

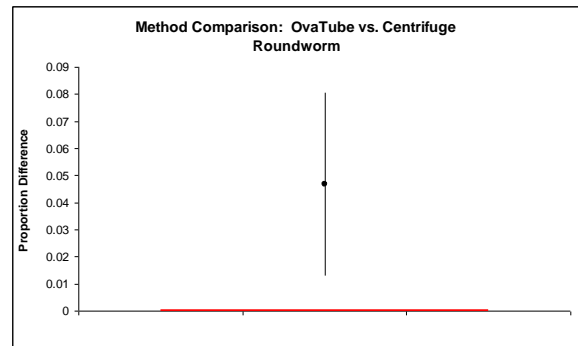
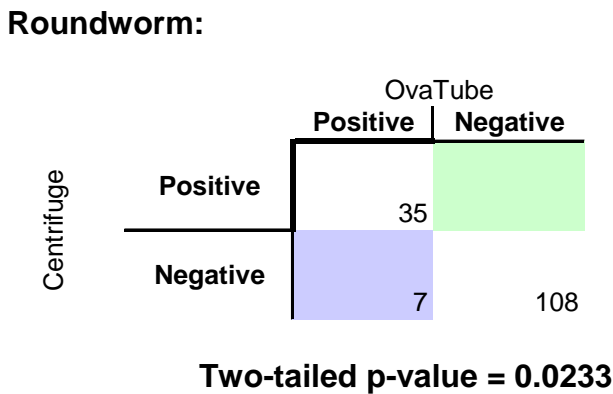
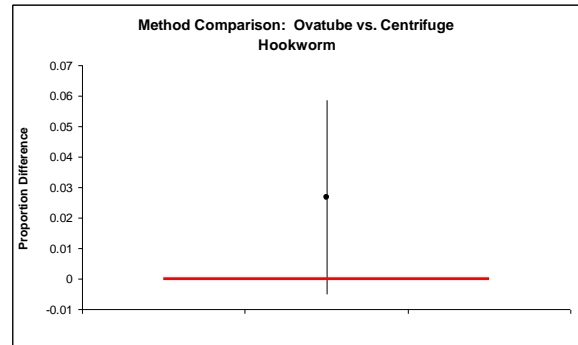
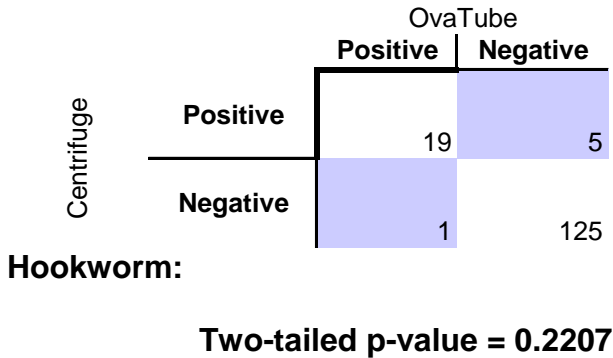
Comparison of Ovatube™ to Centrifuge

3/26/2010

Large Reference Laboratory

Results for 150 samples run across Centrifuge and Ovatube for presence of Roundworm, Hookworm, and Whipworm are included in this report. Two analyses of these data were performed: McNemar's test for method comparison of discordant results, and calculation of sensitivity (with 95% confidence intervals) based on consensus truth.

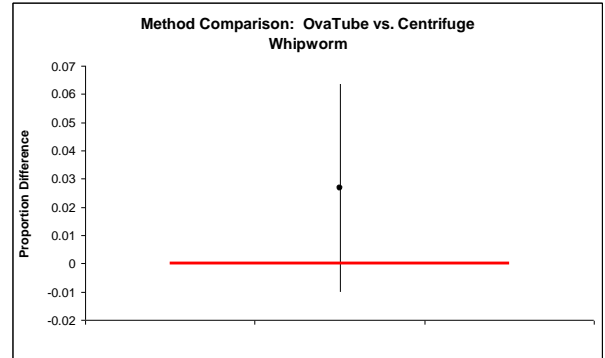
The absence of absolute truth in these data suggested the use of method comparison for determination of equivalence between the two test methods. McNemar's test for discordant results was performed in order to directly compare the two test methods without the need to specify truth for these samples. At an alpha level of 0.05, this analysis of the data showed a statistically significant difference in performance between these test methods for Roundworm, with Ovatube showing more sensitivity than Centrifuge. No statistical differences were observed between Ovatube and Centrifuge for either Hookworm or Whipworm.



Whipworm:

		OvaTube	
		Positive	Negative
Centrifuge	Positive	24	6
	Negative	2	118

Two-tailed p-value = 0.2888



At an alpha level of 0.05, these results for Hookworm and Whipworm are unable to show any differences between these methods. Post-hoc power calculation for these data was calculated to be approximately 0.3, suggesting that this test does not have a high level of power to be able to distinguish differences. This analysis would be greatly improved by increasing the sample size of the dataset. In this case, the sample size that matters is not the total number of samples tested, but those samples that evaluate as discrepant between the two methods.

Estimates of sensitivity with 95% confidence intervals are included in this report as well. For these data, a positive determination was made for a sample if ova were detected by either test method.

