

# Precision, Accuracy, and Total Analytical Error

The National Cholesterol Education Program (NCEP) makes recommendations for analytical performance goals based on total analytical error (TE). This approach takes into account both accuracy and precision. The total error recommendations of the NCEP for lipids are:

Analyte	Total Error Goals
Total Cholesterol	≤ 8.9%
HDL Cholesterol	≤ 13%
Triglycerides	≤ 15%
LDL Cholesterol	≤ 12%

These guidelines are based both on the state of the art of laboratory testing methods, and the test performance required to fulfill clinical needs. The purpose of this technical bulletin is to explain total error, its relationship to precision and accuracy, and how it relates to the results you can expect for each patient you test.

## What are Precision and Accuracy?

A dart board is a good way to illustrate precision and accuracy.

Accuracy refers to the extent that all measurements agree with the true value of what is being measured.

Accuracy refers to how close a value is to the true value. The % difference from the true method is called the bias.

Precision refers to the magnitude of random errors and the reproducibility of measurements. In other words, if you run a test many times on the same sample, precision will be a measure of how close all the test results are to each other. Figure 1 shows results that are both precise (close together) and accurate (close to the true value.)

Figure 2 illustrates a series of results that are again very precise, but this time they are all clustered away from the “bulls eye”, so they are not accurate (e.g. the TC results for a new method are consistently clustered away from the reference assay result).

In Figure 3, you can see that the results are scattered around the “bulls eye”, but only one of them is on the mark. This illustrates that a test can't really be very accurate, unless it is precise.

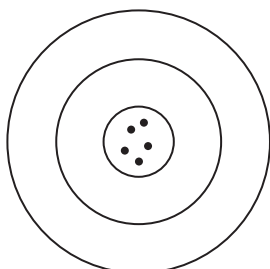


Figure 1

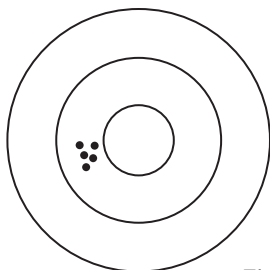


Figure 2

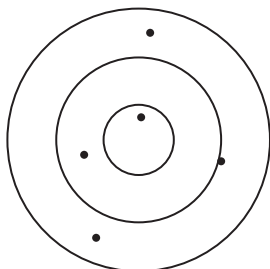
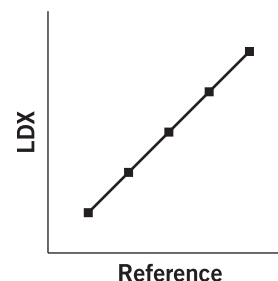


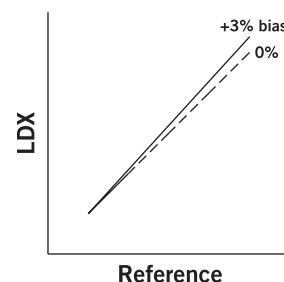
Figure 3

## So, How Do We Determine Accuracy?

One way to assess the accuracy of a test method is to compare its results to a known actual value, or a value from a test method that is known to be very accurate. Let's use results from a TC comparison as an example. A plot of the results for the Cholestech LDX®, on the vertical (y) axis and the reference assay results on the horizontal (x) axis, for a “perfect” system (0% inaccuracy) would look like this:



For a system that has a bias (inaccuracy) of +3%, we will get a graph that looks like this:

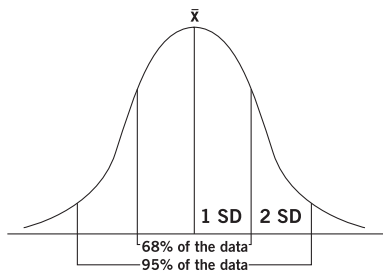


## What About Precision?

Precision is usually discussed in terms of the standard deviation (SD) and percent coefficient of variation (%CV).

