



June 2006

Dear ProTime Customer:

On August 29, 1997, the ProTime<sup>®</sup> Microcoagulation System was approved for waived status under the Clinical Laboratory Improvement Amendment of 1988 (CLIA) and received clearance through the FDA 510(k) process (Number: K951072). This letter explains the ProTime QC system and may be used to address questions that inspectors may raise.

The ProTime instrument performs a self-check before every test and has been designed with redundant systems to ensure proper instrument functions. The self-check at start-up checks temperature, timing functions, battery level, and optical, electrical and mechanical functions. No additional calibration or functional procedures are required.

Each ProTime cuvette has two levels of integral reagent controls that are run with every patient sample. The built-in controls indicate proper sample collection and correct test procedure, ensuring assay reliability and performance. Both control channels contain human coagulation factors designed to normalize the clotting time of the blood sample. In addition, the level 2 control channel has extra reagent which causes an extended clotting time. If the built-in controls do not perform as expected, the result is invalid and the instrument will display an error code. The use of external quality control material is not required.

The ProTime cuvette includes a barcode that contains the cuvette lot number and expiration date and the lot specific algorithm for calculating the results in each channel. The barcode also contains the lot specific requirements for the integral control channels to meet in order for the instrument to report a patient result.

For additional information regarding quality control, please refer to the ProTime cuvette package insert for guidelines. Please contact ITC Technical Support at 1-800-631-5945 or email [techsupport@itcmed.com](mailto:techsupport@itcmed.com) with any questions or concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "Dave Gronostajski". The signature is fluid and cursive, written over a white background.

Dave Gronostajski  
Senior Director, Regulatory Affairs and Quality Compliance