

## Making Sense of Biostatistics: Receiver Operating Characteristic Curves

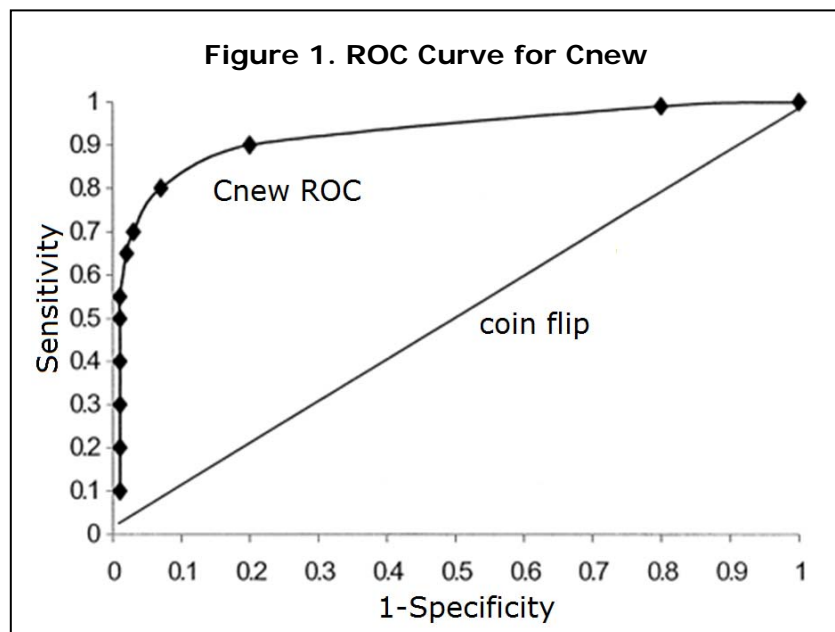
By Ronald E Dechert

Biomarker tests can help differentiate patients who have a disease or condition from those who do not. Each time a new biomarker or other test is developed, clinicians need to know the accuracy of the test. One method that can be employed to assess the accuracy of a new test is to construct a Receiver Operating Characteristic (ROC) curve.

Let us assume that Dr. Smith has developed a new biomarker (Cnew) that tests for the presence of colon cancer. In animal studies, Dr. Smith determined that the higher the value of Cnew, the more likely it is that the animal has colon cancer, even if the cancer is undetectable by other methods. Dr. Smith wants to evaluate the accuracy of this new test in human subjects. He therefore recruits 300 subjects and screens them for colon cancer. He also obtains a blood sample to determine each subject's Cnew value. Using logistic regression modeling, Dr. Smith determines that Cnew is an independent predictor of colon cancer but not the test's accuracy. To assess its accuracy, he constructs a Receiver Operating Characteristic (ROC) curve.

ROC curves are derived from the sensitivity and specificity of the test. Sensitivity is the probability of the test being positive (in this case a higher value) when the disease is present, while specificity is the probability of the test being negative (or lower value) when the disease is absent. The ROC curve plot in Figure 1 shows sensitivity on the vertical axis against 1-specificity on the horizontal axis.

If a test is no better at predicting a disease than flipping a coin, the ROC curve for that test would be represented by the diagonal line. A test that has a high degree of discrimination between the presence and absence of a disease will have an ROC curve that is shifted to the left. The closer the ROC curve is to the upper left corner of the plot, the higher the accuracy of the test. The ROC curve from Dr. Smith's analysis (Cnew ROC) demonstrates a significant shift to the left of the diagonal line, so the new test is highly accurate; it is both sensitive and specific.



Another way to determine the overall discrimination of a test is to examine the Area-Under-the-Curve (AUC), which is calculated as part of the ROC analysis. The AUC from Dr. Smith's analysis is 0.969. This result suggests that Dr. Smith's new test (Cnew) has a significant ability to correctly classify patients as having colon cancer or not having colon cancer. Table 1 categorizes the quality of a test based on AUC scores.

Based on the results of these findings, Dr. Smith believes that Cnew is a very accurate biomarker test for the detection of colon cancer and will allow excellent discrimination of patients with or without the disease.

**Table 1. AUC Quality Ranges**

<b>AUC Range</b>	<b>Test Quality for Discriminating Between Disease and Non-Disease Patients</b>
0.90-1.00	Excellent
0.80-0.89	Good
0.70-0.79	Fair
0.60-0.69	Poor

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