

Streamlining Laboratory Services to Do More with Less

Hospital laboratories are challenged nowadays to meet greater testing demands, improve efficiency, and deliver reliable, high-quality results while at the same time facing problems of space, a shortage of skilled employees, and budget constraints. Core laboratories at a number of hospitals are exploring ways to further improve their performance by consolidating their routine and urgent (STAT) testing systems to achieve reductions in work time, space, manpower, and costs.

Text: Linda Brookes

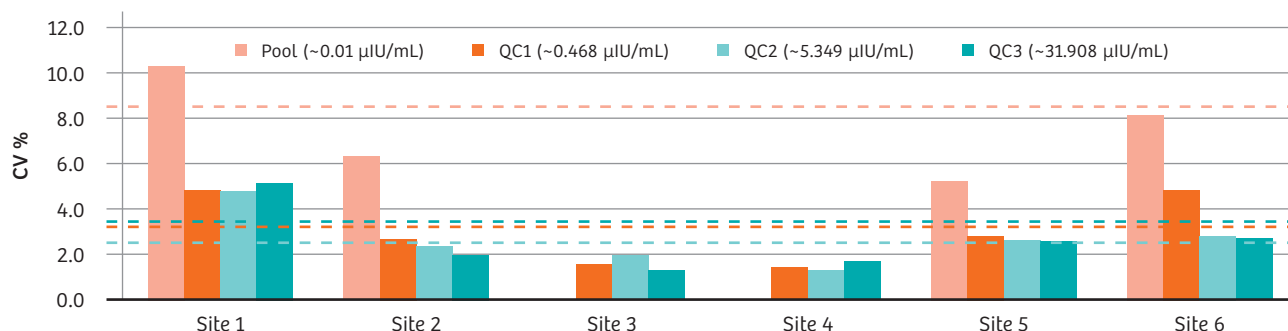
Improved performance with consolidation

In Europe, six high-volume laboratories were among the first to address these challenges by introducing immunoassay and clinical chemical analyzers run on the multicomponent Atellica® Solution^{1,2}. To verify their concordance, precision, linearity, and detection capability as well as their workflow capabilities, the sites (Hospital Universitario La Paz and Clinic

Barcelona in Spain; LBM Bioesterel and Hôpital Beaujon in France; Santa Maria Nuova Hospital, Reggio Emilia in Italy; and Friarage Hospital in the UK) ran twenty commonly used assays following Clinical and Laboratory Standards Institute (CLSI) guidelines.

Antonio Buño Soto, MD, PhD, Head of Laboratory Medicine at Hospital Universitario La Paz, Madrid, Spain, recently described how the findings for the 13 chemistry and seven

Atellica® IM assays: Within-Laboratory precision studies Atellica® IM TSH3-Ultra assay



Study site data: 5-day precision study, 5 runs per day, N ≥ 25 for each sample – CLSI Protocol EP15-A3

IFU data: Precision was determined in accordance with CLSI Document EP05-A3.16. Samples were assayed on an Atellica IM Analyzer in duplicate in 20 runs per day for 20 days (N ≥ 80 for each sample). Sites 3 and 4 did not perform precision testing on pool sample.

QC: Bio-Rad Liquicheck Immunoassay Plus Control lot 40940T



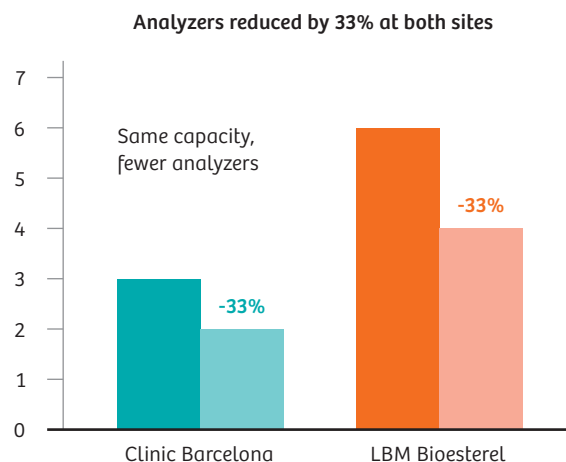
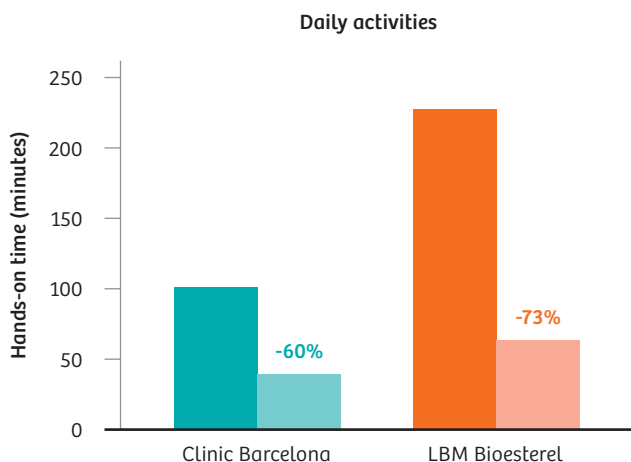
La Paz lab with Dr. Buño Soto and his staff

immunoassays showed “precision that met or exceeded coefficients of variation (CVs) in the Instructions for Use, concordance with existing technology with correlation values close to one, and acceptable linearity across the assay range.”

