Healthmark ChannelCheck™

Limits of Detection and Extraction Efficiency

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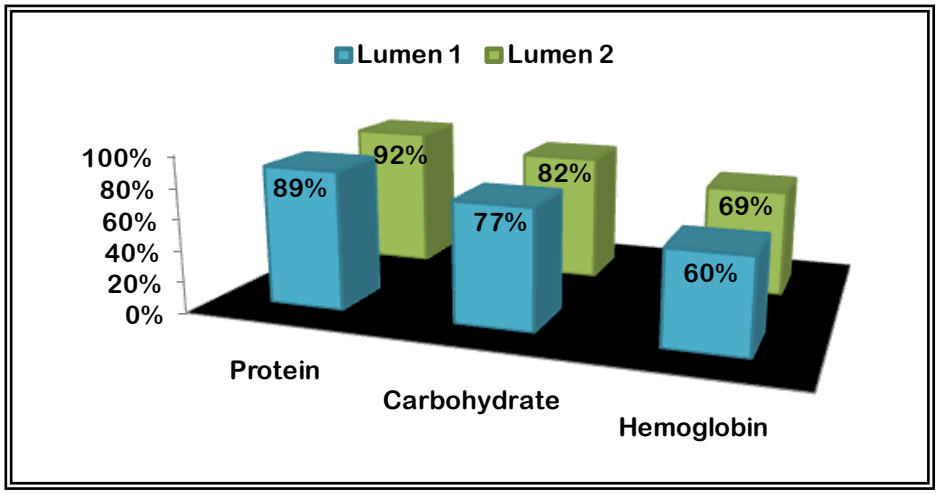
Lower Limit of Detection-To determine the lower limits of detection of the Healthmark ChannelCheck™ dipsticks that detect proteins, carbohydrates, and blood, the concentrations of test samples were measured and compared to results from the ChannelCheck™ dipsticks. Artificial test soil (ATS) served as the sample and is composed of all three components. ATS was diluted until the lower limit of detection was achieved for each component, reflecting a positive result on the ChannelCheck™ dipstick. The definite concentration was determined using standard laboratory methods.

Organic Residue	Lowest Detectable Concentration
Protein	120 ug/ml
Carbohydrate	210 ug/ml
Blood (Hemoglobin)	0.25 ug/ml

Extraction Efficiency-To validate Healthmark ChannelCheck™ Instructions for Use, recovery efficiency of protein, carbohydrate, and hemoglobin from surrogate lumens with 10ml of sterile water was determined as follows:

- 1ml of artificial test soil (ATS) diluted to concentrations, that represent the acceptable benchmarks as published by Alfa et.al, was placed into and spread throughout a surrogate lumen.
- The lumen was dried for 1 hour at room temperature.
- Dried ATS was recovered by flushing 10ml of sterile deionized water through the lumen and collecting the fluid in a sterile bottle.
- The concentrations of protein, carbohydrate, and hemoglobin in the fluid were measured using standard laboratory methods.

Results:



Ten milliliters (10ml) of sterile water is highly effective at removing organic residues from lumens that can then be tested using Healthmark ChannelCheck™ dipsticks.

All validation tests meet AAMI, ISO, and USP guidelines. If you would like more detailed data please contact Healthmark INDUSTRIES at Healthmark@hmark.com.

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