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Comparative Operational Evaluation: Tosoh AIA-CL300 vs. Beckman Coulter Access 2 Immunoassay Analyzers

A Workflow and Efficiency Comparison in Low-Volume Laboratory Settings

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Study Type: Comparative, Observational, Non-Interventional

Analytes: Thyroid-Stimulating Hormone (TSH), Follicle-Stimulating Hormone (FSH)

Study Site: RDI CLIA Lab — Van Nuys, California

Protocol: TSB-2804

Date: March 2026

Disclosure: This study was sponsored by Tosoh Bioscience, Grove City, Ohio. It was then independently designed and executed by RDI which is solely responsible for the content of this report.

Executive Summary

This independent evaluation (Protocol TSB-2804) compared the Tosoh AIA-CL300 and Beckman Coulter Access 2 for TSH and FSH under routine low-volume laboratory conditions. Both platforms showed excellent analytical correlation (TSH $R^2 = 0.994$; FSH $R^2 = 0.982$). The AIA-CL300 delivered markedly lower operational burden: about 401 fewer hours per year of maintenance and QC, 2.6× less-frequent calibration (a uniform 90-day curve versus analyte-specific 28-63 day intervals), faster time to first result, and no unused-reagent waste from its dry, single-test format. Across the full workflow these efficiencies saved an estimated 667 hours per year — roughly \$40,000 in labor — at typical physician-office-laboratory volumes, while matching the Access 2's analytical performance. For low-to-mid-volume laboratories, the result is lower labor cost, simpler scheduling, and reduced infrastructure without compromising result quality.

Introduction

While high-volume reference laboratories typically prioritize automation and throughput, physician-owned and specialty laboratories must maintain high-quality results with limited space, staff, and test volume. For these settings, clinical diagnostic solutions must combine analytical precision with operational efficiency.

This white paper presents a comparative operational evaluation of the Tosoh AIA-CL300 and the Beckman Coulter Access 2 immunoassay analyzers. Both systems are benchtop instruments designed for medium- and low-volume laboratories. The study was conducted by RDI, a

CLIA/CAP laboratory overseen by Dr. Michael Samoszuk, following a comparative, observational, non-interventional protocol (TSB-2804).

The evaluation assessed each analyzer across key workflow parameters including turnaround time, reagent waste, maintenance burden, calibration frequency, and infrastructure requirements. Analytical method correlation was assessed using paired serum specimens for TSH and FSH. The key findings are summarized below.

$R^2 = 0.994$	$R^2 = 0.982$	667 hrs/yr	\$40,000/yr
TSH	FSH	Workflow Time	Est. Labor
Correlation	Correlation	Saved	Savings

Study Overview

Study Design

The study followed a comparative, observational, non-interventional design conducted under standardized laboratory conditions at **RDI (Van Nuys, CA)**. A total of **40 paired serum specimens** were collected to ensure representative concentration ranges for TSH and FSH. The deidentified remnant serum samples that were used in this study were collected from a local reference laboratory under an IRB-approved remnant sample collection protocol. Each specimen was analyzed in duplicate on both instruments. Descriptions of the samples are provided in Table 1.

Concentration Tier	TSH Range (uIU/mL)	FSH Range (mIU/mL)	Specimens (n, per analyte)
Low	0.003–0.75	0.1–4.0	5
Low–Mid	0.75–3.72	4.0–10.0	5
Mid–High	3.72–8.0	10.0–15.0	5
High	8.0–120.0	15.0–250	5
Total	—	—	20 each (40 total)

Table 1. Serum specimen distribution by concentration tier (n = 20 per analyte; 40 total).

System Configurations

Tosoh AIA-CL300: Compact, automated chemiluminescent enzyme immunoassay (CLEIA) analyzer using a dry-reagent format (CL AIA-PACK® twin-cup design). Each cup contains all reagents for a single test — eliminating liquid reagent handling and simplifying inventory management.

Beckman Coulter Access 2: Liquid-reagent immunoassay analyzer for mid-volume clinical use featuring onboard refrigerated reagent storage and random access testing. Liquid reagent management with onboard refrigeration.

