Freedom from Interferences

respons®910 VET

A Fully Integrated Approach

DiaSys Diagnostic Systems Delivers Quality

- **Integrated system of analyzer, reagents and applications are designed to minimize the impact on results caused by the presence of lipids, bilirubin and hemoglobin in samples**
- **System applications are configured to consistently deliver highly accurate results**
- **Performance is optimized for respons®910VET Chemistry Analyzer**

DiaSys

USA

Commitment to Quality

Innovative system design of analyzers, reagents and applications deliver results of the highest quality regardless of sample integrity

Background

Specimen integrity is an important preanalytic factor that affects the accuracy and clinical utility of laboratory test results.[1] The three most prominent endogenous interfering substances in veterinary specimens include lipids, bilirubin and hemoglobin. The source of these components can range from poor sample collection, sample mishandling or certain disease states of the patient. The effect of these interfering substances on clinical chemistry results has been widely studied.

Methodology

Each reagent application available on the respons®910VET Chemistry Analyzer have been carefully studied for the potential impact on diagnostic results when lipids, bilirubin and/or hemoglobin are present. Analyte recovery is measured over a broad range of concentrations of interfering substances. This analysis is also performed for both low and high concentration levels for each chemistry analyte. Results are analyzed over this range for accuracy[2].

The respons®900VET Series Solution to Interfering Substances

The respons®910VET Chemistry Analyzer utilizes a proprietor method for minimizing any impact on the accuracy of reported results due to the presence of lipids (lipemia), bilirubin (icterus) and/or hemoglobin (hemolysis). Result accuracy is ensured utilizing different, yet complimentary methods.

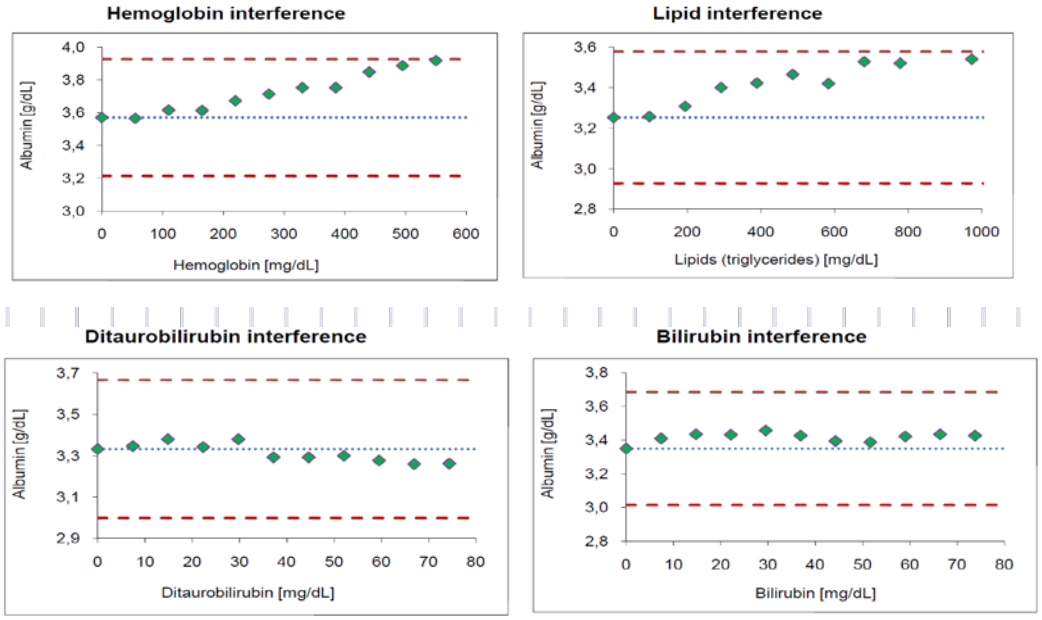
Lipemia. When dealing with lipemia, the chemical makeup of each reagent methodologies is configured to include clarifying agents which chemically break down the fat molecules and remove them from potentially interfering with the test reaction. This process is performed in an automated manner and does not require any manual intervention.

