Customer Case Study

Analytical performance evaluation of a new integrated clinical chemistry analyzer

Like all clinical laboratories, MVZ Labor Dr. Limbach is challenged with reporting accurate results under operational constraints

MVZ Labor Dr. Limbach & Kollegen GbR

Heidelberg, Germany

This laboratory is part of Limbach group SE, and according to its website, the largest network of laboratories in Germany. Limbach group SE is one of the **largest networks of laboratories in Europe**.

Challenge

Deliver precise, clinically relevant, and timely results while managing staff shortage and budgets limitations is the challenge that most of clinical laboratories are facing.

Risks

- Patient misdiagnosis
- Delayed treatment
- Regulatory / Legal
- Reputation damage
- Increased costs

Solution: Atellica CI Analyzer

- Standardization for increased operational efficiency
- Intelligent sample aspiration
- Maintained throughput for rack-based processing
- Fast turnaround time

CC Up to **1000 TPH*** (600 PMs, 400 ISEs*) with 70 reagent positions

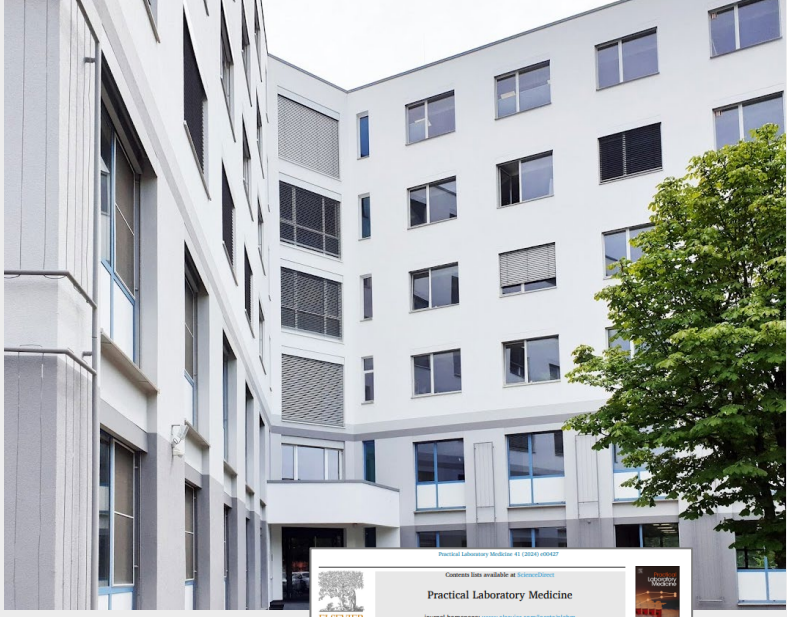
IA Up to **120 TPH*** with 20 primary and 20 ancillary reagent positions

1. Instill confidence in quality and accuracy of results
2. Increase testing efficiency
3. Address staff shortages and budget constraints effectively

↗ siemens-healthineers.com/atellica-ci-analyzer

SIEMENS Healthineers

Study objectives: validation of analytical performances of Atellica CI key assays in real world condition



Practical Laboratory Medicine 41 (2024) e00427

Contents lists available at ScienceDirect

Practical Laboratory Medicine

journal homepage: www.elsevier.com/locate/plabm

Registered Report Stage II

Analytical performance evaluation of a new integrated clinical chemistry and immunoassay analyzer

Ulla Ruffing, Sabrina Mickeler, Michaela Kraft, Peter Findeisen *,1

Laboratory Dr. Limbach and Colleagues, Heidelberg, Germany

ARTICLE INFO

Keywords:
Analytical performance evaluation
Atellica CI analyzer
Chemistry
Immunochemistry
Precision
Method comparison

ABSTRACT

Background: Clinical laboratories perform a wide range of tests that are used by healthcare professionals to guide medical decision making. Use of automated analyzers in the clinical laboratory can improve patient care by not only reducing the turn-around-time (TAT) of results but also improving accuracy of the reported results by reducing human error. The aim of this study was to evaluate the performance characteristics of a new automated laboratory instrument, the Atellica® CI Analyzer, Model 1908, over a 3-month period in a European laboratory setting.

Methods: Analytical performance of 17 analytes (13 chemistry and four immunochemistry) was assessed by evaluating repeatability and within-laboratory precision using anonymized remnant serum samples. Method comparison studies were performed on the Atellica CI Analyzer and the Roche cobas® 6000.

Results: Excellent precision was observed with coefficients of variation (CVs) less than 2 % for repeatability and less than 3 % within-laboratory imprecision for most analytes. Comparisons of select assays with the cobas 6000 system resulted in correlation coefficients ranging from 0.980 to 1.000.

Conclusions: This is the first reported evaluation of the Atellica CI Analyzer in a clinical laboratory setting. The strong analytical performance of the Atellica CI Analyzer demonstrates that this instrument is suitable for routine clinical use.

