

Diagnostic Sensitivity and Specificity for Clinical Laboratory Testing

This job aid reviews basic information about diagnostic sensitivity and specificity for clinical laboratory testing. Clinicians and those performing point-of-care tests need to understand the basics of how clinical performance characteristics of laboratory tests help healthcare providers select appropriate tests for clinical needs and interpret test results.

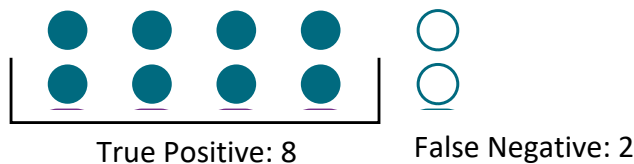
Defining Diagnostic Sensitivity and Specificity

sen-si-tiv-i-ty: ability of the test to identify the **presence** of a disease or illness correctly.

Sensitivity values are associated with **true positives** and **false negatives**.

- **True positive** - the individual has the disease or illness and the test results are positive.
- **False negative** - the individual has the disease or illness, but the test results are negative.

When a test's sensitivity is high, it is more likely to give a true positive result and correctly detect the disease or illness when it is present. A test with low sensitivity is more likely to produce a high number of false negatives and may miss identifying disease or illness in individuals when it is present.



Number of True Positives = 8

Number of True Positives + Number of False Negatives = 10

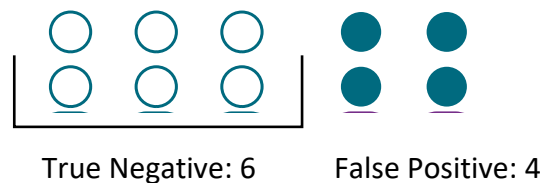
Sensitivity Value: 8/10 or 80%
(proportion of true positive test results among individuals who have disease or illness)

spec-i-fic-i-ty: the ability of the test to identify the **absence** of a disease or illness correctly.

Specificity values are associated with **true negatives** and **false positives**.

- **True negative** - the individual does not have the disease or illness and the test results are negative.
- **False positive** - the individual does not have the disease or illness, but the test results are positive.

When a test's specificity is high, it is more likely to give a true negative result and correctly identify that the disease or illness is not present. A test with low specificity is more likely to produce a high number of false positives and may incorrectly identify disease or illness in individuals when it is not present.



Number of True Negatives: 6

Number of True Negatives + Number of False Positives = 10

Specificity Value: 6 / 10 or 60%
(proportion of true negative test results among individuals who do not have the disease or illness)

How Diagnostic Sensitivity and Specificity Determine Test Selection

While ideal, 100% accuracy of any test is nearly impossible due to the limitations of the test, quality of the specimen, and the potential for operator or equipment errors. Therefore, tests aim to reach sensitivity and specificity values that are high and reliable (consistent in producing accurate results over multiple tests). Understanding how sensitivity and specificity impact test results and test interpretation can help to inform clinical decision-making.

Clinicians often need help in understanding the intrinsic qualities of a diagnostic laboratory test to correctly identify patients with disease. When a diagnostic test has high sensitivity and specificity, that means the test has a high likelihood of accurately identifying those with disease and those without disease (or illness).

For example, a test with 95% sensitivity will generate a positive result for 95% of people with the disease but will return a negative result (a false negative) for 5% of people who actually have the disease. Similarly, a test with 95% specificity will generate a negative result for 95% of people without the disease but will return a positive result (a false positive) for 5% of people who do not have the disease.

The test of choice may vary based on the disease being diagnosed. Both sensitivity and specificity are important when selecting the most appropriate test for a particular disease and clinical situation. A clinician often relies on the laboratory’s help to choose and interpret a diagnostic test.

For details on test recommendations, appropriate testing timeframes, and whether retesting should be considered, refer to your site’s standard operating procedures, test manufacturer’s instructions, and clinical testing guidelines or public health testing guidance (if available).

Diagnostic Sensitivity and Specificity Comparison by Type of Test

| | Molecular Tests | Antigen | Antibody |
|--------------------------|---|--|---|
| Also known as... | Molecular test, diagnostic test, viral test, nucleic acid amplification test (NAAT), reverse transcription-polymerase chain reaction (RT-PCR) test | Diagnostic test, viral test, rapid test, rapid antigen test | Serological test, serology, blood test |
| Intended Use | Detects current infection | Detects current infection | Detects previous infection |
| Sensitivity | Varies by test, but generally high for laboratory-based tests and moderate-to-high for point-of-care tests | Varies depending on antigen levels, but generally moderate-to-high at times of peak viral load | Varies, but generally low depending on the course of infection |
| Specificity | High | High | High |
| Retesting Needed? | Not usually. This type of test is typically highly accurate and usually does not need to be repeated. Some tests may indicate the need to re-test in certain circumstances based on additional clinical review. | Possibly. Positive results are usually highly accurate, but negative results may need to be confirmed with a molecular test based on additional clinical review. | Possibly. A second test may be needed to confirm results based on additional clinical review. |