Instrument Specifications

	Analyzer	Reagent Stability After Opening	TAT (1st result)	Cal Curve Stability	Cal Replicates	Sample Volume	Linearity
TSH	Tosoh AIA-CL300	N/A (dry)	~20 min	90 days	2 levels x 3 reps	50 µL	0.003–120 uIU/mL
TSH	Beckman Access 2	63 days	~40 min	63 days	6 levels x 2 reps	50 µL	0.01–50 uIU/mL
FSH	Tosoh AIA-CL300	N/A (dry)	~20 min	90 days	2 levels x 3 reps	10 µL	0.1–250 mIU/mL
FSH	Beckman Access 2	28 days	~60 min	28 days	6 levels x 2 reps	25 µL	0.2–200 mIU/mL

Table 2. Instrument specifications for TSH and FSH assays. Tosoh rows shaded.

Methodology

All comparative testing was conducted under controlled laboratory conditions. Key steps included:

- System preparation:** Daily maintenance and checks completed per each manufacturer's recommendations.
- Calibration and QC:** Each analyte was calibrated prior to testing. QC materials were analyzed to confirm performance validity.
- Sample testing:** Paired serum specimens were tested in duplicate on both analyzers. Batches of 8 samples were run sequentially on both instruments for comparability. Turnaround time and workflow steps were recorded for each batch.
- Data collection:** Instrument logs and operator time observations were compiled. Statistical analysis was performed on paired measurement data using linear regression.

Results

Results demonstrate workflow efficiencies, cost efficiencies, and reduced space and utility requirements for the Tosoh AIA-CL300 compared to the Beckman Access 2, while maintaining strong analytical correlation between platforms.

Analytical Correlation

Forty paired serum specimens were analyzed across the full reportable range for both TSH and FSH. Method comparison was performed using Deming and Passing-Bablok regression per the TSB-2804 protocol, with OLS regression and Pearson correlation reported alongside. Beckman is treated as the reference (X) and Tosoh as the test method (Y). Results flagged for Beckman system errors, high CV, or large between-platform discrepancies were repeated; repeat values were used in the analysis where applicable.

