Abstract:
An evaluation of the INRatio Prothrombin Time Monitoring system for determination of INR was done in two centers with a total of 5 healthy subjects and 77 subjects on oral anticoagulation. The INRatio and the Coaguchek S were compared with an established laboratory method. The correlation coefficient of the comparison with the laboratory was $r=0.954$ for INRatio and $r=0.937$ for Coaguchek S. The mean relative deviation from the lab method calculated according to Hill was 6.87% for INRatio, which is rated "very goo", and 9.72% for Coaguchek S ("goo"). The imprecision in the normal range (INR=1.1) showed a coefficient of variation (CV) of 7.8% and a standard deviation (SD) of 0.09. In the therapeutic range (INR 3.9) the CV was 5.4%, the SD 0.21 and above therapeutic range (INR 5.3), the CV was 8.4% (SD 0.44), rated satisfactory. The concordances of the compared methods with the routine were 81% for INRatio and 79% for Coaguchek S, which is considered state-of-the-art. Most of the patients' perceptions of the INRatio were very positive. In the hands of professionals the INRatio demonstrated very good accuracy and precision and an excellent technical reliability. Further studies using INRatio for self testing by patients are warranted.