Evaluation of the new ACL TOP coagulation analyser from IL

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Aim of our study has been to evaluate the new ACL TOP coagulation system according to the European Committee for Clinical Laboratory Standards (ECCLS) protocol issued in 1986. The evaluation has been performed on the following tests: PT, APTT, Fibrinogen, AT and D-Dimer. We have evaluated within and between run imprecision, the reagent carry-over and the results correlation obtained versus samples routinely analysed on ACL ADVANCE (IL). The linearity of Fibrinogen and D-Dimer has been properly investigated. The analytical correlation has been performed on about 600 samples for AT and D-D and on about 1000 samples for PT and APTT; all of these samples were representative of normal, low and high pathological values, covering the full analytic range. The statistic analysis of Bland-Altman, or linear regression analysis have demonstrated a very good correlation for PT (r=0.994), APTT (r=0.997), AT (r=0.986) and D-Dimer (r=0.989). Our study has demonstrated good results in terms of within imprecision (maximum CV: 2.3% for clot based tests, 4.1% for AT and 6.3% for D-Dimer) and between imprecision (maximum CV: 3.1% for clot based tests, 5.9% for AT and 8.2% for D-Dimer). No significant carry-over was observed. The linearity range for Fibrinogen Clauss has resulted between 70 to 740 mg/dL and for D-Dimer between 80 to 1050 ng/mL. In general, the instrument ACL TOP, further more some additional interesting technology innovation, has evidenced good analytical and mechanical performance associated to a remarkable easiness of use and speed which make it suitable for its introduction in central as well specialized hemostasis laboratories.