

This is a power calculation based on the total sample size calculated for the primary objective. For this calculation, power is calculated assuming a 1:2 cases to controls ratio, and the test is a difference in the area under the AUC curve for prediction of case status with the addition of the fetal functional parameter to a conventional model. I have assumed that there are 3 levels of AUC obtained from the conventional model (0.7, 0.75 and 0.8) and calculated power if the new model showed AUC values of 0.72 - 0.96. I have highlighted in yellow the value at which power is greater than 80% in testing the difference between model performance according to this test.

So, you can see that if the conventional method shows an AUC of 0.70, you would have greater than 80% power to detect a difference in models if adding the fetal parameter resulted in a AUC of 0.78.

Statement for the protocol:

A sample of 163 cases and 332 controls would achieve greater than 90% power to detect a difference of 0.08 between a diagnostic test with an area under the ROC curve (AUC) of 0.70 and another diagnostic test with an AUC of 0.78 using a two-sided z-test at a significance level of 0.050. The correlation between the two diagnostic tests is assumed to be 0.60 for the positive group and 0.60 for the negative group. This calculation was performed using PASS software.

PASS 2020 Power Analysis and Sample Size Software (2020). NCSS, LLC. Kaysville, Utah, USA, ncss.com/software/pass.

Tests for Two ROC Curves

Numeric Results for Testing AUC1 = AUC2 with Continuous Data

Test Type = Two-Sided. FPR1 = 0.0000. FPR2 = 1.0000. B1 = 1.0000. B2 = 1.0000. Corr+ = 0.6000. Corr- = 0.6000.

