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Laboratory statistics and its impact on your practice

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Introduction

Laboratory tests are used in the detection, diagnosis or monitoring of disease. Within this context, asymptomatic patients are tested to confirm or identify disease whereas symptomatic patients are tested to confirm or identify disease.

The decision on whether a test result is normal or abnormal is based on the use of reference intervals in normal and abnormal populations. If these values overlap, false-positive and false-negative results are obtained (figure 1).

It is essential to understand which factors may affect our interpretation of results to ensure that the clinical decisions made based on these results, are correct.

Variability of results in normal patients

Variability is a function of what happens within patients and what happens within the laboratory. Within patients, there are two important variables.

Firstly, inter-individual variation is a function of the fact that each person has a 'normal' setpoint of specific values of their laboratory parameters.

Secondly, intra-individual variability is the degree of variation that occurs within a single patient over time.

This may be a function of cyclical physiological changes (notably hormone levels or circadian influences) or less defined fluctuation over time.

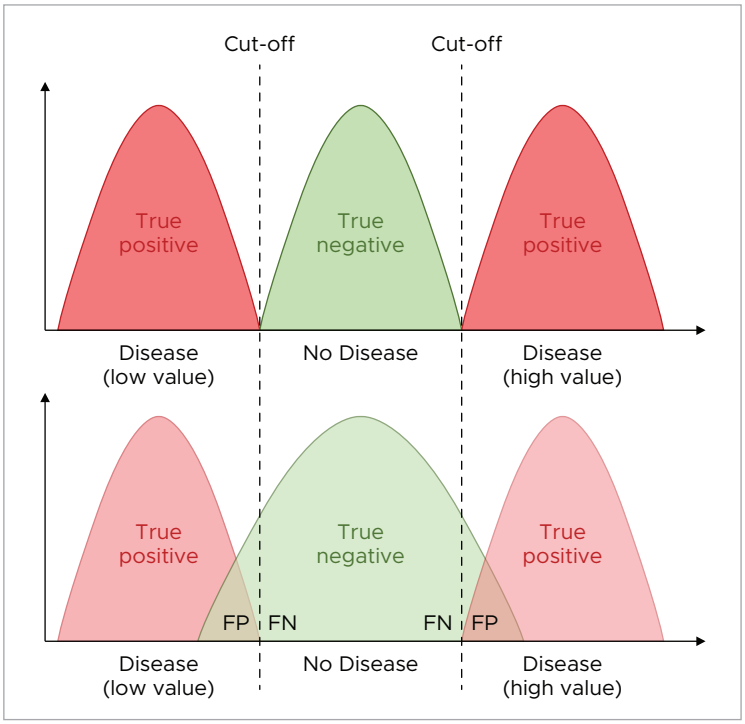

Figure 1. The clarity between the distribution curves determine to what degree an assay will be prone to false positive (FP) or false negative (FN) results.

From a laboratory perspective, variability occurs as a function of the test assay.

Each assay has a specified inherent uncertainty.

As an example, if you use a highly sensitive scale to weigh yourself, and you repeat this 20 times, there will be a degree of difference between these measurements.

This is referred to the inherent uncertainty of measurement of the method.

Within a laboratory, the value of uncertainty is quantified for every laboratory test at various levels to ensure that this does not impact on the interpretation of results.

Diagnostic accuracy

The accuracy of a test is the ability to distinguish between disease and non-disease states.

This is often expressed as sensitivity and specificity.

Sensitivity expresses the ability to detect disease amongst the ill, therefore stated as the proportion of those with disease in which the test is positive.

The specificity expresses the ability to detect the absence of disease in those that do not have it, therefore stated as the proportion of those without disease in whom the test is negative (Table 1).

Population of hospital patient = 1000

Prevalence of virus X in population = 0,5%

Therefore 50/1000 have virus X, and 950 do not.

Laboratory test for Virus X
Validation testing reveal the following:

	Positive	Negative
Positive	196	180
False	20	4

Sensitivity = TP / (TP + FN) x 100
= 98%
Specificity = TN / (TN + FP) x 100
= 90%

Predictive value

True positive = 50 patients x 0,98 sensitivity	= 49
False negative = 50 - 49	= 1
True negative = 950 non-patients x 0,90 specificity	= 855
False positive = 950 - 855	= 95

One patient with virus X will test negative.

95 patients without virus X will test positive.

Predictive value of a positive test
= TP / (TP + FP) x 100 = 49 / (49 + 95) = 35%
Predictive value of a negative test
= TN / (TN + FN) x 100 = 855 / (855 + 1) = 100%

Efficiency
= (TP + TN) / (TP + TN + FP + FN) x 100 = 90%

Table 1. Practical example to illustrate

The predictive value of a test is much more useful in a clinical setting as it provides a more tangible guide to the clinician in their decision process.

The predictive value makes use of sensitivity and specificity parameters of the test, but also the prevalence of the condition. This can be expressed both as predictive value of a positive or a negative test for your patient. The usefulness of the assay can use all these parameters to express the so-called efficiency.

Conclusions

The true aim in design of a specific laboratory test should be known and understood prior to submitting a patient to its results.

Screening tests overestimate disease with the proviso that these should be confirmed. Diagnostic tests may miss certain cases, but if found positive, serves as confirmation.

It is essential to understand what a test is used for, and what the current epidemiology is to ensure the necessary caution in interpretation.

Fortunately, this is quite stable for most diseases, however as noted in the COVID-19 pandemic, epidemiology rapidly shifted, which altered the approach to testing and vaccine strategies.

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