

Package ‘SampleSizeDiagnostics’

May 7, 2026

Type Package

Title Choosing Sample Size for Evaluating a Diagnostic Test

Version 0.1.1

Description Calculates the sample size needed for evaluating a diagnostic test based on sensitivity, specificity, prevalence, and desired precision. Based on Buderer (1996) <[doi:10.1111/j.1553-2712.1996.tb03538.x](https://doi.org/10.1111/j.1553-2712.1996.tb03538.x)>.

License GPL-3

Encoding UTF-8

RoxygenNote 7.3.3

Suggests testthat, roxygen2, knitr, rmarkdown

VignetteBuilder knitr

NeedsCompilation no

Author Mohamed Kamal [aut, cre]

Maintainer Mohamed Kamal <mohamedkamalhospital@gmail.com>

Repository CRAN

Date/Publication 2025-12-16 22:10:02 UTC

Contents

SampleSizeDiagnostics	1
Index	4

SampleSizeDiagnostics *Calculate Sample Size for Evaluating a Diagnostic Test*

Description

This function calculates the sample size needed for evaluating a diagnostic test based on sensitivity, specificity, prevalence, and desired precision.

Usage

```
SampleSizeDiagnostics(sn, sp, p, w = 0.1, CI = 0.95)
```

Arguments

sn	Sensitivity of the diagnostic test.
sp	Specificity of the diagnostic test.
p	Prevalence of the disease.
w	Desired half-width (margin of error) of the confidence interval. This is the maximum distance from the point estimate to either CI boundary. For example, w = 0.1 means the CI will extend ± 0.1 from the point estimate, creating a total CI width of 0.2. Must be between 0 and 1. (default is 0.10).
CI	Confidence interval level, either 0.95 or 0.9 (default is 0.95). Only 0.95 and 0.9 are allowed.

Details

Abstract of Buderer (1996): Careful consideration of statistical issues related to the choice of a sample size is critical for achieving meaningful results in research studies designed to evaluate diagnostic tests. When assessing the ability of a diagnostic test to screen for disease, the parameters sensitivity, specificity, and predictive values are of interest. Study sample size requirements can be calculated based on a clinically acceptable degree of precision. the hypothesized values of sensitivity and specificity, and the estimated prevalence of disease in the target population. The simple methods and tables in this paper guide the researcher when deciding how many subjects to sample in a study designed to estimate both the sensitivity and the specificity of a diagnostic test, given a specified precision and estimated disease prevalence.

Value

A data frame containing the calculated sample sizes and input parameters:

Precision Desired half-width of the CI (margin of error). Total width = $2 \times$ Precision

Sensitivity Sensitivity of the diagnostic test

Specificity Specificity of the diagnostic test

Prevalence Prevalence of the disease

SS_sensitivity Sample size for sensitivity

SS_specificity Sample size for specificity

Total_Sample_Size Total sample size needed (maximum of ss_sensitivity and ss_specificity)

CI Confidence interval level

References

Buderer, N. M. F. (1996). Statistical methodology: I. Incorporating the prevalence of disease into the sample size calculation for sensitivity and specificity. *Academic Emergency Medicine*, 3(9), 895-900.

Examples

```
SampleSizeDiagnostics(sn = 0.9, sp = 0.85, p = 0.2, w = 0.1, CI = 0.95)
```

```
SampleSizeDiagnostics(sn = 0.9, sp = 0.85, p = 0.2, w = 0.1, CI = 0.9)
```

Index

SampleSizeDiagnostics, 1