Icterus and Hemolysis. The presence of these two interfering substances in diagnostic samples potentially affects results by changing the measured absorbance of the chemical reaction between sample and reagent. This change is minimized on the respons®910VET Chemistry Analyzer by reducing this photometric interference for each reaction. This is accomplished through a combination of optimized parameter definition and reagent makeup. Precise parameter definition for each chemistry creates minimal, yet optimal, sample to reagent ratios. The result of this application optimization is that these interfering substances are effectively diluted to the point where interference is minimized. This total system optimization is designed to reduce the impact of interfering substances and ensures consistent and high quality results every time.

[1]Analytical Interference More than Just a Laboratory Problem. American Journal of Clinical Pathology, 2/2000. Steven C. Kazmierczak, PhD, and Paul G. Catrou, MD

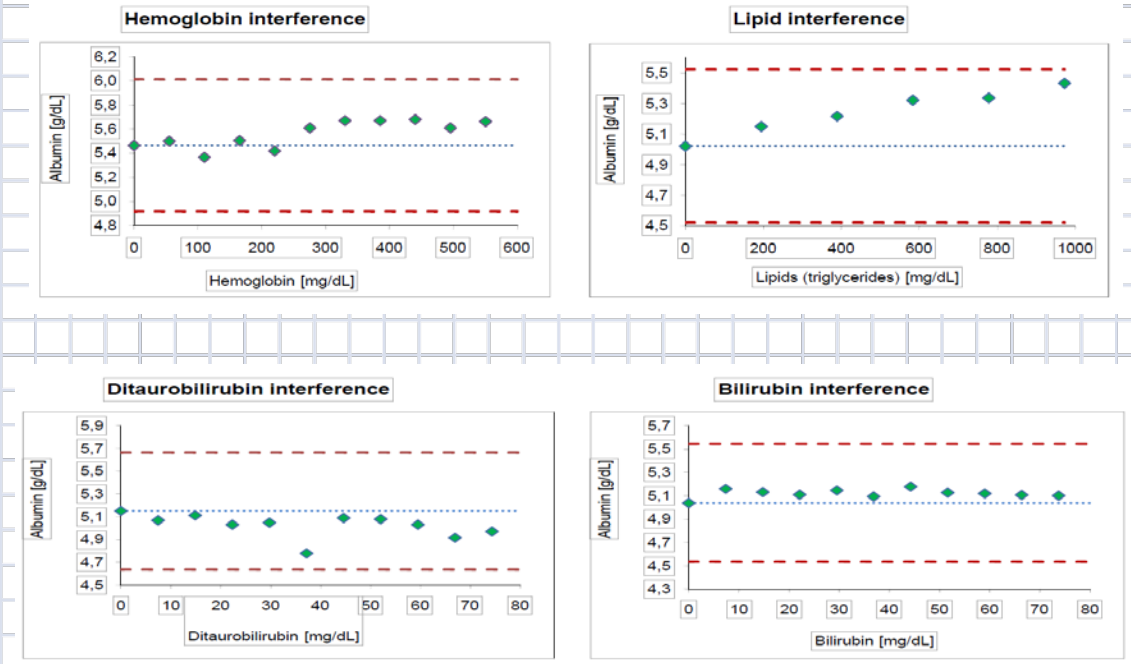
[2]See attached interference data.