Power	N+	N-	Target		Actual		AUC1'	AUC2'	Diff'	AUC1	AUC2	Diff	Alpha
			N	%N+	%N+								
0.12621	163	332	495	33.0	32.9	0.7000	0.7200	0.0200	0.7000	0.7200	0.0200	0.050	
0.37602	163	332	495	33.0	32.9	0.7000	0.7400	0.0400	0.7000	0.7400	0.0400	0.050	
0.70132	163	332	495	33.0	32.9	0.7000	0.7600	0.0600	0.7000	0.7600	0.0600	0.050	
0.91778	163	332	495	33.0	32.9	0.7000	0.7800	0.0800	0.7000	0.7800	0.0800	0.050	
0.98846	163	332	495	33.0	32.9	0.7000	0.8000	0.1000	0.7000	0.8000	0.1000	0.050	
0.99925	163	332	495	33.0	32.9	0.7000	0.8200	0.1200	0.7000	0.8200	0.1200	0.050	
0.99998	163	332	495	33.0	32.9	0.7000	0.8400	0.1400	0.7000	0.8400	0.1400	0.050	
1.00000	163	332	495	33.0	32.9	0.7000	0.8600	0.1600	0.7000	0.8600	0.1600	0.050	
1.00000	163	332	495	33.0	32.9	0.7000	0.8800	0.1800	0.7000	0.8800	0.1800	0.050	
1.00000	163	332	495	33.0	32.9	0.7000	0.9000	0.2000	0.7000	0.9000	0.2000	0.050	
1.00000	163	332	495	33.0	32.9	0.7000	0.9200	0.2200	0.7000	0.9200	0.2200	0.050	
1.00000	163	332	495	33.0	32.9	0.7000	0.9400	0.2400	0.7000	0.9400	0.2400	0.050	
1.00000	163	332	495	33.0	32.9	0.7000	0.9600	0.2600	0.7000	0.9600	0.2600	0.050	
0.25682	163	332	495	33.0	32.9	0.7500	0.7200	-0.0300	0.7500	0.7200	-0.0300	0.050	
0.06433	163	332	495	33.0	32.9	0.7500	0.7400	-0.0100	0.7500	0.7400	-0.0100	0.050	
0.06218	163	332	495	33.0	32.9	0.7500	0.7600	0.0100	0.7500	0.7600	0.0100	0.050	
0.24962	163	332	495	33.0	32.9	0.7500	0.7800	0.0300	0.7500	0.7800	0.0300	0.050	
0.58202	163	332	495	33.0	32.9	0.7500	0.8000	0.0500	0.7500	0.8000	0.0500	0.050	
0.86735	163	332	495	33.0	32.9	0.7500	0.8200	0.0700	0.7500	0.8200	0.0700	0.050	
0.97964	163	332	495	33.0	32.9	0.7500	0.8400	0.0900	0.7500	0.8400	0.0900	0.050	
0.99867	163	332	495	33.0	32.9	0.7500	0.8600	0.1100	0.7500	0.8600	0.1100	0.050	
0.99997	163	332	495	33.0	32.9	0.7500	0.8800	0.1300	0.7500	0.8800	0.1300	0.050	
1.00000	163	332	495	33.0	32.9	0.7500	0.9000	0.1500	0.7500	0.9000	0.1500	0.050	
1.00000	163	332	495	33.0	32.9	0.7500	0.9200	0.1700	0.7500	0.9200	0.1700	0.050	
1.00000	163	332	495	33.0	32.9	0.7500	0.9400	0.1900	0.7500	0.9400	0.1900	0.050	
1.00000	163	332	495	33.0	32.9	0.7500	0.9600	0.2100	0.7500	0.9600	0.2100	0.050	
0.95032	163	332	495	33.0	32.9	0.8000	0.7200	-0.0800	0.8000	0.7200	-0.0800	0.050	
0.78289	163	332	495	33.0	32.9	0.8000	0.7400	-0.0600	0.8000	0.7400	-0.0600	0.050	
0.45807	163	332	495	33.0	32.9	0.8000	0.7600	-0.0400	0.8000	0.7600	-0.0400	0.050	
0.15435	163	332	495	33.0	32.9	0.8000	0.7800	-0.0200	0.8000	0.7800	-0.0200	0.050	
0.02500	163	332	495	33.0	32.9	0.8000	0.8000	0.0000	0.8000	0.8000	0.0000	0.050	
0.14642	163	332	495	33.0	32.9	0.8000	0.8200	0.0200	0.8000	0.8200	0.0200	0.050	
0.45525	163	332	495	33.0	32.9	0.8000	0.8400	0.0400	0.8000	0.8400	0.0400	0.050	
0.80544	163	332	495	33.0	32.9	0.8000	0.8600	0.0600	0.8000	0.8600	0.0600	0.050	
0.96924	163	332	495	33.0	32.9	0.8000	0.8800	0.0800	0.8000	0.8800	0.0800	0.050	
0.99819	163	332	495	33.0	32.9	0.8000	0.9000	0.1000	0.8000	0.9000	0.1000	0.050	
0.99996	163	332	495	33.0	32.9	0.8000	0.9200	0.1200	0.8000	0.9200	0.1200	0.050	
1.00000	163	332	495	33.0	32.9	0.8000	0.9400	0.1400	0.8000	0.9400	0.1400	0.050	
1.00000	163	332	495	33.0	32.9	0.8000	0.9600	0.1600	0.8000	0.9600	0.1600	0.050	

References

- Hanley, J. A. and McNeil, B. J. 1983. 'A Method of Comparing the Areas under Receiver Operating Characteristic Curves Derived from the Same Cases.' *Radiology*, 148, 839-843. September, 1983.
- Obuchowski, N. and McClish, D. 1997. 'Sample Size Determination for Diagnostic Accuracy Studies Involving Binormal ROC Curve Indices.' *Statistics in Medicine*, 16, pages 1529-1542.

Tests for Two ROC Curves

Report Definitions

Power is the probability of rejecting a false null hypothesis.

N+ and N- are the number of items sampled from each population.

N is the total sample size, $N+ + N-$.

Target %N+ is the desired percent (or percents) of the total sample size to be allocated to the + group, as entered in the procedure.

Actual %N+ is the percent in N1 obtained. Because N+ and N- are discrete, this value is sometimes slightly different than the target %N+.

AUC1' and AUC2' are the adjusted areas under the ROC curve for diagnostic tests 1 and 2, respectively.

Diff' is $AUC2 - AUC1$. This is the adjusted difference to be detected.

AUC1 and AUC2 are the actual areas under the ROC curve for diagnostic tests 1 and 2, respectively.

Diff is $AUC2 - AUC1$. This is the difference to be detected.

