

Understanding Sensitivity and Specificity

Applies to the following: ALL SQA-V (V, Vb, Ve, Vp and Vt)
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OVERVIEW:

Sensitivity and Specificity are the elements that are used to perform what is called "ROC" analysis. (ROC = **receiver operating characteristic**). ROC statistical analysis analyzes TRUE and FALSE POSITIVE and NEGATIVE clinical/disease test results as defined below:

- TN - True Negative (correctly classified as negative in absence of disease)
- TP - True Positive (correctly classified as positive in presence of disease)
- FN - False Negative (not correctly classified as negative in presence of disease)
- FP - False Positive (not correctly classified as positive in absence of disease)

Further: In semen analysis, the "presence of disease" is related to abnormal semen test results. And the "absence of disease" is related to normal levels of semen test results.

- **Sensitivity** shows the **% probability** that a test result will be positive when the disease is present (TRUE POSITIVE) based on this formula: $TP / (TP + FN) * 100\%$
- **Specificity** shows the **% probability** that a test result will be negative when the disease is not present (TRUE NEGATIVE) based on this formula: $TN / (TN + FP) * 100\%$

APPLICATION IN STUDIES:

When comparing a new method of analysis to the standard (or existing) one, the results of the standard method (for example, manual) are accepted as the "true value" and the results of the new method are classified (graded) vs. these "true values" by using the reference cutoffs published by the WHO manual.

The following 4 combinations are possible:

- Both results are below the cutoff – TP (TRUE POSITIVE)
- Both results are above the cutoff – TN (TRUE NEGATIVE)
- Standard method shows result below the cutoff and the new method above – FN (FALSE NEGATIVE)
- Standard method shows result above the cutoff and the new method below – FP (FALSE POSITIVE)

Finally Sensitivity and Specificity are calculated from the numbers representing each combination. For statistically significant outcome, the sufficient number of observations equally representing normal and abnormal cases is required.

Example:

Morphology Reference Cutoff, %						15
MORPHOLOGY, %		Morph. Grade			Morph. Grade Final	
SQA-V	Manual					
47.0	34.0		TN			TP 7
8.0	7.0				TP	TN 9
3.0	5.0				TP	FP 1
20.0	23.0		TN			FN 1
12.0	34.0	FP				
25.0	32.0		TN			Sensitivity = $TP / (TP + FN) * 100$
13.0	14.0				TP	87.5%
10.0	12.0				TP	Specificity = $TN / (TN + FP) * 100$
0.0	0.0				TP	90.0%
30.0	10.0			FN		
64.0	54.0		TN			
25.0	23.0		TN			
42.0	40.0		TN			
36.0	30.0		TN			
9.0	8.0				TP	
36.0	31.0		TN			
7.0	6.0				TP	
38.0	26.0		TN			

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