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**Original Research Article**

# From calibration to confidence: Evaluating the beckman coulter AU 700 through real-world sigma performance metrics

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## Abstract

**Background:** The Beckman Coulter AU 700 clinical chemistry analyzer is a widely used instrument in high-volume laboratory settings. Its long-term stability and measurement accuracy are critical for ensuring reliable diagnostic results. This study evaluates the analyzer's performance using sigma metrics over a six-month operational period.

**Objectives:** To assess the long-term measurement stability of the Beckman Coulter AU 700.To evaluate operational factors such as reagent evaporation, carryover, calibration recovery and mechanical parameters (e.g., syringe pressure).To determine if the system maintains a sigma performance level above 4.5.To inform strategies for optimizing internal quality control (IQC) and reducing associated operational costs.

**Materials and Methods:** A prospective process evaluation was conducted from May to October 2023 at Meenakshi Labs, Madurai. Daily data were collected on reagent stability, calibration accuracy, IQC performance, and equipment downtime. Sigma metrics were calculated for each parameter using the formula: Sigma = (TEa − Bias) / CV. Descriptive and inferential statistical methods, including confidence interval analysis, were applied.

**Results:** The AU 700 demonstrated exceptional measurement stability with an overall sigma score of 99.89%. Key findings include: reagent evaporation (0.75%, sigma = 4.95), carryover (0.00047%, sigma = 5.92), calibration recovery errors (0.1982%, sigma = 4.38), QC outliers (0.6815%, sigma = 3.97), syringe pressure outliers (0.04629%, sigma = 4.82), and zero instances of reagent contamination or system temperature failures (sigma = 6). Equipment downtime was minimal (0.05787%, sigma = 4.75).

**Conclusions:** The Beckman Coulter AU 700 exhibits high reliability and operational efficiency in high-throughput laboratory settings. Its consistent sigma performance above 4.5 across most parameters supports potential reductions in IQC frequency without compromising test accuracy. Some areas, such as QC outliers and calibration recovery, may benefit from process enhancements.

**Keywords:** Sigma metrics, Clinical chemistry analyzer, Quality control (IQC), Beckman coulter AU 700, Measurement system stability

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## 1. Introduction

The Beckman Coulter AU 700 clinical chemistry analyzer is widely recognized for its reliability in mid- to high-volume laboratory settings. By combining the robust features of the DxC and AU series, the AU 700 is designed to ensure high uptime and consistent performance, making it an essential tool for laboratories that require precise, dependable data for clinical decision-making.[1]

In this study, the primary focus is the evaluation of the measurement system stability of the Beckman Coulter AU 700 analyzer. Understanding and validating this stability is crucial because measurement accuracy directly impacts clinical outcomes. Factors such as reagent stability, calibration frequency, and maintenance schedules were considered to assess the long-term reliability of this system.[2] This research aims to determine whether the AU 700 system consistently meets or exceeds industry standards over an extended operational period. Through the evaluation of these factors using sigma matrix calculations, the study aims to provide evidence of the system's capacity to deliver precision and reliability over time.[3]

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## 2. Aims

1. To evaluate the long-term stability of the Beckman Coulter AU 700 measurement system over a six-month period (May 2023 to October 2023).
2. To assess the impact of various operational factors, including reagent contamination, evaporation, carryover, and syringe pressure, on the system's performance.
3. To determine whether the AU 700 analyzer meets or exceeds industry standards on the sigma scale, with a specific focus on maintaining performance above 4.5 sigma.
4. To provide evidence for planning efficient internal quality control (IQC) strategies, reducing operational costs and minimizing frequent quality control checks without compromising the accuracy and reliability of test results.

