

## Objective

To determine the Confidence Interval (CI) of the Limit of Detection (LOD) for ChannelChecks™.

## Protocol

10 lots of ChannelChecks™ were tested, with 10 strips tested per lot for each analyte.

### LOD test solutions were prepared as follows:

25.00 mg Glucose, 30.00 mg Bovine Albumin, or 25.00 mg Bovine Hemoglobin were weighed out into a clean 1L glass bottle using an analytical balance. Then 1L of double distilled water was measured by weight and added to the same bottle, and solution was mixed well to dissolve. For Hemoglobin solutions, 990 mL of double distilled water was then weighed out into another clean 1L glass bottle, and 10 mL of the 25 mg/L solution was pipetted into the 990 mL of water. Solution was then mixed well.

This created 25 ug/mL Glucose, 30 ug/mL Albumin, and 0.25 ug/mL Hemoglobin solutions respectively. All solutions were used the same day they were made.

Test strips were then tested one at a time, according to the ChannelCheck™ Instructions for Use.

When testing was completed, Confidence Interval calculations were done using an Exact Method calculation for Discrete Binary data sets. Confidence Level was set at 95% for each analyte.

## Conclusion

Statistically speaking 100% certainty is impossible. There is always a chance of unforeseen failure. This is what Confidence Intervals are for, to predict the likelihood that a given population will fall within a given range for a variable.

According to this data set for the Protein and Hemoglobin pads, there is a 95% certainty that the pads will pass at LOD between 97.05% and 100% of the time, with the most likely number being 100%. The margin of error for both pads is about 1.48%, meaning that there is a possible fluctuation in that range of just under 1.5%.

For the Carbohydrate pad there is a 95% certainty that the pad will pass at LOD between 91.48% and 99.38% of the time, with a most likely estimate of 97% and a margin of error at 3.95%.

Overall, these Confidence Intervals are quite high and with extremely low margins of error. The primary cause of failure in the Carbohydrate pad seems to have been that the color change is from yellow to brown, which is an easy change to miss if the change is very slight as it often is at LOD.

## Results

Out of the 100 strips tested per analyte, the test pads had passing results at the following ratios:

**Carbohydrate Pad: 97/100**

**Protein Pad: 100/100**

**Hemoglobin Pad: 100/100**

Confidence Intervals for each test pad are as follows:

Confidence Parameters	Carbohydrate Pad	Protein Pad	Hemoglobin Pad
Confidence Level	95%	95%	95%
Lower Bound	0.9148	0.9705	0.9705
Upper Bound	0.9938	1.0000	1.0000
Margin of Error	0.0395	0.0148	0.0148
Most Likely Estimate	0.97	1.0000	1.0000

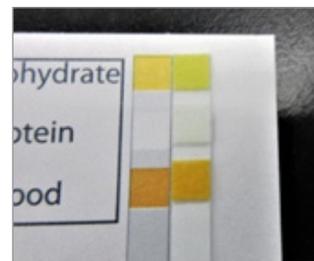


Figure 1: Carbohydrate Pad Fail and Pass Examples

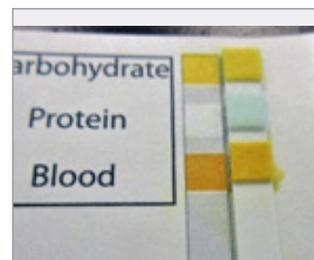


Figure 2: Protein Pad Example

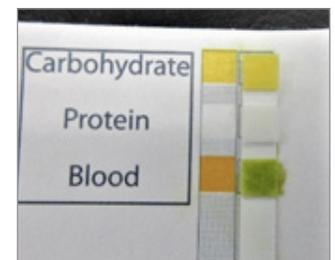


Figure 3: Hemoglobin Pad Example