Thrombosis Research (2007) **120**, 733–743

ELSEVIER

THROMBOSIS RESEARCH

intl.elsevierhealth.com/journals/thre

REGULAR ARTICLE

Evaluation and performance characteristics of the automated coagulation analyzer ACL TOP

Anny Appert-Flory [b], Florence Fischer [b], Didier Jambou [b], Pierre Toulon [a,b,*]

[a] *Université Nice Sophia-Antipolis, Faculté de Médecine, Département d'Hématologie Biologique, France*
[b] *CHU, Hôpital de Cimiez, Département d'Hématologie, Nice, France*

Received 26 June 2006; received in revised form 12 September 2006; accepted 4 December 2006
Available online 1 February 2007

KEYWORDS
Coagulation analyzer;
Evaluation;
ACL TOP

Abstract

Introduction: The ACL TOP is a fully-automated random-access multiparameter coagulation analyzer equipped with a photo-optical clot-detection unit. It is designed to perform coagulation, chromogenic and immunologic assays with continuous loading capabilities for samples, reagents and disposables.
Materials and methods: The instrument was evaluated in a coagulation laboratory of a university hospital with respect to its technical features in the determination of routine coagulation (prothrombin time, activated partial thromboplastin time, fibrinogen and single coagulation factor levels), chromogenic (anti-activated factor X, antithrombin and protein C activities) and immunologic assays (free protein S and von Willebrand factor antigen concentrations).
Results: Using fresh and lyophilized plasma samples, the intra-assay and inter-assay coefficients of variation were below 5% for most of the parameters both in the normal and in the pathological ranges. For clotting assays performed at 671 nm, no significant interference could be demonstrated with hemolytic, icteric and lipemic samples as demonstrated by results similar to those obtained using a mechanical clot-detection-based analyzer (STAR). No sample carryover was detected in measuring alternatively heparinized (1.0 IU/mL unfractionated heparin) and normal plasma samples. The results of the different coagulation, chromogenic and immunologic assays obtained on the ACL TOP were well correlated with those obtained on the STAR analyzer with the correlation coefficient (r) in the range from 0.876 to 0.990.

Abbreviations: Anti-FXa, anti-activated factor X; APC, activated protein C; aPTT, activated partial thromboplastin time; AT, antithrombin; CV, coefficient of variation; FV, (coagulation) factor V; FVIII, (coagulation) factor VIII; INR, international normalized ratio; OD, optical density; PC, protein C; PS, protein S; PT, prothrombin time; vWF, von Willebrand factor.

* Corresponding author. CHU de Nice, Hôpital de Cimiez, Département d'Hématologie, 4 avenue de la Reine Victoria, BP 1179, F-06003 Nice Cedex 1, France. Tel.: +33 4 92 03 42 07; fax: +33 4 92 03 42 12.
E-mail address: toulon.p@chu-nice.fr (P. Toulon).

doi:10.1016/j.thromres.2006.12.002

Conclusions: Our results demonstrated that using the ACL TOP analyzer, routine hemostasis testing can be performed with satisfactory precision and the same applied to more specialized and specific tests such as single factor activity or antigen concentration.

Introduction

The increasing demand for coagulation tests as well as the economical pressure for tight staff and decreasing reagents budgets has raised interest in hemostasis laboratory automation [1]. The current generation of coagulation analyzers is fully automated. Their capabilities include primary tube sampling, automatic rerun, dilution capabilities and in some cases cap piercing. They can perform basic coagulation tests such as the prothrombin time (PT) or the activated partial thromboplastin time (aPTT) as well as more sophisticated coagulation, chromogenic and immunologic assays [2,3] using smaller sample and reagent volumes than the manual methods.

Here, we report an evaluation of the new automated hemostasis analyzer ACL TOP in the routine practice. The evaluation addressed several topics including ease of operation, method availability, reagent and patient sample on-board capabilities, ability to perform automatic dilution, rerun and reflex testing, and validation of performances.

Materials and methods

Description of the ACL TOP analyzer

The ACL TOP analyzer (Instrumentation Laboratory, Paris, France) is a fully-automated stand-alone random-access multiparameter coagulation analyzer. The clot detection is performed using photo-optical technology. The optical reading unit allows 16 simultaneous reaction readings at two currently available wavelengths i.e. 405 and 671 nm. Clotting, chromogenic and immunologic assays can be performed in a true random fashion. The cuvette loading area, located on the left side of the instrument, can be filled, even while running, with up to 20 clips of 10 cuvette-strips each for a total of 800 cuvettes (4 cuvettes per strip). A conveyor belt moves the cuvette-strips to a cuvette shuttle which places them in position to be used by the analyzer for sample handling. Up to 120 samples can be loaded at once using the rack system (12 racks of 10 tubes each) with a possibility to mix primary tubes and cups at once on the same rack. There is a true positive identification of both patients and control samples, reagents and diluents using an integrated laser bar-code reader that moves to each rack position, but there is no auto-positioning of the bar-code labels. The sample area is at ambient temperature. The sample arm consists of a pre-heated probe, with capacitive detection to allow sample volume monitoring, used for aspirating and dispensing samples. However, caps had to be removed before primary tubes were preceded to the instrument with the help of sample racks, since the evaluated version of the analyzer was not equipped with cap-piercing capabilities (upgrade expected for mid-2006). Up to 60 reagents can be stored on board using the rack system, with a total of 44 positions cooled at 15 °C (including 12 positions under constant stirring) and 16 positions at ambient temperature dedicated for controls, calibrators and diluents. Reagents can be continuously loaded. Using reagents from the analyzer manufacturer, positive identification of bar codes allows batch number, expiration date and vial size monitoring. Reagent on-board stability is ensured. Various adaptors are available from the manufacturer allowing the use of reagents from different manufacturers other than Instrumentation Laboratory in their original vials. There are two reagent arms consisting of pre-heated probes with capacitive detection which allows "real time" reagent volume monitoring. The left arm is used for aspirating/dispensing materials placed into the diluents racks and intermediate reagents (positions 1–24 of the reagent area) while the right arm is used for aspirating/dispensing start reagents (positions 13–36 of the reagent area). There are two different wash stations specific for each arm, located at the back of the reagent area. The user interface consists of a large-scaled touch-screen and a software running under Windows® environment. Using the software available at the time of the evaluation (v.1.9.1), 500 different tests with 6 programmable steps can be adapted on the analyzer. Two hundred and fifty test parameter tables are defined by the instrument manufacturer for its own reagents/methodologies and cannot be modified. Two hundred and fifty other test parameter tables are available for user definition in order to fit with its own reagents/methodologies. The analyzer has the software capabilities for rerun, automatic reflex testing and it is able to run multiple assays at various dilutions simultaneously with an on-screen presentation of factor parallelism testing. The LIS interface is based on the bi-directional host-