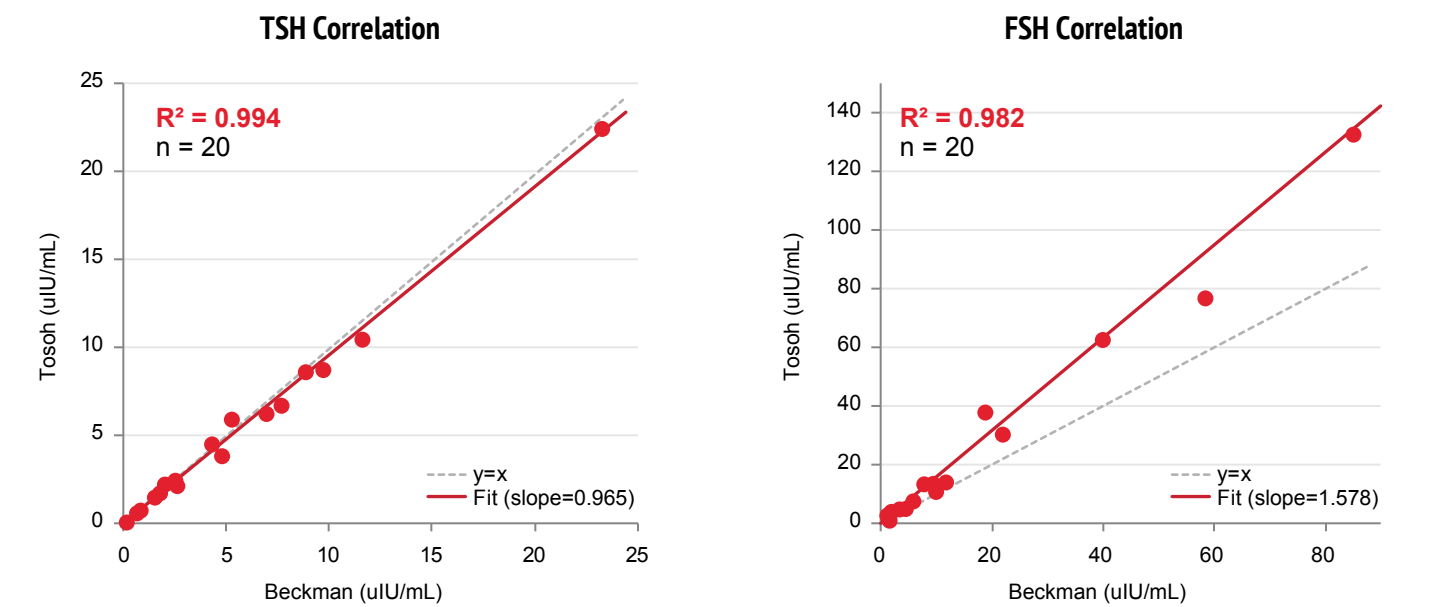


Figure 1. Method correlation: Tosoh AIA-CL300 vs. Beckman Coulter Access 2 for TSH (left) and FSH (right). Each point represents the mean of duplicate measurements (n = 20 per analyte).

Analyte	n	R ²	Slope	Intercept	Pearson r	Assessment
TSH	20	0.994	0.965	0.06	0.997	✓ Excellent
FSH	20	0.982	1.578	-0.42	0.991	✓ Very Good

Table 3. OLS regression statistics. Per-protocol Deming and Passing-Bablok regression with 95% CIs.

TSH demonstrated excellent correlation ($R^2 = 0.994$). Deming slope 0.9558 [95% CI 0.9009–0.9739] and Passing-Bablok slope 0.9472 [0.8985–0.9970] are near unity; intercept 95% CIs contain zero. There is no statistically significant proportional or constant bias – TSH results align directly across platforms. FSH showed very strong linearity ($R^2 = 0.982$), but the proportional slope offset is statistically significant: Deming slope 1.5837 [1.3162–1.7085] and Passing-Bablok slope 1.4303 [1.3106–1.5973] both exclude 1. Tosoh reads approximately 1.4–1.6× the Beckman value for FSH; intercept CIs include zero (no constant bias). FSH results are highly correlated but should not be mixed interchangeably across platforms without applying method-specific interpretation. Each platform should be interpreted against its own manufacturer’s reference range.

Maintenance

Daily and periodic maintenance procedures were performed on both analyzers on the official study day (March 17, 2026). All time was recorded from preparation start through procedure completion. The AIA-CL300 required significantly less hands-on time across all maintenance categories.

