White Paper

Real World Assessment of the Impact of Infectious Disease Assays on Workflow Capabilities of Atellica IM Analyzer

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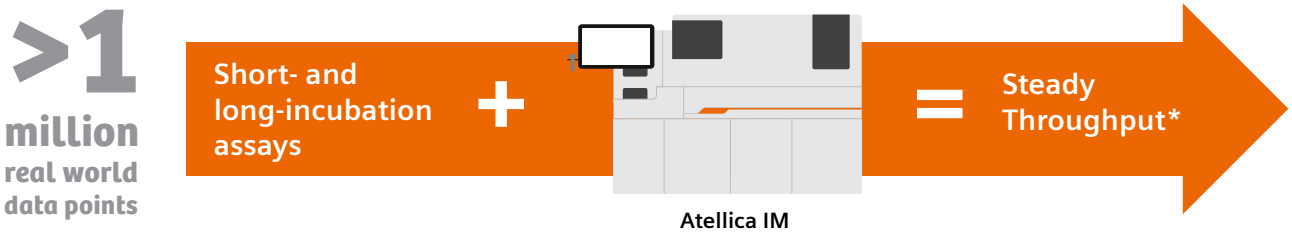
Introduction

Turnaround time (TAT) and throughput are two key performance metrics in the clinical laboratory that not only affect overall laboratory performance but can also significantly impact patient care and operational efficiency.[1] TAT in the laboratory is generally defined as the time taken from sample receipt to when results are verified for reporting to the healthcare provider (HCP), while throughput refers to the number of tests that can be processed in a defined period (generally represented as tests per hour). An inverse relationship exists between TAT and throughput, where a decrease in throughput can prolong overall TAT.

Shorter TATs ensure that HCPs receive patient test results promptly, allowing for quicker diagnosis and treatment decisions. Efficient throughput enables clinical laboratories to process a higher volume of tests within a given timeframe, translating to increased productivity, reduced backlogs, and optimize operational resources. A high throughput capacity also allows laboratories to meet the demands of fluctuating testing volumes that can occur during peak testing periods or during disease outbreaks without compromising TAT. Delays in TAT or fluctuations in throughput can lead to errors, compromised sample integrity, decreased confidence in laboratory services, as well as result in labs not meeting their key performance indicators (KPIs). Because maintaining consistent TATs and throughput levels is crucial for ensuring the quality and reliability of test results, laboratories often monitor and optimize these metrics as essential components of quality assurance programs.

Although several factors can impact both laboratory TAT and throughput, the Atellica® Solution has two technological innovations that help mitigate these scenarios during the analytical phase of processing: a dual incubation ring on the Atellica® IM and artificial intelligence (AI)-driven smart sampling. Traditional systems with a single incubation ring force assays to compete for analytical space. When there are more assays that require longer incubation times, incubation cuvettes are occupied for longer periods of time, reducing the space available for shorter tests, including STAT assays. A dual incubation ring allows longer assays, such as infectious disease (ID) assays, to be moved to an internal ring, thereby freeing up space on the outer incubation ring for assays with shorter incubation times. This approach maintains expected throughput for both short (e.g., Atellica® IM TnIH assay) and longer (e.g., Atellica IM Hepatitis panel) incubation assays.



Atellica IM

*Increasing the percentage of ID tests as a function of total tests does not significantly impact analyzer throughput. The total tests per hour remain within ±15% of the throughput observed when no ID assays are tested, indicating stable efficiency and capacity regardless of test type (Figure 2).

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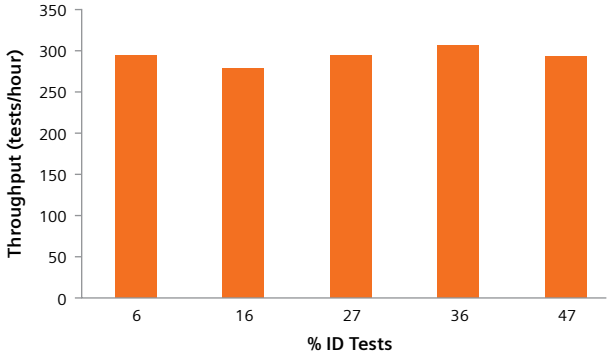

Figure 1. Throughput evaluation of Atellica IM Analyzer at a single site in 2017.[2]