Alpha is the probability of rejecting a true null hypothesis.

FPR1, FPR2 are the lower and upper bounds on the false positive rates.

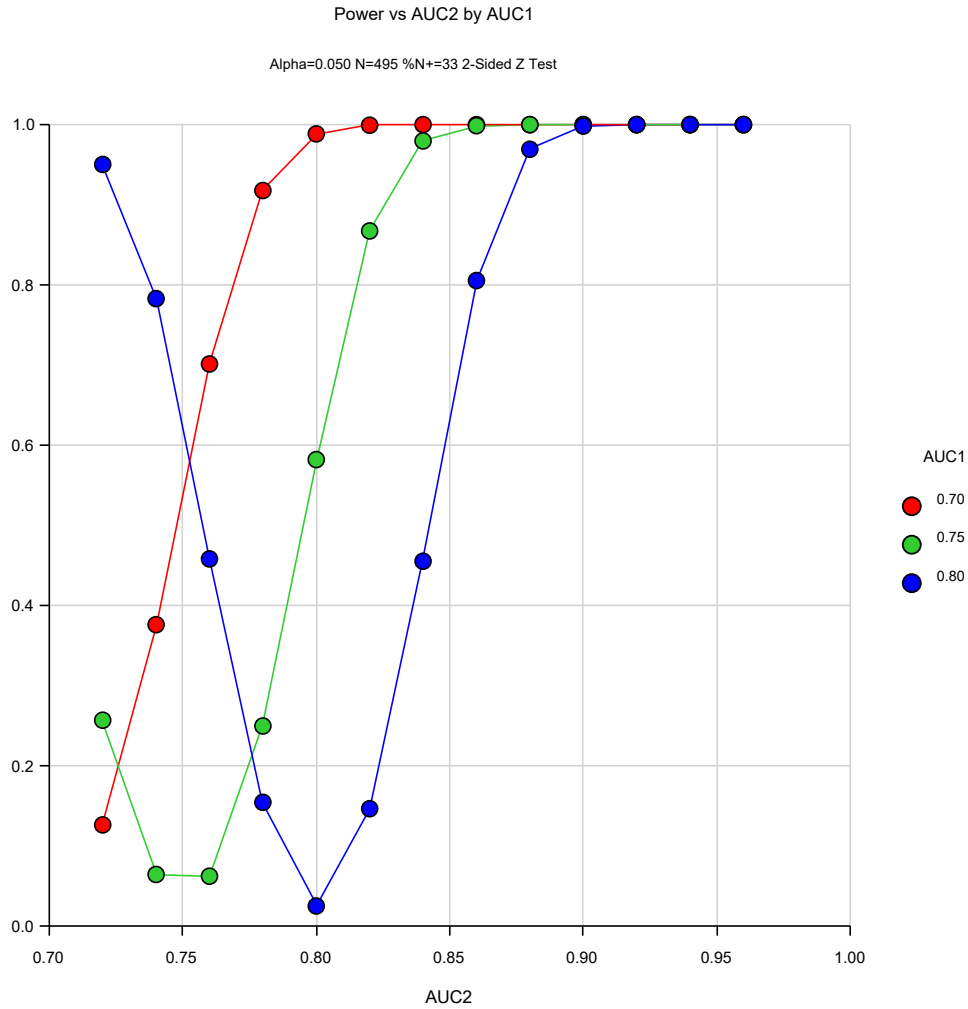
B1 and B2 are the ratios of the standard deviations of the negative and positive groups for each test.