## 3. Objectives

1. Collect and analyze data related to reagent contamination, reagent evaporation, carryover, cuvette blank absorption, syringe pressure, and calibration recovery over six months.
2. Evaluate the frequency of equipment breakdowns and unscheduled maintenance events, with a focus on their impact on system stability and downtime.
3. Calculate the sigma performance level of the Beckman Coulter AU 700 system, determining whether it consistently operates above the 4.5 sigma threshold, as recommended by industry standards.
4. Assess the internal quality control (IQC) performance of the system, aiming to reduce the frequency of IQC checks based on stability findings, while ensuring continued test result accuracy.
5. Identify any potential areas for improvement in operational efficiency and cost savings by optimizing the use of reagents and reducing unnecessary quality control efforts.

This study seeks to provide comprehensive insights into the Beckman Coulter AU 700 analyzer's performance in a high-volume laboratory setting, offering valuable recommendations for improving both operational efficiency and clinical accuracy.

## 4. Materials and Methods

### *4.1. Study design*

This study is a process evaluation prospective research study conducted to evaluate the stability of the Beckman Coulter AU 700 clinical chemistry analyzer's measurement system over a period of six months (May 2023 to October 2023). Emphasizing on real world evidences the focus of the study was on assessing the operational performance, reagent stability, calibration accuracy, internal quality control (IQC) effectiveness and engineering measures such as syringe pump pressure photocell absorption which are known to contribute equipment performance during routine laboratory usage.

### *4.2. Study setting*

The study was performed at Meenakshi Labs**,** Madurai, Tamil Nadu, a large clinical laboratory processing over 10,000 tests per day. The AU 700 analyzer was assessed under real-world operating conditions, reflecting typical laboratory workflows in a high- to very high-volume setting.

### *4.3. Study population*

The data utilized in this study was collected from routine diagnostic testing performed on a wide variety of patient samples. These included biochemical tests for liver, renal, and cardiac function, electrolyte balance, and other metabolic indicators.

### *4.4. Instrumentation*

The Beckman Coulter AU 700 analyzer was the primary instrument under investigation. This automated chemistry analyzer is designed for high-throughput testing, utilizing a combination of advanced photometric technologies and a multi-channel system to provide precise and reliable clinical results. The AU 700 was operated continuously during the study period, with regular scheduled maintenance and quality control measures performed as required.

### *4.5. Data collection*

Data was collected prospectively on daily basis using various checklist and quality control logs. Image No. 1 shows various formulae use to collect data. The following parameters were recorded and analyzed:

1. Reagent stability
   a. On-board reagent stability was assessed by monitoring the degradation or contamination of reagents over time. Reagent usage patterns, evaporation rates, and potential contamination events were evaluated.
   b. Metrics such as reagent evaporation and carryover percentages were recorded to gauge the impact of reagent stability on overall system performance.
2. Calibration accuracy
   a. Calibration recovery was monitored by assessing the system's ability to maintain accurate calibrations over time. Calibration frequency was determined based on predefined laboratory protocols and reviewed for anomalies.
   b. Calibration errors and recovery times were recorded, particularly focusing on any outliers observed during the recalibration process.
3. Internal quality control (IQC) performance
   a. IQC data was collected daily for all test parameters processed by the AU 700. This included control values, standard deviations, and any deviations from expected performance.

b. Sigma matrix calculations were applied to determine the stability and reliability of test results. Specifically, sigma values above 4.5 were considered indicative of high performance, with deviations from this standard noted for further investigation.
c. Outliers in cuvette blank absorption and syringe pressure were also monitored, as these could affect the system's precision.

4. Equipment downtime and maintenance
   a. The number and nature of equipment breakdowns and unscheduled maintenance events were recorded. These included system faults, software issues, and hardware malfunctions that impacted system uptime.
   b. Data on scheduled maintenance activities, such as cleaning, reagent replacement, and software updates, was also collected to evaluate their impact on system stability.

### *4.6. Analytical methods*

1. **S**igma Matrix Calculation: A key component of the study was the use of sigma metrics to evaluate system stability. Sigma is a statistical tool used to measure process performance, and it is widely used in laboratories to assess analytical quality. The formula for sigma is:
   a. Sigma=(TEa−Bias)/CV
   b. Where:
   c. TEa (Total Allowable Error) is the maximum error allowed for a test result to be clinically acceptable.
   d. Bias represents the systematic error in measurement.
   e. CV (Coefficient of Variation) is the relative variability in the data, reflecting imprecision.