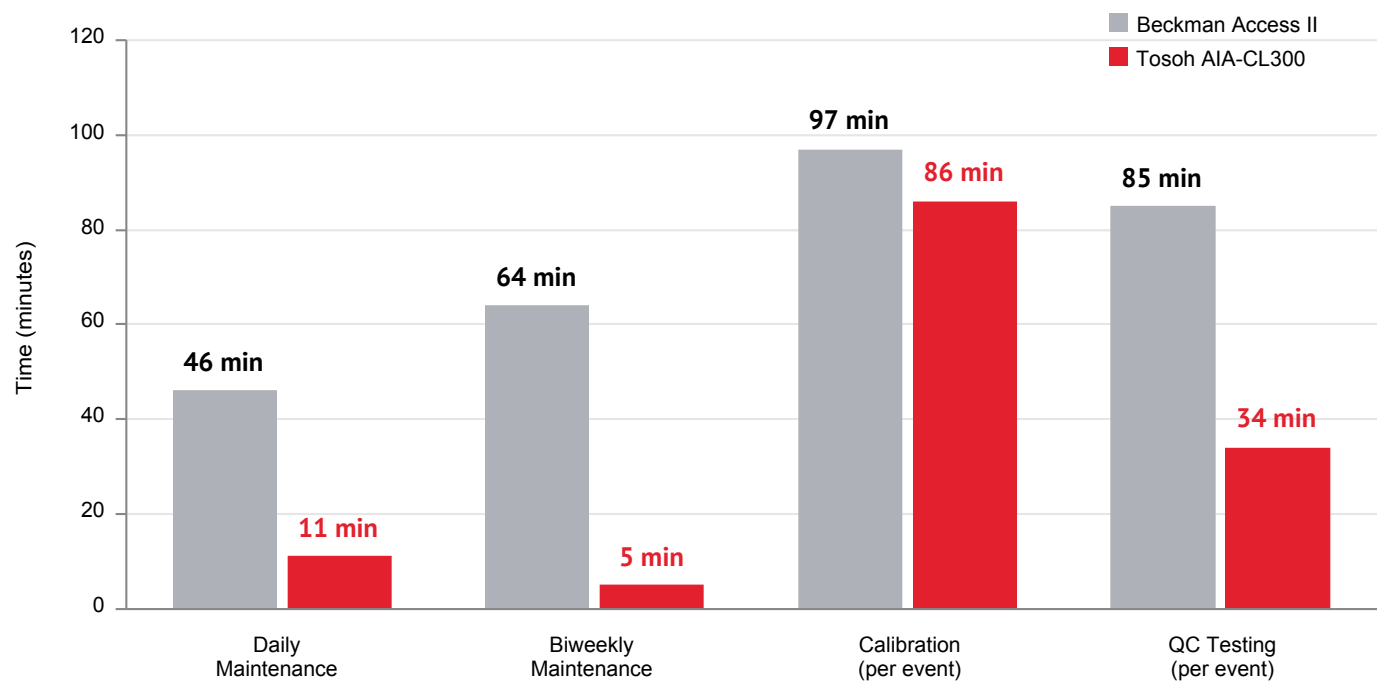


Figure 2. Observed maintenance time comparison (minutes). Beckman periodic maintenance is weekly; Tosoh is biweekly. Tosoh quarterly maintenance (~121 min, 4×/year) was measured separately.

Maintenance Type	Beckman Access 2	Tosoh AIA-CL300	Time Saved	Frequency
Daily QC	85 min	34 min	51 min/day	Daily
Daily Maintenance	46 min	11 min	35 min/day	Daily
Periodic Maintenance	64 min	5 min	59 min/event	Beckman: weekly; Tosoh: biweekly
Quarterly Maintenance	N/A	122 min	—	4×/year (Tosoh only)
Annual Maintenance + QC Time	~599 hrs/yr	~198 hrs/yr	~401 hrs saved	—

Table 4. Maintenance and daily-QC time, annualized over 250 operating days/year (50 weeks). Annual Maintenance + QC Time sums Daily QC, Daily Maintenance, Periodic, and (Tosoh) Quarterly Maintenance.

Calibration

The AIA-CL300 holds a 90-day calibration curve across both assays, so each analyte is recalibrated only about 5 times per year. The Access 2 recalibrates more often, and on an analyte-specific schedule rather than a uniform one — every 63 days for TSH but every 28 days for FSH, the latter requiring roughly 13 recalibrations per year. Tosoh’s single 90-day interval for both assays reduces calibration frequency and the associated hands-on time and simplifies scheduling because one interval applies across the menu.

