INRATIO® Tech Support **Update**

Evaluation Guidelines

Purpose

These guidelines provide the basis for a well-organized evaluation. When completed it should demonstrate acceptable performance of the HemoSense PT INRatio System and give an indication of how the test results obtained on the INRatio System compare to a reference method. Many pre-analytical variables may affect the results of routine coagulation assays. To better assess the performance of any method, it is important to identify these variables and to assess their impact on the test results. Pre-analytical variables pertinent to routine coagulation testing can be classified into three major categories: specimen collection, specimen transportation and storage, and specimen processing. Adherence to the guidelines established by the National Committee of Clinical Laboratory Standards serves to minimize the effects of pre-analytical variability.[1]

Influencing Factors In Evaluation

Sample Type selection of is critical to conducting a successful evaluation. It is best to compare same sample types. The INRatio system uses Finger Stick whole blood while a reference lab uses plasma. This difference in sample type can give some variability in the evaluation.[3]

Sample Tube type is also important. The World Health Organization (WHO) and the National Committee for Clinical Lab Standards (NCCLS) recommend using 3.2% (0.109 mol/L) blue top plastic tubes.[2]
Knowledge of the equipment used by the reference lab and the **lab reagents** is important. Variations in thromboplastin type and sensitivity may be responsible for bias seen between methods.

Sample Handling is extremely important to ensure the validity of the evaluation. Samples should be collected within an hour of each other.[4] The draw tube should be centrifuged to produce a platelet poor plasma aliquot. These should be frozen on dry ice if they will be stored for more than a few days or shipped to another site.

Sample Volume: Under filling of the sample tube causes higher citrate concentration in the plasma and this may cause erroneous results. Tubes should be filled to at least 90% of their capacity.

Number of samples

There are several pre-analytical and analytical factors which can influence a result so that it does not reflect the patient's actual PT/INR. Confidence in the results will increase with the number of samples run. Normally, we recommend testing **at least 20 samples**.

Remember that correlation tests between instruments should be performed over the **reportable range** of the instrument.

Interpretation of Results

This performance evaluation should raise your confidence in the INRatio System's ability to give accurate results. Because of the varying sensitivities of PT reagents, and different methodologies used on coagulation instrumentation, results obtained using various combinations of instrument/reagent systems will differ. While no two coagulation instrument/reagent systems produce results that match exactly, systems can be correlated to provide statistically acceptable results so as not to alter the overall clinical interpretation of the test results.[5]

Data Analysis

Data should be analyzed using regression analysis. The INRatio results should be compared to the laboratory results. The correlation coefficient (r), slope and offset will be determined for the data set.[6]

It is important to bear in mind that the correlation coefficient might be vary depending upon the reference instrument, whether it is a Lab analyzer or another POC analyzer.

On the next page are some evaluations done against a Sysmex 1500, MLA 1000, Biomerieux, Amax 190+, Roche Coagucheck S and the ITC Protime.

Conclusion

The results from the INRatio system compared well to the results from these systems. An overall mean correlation coefficient or the **R value is 0.94**
This was obtained with no exclusions for outliers. These studies confirm that the INRatio System compares well to established laboratory standard instruments as well as the POC instruments.

References

1. NCCLS Document H21-A2. Collection, transport, and processing of blood specimens for coagulation testing and performance of coagulation assays, 3rd ed. Approved Guideline, 1998.
2. Reneke J Etzell J, Leslie S Ng VL and Gottfried EL (1998): Prolonged PT and APTT due to underfilled specimen tubes with 3.2% citrate anticoagulant. AM J Clin Pathol 109(6):754-757.
3. NCCLS. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline. NCCLS document EP9-A (ISBN 1-56238-283-7).
4. NCCLS. How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline---Second Edition. NCCLS document C28-A2 (ISBN 1-56238-406-6).
5. Rock RC interpreting laboratory tests: a basic approach. Geriatrics 1984;39(1):49-54.
6. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1986; 8:307-10.

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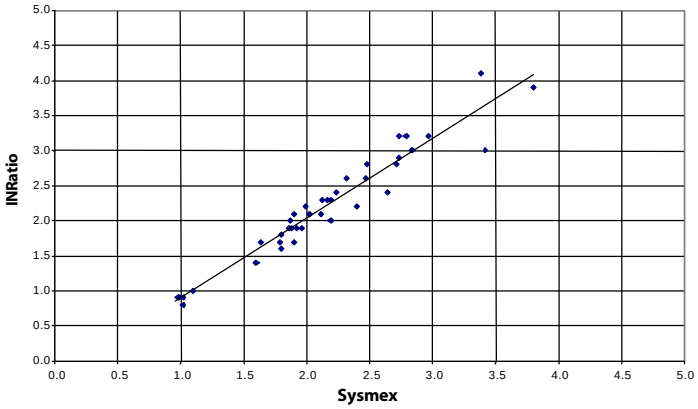
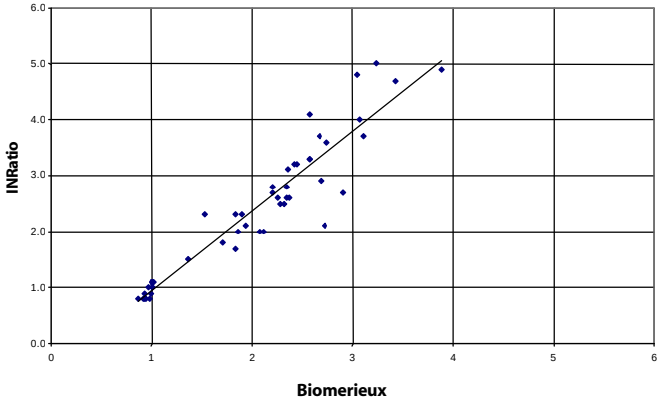
Sysmex 1500 vs. INRatio Meter