Summary Statements

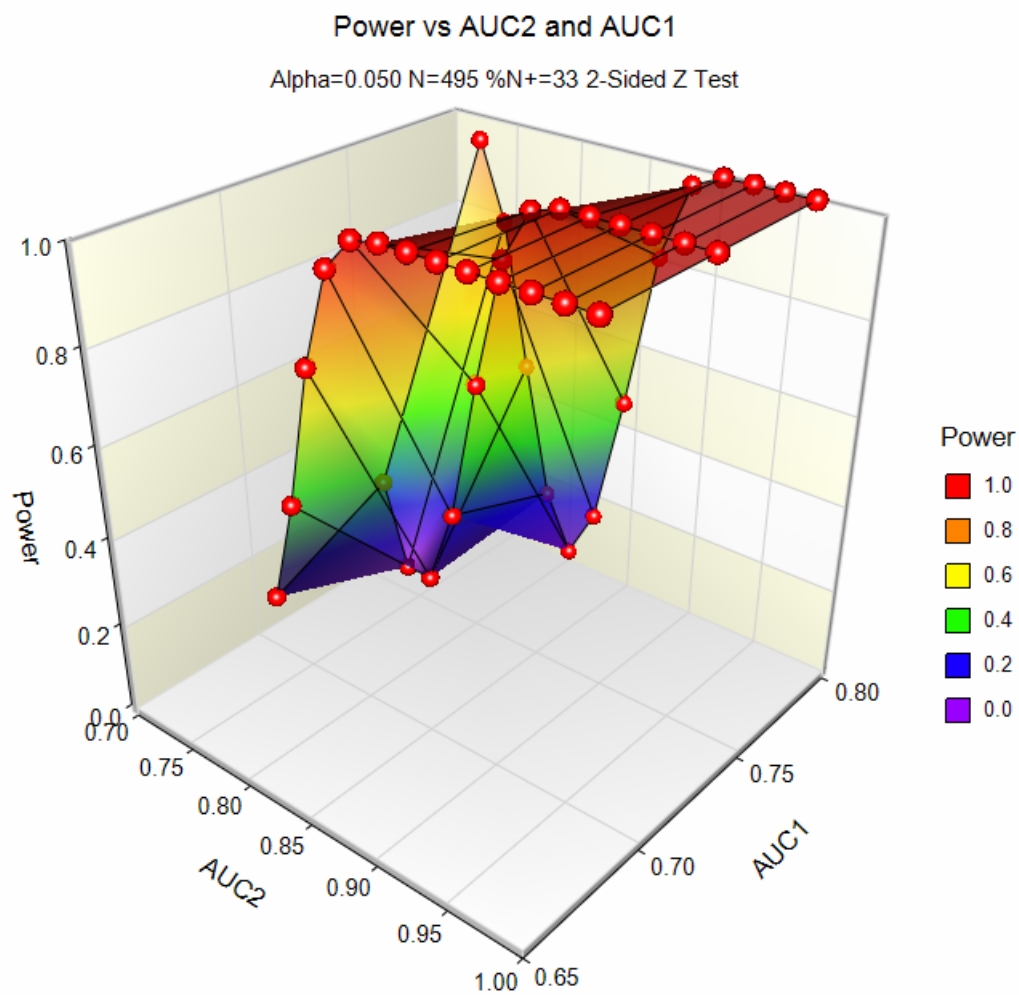
A sample of 163 from the positive group and 332 from the negative group achieve 13% power to detect a difference of 0.0200 between a diagnostic test with an area under the ROC curve (AUC) of 0.7000 and another diagnostic test with an AUC of 0.7200 using a two-sided z-test at a significance level of 0.050. The data are continuous responses. The AUC is computed between false positive rates of 0.00 and 1.00. The ratio of the standard deviation of the responses in the negative group to the standard deviation of the responses in the positive group for diagnostic test 1 is 1.00 and for diagnostic test 2 is 1.00. The correlation between the two diagnostic tests is assumed to be 0.60 for the positive group and 0.60 for the negative group.

Tests for Two ROC Curves

Chart Section



Tests for Two ROC Curves



Tests for Two ROC Curves**Procedure Input Settings**

Autosaved Template File

C:\Users\Nancy Briggs\OneDrive - UNSW\Documents\PASS 2020\Procedure Templates\Autosave\Tests for Two ROC Curves - Autosaved 2023_10_11-13_36_25.t159

Design Tab

Solve For:	Power
Alternative Hypothesis:	Two-Sided Test
Alpha:	0.05
Group Allocation:	Enter total sample size and percentage in Group 1 (+)
Total Sample Size (N):	495
Percent in Group 1 (+):	33
AUC1 (Area Under Curve 1):	0.7 .75 .8
AUC2 (Area Under Curve 2):	.72 to .96 by .02
Type of Data:	Continuous
Correlation+:	0.6
Correlation-:	.6