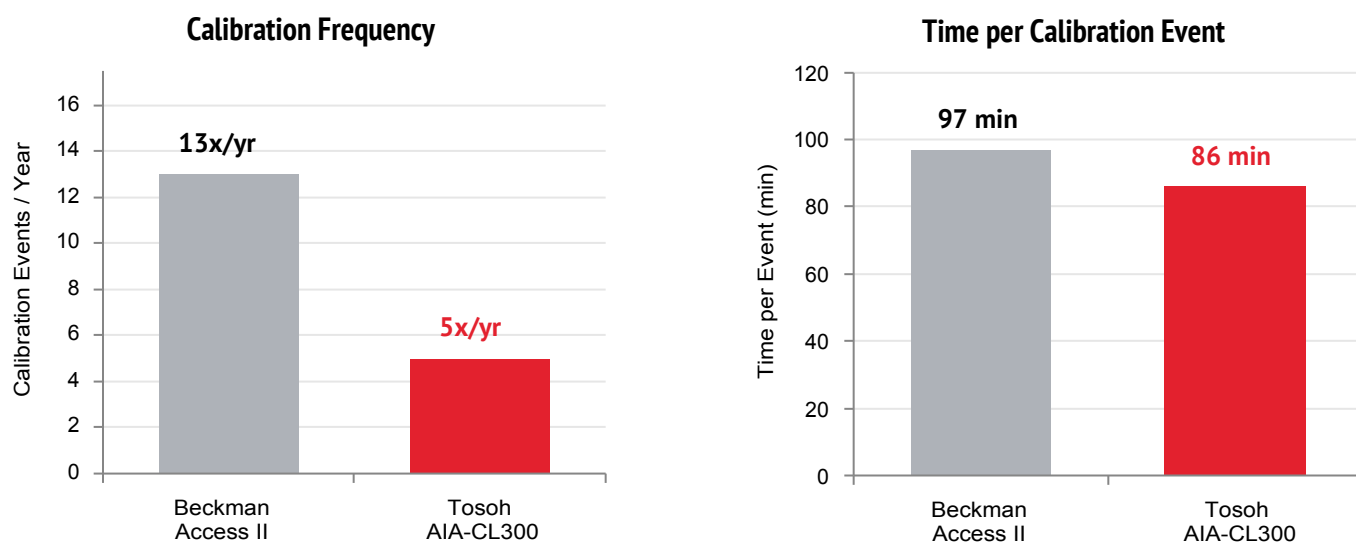


Figure 3. Calibration frequency (left) and time per calibration event (right). AIA-CL300 requires 2.6× fewer events annually (5 vs. 13).

Parameter	Beckman Access 2	Tosoh AIA-CL300	Tosoh Advantage
Calibration Stability	28 days	90 days	3.2× longer
Cal Events/Year	13×/year	5×/year	2.6× fewer events
Time per Event (TSH+FSH)	97 min	86 min	11 min faster/event
Annual Cal Time	~21.0 hrs/yr	~7.2 hrs/yr	~13.8 hrs saved/yr

Table 5. Calibration comparison. Annual time based on 13 Beckman events vs. 5 Tosoh events per year. Beckman's 28-day stability and 13×/yr reflect FSH; TSH recalibrates every 63 days. The AIA-CL300's 90-day interval is uniform across all assays.

Workflow Efficiency

During the correlation study, time to first result was measured across 5 runs. The AIA-CL300 returned its first result roughly twice as fast as the Access 2 — 20 min vs. 40 min for TSH (50% faster) and 20 min vs. 60 min for FSH (67% faster). For physician-office laboratories that aim to deliver results during the patient visit, this difference directly affects whether a result can be reviewed before the patient leaves. Beyond first result, total batch turnaround was also more predictable on the AIA-CL300: across four 8-sample batches it held to ~55 min regardless of analyte mix, while the Access 2 ranged from 62 min (all-TSH) to 99 min (all-FSH).