ALBUMIN
Interferences Low Level



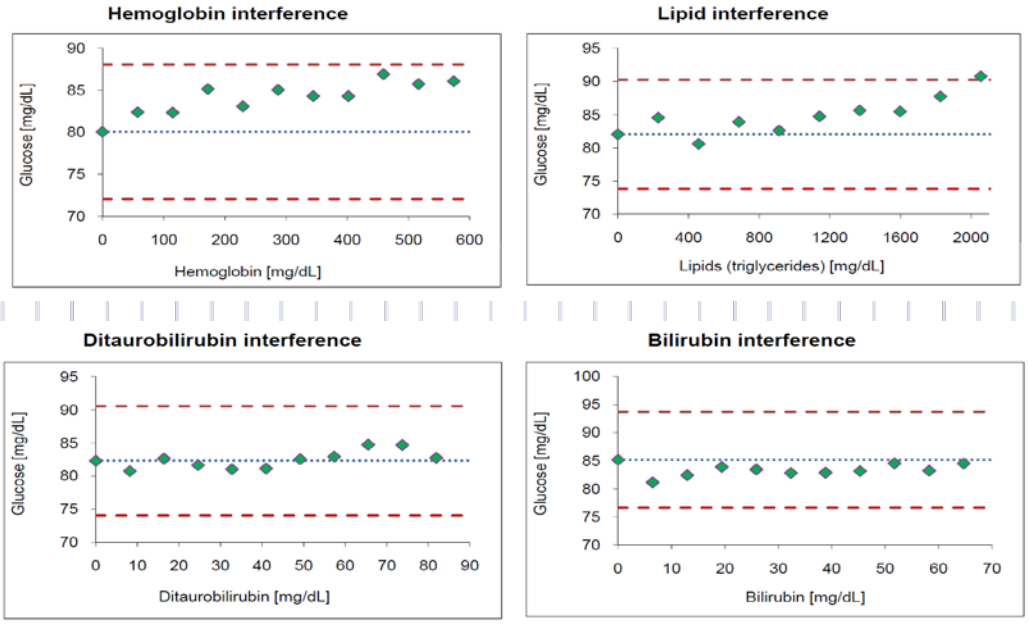
No significant interferences (less than +/- 10%) were observed by hemoglobin up to 500 mg/dL (albumin conc. 3.57 g/dL), lipids up to 800 mg/dL (albumin conc. 3.25 g/dL), ditaurobilirubin up to 70 mg/dL (albumin conc. 3.33 g/dL) and bilirubin up to 70 mg/dL (albumin conc. 3.35 g/dL).

ALBUMIN
Interferences High Level



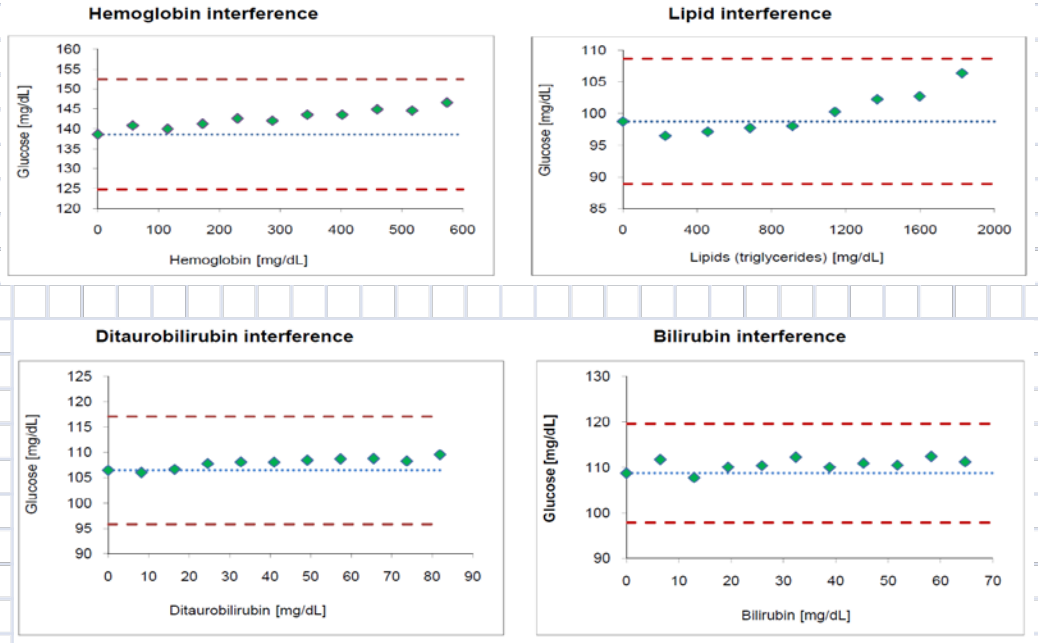
No significant interferences (less than +/- 10%) were observed by hemoglobin up to 550 mg/dL (albumin conc. 5.47 g/dL), lipids up to 950 mg/dL (albumin conc. 5.02 g/dL), ditaurobilirubin up to 70 mg/dL (albumin conc. 5.15 g/dL) and bilirubin up to 70 mg/dL (albumin conc. 5.04 g/dL).

