Poster 26

FDA Regulation of Point of Care Testing (POCT) Coagulation Devices

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POCT is commonly defined as diagnostic testing performed at or near the site of patient care. The benefit of POCT devices is rapid turnaround, resulting in decreased time until treatment onset. However, the benefit of rapid turnaround is accompanied by challenges including less controlled testing environment. The smaller specimen type required in POCT coagulation devices further increases potential for pre-analytic errors, while factors such as limited operator training can contribute to increased post- analytic errors. This presentation will provide an overview of challenges and requirements of FDA regulation for POCT coagulation testing devices to ensure predictable performance to balance between increased accessibility and degradation of quality of results.