

Special INR Evaluation

In a continuing effort to monitor the accuracy and reporting of the International Normalized Ratio (INR), the College of American Pathologists (CAP) has implemented an additional grading scheme for the INR. In addition to the grading scheme that is based upon the comparison of your laboratory's INR to that of your peer group, a second evaluation will be provided. This evaluation compares your laboratory's reported INR to a calculated INR that is based upon the International Sensitivity Index (ISI), the Mean Normal PT used to calculate the INR, and the PT result reported for each challenge that you provided on the result form. If you report the INR, but did not report the ISI, the Mean Normal PT and the PT on the result form, the summary will indicate unacceptable performance. For regulatory and proficiency testing purposes, you must report the PT, even if your institution only requires the reporting of the INR on patients. Prothrombin Time is a regulated analyte required under CLIA.

For the Special INR evaluation, there are several criteria required to determine the accuracy of the reported INRs. We must receive the PT INR results and reported INRs for at least four challenges in addition to the reported ISI and mean reference range PT. If fewer than four challenges are provided, we cannot assess the accuracy of the INRs and the result will be Insufficient Data for Evaluation. If at least 80% of the reported INRs are within \square 0.2 of the calculated INR, the result is Acceptable Performance.

The values that your laboratory reported might not have been sufficiently abnormal to cause a failing INR score in comparison with your peer group. However, a systematic error of the type detected and reported in this summary could be clinically significant, now and/or at the time of a change of reagents.

As you know, it is extremely important for patient care to produce accurate INRs. Accordingly, the CAP strongly recommends that you examine the method used in your laboratory, if your laboratory fails the Special INR Evaluation.