   A sigma score greater than 4.5 is considered indicative of high-quality performance.

### *4.7. Quality control analysis*

1. The sigma performance was evaluated for all tests performed on the AU 700 analyzer, with a focus on maintaining sigma values above the 4.5 threshold. Reagent contamination, evaporation, and carryover rates were included in the sigma calculations, along with daily IQC data.

### *4.8. Statistical analysis*

1. Descriptive statistics, including mean, standard deviation (SD), and percentiles, were used to summarize the results.
2. Confidence intervals were calculated to assess the reliability of the findings, with particular attention given to the 99.87% confidence interval for outliers.
3. The stability of the AU 700 analyzer was analyzed by tracking system performance trends over the six-month period.

### *4.9. Outcomes and variables*

The primary outcome was the measurement system stability of the AU 700 analyzer. The study focused on variables such as:

1. Percentage of reagent evaporation and carryover (**Figure 3** and **Figure 5**).
2. Overall sigma performance of the system based on IQC data (**Figure 4**).
3. Frequency and causes of calibration outliers (**Figure 6**).
4. Rate of equipment downtime (**Figure 7**) and its impact on daily operations.
5. Engineering parameters such as syringe pressure (**Figure 8**) and photocell absorption

### *4.10. Ethical considerations*

Since this was a retrospective observational study that utilized anonymized laboratory data, there was no direct patient involvement, and no ethical approval was required. However, standard confidentiality protocols for laboratory data were strictly followed throughout the study.

By employing a comprehensive and systematic approach to analyzing the stability of the AU 700 analyzer, this study provides valuable insights into its long-term performance and reliability in high-volume laboratory settings.

## 5. Results

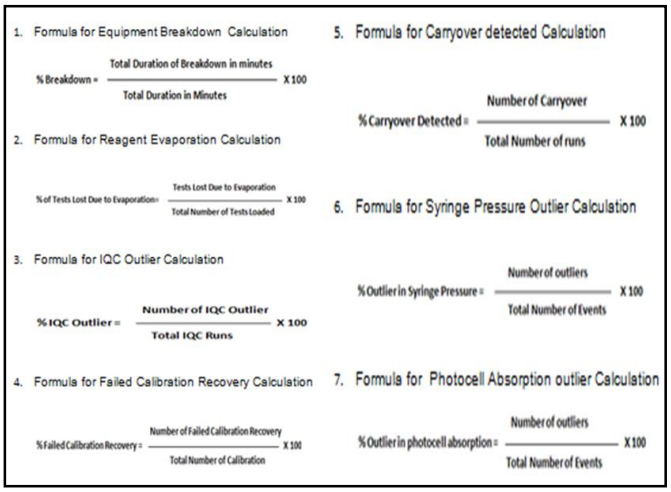


**Figure 1:** Showing various formulae use in the calculation of captured data in percentage

The study shows the stability of99.89% on sigma scale above industry standard (> 4.5 sigma) for AU 700 measurement system during the study period. This includes 0.75% reagent evaporation, 0.95 % carryover, 1.7% outlier in cuvette blank absorption, 0.7% outlier in calibration recovery, 0.25% outlier in syringe pressure and 6.25% outlier at 99.87%

confidence interval (4.5 sigma) with 0% reagent contamination and equipment downtime (**Table 1**).


