

H54-A

Procedures for Validation of INR and Local Calibration of PT/INR Systems; Approved Guideline

This document describes the use of certified plasmas to enhance performance of the prothrombin time (PT)/International Normalized Ratio (INR) system test; reviews limitations of the INR system that may occur when a manufacturer-determined ISI is used without local verification or calibration; and provides a rationale for performing local ISI verification with recommendations as to when PT calibration may be indicated.

Part I is a detailed, expanded account for manufacturers and Part II is an abbreviated version useful for the clinical laboratory.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.