Accuracy and Precision

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

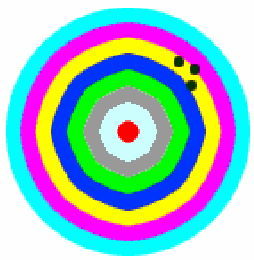

Fig. 1 Precision

Precision is the strength of agreement between replicate measurements. It tells us how close multiple values are to each other. It 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 illustrates a series of results that are very close to each other i.e. have good precision.

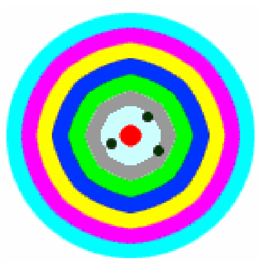

Fig. 2 Accuracy

Accuracy is a measure of the agreement between the estimates of a value and the "true" value. Accuracy refers to how close a value is to the "true" value. Figure 2 illustrates a series of results that are accurate i.e. close to true value.

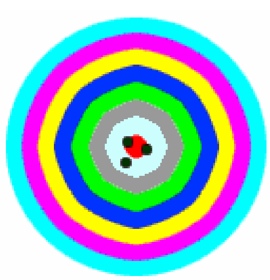

Fig. 3 Total Error

Total Error takes into account the combined effect of accuracy and precision. Figure 3 illustrates total error i.e. results that are close to each other and to the true value.

Measuring Precision

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

Standard Deviation is a measure of the variability (scatter of a method). It is used when the results fall into a normal distribution (bell shaped curve) as illustrated in Figure 4.

Fig. 4 Normal Distribution Curve

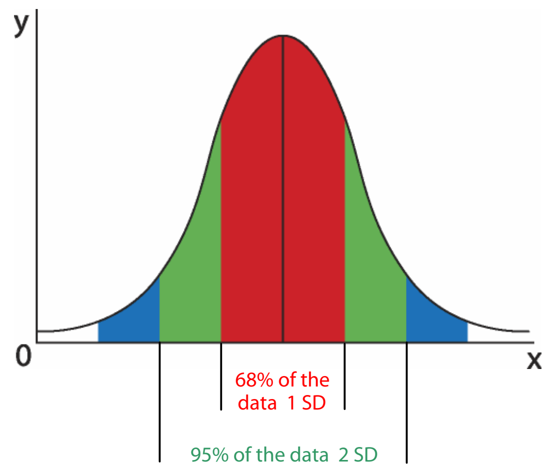

Figure 4 illustrates that 68% of the results will fall into the range of the Mean $\pm$ 1 SD and 95% of the results will fall into the range of Mean $\pm$ 2 SD.

Coefficient of Variation looks at the variability of data points. The %CV describes the SD as a percent of the average value.

The INRatio system %CV has been determined at <u>11%</u> for Normal results, and at <u>10%</u> for results in the Therapeutic range.

Let us consider a sample with a mean of 2.0 INR and a %CV of 10% as our example. The SD will be 0.2 INR.

95% of the results will be in the range of $\pm$2SD (2 x 0.2=0.4). That means the range will be, 2.0 $\pm$ 0.4 = 1.6 to 2.4 INR

It follows naturally that at higher INR results the range will widen. For example INR of 4.0 with 10%CV will give us a range of 3.2 to 4.8 INR.
Explained by the calculation:
4.0 $\pm$ 0.8 {2 x 0.4} = 3.2 to 4.8 INR

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Measuring Accuracy – Linear Regression

Accuracy is frequently measured by looking at the slope of the linear regression line. This is obtained by plotting the values from the reference system versus those obtained on the test system (usually a new system). The closer the slope is to 1.0, the more accurate the test system is relative to the reference.

Figure 5 illustrates the linear regression plot of INR values obtained from the INRatio compared to INR values from the MLA Electra 900c. The slope of the regression line is 0.95 indicating that the INRatio system was accurate when compared to the MLA 900c in this study.

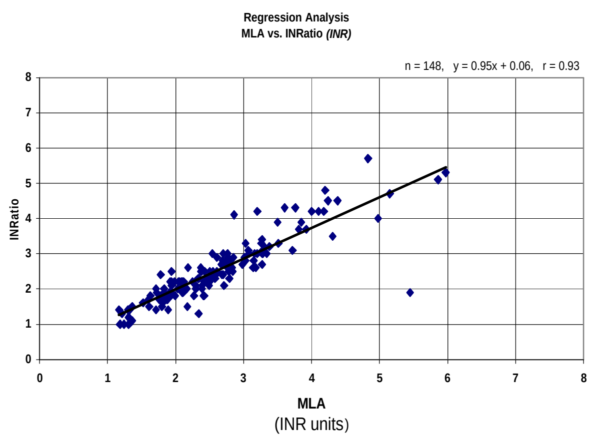

Fig. 5 Linear Regression Plot

Measuring Accuracy – Bias Plot

Another way to look at accuracy is using a bias plot. A frequently used type of bias plot is the Bland Altman. The use of the Bland-Altman analysis serves as a valuable statistical tool for the practicing clinician because it assumes that neither system is a "gold standard"; it is only a comparison between the two systems.

The mean of the results from the reference and test methods is plotted against the difference between the reference and test results. The accuracy is assessed by looking at how close the data points are to the x axis and whether there is a trend as the value on the x axis increases.

Figure 6 illustrates a Bland Altman plot for INR values from the INRatio compared to the INR values from the MLA Electra 900c. The graph shows that the majority of the difference values (MLA INR – INRatio INR) fall within ± 0.5 INR units of the x axis and there is no trend in the data as the mean INR increases.

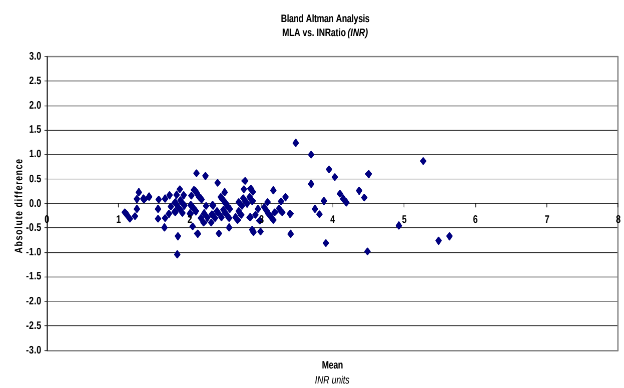

Fig. 6 Bland Altman Plot

Conclusion

The data shown in Figures 5 and 6 demonstrate that the HemoSense INRatio Prothrombin Time Monitoring System compares closely to the well established laboratory instrument, the MLA Electra 900C using both regression and Bland-Altman analyses.

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