Thrombosis Research (2005) **116**, 171—179

ELSEVIER

THROMBOSIS RESEARCH

intl.elsevierhealth.com/journals/thre

Regular Article

Evaluation of the automated coagulation analyzer Sysmex® CA-7000☆

Alexandra Dorn-Beineke[a,*], Carl-Erik Dempfle[b], Thomas Bertsch[a], Herrmann Wisser[a]

[a]*Institute for Clinical Chemistry, Faculty for Clinical Medicine Mannheim, University of Heidelberg, Theodor-Kutzer-Ufer 1-3, Mannheim 68167, Germany*
[b]*Department of Internal Medicine I, Faculty for Clinical Medicine Mannheim, University of Heidelberg, Mannheim, Germany*

Received 11 October 2004; received in revised form 30 November 2004; accepted 1 December 2004
Available online 28 January 2005

KEYWORDS
Coagulation;
Automation;
Prothrombin time;
Partial thromboplastin time;
Fibrinogen;
Antithrombin

Abstract

Introduction: Centralization of laboratory diagnostics and an increasing number of urgent requests and nonstandard samples raise the need for short turn-around times and high-throughput analyzers for coagulation tests. The aim of the present study was to evaluate the analytical and technical performance of the Sysmex® CA-7000 coagulation analyzer under routine laboratory conditions.
Materials and methods: We evaluated the Sysmex® CA-7000 in comparison to the Sysmex® CA-6000 analyzer for PT, INR, aPTT, Clauss, and derived fibrinogen. We also compared antithrombin (AT) measured on the Sysmex® CA-7000 and Dimension® RxL. Imprecision studies were performed, and throughput, online, and STAT functions and the handling of routine samples were evaluated.
Results: The Sysmex® CA-7000 showed very low intra-assay and interassay variability for all parameters. The method comparison study showed good comparability to the Sysmex® CA-6000 and Dimension® RxL. The throughput of the Sysmex® CA-7000 was 2.5—3 times faster than that of Sysmex® CA-6000. No interference was seen for total

Abbreviations: ANOVA, analysis of variance; aPTT, activated partial thromboplastin time; AT, antithrombin; CI, confidence interval; CV, coefficient of variance; INR, international normalized ratio; NCCLS, National Committee for Clinical Laboratory Standards; PT, prothrombin time; QC, quality control; SD, standard deviation; STAT, shortest turn-around time; TAT, turn-around time; TV, target value.

☆ The work was presented as a poster at the EUREGIO congress, Aachen, Germany, October 8—10, 2003.

* Corresponding author. Tel.: +49 621 383 3561; fax: +49 621 383 3819.
E-mail addresses: alexandra.dorn-beineke@ikc.ma.uni-heidelberg.de (A. Dorn-Beineke), carl-erik.dempfle@med.ma.uni-heidelberg.de (C.-E. Dempfle), thomas.bertsch@klinikum-nuernberg.de (T. Bertsch), H.Wisser@t-online.de (H. Wisser).

0049-3848/$ - see front matter
doi:10.1016/j.thromres.2004.12.001

bilirubin up to 710 μmol/L. Triglyceride levels >11.4 mmol/L resulted in invalid PT measurements and levels >3.42 mmol/L gave invalid results for Clauss fibrinogen on the CA-7000 analyzer.
Conclusions: This is the first published evaluation of the analytical and technical performance of the coagulation analyzer Sysmex® CA-7000. We conclude that the CA-7000 is well suited for coagulation laboratories with high sample throughput and a high number of nonstandard samples.

Introduction

Centralization of laboratory diagnostics created the need for high-throughput analyzers with the ability to perform basic and special coagulation tests. Emergency room and intensive care, as well as pediatric samples, require short turn-around times (TAT) and small volume sample handling. The aim of the present study was to evaluate the analytical and technical performance of the Sysmex® CA-7000 coagulation analyzer under routine laboratory conditions. We compared the Sysmex® CA-7000 to the Sysmex® CA-6000 analyzer for prothrombin time (PT), international normalized ratio (INR), activated partial thromboplastin time (aPTT), Clauss fibrinogen and derived fibrinogen, and antithrombin (AT) on the Sysmex® CA-7000 and Dimension® RxL clinical chemistry analyzer. We performed imprecision studies for the methods used on all analyzers mentioned above, and evaluated the throughput, online, and "shortest turn-around time" (STAT) function of the Sysmex® CA-7000 as well as the handling of routine samples with different request profiles during a period of 10 days (3226 results).

Materials and methods

Sample collection and preparation

Patient specimens were collected in 3 mL Sarstedt Monovettes® or in 1.3 mL microtubes (pediatric specimen, both from Sarstedt AG, Nümbrecht, Germany). Blood was centrifuged (3000×*g*; 10 min) and the centrifuged tubes were put directly in the Sysmex® analyzers. For AT, an aliquot of plasma was transferred in polystyrol sample tubes. Pediatric plasma samples were transferred in polystyrol tubes for all analyses. The appearance of each specimen was recorded. In case of discrepant or invalid results, plasma triglycerides and total bilirubin were measured.

Analyzer

Sysmex® CA-7000 coagulation analyzer

The Sysmex® CA-7000 is a fully automated random access analyzer for coagulometric, chromogenic, and immunologic measurements. For high throughput, the Sysmex® CA-7000 analyzer is equipped with eight dispensing pipettes and 10 racks for 10 samples each, 40 reagent positions, 8 for factor deficient plasma, and 10 for controls or calibrators, respectively. All reagents in the reagent rack are kept at a temperature of 15 °C±2 °C. The buffer tablet, equipped with eight positions for diluent and rinse solution, is kept at room temperature. The Sysmex® CA-6000 has 30 cooled positions for reagents, calibrators, and controls. In the Sysmex® CA-7000, up to three vials of a single reagent type can be loaded. The rack system also includes two barcode readers. Thus, reagent information, including reagent name, lot number, vial type, and reagent set position, is recorded automatically when the reagent is inserted. The loading of reagents via barcode is possible continuously. Up to 20 parameters for simultaneous analysis can be selected from a total of 40 on-board parameters. Sample aliquots can be pipetted automatically into the sample ring, which has the capacity for 60 reaction tubes, enabling repeated testing, auto-redilution, as well as panel testing and reflex testing. The Sysmex® CA-7000 analyzer is equipped with a cap piercing unit, which processes capped and uncapped sample tubes. In contrast to the Sysmex® CA-6000, sample processing on the Sysmex® CA-7000 can be interrupted to allow STAT samples to be placed in a dedicated holder with five positions. The Sysmex® CA-7000 analyzer allows LED calibration by the operator.