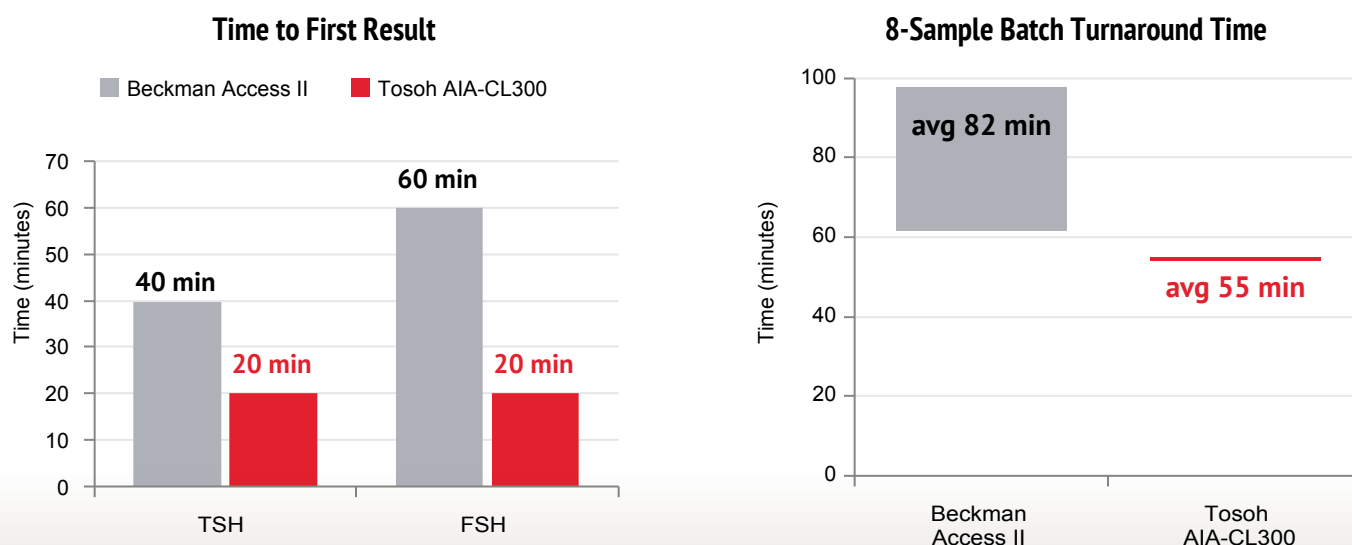


Figure 4. Time to first result by analyte (left) and 8-sample batch turnaround time by run (right). Tosoh AIA-CL300 batches held to ~55 min across mixed and all-FSH compositions; the Access 2 ranged 62–99 min depending on composition. Tosoh avg 55.4 min ($\sigma \approx 0.5$); Beckman avg 82.1 min ($\sigma \approx 14.5$).

Reagent Waste

Beckman’s liquid reagent packs hold a fixed number of tests and carry a fixed onboard stability once opened — 28 days for FSH, 63 days for TSH — so any tests not used before a pack expires are discarded. The effect is largest at low volume: an FSH pack holds 50 tests, and a laboratory running about one FSH per day uses only ~28 of them within the 28-day window — roughly 44% wasted. That fraction falls as daily volume rises and disappears only near full pack utilization (50 tests within 28 days). Because the AIA-CL300 uses dry, single-test cups with no multi-test pack to expire, unused-reagent waste is effectively zero regardless of daily volume.

Feature	Beckman Access 2	Tosoh AIA-CL300	Advantage
Reagent Format	Liquid cassettes	Dry single-use cups	Tosoh — no expiry waste
FSH Onboard Stability	28 days (50 tests/pack)	N/A — dry format	Tosoh — zero waste risk
TSH Onboard Stability	63 days (100 tests/pack)	N/A — dry format	Tosoh — zero waste risk
Dead Volume	~150 µL	~100–120 µL	Tosoh — 20–33% less
Potential Waste (low volume 1x/day)	44%	0%	Tosoh — eliminates waste

Table 6. Reagent format and potential waste at low test volume.

Space and Infrastructure Requirements

Space: The AIA-CL300’s compact design and dry reagent format eliminate the need for dedicated refrigerated reagent storage. The Beckman Access 2 requires additional bench space for a PC unit and reagent refrigeration as well as external fluidics.

