

COVID-19 Diagnostic test performance explained

Test performance is usually characterized by:

- > **Sensitivity** – This is the ability of the test to detect disease state, defined as the proportion of positive results from a pool of true positive specimens.

How is this calculated?

In 100 specimens from true positive cases, if diagnostic test reads **POSITIVE in 95** specimens and **NEGATIVE in 5** specimens, then sensitivity = **95%**

- > **Specificity** – This is the ability of the test to correctly characterize absence of disease, defined as the proportion of negative results from a pool of true negative specimens

How is this calculated?

In 100 specimens from true negative persons, if diagnostic test reads **NEGATIVE in 96** specimens and **POSITIVE in 4** specimens, then specificity = **96%**



How specificity and sensitivity relate to a population:

Positive Predictive Value (PPV):

- > This is the probability (expressed as a percentage) that a POSITIVE test result reflects true disease.

Negative Predictive Value (NPV):

- > This is the probability (expressed as a percentage) that a NEGATIVE result reflects true absence of disease.

PPV and NPV depend upon the specificity and sensitivity of the assay AND upon the prevalence of disease in the population being tested.

Here are examples:

1. A COVID-19 diagnostic assay has a sensitivity = 80% and specificity = 97.5%

Case (a)

Test 1000 people with the symptoms of respiratory virus infection from a defined community. There is a moderately high community transmission.

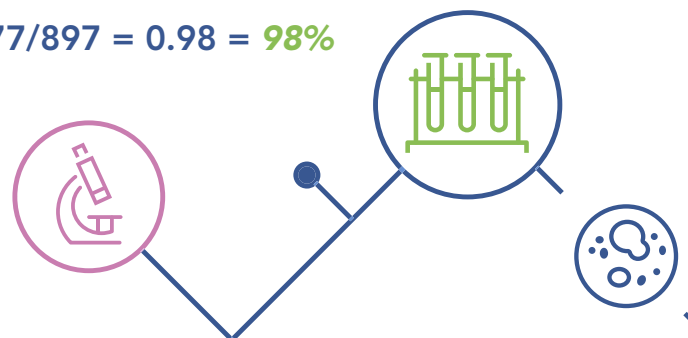
The disease prevalence = 10% (100 have disease, 900 do not)

		TRUE DISEASE		
		POS	NEG	
TEST RESULT	POS	80	23	103
	NEG	20	877	897
		100	900	1,000

Sens= 80% Spec= 97.5%

$$\text{PPV} = \text{True positives} / \text{Total positives} = 80 / 103 = 0.78 = 78\%$$

$$\text{NPV} = \text{True negatives} / \text{total negatives} = 877 / 897 = 0.98 = 98\%$$



Case (b)

Test 1000 asymptomatic people from a defined community. There is a low/controlled community transmission.

The disease prevalence = **0.5%** (5 have disease, 995 do not) Asymptomatic people

		TRUE DISEASE		
		POS	NEG	
TEST RESULT	POS	4	25	29
	NEG	1	970	971
		5	995	1,000

Sens= 80% Spec= 97.5%

PPV = True positives/Total positives = $4/29 = 0.14 = 14\%$

NPV = True negatives/total negatives = $970/971 = 1 = 100\%$

2. A COVID-19 diagnostic assay has a sensitivity = 80% and specificity = 97.5%

Case (c)

Test 1000 asymptomatic people from a defined community. There is a low/controlled community transmission.

		TRUE DISEASE		
		POS	NEG	
TEST RESULT	POS	4	25	29
	NEG	1	970	971
		5	995	1,000

PPV = True positives/Total positives = $4/6 = 0.67 = 67\%$

NPV = True negatives/total negatives = $990/991 = 1 = 100\%$

Key takeaway:

In a low prevalence population, a diagnostic test must have very high specificity or else the vast majority of positives will be false positives (low PPV).