The Atellica Solution also improved workflows in terms of daily maintenance, quality control (QC), and reagent loading. Typical daily workloads were replicated at two of the laboratories;

Core Laboratory at Hospital Clinic Barcelona in Spain; and LBM Bioesterel, in Mouans-Sartoux, France, where hands-on time in the labs was reduced by 60% and 73%, respectively. This was attributed in large part to automated maintenance, onboard refrigerated, automated QC, and on-the-fly reagent loading, according to José Luis Bedini, MD, head of the Barcelona laboratory. The number of analyzers needed at both sites was reduced by 33%.

Finding: Simplified, automated processes reduced manual labor, giving professionals more time for clinical analysis





View of the Core Laboratory at Hospital Clinic Barcelona in Spain

Simultaneous STAT and routine tests

The Hospital Universitario La Paz, which currently uses an independent dedicated lab for STAT testing, also investigated whether the Atellica Solution could run STAT tests along with routine testing. Buño Soto and his colleagues used 650 routine samples with 1,561 immunoassay test requests corresponding to a typical three-hour peak daily work period along with a representative number of STAT requests corresponding to the same period. For the STAT tests, high-sensitivity troponin I (TnIH), B-type natriuretic peptide (BNP), and total hCG (thCG), the mean time from sample aspiration to result was around ten minutes – “very impressive,” Buño Soto said. Variability was “really low” (CV 4–6) and routine samples were not impeded by STAT testing and also demonstrated fast, predictable TAT.

Fast troponin testing crucial

A 7-year study highlighted the need for improved medical care during emergency admission for suspected myocardial infarction in Spain [1], so the need for cardiac troponin STAT tests was even more critical, Buño Soto stressed. In Madrid, the Atellica IM TnIH Assay run on the Atellica Solution showed good precision in detecting low concentrations and good correlation with established ADVIA Centaur® and Dimension Vista® TnIH assays.

One of the assay tests run by the Santa Maria Nuova Hospital, Reggio Emilia, assessed the impact of interfering substances (like the vitamin biotin) on the performance of the high-sensitivity troponin assay. There was less than 10% change in results with biotin ≤ 1500 ng/mL and hemolysis ≤ 500 mg/dL. According to Tommaso Fasano, MD, PhD, from the Arcispedale Santa Maria Nuova in Reggio Emilia, Italy, both the Atellica and ADVIA Centaur are “good assays,” but the Atellica Assays “seem to be even better.” In their Clinical Chemistry and Endocrinology Laboratory, Fasano and colleagues found that the Atellica IM TnIH Assay showed “very low CVs” at concentrations close to the 99th percentile (2.5% at 40.3 ng/L, 99th percentile 45 ng/L). In samples with undetectable levels of troponin on a “contemporary sensitive assay” (ADVIA Centaur TnI-Ultra), detectable levels of troponin (> limit of quantitation (LoQ)) were found in 70% on the Atellica IM TnIH compared with 61% on the ADVIA Centaur TnIH.

Laboratory upgrade plans

For Hospital Universitario La Paz in Madrid, the central routine and urgent testing labs together perform over eleven million laboratory tests per year. Planning is underway to merge the two testing facilities, which Buño Soto anticipates will allow staff to spend more time on clinical work and less time on manual operations, while facilitating faster, more efficient triage of patients presenting with critical symptoms.



Atellica IM TnI assay² – Overview of assay performance and study protocol

Characteristic	Atellica Solution
Technology	Performed latex magnetic solid phase with new TSPA molecule
Antibodies	mAb (sheep and mouse), recombinant sheep monoclonal F _{ab}
Sample volume	100 µL
Time to first result (min)	10 minutes
99 th percentile	Lithium heparin (combined M/F): 45.20 ng/L; Serum (combined M/F): 45.43 ng/L
LoD	1.60 ng/L
LoQ (dose at 20% CV); Dose at 10% TCV	2.50 ng/L; < 6.00 ng/L
Interferences ≤ 10% change in results up to:	Biotin – 3500 ng/mL; hemoglobin – 500 mg/dL

At Hospital Clinic Barcelona, the current annual workload is 5.4 million tests performed by seven operators (six for routine and one operator for STAT samples). Following re-evaluation of the workflow and impact of the Atellica Solution already in use, the lab decided to replace the current ten connections with just three Atellica Solution configurations connected to Aptio Automation, removing the need for a dedicated STAT area. Bedini expects this reorganization to lead to a 25% reduction in necessary workspace and allow redeployment of 3 operators. “These important changes to the organization of the lab will lead to more capacity, more throughput, and greater productivity,” he predicts. ●

Linda Brookes is a freelance medical writer and editor who divides her time between London and New York, working for a variety of clients in the healthcare and pharmaceutical fields.

Reference

[1] Andrés E, Cordero A, Magán P, et al. Long-term mortality and hospital readmission after acute myocardial infarction: an eight-year follow-up study. *Rev Esp Cardiol (Engl Ed)*. 2012;65:414–20. <https://doi.org/10.1016/j.recesp.2011.09.009>. Last accessed Aug. 21, 2018

¹ Siemens Healthineers supported the study by providing systems, reagents, and protocols and contributed to data analysis.

² Product availability varies from country to country and is subject to varying regulatory requirements. Results from case studies are not predictive of results in other cases. Results in other cases may vary.

The outcomes obtained by the Siemens Healthineers customers described here were realized in the customers' unique settings. Since there is no typical laboratory, and many variables exist, there can be no guarantee that others will achieve the same results. Product availability varies by country.