GLUCOSE (Hexokinase)
Interference Low Level



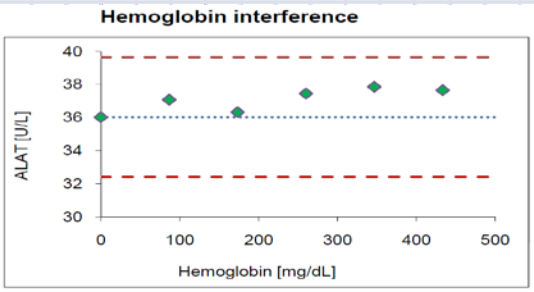
No significant interferences (less than +/- 10%) were observed by hemoglobin up to 550 mg/dL (glucose conc. 80.1 mg/dL), lipids up to 1800 mg/dL (glucose conc. 82.1 mg/dL and bilirubin up to 60 mg/dL (glucose conc. 85.2 mg/dL).

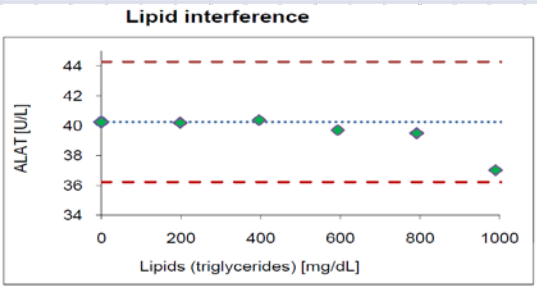
GLUCOSE (Hexokinase)
Interference High Level

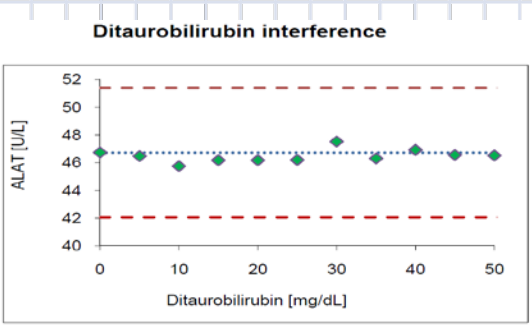


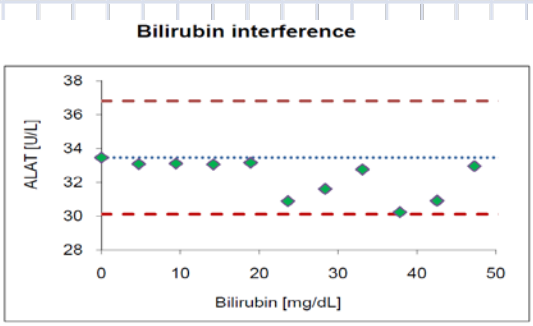
No significant interferences (less than +/- 10%) were observed by hemoglobin up to 550 mg/dL (glucose conc. 139 mg/dL), lipids up to 2000 mg/dL (glucose conc. 98.8 mg/dL), and bilirubin up to 60 mg/dL (glucose conc.109 mg/dL).

