

cobas[®] 6000 analyzer series: STAT consolidation

A multi-center evaluation of the 9 minute STAT applications

Introduction

Results for critical tests often require a dedicated workstation to achieve fast turnaround time (TAT). While this approach reduces TAT for STAT samples, it requires more staff and increases costs. In response Roche has developed 9 minute STAT applications that can be performed in conjunction with routine testing on the cobas 6000 analyzer series. These applications include the most time-critical immunoassays:

- Troponin T high sensitive (Gen. 5)
- Myoglobin
- NT-proBNP
- Intra-operative PTH
- Troponin I
- CK-MB
- hCG

A multi-centre evaluation study was conducted to assess the impact on turnaround time and workflow of introducing the 9 minute applications on systems with existing routine workloads. Prepared by a Roche site investigator, with active participation of clients, findings are presented from Henri Mondor Hospital (France, referred to as “Henri Mondor”), Massachusetts General Hospital (USA, “MGH”), and University of Regensburg Clinic (Germany, “Regensburg”).

Flexible consolidation

The clients conducted workflow assessments typical of their workload in off-peak, peak and night shift scenarios. They evaluated the TAT of STAT samples and monitored the impact on TAT for the routine workload.

STAT consolidation

Off-peak workload: MGH conducted a run typical of an afternoon shift: 124 samples were processed in four hours with a total of 1,174 requests, of which 46 were STAT. Test mix was 64% clinical chemistry (CC) only, 19% mixed and 16% immunochemistry (IC) only.

Results: TAT of STAT samples were achieved in less than 12 minutes (11 minutes average), with no adverse effect on rou-

tine TAT of 16 minutes (12 minutes average). The observed time to result was 5 to 7 minutes faster (Fig. 1).

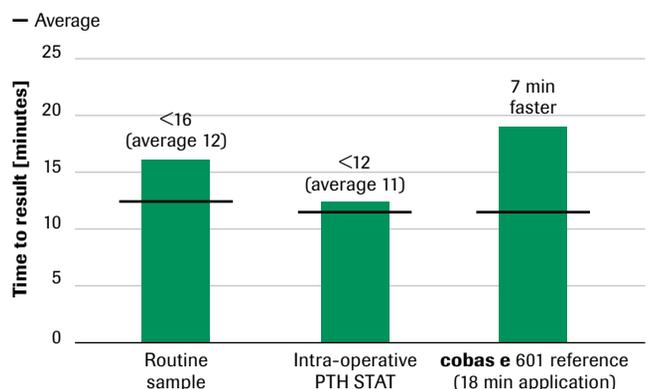


Fig. 1: Night shift scenario, MGH



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Life needs answers

Peak workload: Regensburg conducted a run typical of its peak workload: 207 samples were processed in four hours with a total of 1,699 requests, of which 15 were STAT. Test mix was 72% CC only, 25% mixed and 3% IC only.

Results: TAT of STAT samples was achieved in less than 17 minutes (15 minutes average), with no adverse impact on routine TAT. The observed TAT was 7 minutes faster than the reference run with 18 minutes applications (Fig. 2).

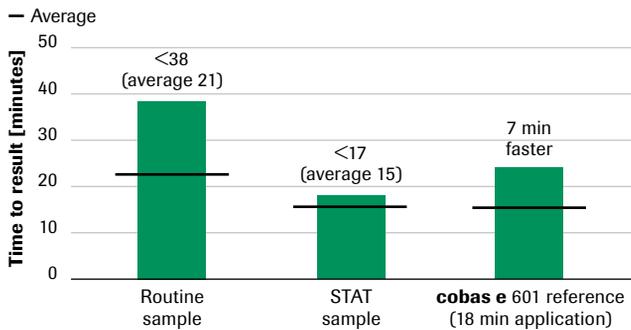


Fig. 2: Peak workload scenario, Regensburg

Night shift workload: Henri Mondor conducted a run typical of its night shift: 40 samples were processed per hour with a total of 432 requests. Of these samples, 10 were STAT with each sample having 12 requests (“Chest Pain” Panel: Basic Metabolic Panel¹ + CK + LDH + troponin T + myoglobin. Test mix was 60% CC only, 30% mixed and 10% IC only.