N = 40, y = 1.14, r = 0.96



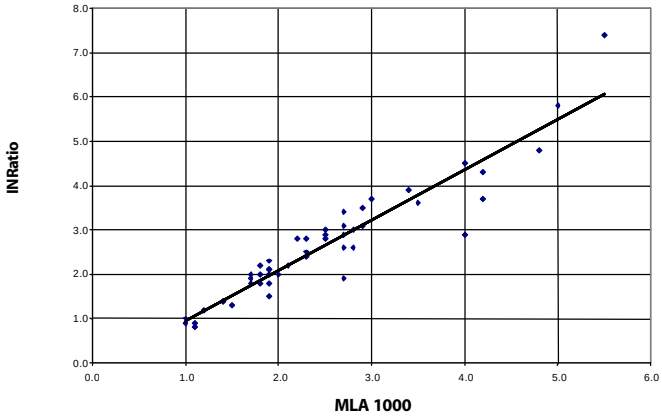
Biomerieux vs. INR

N = 47, Y =1.42, R= 0.94



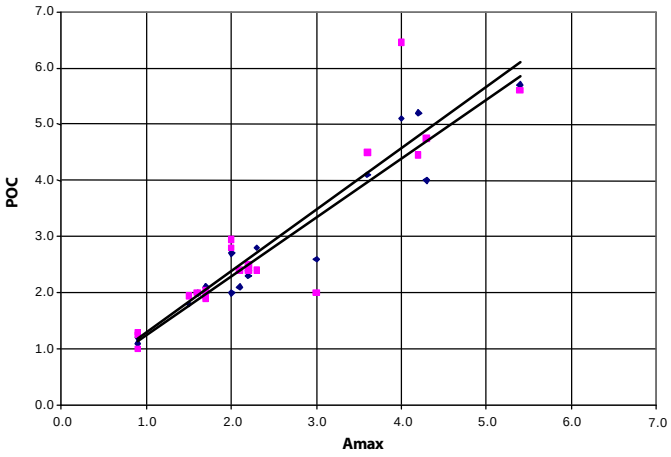
MLA 1000 vs. INRatio

N=40, Y= 1.13 R= 0.95



Amax 190 vs. INRatio/Protime

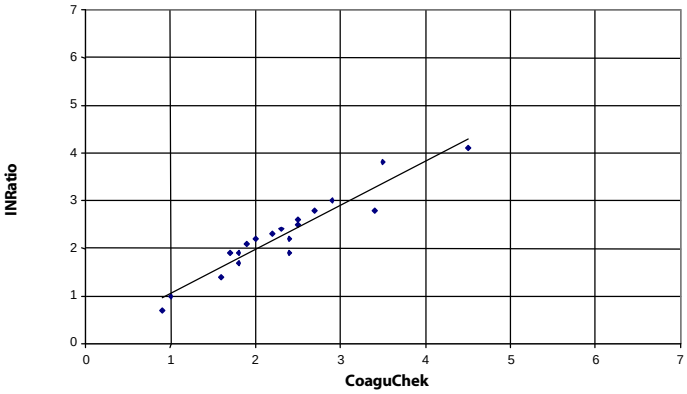
N = 20, Y= 1.05, r= 0.96 INRatio
N = 20, Y= 1.09, r= 0.91 Protime



POC vs. POC Instruments:

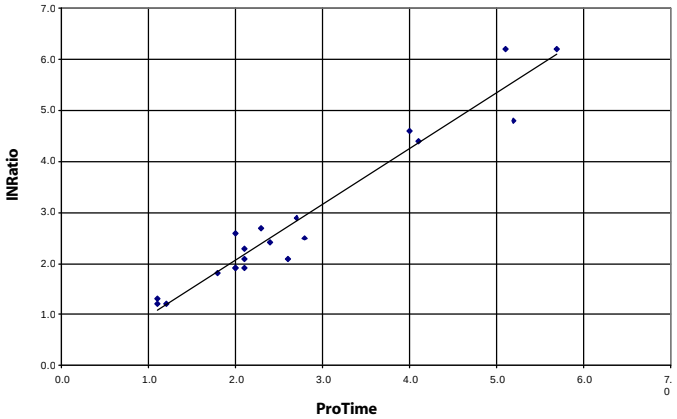
Coaguchek vs. INRatio

N = 19, Y= 0.93, r= 0.96



Protime vs. INRatio

N = 20, Y= 1.09, r= 0.97



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