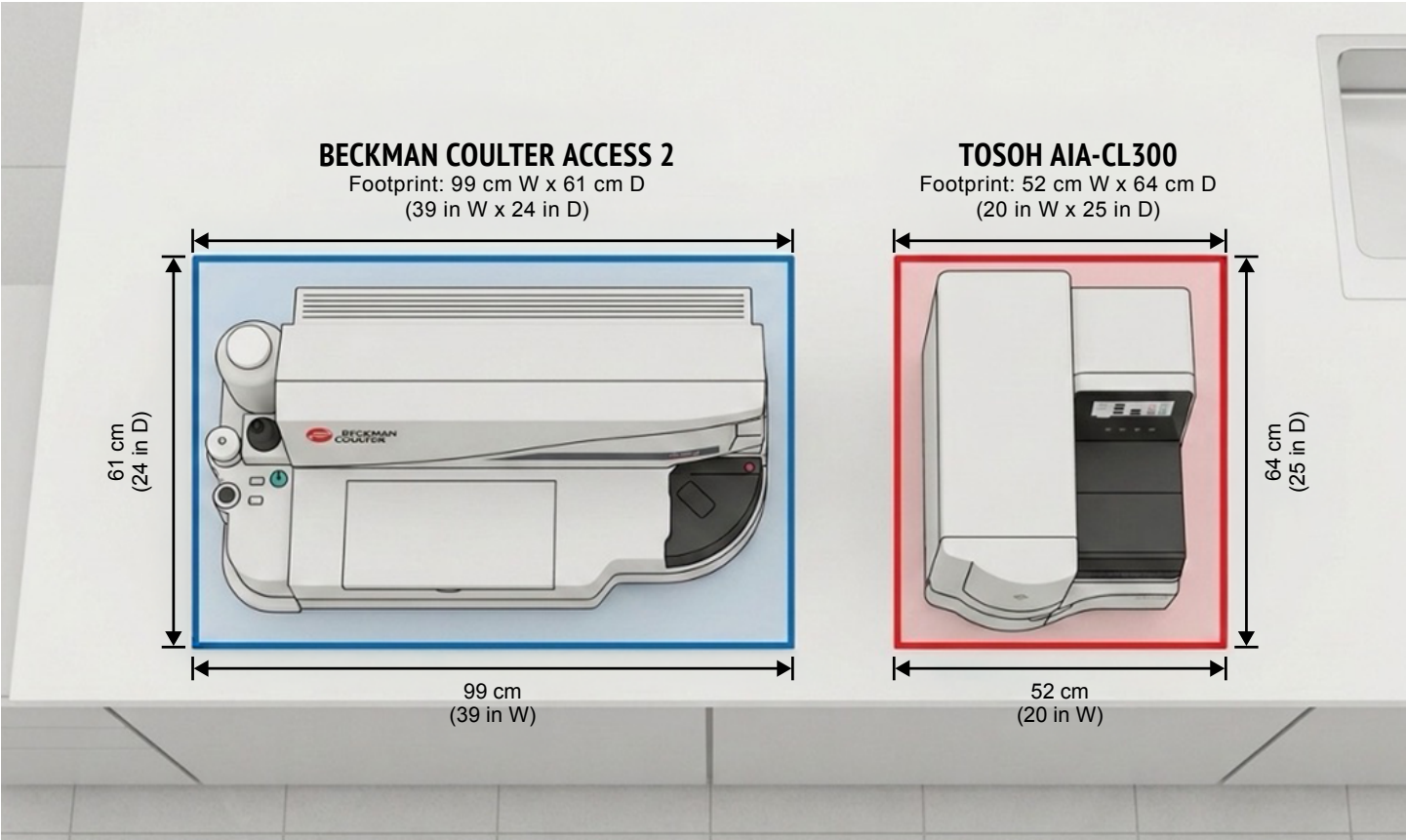


Figure 5. Benchtop footprint, drawn to scale (top-down view). The AIA-CL300 occupies about 517 sq in of bench space versus 936 sq in for the Access 2 — roughly 45% less, driven mainly by its narrower width (20.5 vs. 39 in). Dimensions measured at RDI Trials.

Conclusion

The Tosoh AIA-CL300 demonstrated strong operational advantages across all measured categories while delivering analytically comparable performance to the Beckman Coulter Access 2. For physician-owned and specialty laboratories, these advantages translate directly into reduced labor burden, lower reagent costs, and a simpler, more flexible workflow.

Category	Beckman Access 2	Tosoh AIA-CL300	Finding
TSH Correlation	Reference	R² = 0.994	✓ Excellent agreement
FSH Correlation	Reference	R² = 0.982	✓ Very strong agreement
Daily Maintenance	46 min/day	11 min/day	✓ 76% time reduction
Calibration Frequency	13×/year (28-day)	5×/year (90-day)	✓ 2.6× less frequent
TTFR – TSH	~40 min	~20 min	✓ 50% faster
TTFR – FSH	~60 min	~20 min	✓ 67% faster
Reagent Waste	Up to 44% (liquid pack)	0% (dry single-use)	✓ Eliminates waste
Annual Maintenance + QC Time	599 hrs/yr	198 hrs/yr	✓ 401 hrs saved/yr
Est. Annual Labor Cost	\$80,200/yr	\$40,300/yr	✓ \$39,900 saved/yr
POL Throughput Fit	Labor-intensive	Optimized for POL	✓ Breakeven >25 samples/day

Table 7. Overall operational metrics comparison.

For physician-owned laboratories and other low-to-mid volume clinical settings, the Tosoh AIA-CL300 offers a compelling combination of analytical reliability and operational simplicity. Its dry-reagent, zero-waste architecture eliminates the infrastructure, maintenance, and reagent management burden associated with liquid-reagent platforms – delivering measurable time and cost savings at the volume levels typical of the POL market.



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