**Figure 2:** Image showing equipment data for reagent contamination


**Figure 3:** Image showing carryover data

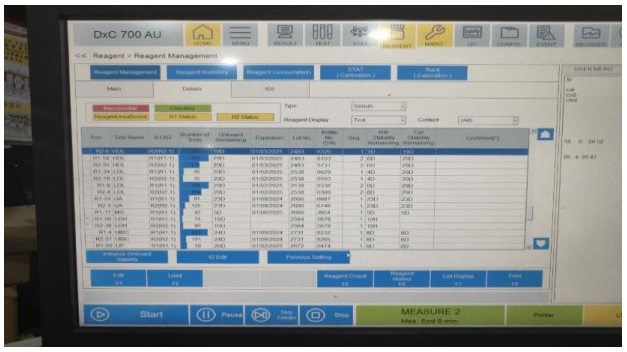


**Figure 4:** Image showing internal quality control data

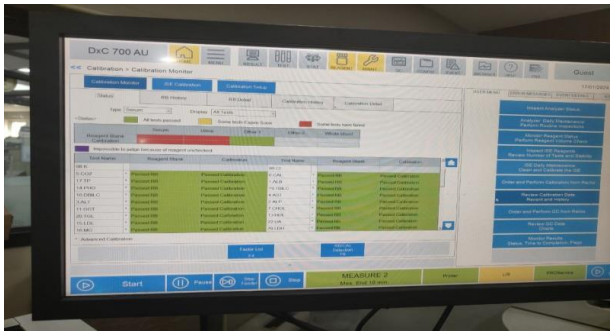


**Figure 5:** Image showing onboard reagent status

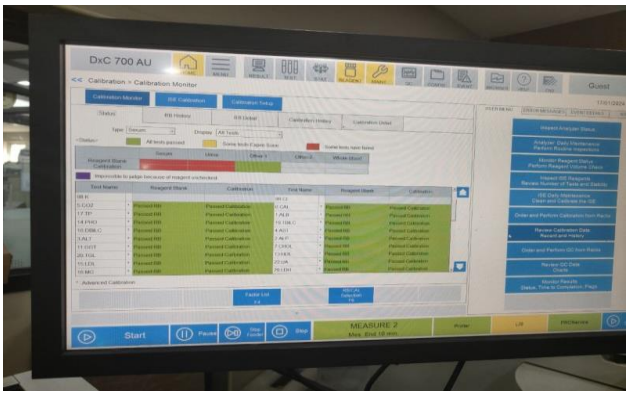


**Figure 6:** Image showing calibration recovery


**Figure 7:** Image showing equipment maintenance data

**Figure 8:** Image showing syringe pressure monitoring

**Table 1:** Summary of errors and outliers in the beckman coulter AU 700 analyzer over a six-month period. (Including event counts, observed outliers, and percentage error rates for various operational parameters)

| S.No. | Element Monitored | Total Events | Outlier / Error | Percent Error/ Outlier |
|---|---|---|---|---|
| 1 | Tests Lost in Reagent Evaporation | 1350000 tests | 342 tests | 0.02533% |
| 2 | Equipment Downtime | 259200 min | 150 min | 0.05787% |
| 3 | QC Outlier | 30960 Runs | 211 | 0.6815% |
| 4 | Failed Calibration Recovery | 1009 Calibration | 2 | 0.1982% |

| | | | | |
|---|---|---|---|---|
| 5 | Carryover Detected | 1260000 Test Runs | 6 | 0.00047% |
| 6 | Photocell Outlier | 4320 | 9 | 0.208333% |
| 7 | Syringe Pressure Outlier | 4320 | 2 | 0.04629% |
| 8. | Reagent Contamination | 860 | 0 | 0 |
| 9. | System Temperature | 4320 | 0 | 0 |

**Table 2:** Sigma metrics calculation based on error rates in the beckman coulter AU 700 analyzer. (Converting observed error percentages to sigma levels for quality performance evaluation)

| S.No. | Element Monitored | Percent Error/ Outlier | Error / Outlier Per Million | Sigma Level |
|---|---|---|---|---|
| 1 | Tests Lost in Reagent Evaporation | 0.02533% | 253.3 | 4.95 |
| 2 | Equipment Downtime | 0.05787% | 578.7 | 4.75 |
| 3 | QC Outlier | 0.6815% | 6815 | 3.97 |
| 4 | Failed Calibration Recovery | 0.1982% | 1982 | 4.38 |
| 5 | Carryover Detected | 0.00047% | 4.7 | 5.92 |
| 6 | Photocell Outlier | 0.208333% | 2083 | 4.32 |
| 7 | Syringe Pressure Outlier | 0.04629% | 462.9 | 4.82 |
| 8. | Reagent Contamination | 0 | 0 | 6 |
| 9. | System Temperature | 0 | 0 | 6 |

