Establishing Reference Intervals for Routine Coagulation Tests

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Abstract : Introduction: Establishing population-based reference intervals (RI) are essential when evaluating laboratory test results and for method verification. Our laboratory initiated an exercise to establish RI for routine coagulation profile as part of the method verification procedure and to determine any differences in RI between three analyzers planned to be used in the laboratory. Methodology: 145 blood samples were collected and analysed for activated partial thromboplastin time (aPTT), prothrombin time (PT), international normalized ratio (INR), and fibrinogen] using three coagulation analysers which were CA104, CA660, and CS-2500 (Sysmex, USA). RI was established at 2.5th and 97.5th percentiles. Results: The RI for aPTT between C104, C660 and CS-2500 are (RI: 20.5-30.2 sec), (RI: 21.5-29.2 sec) and (RI: 22.7-30.3 sec) respectively. The RI for PT were (RI: 7.5-10.3 sec), (RI: 9.2- 11.1 sec) and (RI: 9.8-11.9 sec) for C104, CA660 and CS-2500 respectively. INR had an RI of (RI: 0.87- 1.16), (RI: 0.89-1.10) and (0.90-1.11) respectively on CA104, C660 and CS-2500. Fibrinogen RI was (RI: 2.04-4.62 g/L) and (2.05-4.76 g/L) on the CA660 and CS-2500, respectively. Conclusion: The RI was similar across the analytical platforms for aPTT, INR, and fibrinogen. However, CA104 showed lower RI compared to the other two analysers for PT. This highlights the potential variability in results between instruments that need to be addressed when verifying RI.

Keywords : coagulation, reference interval, APTT, PT, INR, fibrinogen

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