

# Evaluation of Diagnostic Chemicals Limited (DCL) Albumin, Carbon Dioxide-L<sub>3</sub>K and Iron-PC Reagents on the Roche/Hitachi MODULAR™ D System

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## Abstract

Performance characteristics of Diagnostic Chemicals Limited (DCL) Albumin (Cat. No. 200-05), Carbon Dioxide-L<sub>3</sub>K (Cat. Nos. 299-30/50) and Iron-PC (Cat. No. 102-25) reagents were evaluated on a Roche/Hitachi MODULAR™ D System. These assays were evaluated as alternative reagents for the Roche/Hitachi MODULAR Systems. Within-Run and Between-Run Precision studies were performed on two serum-based controls. Linearity and sensitivity studies confirmed reportable ranges as listed below. Interferences due to hemolysis, icterus and lipemia were evaluated following NCCLS EP7-P dose-response guidelines. Maximum levels studied were 1000 mg/dL hemoglobin, 40 mg/dL bilirubin and 1000 mg/dL Intralipid (fat emulsion) (3000 mg/dL triglyceride). Using a significance criterion of >10% variance from control, both the Albumin and Carbon Dioxide-L<sub>3</sub>K assays demonstrate no significant interference from lipemia and icterus, with acceptable results up to a concentration of 600 mg/dL hemoglobin. No significant interference of any kind was noted with the Iron-PC assay. Method comparison studies (using serum samples) were performed against the Roche Albumin (Cat. Nos. 1929631, 1970917), Carbon Dioxide (Cat. Nos. 1877879, 1877887) and Iron (Cat. Nos. 1929658, 1929666) methods. The Deming regression statistics are included below.

Analyte (Units)	Within-Run Precision (% CV)	Between-Run Precision (% CV)	Correlation to Roche (Deming regression)	Reportable Range
Albumin (g/dL)	2.0% at 2.12 1.8% at 2.84	2.3% at 2.17 1.8% at 2.95	DCL = 1.06 (Roche) - 0.16 g/dL R = 0.9826 n = 55	1.5 to 5.5 g/dL
Carbon Dioxide (mEq/L)	2.6% at 12.1 1.3% at 24.9	4.9% at 12.1 3.2% at 21.9	DCL = 0.901 (Roche) + 1.5 mEq/L R = 0.9741 n = 56	10 to 50 mEq/L
Iron (µg/dL)	0.5% at 96.4 0.2% at 276.3	1.7% at 99.9 1.4% at 274.3	DCL = 0.9943 (Roche) - 0.2 µg/dL R = 0.9995 n = 53	5 to 1000 µg/dL

In conclusion, all the DCL reagents correlate to their Roche counterparts on the Roche/Hitachi MODULAR D System using patient serum. The DCL reagents also demonstrate excellent precision and linearity with little to no interference due to hemoglobin, icterus and lipemia. These studies support the use of DCL reagents as cost effective alternative reagents for the Roche/Hitachi MODULAR D System.

## Introduction

Diagnostic Chemicals Limited (DCL) is a manufacturer of alternative reagents for use on clinical chemistry analyzers. The performance of three routine chemistries was evaluated at an external site on the Roche/Hitachi MODULAR D System. In this study, the performance characteristics of the Albumin (Cat. No. 200-05), Carbon Dioxide-L<sub>3</sub>K (Cat. Nos. 299-30/50) and Iron-PC (Cat. No. 102-25) were evaluated. Performance studies included evaluations of precision, linearity, interference, sensitivity and correlation to their Roche counterparts: Albumin (Cat. Nos. 1929631, 1970917), Carbon Dioxide (Cat. Nos. 1877879, 1877887) and Iron (Cat. Nos. 1929658, 1929666).

## Methods

Reagents used in the evaluation were DCL's Albumin (Cat. No. 200-05), Carbon Dioxide-L<sub>3</sub>K (Cat. Nos. 299-30/50) and Iron-PC (Cat. No. 102-25) and the Roche Albumin (Cat. Nos. 1929631, 1970917), Carbon Dioxide (Cat. Nos. 1877879, 1877887) and Iron (Cat. Nos. 1929658, 1929666). All DCL reagents were calibrated with DC-Cal (Cat. No. SE-035). The Roche Albumin and Carbon Dioxide reagents were calibrated with the Roche CFAS (Cat. No. 759350) while the Iron reagent was calibrated with the Roche Iron Standard (Cat. No. 1965922).

### Precision

Within-Run Precision studies were estimated by analyzing replicates of two serum-based controls {DC-Trol, Level 1 (Cat. No. SM-052) and DC-Trol, Level 2 (Cat. No. SM-056)}. Between-Run Precision was estimated by analyzing the DC-Trol Levels 1 & 2 in triplicate over five runs.

### Reportable Range

Reportable Range was established by quadruplicate analysis of dilutions of both low end and high end linearity materials.

