

## Sample Size Calculation for Screen-Positive Designs of Screening Tests

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Screening is defined as the presumptive identification of unrecognized disease or defect by the application of tests, examinations or other procedures, which can be applied rapidly. Before a new disease screening test is performed for public use, its accuracy should be shown to be superior than or not inferior to a standard test. The basic comparison of two screening test is to apply both screening tests and the gold standard test to all subjects. After this process the accuracy of each screening test (TPR and FPR) would be estimable. But in some situations it is not possible to apply the gold standard test to all subjects so determination of disease status is not possible. Screen-positive designs are effective for this condition. There are three screen-positive designs are defined: Paired screen positive design (PSP), unpaired screen positive design (USP), randomized paired screen positive design (RPSP). In PSP design all subjects receive both screening tests but only have the gold standard test if one of the screening tests is positive. In USP design each subjects receive one of the two screening tests and the gold standard test only if the screening test is positive. In RPSP design subjects are randomized to receive one of the two screening tests first, and only receive the other screening test and gold standard test if the first screening test is positive. Sample sizes to be taken for these designs are different. Sample size formulae will be applied to the various types of screening example and the efficiency of these designs will be compared with each other.