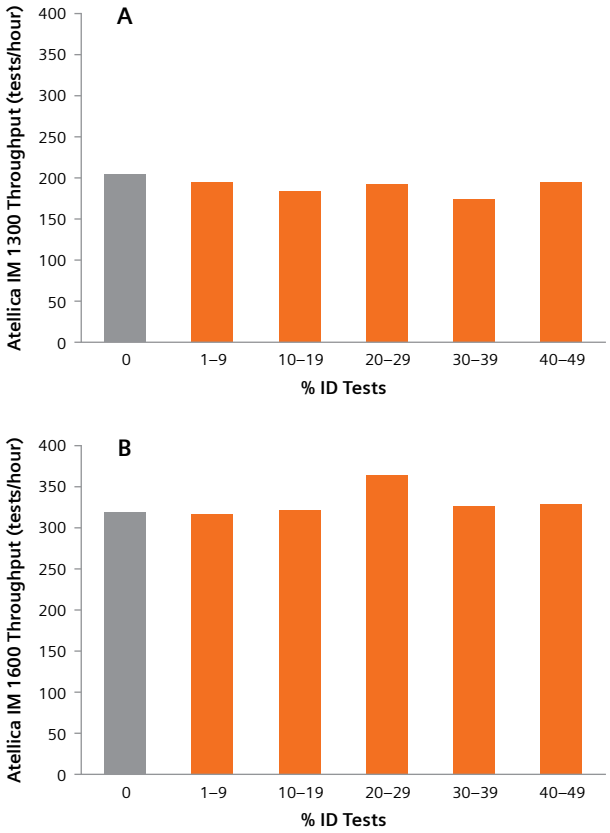

Figure 2. The percentage of ID tests does not significantly impact throughput of Atellica IM Analyzers. Each bar represents the throughput at the 97.5% quantile for Atellica IM 1300 Analyzers (A) and Atellica IM 1600 Analyzers (B). Operationally the Atellica IM 1300 and 1600 are identical, however the Atellica IM 1600 has a higher potential throughput of up to 440 tests/hour compared to 220 tests/hour for the Atellica IM 1300.

Traditional systems aspirate tests in sequential sample order, processing all tests for one sample before moving to the next. As a result, long and short assays for a sample are aspirated almost simultaneously. With AI-driven smart sampling on the Atellica Solution, aspiration is optimized by tests requested across multiple samples, reducing the impact of sequential processing. This minimizes special washes and prioritizes longer assays for improved and predictable throughput.

Analyzer throughputs publicized by various manufacturers are often theoretical or representative of a best-case scenario, where only assays with the shortest incubation times are used, and do not provide laboratories with a complete picture of what can be expected in a real-world, clinical setting. A previous study performed in 2017 evaluated the throughput of a single Atellica IM system using five variations of assay mix that would be expected in a routine clinical laboratory.[2] For each of the five runs, a total of 665 immunoassays were processed using 300 samples across an increasing percentage of ID assays, which typically have a longer assay time. Results per hour ranged from 280–308 for each of the worklists tested (Figure 1). Thus, throughput on the Atellica IM Analyzer was relatively unaffected by the mix of longer- and shorter-incubation assays, as the dual incubation ring design allow for more flexibility in the mix of incubation times.

In this study, we evaluated the impact of test mix (short vs. long) on TAT and throughput using global fleet-wide data obtained from >1000 Atellica IM 1300 and 1600 systems running 0–50% ID assays as part of their total immunoassay mix over a 2-week period. Short assays are defined as taking up to 26 minutes from aspiration to results, while long assays take up to 54 minutes from aspiration to result. To our knowledge, this is a unique approach for evaluating real-world throughput using big data from a worldwide fleet of analyzers independent of clinical setting.

Materials and Methods

- Assay mix, test volumes, throughput, and STAT high-sensitivity troponin (TNIH) TAT data were derived from Siemens Remote Services (SRS), a Siemens Healthineers proprietary remote connectivity platform, over three distinct 2-week periods.
- Real-world instrument data for Atellica IM ID assays with long (e.g., HIV, Hepatitis B, Hepatitis C, TORCH, Syphilis) and short (e.g., TNIH, Thyroid Stimulating Hormone 3-Ultra™ [TSH3UL], Total Human Chorionic Gonadotropin [ThCG], and N-terminal Pro-Brain Natriuretic Peptide [PBNP]) analytical times from the entire Atellica IM installed base running 15,000 to >300,000 tests/year were used for this analysis.
- TAT for this study is calculated from barcode read to resulted time.

Results

- More than 1 million data points were used for this analysis.
- Increasing the percentage of ID tests as a function of total tests does not significantly impact analyzer throughput. The total tests per hour remain within ±15% of the throughput observed when no ID assays are tested, indicating stable efficiency and capacity regardless of test type (Figure 2).
- The mean TAT for STAT TNIH is consistent even when the percentage of ID tests increases, differing by ≤12 seconds on average across each scenario presented (Figure 3).
- 90% of mean STAT TNIH tests were completed in ≤12 minutes across increasing percentages of ID tests (Table 1).

