Corporation. Multiquant™ is a registered trademark of Bio-Rad, Hercules, California, 94547.