Standard deviation is a measure of the variability (scatter of a method). Its

value is expressed in the same units as the data points (e.g. mg/dL). SD is used when the results fall into a normal distribution (bell shaped curve) as illustrated below:



So 68% of the results will fall into the range of the mean  $\pm$  1 SD and 95% of the results will fall into the range of the mean  $\pm$  2 SD.

$$1 \text{ SD} = \sqrt{\frac{\sum(x - \bar{x})^2}{n - 1}}$$

See Figure 4 for a calculation of the SD for a few total cholesterol values.

### Coefficient of Variation

% CV also looks at the variability of data points. The % CV describes the SD as a percent of the average value. This provides a means for comparison with other test methods, and makes it easier to compare variations in one group of test results with another group of test results. The 3% precision

guideline of the NCEP refers to the % CV.

$$\% \text{ CV} = 1 \text{ SD} / \bar{x} \times 100$$

Here is the calculation for the data set from above:

$$\% \text{ CV} = (5.9/200) \times 100 = 3.0\%$$

A % CV of 3% for precision means that 68% of the results will fall in the range of the Mean  $\pm$  1 SD or the Mean  $\pm$  3%. Since we want to know what will happen "most of the time", for 95% of the results, we will look at the Mean  $\pm$  2 SD or the Mean  $\pm$  6%.

Let's use a control material with a mean of 200 mg/dL for total cholesterol and a % CV of 3% as an example. The SD will be 200 mg/dL x 3% = 6 mg/dL.

95% of the results will be in the range:

$$\begin{aligned} &\text{Mean (200 mg/dL) } \pm 2 \text{ SD} \\ &\quad (2 \times 6 \text{ mg/dL}) \\ &200 \text{ mg/dL } \pm 12 \text{ mg/dL} \\ &\text{Range} = 188 \text{ to } 212 \text{ mg/dL} \end{aligned}$$

If we run this control material 100 times, 95 of the results will be in the range 188-212 mg/dL. Five (5) of the results may fall outside of this range.

### Total Error

What can we expect if we run one sample, one time? To figure that out, we need to combine the precision and the accuracy to determine the total error:

$$\text{TE} = \% \text{ Bias} + 1.96 \times \% \text{ CV}$$

So for our total cholesterol example:

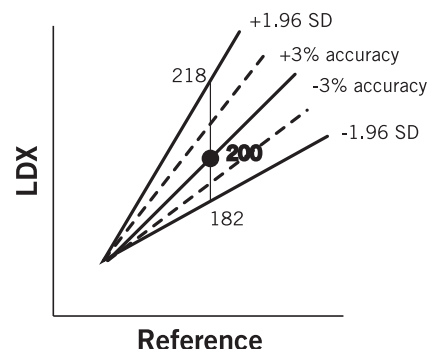
$$\text{TE} = 3\% + 1.96 \times 3\% = 8.9\%$$

So for a TC of 200 mg/dL:

$$\begin{aligned} 200 + 8.9\% \times 200 &= 182 \\ 200 - 8.9\% \times 200 &= 218 \end{aligned}$$

95% (2 SD) of the time, the results will be within **182-218 mg/dL**.

5% of the time, results may be below **182** or above **218 mg/dL!**



When you consider the variability due to accuracy and precision, and the biological variability (how much your cholesterol varies over time) which may be as much as another 10%, you can see why it is important to measure cholesterol more than once to really know your "number"!

**If you have further questions,  
please call Technical Service:  
800-733-0404**

Figure 4

Sample #	Test Results (x)	x - $\bar{x}$	(x - $\bar{x}$ ) <sup>2</sup>
1	200 mg/dL	0	0
2	208 mg/dL	8	64
3	204 mg/dL	4	16
4	193 mg/dL	-7	49
5	197 mg/dL	-3	9
			138

$$x = \text{mean} = 200 + 208 + 204 + 193 + 197 = 1002/5 = 200$$

$$\text{Therefore: } 1 \text{ SD} = \sqrt{\frac{138}{5-1}} = \sqrt{34.5} = 5.9 \text{ mg/dL}$$

$$2 \text{ SD} = 2 \times 5.9 = 11.8 \text{ mg/dL}$$