Alanine Aminotransferase (ALT)
Interference Low Level



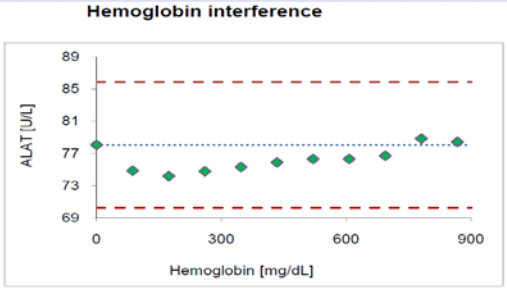


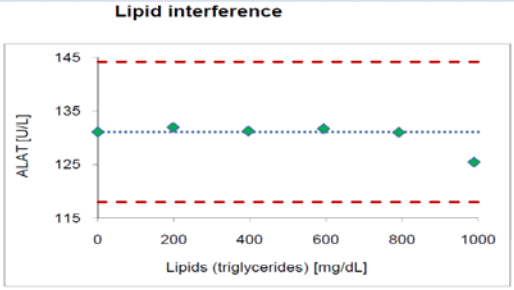


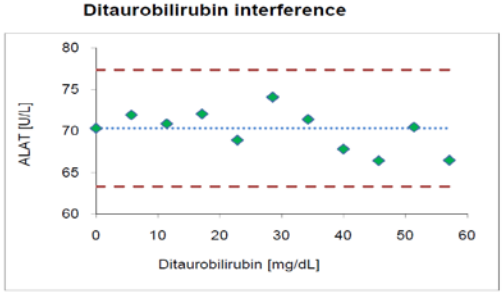


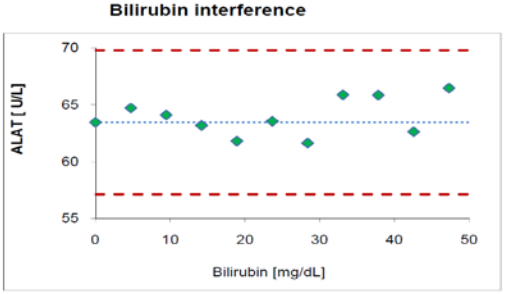
No significant interferences (less than +/- 10%) were observed by hemoglobin up to 500 mg/dL (ALAT activity 36.0 U/L), lipids up to 1000 mg/dL (ALAT activity 40.3 U/L), ditaurobilirubin up to 50 mg/dL (ALAT activity 46.7 U/L) and bilirubin up to 45 mg/dL (ALAT activity 33.5 U/L).

