IDEXX **SNAP® Bile Acids**
Method Comparison Study

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ABSTRACT: The purpose of this study was to compare serum bile acids results obtained from two different methods: DCL's Bile Acids-L_3K® run on the Hitachi® 717 instrument (reference method) and the IDEXX SNAP® Bile Acids Test run on the IDEXX SNAP® Reader. Preprandial and postprandial serum samples from eight hundred sixty-one patients were run on both analyzers and the bile acids results were compared. The agreement between the reference method and the SNAP Bile Acids Test results was 95.2%.

INTRODUCTION: Increased bile acids serum concentrations occur in patients with decreased liver function, obstruction of the biliary system or decreased blood flow to the liver. Measurement of bile acids is used to evaluate patients with portosystemic shunts (congenital or acquired), indicate the presence of liver disease prior to the development of icterus, and assess recovery of liver function in a patient being treated for liver disease. The in-clinic SNAP Bile Acids Test allows the veterinarian to quickly rule out decreased liver function and allows for immediate follow-up diagnostics. The objective of this study was to compare the SNAP Bile Acids Test results obtained with the IDEXX SNAP Reader to the reference method (Bile Acids-L_3K run on the Hitachi 717 instrument).

MATERIALS AND METHODS: Canine and feline patient samples were obtained from IDEXX Reference Laboratories. The sample population tested in this study represents the distribution of samples sent to IDEXX for bile acids testing. Both preprandial and postprandial serum samples were collected from 861 patients (734 canine, 127 feline) and analyzed for bile acids concentration. Testing of each sample was performed on both the reference method (Bile Acids-L_3K from DCL) and the IDEXX SNAP Bile Acids Test. The reference method is an enzyme-based assay with a dynamic range of 1 to 140 μmol/L. The SNAP Bile Acids Test is a competitive immunoassay with a dynamic range of 5 to 30 μmol/L. A SNAP Bile Acids Test result of <5 μmol/L indicates the presence of very low levels of bile acids in the patient and a SNAP Bile Acids Test result >30 μmol/L indicates the presence of high levels of bile acids. Each analyzer (IDEXX SNAP Reader and Hitachi 717) was maintained to the manufacturer's specifications, including calibration and quality-control procedures.

RESULTS: Each patient was categorized as "low," "high" or "inconclusive" according to the SNAP Bile Acids Test reference ranges, using both the preprandial and postprandial bile acids results. "Low" patients had bile acids concentrations <12 μmol/L for both preprandial and postprandial samples, consistent with normal bile acids levels. "High" patients had a postprandial bile acids concentration >25 μmol/L, consistent with impaired liver function. "Inconclusive" patients had a preprandial or postprandial bile acids concentration of 12–25 μmol/L, where bile acids were moderately elevated, but not to the extent that confirmed impaired liver function.

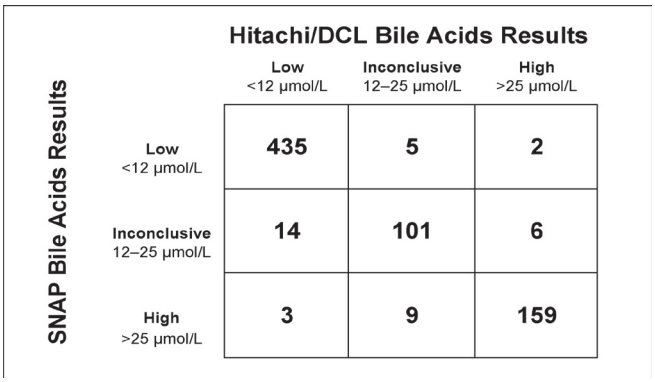

Figure 1. Method comparison results for the 734 canine patients run on the SNAP Bile Acids Test and the reference method.

The results for the canine patients are summarized in Figure 1. There were 452 canine patients categorized as "low" based on the bile acids results obtained by the reference method. Of these 452 patients, 435, or 96.2%, were also "low" based on the SNAP Bile Acids Test results. There were 167 canine patients categorized as "high" based on the reference method bile acids results, with 159, or 95.2%, also being "high" based on the SNAP Bile Acids Test

results. Of the 115 canine patients categorized as "inconclusive" based on the bile acids results obtained by the reference method, 101, or 87.8%, were also "inconclusive" based on the SNAP Bile Acids Test results.

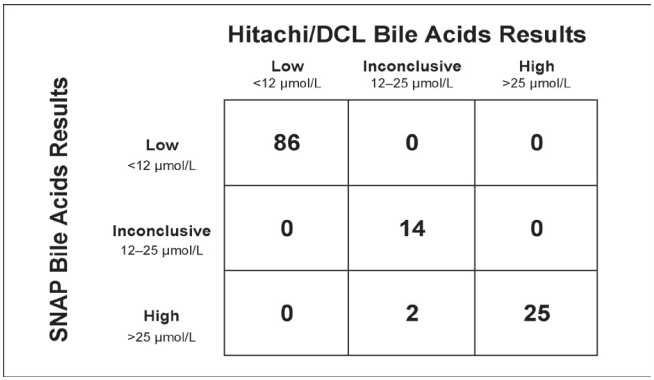

Figure 2. Method comparison results for the 127 feline patients run on the SNAP Bile Acids Test and the reference method.

The results for the feline patients are summarized in Figure 2. There was 100% agreement between the reference method results and the SNAP Bile Acids Test results for the 86 feline patients categorized as "low" and for the 25 feline patients categorized as "high." Of the 16 feline patients categorized as "inconclusive" based on the bile acids results obtained by the reference method, 14, or 85.7%, were also "inconclusive" based on the SNAP Bile Acids Test results.

The overall agreement between the SNAP Bile Acids Test and the reference method for canine and feline patients combined was 95.2%, with 521 patients being "low," 192 patients being "high," and 131 patients being "inconclusive" based on the bile acids results from both methods.

DISCUSSION: There was strong agreement between the SNAP Bile Acids results (run on the IDEXX SNAP Reader) and the reference method results (DCL's Bile Acids-L_3K run on the Hitachi 717) for the 861 canine and feline patients evaluated. The results agreed very well, especially considering the methodology differences for the two tests, the reference method being an enzyme-based assay and the SNAP Bile Acids Test being a competitive immunoassay. The results obtained in the method comparison study indicate that the SNAP Bile Acids Test, used in combination with the patient's clinical signs and symptoms, effectively allows the veterinarian to determine whether there is decreased liver function.

CONCLUSION: The SNAP Bile Acids Test provides accurate and reliable quantitative test results as compared to the Hitachi/DCL Bile Acid-L_3K reference method. The use of the SNAP Bile Acids Test allows the practitioner to quickly assess liver function of canines and felines in-clinic, resulting in prompt follow-up diagnostics when needed.

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