The lower limit of detection (LLD) was determined by assaying ten replicate samples of an isotonic saline solution. The LLD was calculated as the mean plus three standard deviations.

### Interferences

Interferences due to bilirubin, hemoglobin and lipemia were studied using the dose-response method described in NCCLS document EP7-P. Bilirubin interference from 0-40 mg/dL (0-684 µmol/L) was evaluated in a serum pool spiked with a reference grade bilirubin (Pfanstiehl, Waukegan, IL), which was dissolved in a 0.1 M solution of TRIS in DMSO. Hemoglobin interference from 0-1000 mg/dL (0-155 µmol/L) was evaluated in a serum pool spiked with hemolysate produced by osmotic shock of red blood cells. Lipemia was simulated by adding 10% Intralipid solution (DIN02065681, Pharmacia & Upjohn) to pooled serum to produce lipid levels from 0-1000 mg/dL (1000 mg/dL Intralipid is equivalent to 3000 mg/dL triglyceride).

### Method Comparison

Method comparison studies were carried out against the Roche Albumin (Cat. Nos. 1929631, 1970917), Carbon Dioxide (Cat. Nos. 1877879, 1877887) and Iron (Cat. Nos. 1929658, 1929666), following NCCLS guideline EP9-P, vol. 6, no. 1.

### Statistics

Precision, linearity and method correlation comparison data were analyzed using EP Evaluator software, EE Release: CLIA 1.2.6.67.

## Results

### Precision

Within-Run and Between-Run Precision results are presented in Table 1.

Table 1

Analyte (Units)	Within-Run Precision				Between-Run Precision			
	N	Mean	SD	CV (%)	N	Mean	SD	CV (%)
Albumin (g/dL)	10	2.12	0.04	2.0	15	2.17	0.05	2.3
		2.84	0.05	1.8		2.95	0.05	1.8
Carbon Dioxide (mEq/L)	10	12.1	0.3	2.6	15	12.1	0.6	4.9
		24.9	0.3	1.3		21.9	0.7	3.2
Iron (µg/dL)	10	96.4	0.5	0.5	15	99.9	1.7	1.7
		276.3	0.7	0.2		274.3	3.8	1.4

### Reportable Range

Reportable Range results are presented in Table 2.

Table 2

Analyte (Units)	Reportable Range	LLD
Albumin (g/dL)	1.5 to 5.5 g/dL	0.0
Carbon Dioxide (mEq/L)	10 to 50 mEq/L	0.0
Iron (µg/dL)	5 to 1000 µg/dL	1.4

### Interferences

Significance criterion of >10% variance from control

#### Albumin:

**Lipemia:** No significant interference noted to 1000 mg/dL (11.29 mmol/L) Intralipid equivalent to 3000 mg/dL (33.87 mmol/L) triglyceride.

**Bilirubin:** No significant interference was noted to 40 mg/dL (684 µmol/L).

**Hemoglobin:** Acceptable results were obtained up to 600 mg/dL (93 µmol/L). At an added hemoglobin concentration of 600 mg/dL, a positive 6.1% variance was observed in a 4.9 g/dL (49 g/L) Albumin sample.

#### CO<sub>2</sub>-L<sub>3</sub>K:

**Lipemia:** No significant interference noted to 1000 mg/dL (11.29 mmol/L) Intralipid equivalent to 3000 mg/dL (33.87 mmol/L) triglyceride.

**Bilirubin:** No significant interference was noted to 40 mg/dL (684 µmol/L).

**Hemoglobin:** Acceptable results were obtained up to 600 mg/dL (93 µmol/L). At an added hemoglobin concentration of 600 mg/dL, a negative 6.7% variance was observed in a 30 mEq/L (mmol/L) CO<sub>2</sub> sample.

#### Iron-PC:

**Lipemia:** No significant interference noted to 1000 mg/dL (11.29 mmol/L) Intralipid equivalent to 3000 mg/dL (33.87 mmol/L) triglyceride.

**Bilirubin:** No significant interference was noted to 40 mg/dL (684 µmol/L).

**Hemoglobin:** No significant interference noted to 1000 mg/dL (155 µmol/L).

### Method Comparison

Analyte (Units)	Correlation to Roche (Deming regression)
Albumin (g/dL)	DCL = 1.06 (Roche) - 0.16 g/dL R = 0.9826 n = 55
Carbon Dioxide (mEq/L)	DCL = 0.901 (Roche) + 1.5 mEq/L R = 0.9741 n = 56
Iron (µg/dL)	DCL = 0.9943 (Roche) - 0.2 µg/dL R = 0.9995 n = 53

## Conclusion

In conclusion, the DCL reagents correlate well to their Roche counterparts on the Roche/Hitachi MODULAR D System using patient serum. The DCL reagents also demonstrate excellent precision and linearity with little to no interference due to hemoglobin, icterus and lipemia. These studies support the use of DCL reagents as cost effective alternative reagents for the Roche/Hitachi MODULAR D System.