Results: TAT of STAT Chest Pain Panel samples was achieved in less than 19 minutes (16 minutes average) with no adverse effect on routine TAT of 19 minutes (15 minutes average). The observed TAT was 6 minutes faster than the reference run with 18 minute applications (Fig. 3).

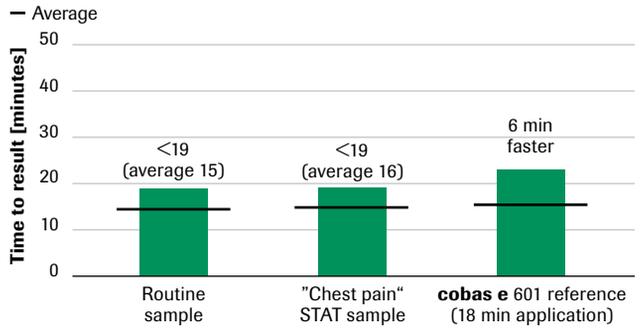


Fig. 3: Night shift scenario, Henri Mondor

With the **cobas 6000** analyzer series, each client was able to eliminate a dedicated STAT analyzer by consolidating STAT and routine onto a single platform. And by using the 9 minute STAT applications, they were able to improve the TAT of their STAT samples without impacting the routine, even during peak hours.

Superior analytical performance

The **cobas 6000** analyzer series also demonstrated high analytical performance in terms of comparability, time to result, and precision.

High comparability

Method comparisons demonstrated good comparability between the 18 minute and 9 minute applications, as well as between the **cobas e 411** 9 minute applications and the **cobas 6000** 9 minute applications. Total precision was comparable between the 18 minute and 9 minute applications. In fact, assay precision exceeded expectations and performed consistently better than required according to Roche product specification documents (Fig. 4). Limit of quantification was consistently better than the predefined performance limit.

“Lab-specific workflow analysis simulating Regensburg University’s central laboratory morning shift of typical routine and STAT parameters on cobas® 6000 revealed a significant reduction of mean sample times...”

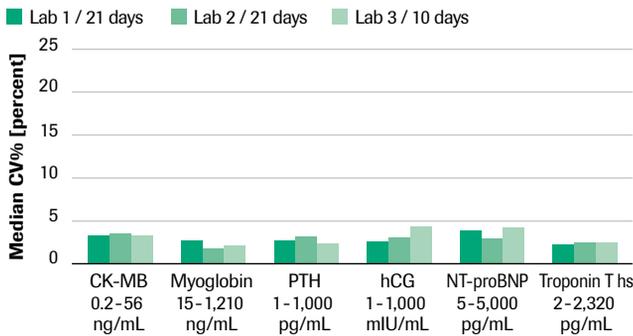


Fig. 4: Total precision according to CLSI for 9 min STAT applications on the cobas e 601 module

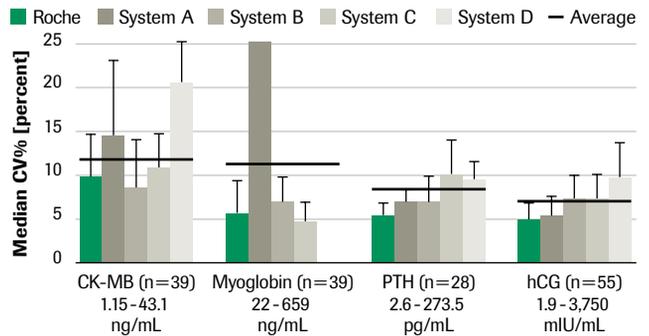


Fig. 6: Median CV% calculated using consolidated data from an external quality survey (2008 until January 2009)

Fast time to result

In comparison with representative assays in the market - the 9 minute STAT applications have the fastest time to result.

