

New Horizon Point-of-Care Coagulation Instrument

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The Elite Horizon (Horizon) is a next generation Hemochron® point-of-care microcoagulation instrument in development capable of measuring responses to both heparin (ACT and APTT) and warfarin (PT). A unique clot detection method employed provides high level reproducibility yielding assay precision and accuracy. The Horizon instrument is backwards compatible with current Hemochron ACT+ and ACT-LR test cuvettes for management of heparin, and produces results that are comparable to those obtained with the predicate Hemochron® Signature Elite instrument. When identical heparinized samples were tested using ACT+ cuvettes on either Horizon or Signature Elite, a correlation of $R^2 = 0.98$ and a slope 0.93 was achieved (Figure 1). When identical heparinized samples were tested using ACT-LR cuvettes on either Horizon or Signature Elite, a correlation of $R^2 = 0.96$ and a slope 1.06 was achieved (Figure 2). A future development exclusively designed for Horizon will be a Universal ACT (U-ACT) test cuvette, which will allow management of all doses of heparin for all applications using a single disposable cuvette. Initial laboratory studies demonstrate a correlation of $R^2 = 0.91$ and a slope of 0.91 using the Horizon U-ACT compared to the Signature Elite ACT+ cuvette. Building on the user capabilities of the predicate Elite system, the hand-held Horizon instrument will offer a state-of-the-art graphical user interface (GUI) with a color touch screen display, wireless communication, POCT1A/POCT2A compliant data output, ability to support TCP/IP network connectivity, a 2D bar code scanner, user replaceable battery, an expanded database for test record storage, and capability for future menu expansion.

Figure 1: Comparison of ACT+ on Horizon vs. Elite

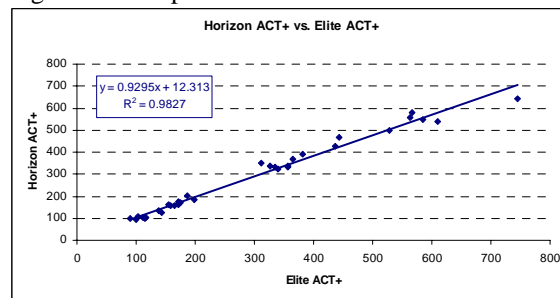


Figure 2: Comparison of ACT-LR on Horizon vs Elite