Table 1. TAT for the 90th percentile of STAT TNIH* tests.

% ID Tests	0%	1–9%	10–19%	20–29%	30–39%	40–49%
Samples (n)	54,427	20,767	22,425	13,029	6109	2367
90th percentile (min)	11.6	11.3	11.4	11.7	11.4	11.5

**TNIH incubation time is 10 minutes. The variation in mean TAT is related to the sample travel time from barcode read to aspiration.*

- To demonstrate the novel STAT prioritization of the Atellica Solution, STAT TNIH samples (n = 120,155) were aspirated in an average of 47 seconds from barcode read.

Conclusions

- Full Atellica IM fleet real-world instrument data support findings from the original launch study performed in 2017 that throughput is consistent and predictable even as the percentage of ID assays increases.
- When increasing the percentage of ID assays in the Atellica IM test mix, throughput is not significantly impacted, and there is little to no impact on the TAT of STAT assays such as TNIH.
- The dual incubation ring and AI-driven smart sampling on Atellica IM Analyzer negates the need for dedicated platforms and batching for ID testing, enabling laboratories to consolidate a comprehensive menu of ID tests with other immunoassays onto a single analyzer without significantly impacting workflow efficiency while optimizing lab resources.

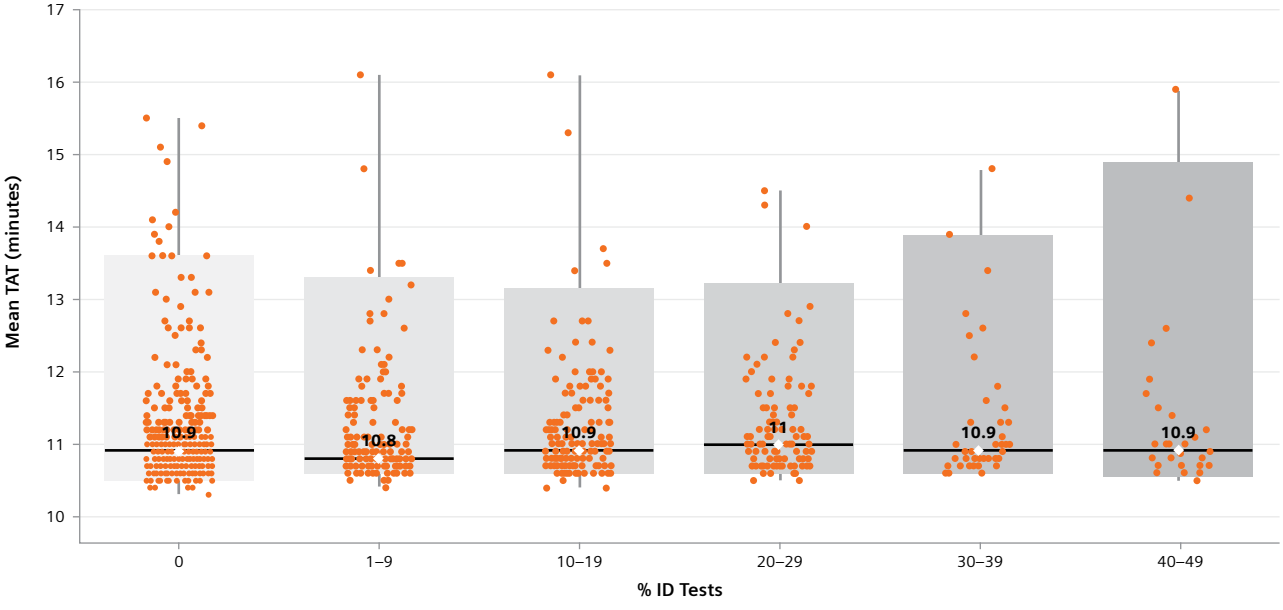

Figure 3. Mean TAT for STAT TNIH is not significantly impacted by increasing % ID tests.

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**Personalization of diagnosis, therapy selection and monitoring, aftercare, and managing health.*

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References:

1. Dawande PP, et al. Turnaround time: an efficacy measure for medical laboratories. Cureus. 2022;14(9):e28824. doi: 10.7759/cureus.28824
2. Bedini J, et al. Throughput evaluation of the Atellica IM 1600 Analyzer with varying clinical immunoassay test mix [AACC Abstract B-031]. 2018.

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