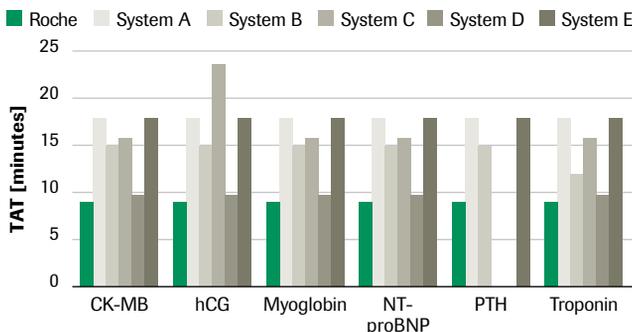


Fig. 5: Analytical time to result comparison of available STAT tests

Low imprecision

In comparison with representative assays in the market - the 9 minute STAT applications also had the lowest average imprecision in terms of inter-laboratory Coefficient of Variation (CV%) (Fig. 6).

Troponin T: 10% CV at the 99th percentile

The Troponin T high sensitive (Gen. 5) assay meets the precision recommendations established in recent guidelines² by achieving less than 10% CV at the 99th percentile upper reference limit of 14 pg/mL. This assay was designed to support cardiologists and emergency physicians with a higher sensitivity for myocardial necrosis (Fig. 7). In addition, the 9 minute application delivers cardiac results that help to meet the NACB recommendations³ for turnaround time.

	C Tn T	C Tn I
Aid in the differential diagnosis of acute coronary syndrome (ACS) to identify acute myocardial infarction (AMI)	•	•
Risk stratification of patients presenting with ACS	•	•*
Cardiac risk stratification in patients with chronic renal failure (CRF)	•	
Helpful for the selection of more intensive therapy and intervention in patients with elevated levels of cardiac Tn	•	

Fig. 7: Intended use of cardiac Troponin T and Troponin I assays according to Roche package inserts

“TnT-hs assays... are well adapted for clinical use where in some instances of pathological issues (renal insufficiency) clinical biochemistry has to be very precise to give the best reliable patient follow-up.”

“I recommend release of these STAT assays to the market, unconditionally. I would use the evaluated [cobas® 6000] unit to replace my lab’s current STAT instrumentation without hesitation.”

Dr. James Flood, MGH

Seamless implementation

Roche is committed to ensuring the seamless implementation of the **cobas 6000** analyzer. To this end the **cobas 6000** simulation tool has been developed to assist Roche representatives in designing the optimum system configuration for each laboratory. It assesses the suitability of the 9 minute STAT applications for different workloads (Fig. 8).

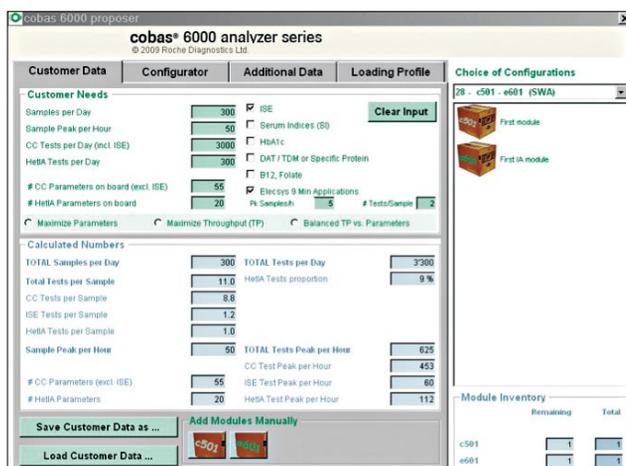


Fig. 8: cobas® 6000 simulation tool

Conclusion

A multi-center evaluation of the 9 minute STAT applications demonstrated the ability of the cobas 6000 analyzer series to consolidate STAT samples without disrupting the routine workload. STAT sample turnaround time was significantly improved, and analytical performance maintained excellent comparability and precision.

References

- 1 Basic Metabolic Panel: Sodium, Potassium, Chloride, CO₂, Calcium, Glucose, Urea, Creatinine (8 tests).
- 2 Thygesen, K., Alpert, J.S., White, H.D. (2007). Joint ESC/ACCF/AHA/WHF Task Force for the Redefinition of Myocardial Infarction. *Circulation*; 106: 2634-53.
- 3 National Academy of Clinical Biochemistry and IFCC Committee for Standardization of Markers of Cardiac Damage Laboratory Medicine Practice Guidelines: Analytical issues for biochemical markers of acute coronary syndromes. Apple FS et al. *Clinical Chemistry* 2007, 53:4.; 547-541.

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