1. Introduction

Clinical laboratories perform a wide range of tests, the results of which are used to aid in the diagnosis, treatment, and follow-up of a variety of diseases and medical conditions [1]. Given the key role that laboratory testing plays in guiding clinical decision making, laboratories are expected to provide clinically relevant, accurate, and timely results [2,3]. This demand must be met despite increasing pressures from shortages in both clinical laboratory personnel and financial resources. Thus, improvements in laboratory testing that increase efficiency and reduce cost while preserving the quality and accuracy of results are needed [3].

Abbreviations: BV, Biological Variation; CI, Confidence Interval; CV_a, analytical variation; CV_{apa}, analytical performance specification; CV_i, intra-individual variation; CLSI, Clinical & Laboratory Standards Institute; CV, Coefficient of Variation; QC, quality control; SD, standard deviation; TAT, turn-around-time.

* Corresponding author. MVZ Labor Dr. Limbach & Kollegen GbR, Im Breitspiel 16, 69126, Heidelberg, Germany.
E-mail addresses: Ulla.ruffing@labor-limbach.de (U. Ruffing), Sabrina.mickeler@labor-limbach.de (S. Mickeler), Michaela.kraft@labor-limbach.de (M. Kraft), Peter.Findeisen@labor-limbach.de (P. Findeisen).

1 https://www.labor-limbach.de.

https://doi.org/10.1016/j.plabm.2024.e00427
Received 28 May 2024; Received in revised form 16 August 2024; Accepted 31 August 2024
Available online 2 September 2024
2352-5517/© 2024 The Authors. Published by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

17 commonly used assays

- ☑ **13 chemistry tests (CC):** Albumin, Alkaline Phosphatase, ALAT, AST, Amylase, Calcium, Cholesterol, Glucose, HDL Cholesterol, LDL Cholesterol, Triglycerides, Uric Acid, Urea Nitrogen
- ☑ **4 immunoassay tests (IA):** TSH, FT4, PSA, HCG

Assessment of precision

- ☑ CLSI - EP15-A3
- ☑ QC materials or patient pools
- ☑ Repeatability and within-laboratory

Method comparisons vs. Roche COBAS 6000

- ☑ CLSI EP09-A3
- ☑ Remnant anonymized serum patient samples
- ☑ Correlation coefficients of ≥0.95 were considered acceptable

Outcomes

Precision

CC	Repeatability CVs	*from* 0 % *to* 1.9 %		*from* 0.5 % *to* 5.1 %	
	Within-laboratory CVs	*from* 0.5 % *to* 3.7 %		*from* 0.9 % *to* 5.2 %	
IA	Repeatability CVs	*from* 1.1 % *to* 2.5 %		*from* 0.6 % *to* 2.3 %	
	Within-laboratory CVs	*from* 1.6 % *to* 3.8 %		*from* 1.6 % *to* 5.4 %	
In total	Within-laboratory CVs*	**< 3%**	**< 4%**	**< 3%**	**< 4%**
	% of CC and IA tests	**76%**	**100%**	**65%**	**85%**

- ☑ Results of the Atellica CI Analyzer precision studies met manufacturer's specifications.
- ☑ Evaluations using pooled patient samples and QC materials showed comparable results.

Method comparisons

Passing Bablok	Correlation coef. (r) values from 0.98 to 1 (*CC: 0.989 to 1.0 – IA: 0.98 to 0.999).*
	Slopes: CC tests from 0.946 to 1.143. - IA tests from 0.798 to 1.276.
Bland Altman	CC tests : mean bias from -0.4% (smallest) to 12,4% (largest).
	IA tests: mean bias from -3.9% (smallest for TSH) to 26.2% (largest for HCG).

- ☑ Overall, results of method comparisons were acceptable.

1 Analytical performances meet specifications

2 Atellica CI Analyzer is suitable for routine clinical use

References

Ruffing, S. Mickeler, M. Kraft, P. Findeisen, Analytical performance evaluation of a new integrated clinical chemistry and immunoassay analyzer, Practical Laboratory Medicine, https://doi.org/10.1016/j.plabm.2024.e00427

The statements by Siemens Healthineers' customers described herein are based on results that were achieved in the customer's unique setting. Because there is no "typical" hospital or laboratory and many variables exist (e.g., hospital size, samples mix, case mix, level of IT and/or automation adoption) there can be no guarantee that other customers will achieve the same results).

Product availability varies by country and is subject to varying regulatory requirements. Their future availability cannot be guaranteed. Please contact your local representative for availability.

This study was funded by Siemens Healthineers.

Siemens Healthineers Headquarters
Siemens Healthineers AG
Siemensstr. 3
91301 Forchheim, Germany
Phone: +49 9191 180
siemens-healthineers.com

Published by
Siemens Healthcare Diagnostics Inc.
Core Lab Solutions
511 Benedict Avenue
Tarrytown, NY 10591-5005
USA
Phone: +1 914-631-8000

Published by Siemens Healthcare Diagnostics Inc. · QR700017184 · 12-2024 · © Siemens Healthcare Diagnostics Inc., 2024