Alanine Aminotransferase (ALT)
Interference High Level



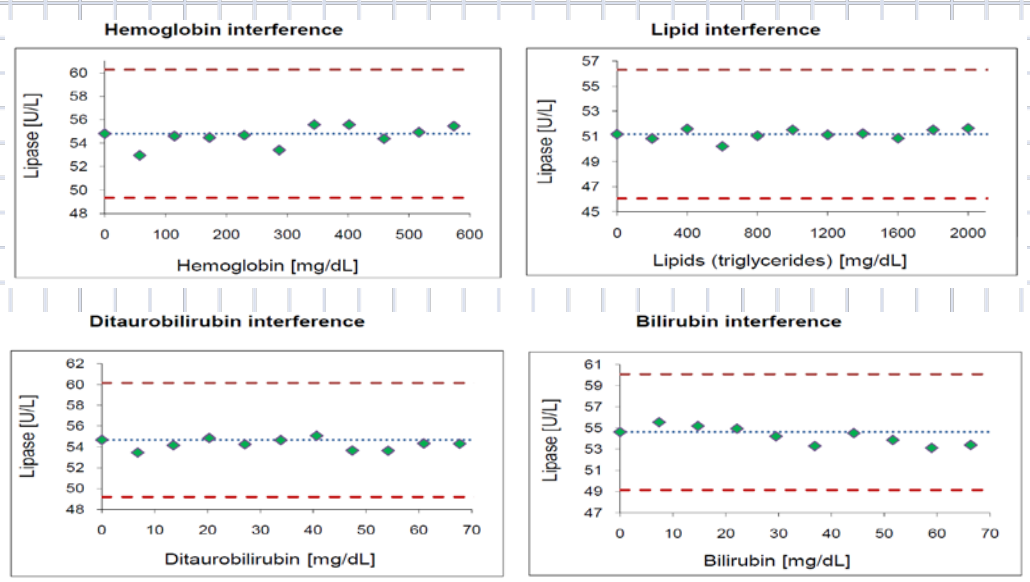






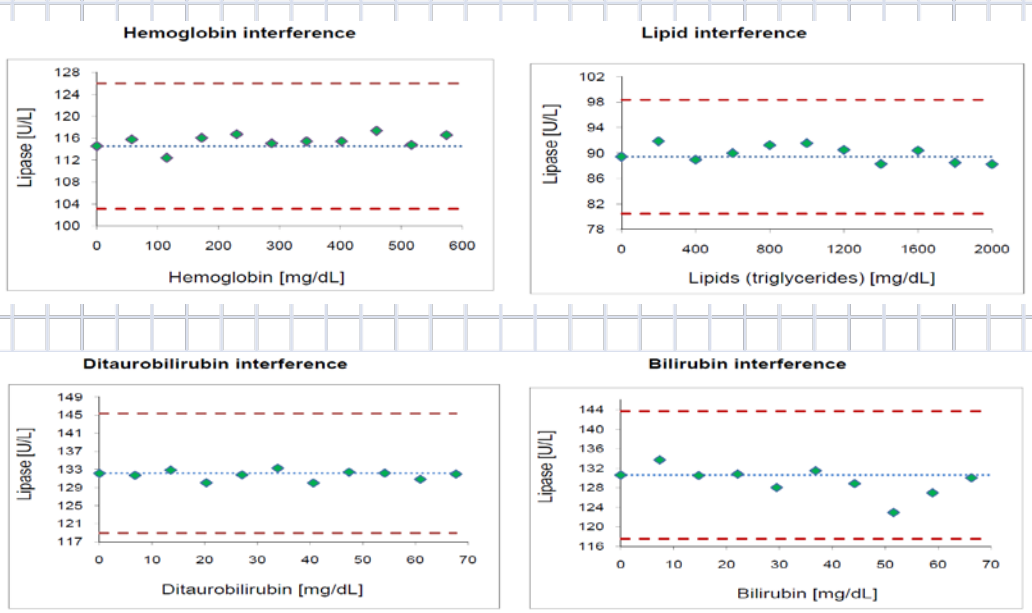
No significant interferences (less than +/- 10%) were observed by hemoglobin up to 850 mg/dL (ALAT activity 78.1 U/L), lipids up to 1000 mg/dL (ALAT activity 131 U/L), ditaurobilirubin up to 55 mg/dL (ALAT activity 70.3 U/L) and bilirubin up to 45 mg/dL (ALAT activity 63.5 U/L).

Lipase
Interference Low Level



No significant interferences (less than +/- 10%) were observed by hemoglobin up to 550 mg/dL (lipase activity 54.8 U/L), lipids up to 2000 mg/dL (lipase activity 51.2 U/L), ditaurobilirubin up to 60 mg/dL (lipase activity 54.7 U/L) and bilirubin up to 70 mg/dL (Lipase activity 54.6 U/L).

Lipase
Interference High Level



No significant interferences (less than +/- 10%) were observed by hemoglobin up to 550 mg/dL (lipase activity 115 U/L), lipids up to 2000 mg/dL (lipase activity 89.4 U/L), ditaurobilirubin up to 60 mg/dL (lipase activity 132 U/L) and bilirubin up to 70 mg/dL (lipase activity 131 U/L).

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