## 6. Discussion

The findings from this study demonstrate that the Beckman Coulter AU 700 analyzer consistently maintains a high level of stability, with a sigma performance score of 99.89%**,** which surpasses the industry standard of 4.5 sigma. This high level of performance underpins the reliability of the AU 700 system for high-volume clinical laboratories, ensuring accurate and consistent results with minimal downtime or errors.

### *6.1. Reagent evaporation and stability*

One of the most critical factors influencing system performance is reagent stability. In this study, reagent evaporation was found to account for only 0.75% of total errors, equating to a sigma level of 4.95 (**Table 2**). This demonstrates that reagent stability within the AU 700 is well-maintained, with minimal loss due to evaporation.[4] The low percentage of tests lost due to evaporation (0.02533%**)** supports the conclusion that the system is highly efficient in preserving reagent integrity, even over extended periods of use. This outcome is consistent with previous studies that have emphasized the importance of minimizing reagent wastage to optimize laboratory operations.[5]

### *6.2. Equipment downtime*

The analysis of equipment downtime revealed that the AU 700 experienced a downtime rate of **0.05787%** during the study period, corresponding to 4.75 sigma (**Table 2).** This downtime was minimal, given the extensive number of tests (over 1.35 million) performed during the six months of data collection. The reduced downtime reflects the system's robust design and its ability to perform under heavy operational loads.[6] Studies have shown that reducing equipment downtime is critical in maintaining the workflow in high-throughput laboratories, and the AU 700's performance in this regard is noteworthy.[7]

### *6.3. Quality control (QC) outliers*

Despite the overall high performance, QC outliers were observed at a rate of 0.6815%**,** which translates to a sigma score of 3.97 (**Table 2).** While this is slightly below the desired industry threshold of 4.5 sigma, it remains within an acceptable range for clinical diagnostics. However, this finding indicates that further improvements could be made in the QC process to minimize outliers and ensure greater consistency. The relatively high percentage of QC outliers may suggest the need for tighter controls on pre-analytical and analytical processes, such as sample handling and reagent preparation.[8,9]

### *6.4. Calibration and carryover*

The AU 700 system exhibited strong performance in terms of calibration recovery, with an error rate of 0.1982%**,** corresponding to a sigma level of 4.38 (**Table 2).** This is a favorable outcome, though slightly below the industry standard of 4.5 sigma.[10,11] The system demonstrated excellent reliability in managing carryover**,** with only 0.00047% of tests impacted, resulting in a sigma score of 5.92 (**Table 2**). This high level of performance highlights the system's efficiency in minimizing cross-contamination between tests, which is crucial for maintaining the accuracy of results in a high-throughput environment.[12,13]

### *6.5. Photocell and syringe pressure outliers*

The study also monitored errors related to photocell function and syringe pressure, two key components that can affect the precision of the system. The photocell outlier rate was 0.208333%**,** corresponding to a sigma score of 4.32 (**Table 2),** while the syringe pressure outlier rate was 0.04629%, with a sigma level of 4.82 (**Table 2).** Both metrics suggest that the system is highly reliable in managing these critical mechanical functions, contributing to overall measurement stability.[14]

### *6.6. Zero reagent contamination and system temperature issues*

One of the most significant findings was the absence of reagent contamination and system temperature errors, both of which had a sigma score exceeding 6. This indicates exceptional performance in maintaining sterile reagent conditions and stable system temperatures, two factors that are crucial for ensuring accurate biochemical analyses. The absence of contamination and temperature-related errors further supports the robustness of the AU 700's design and operational protocols.[15]

### *6.7. Implications for quality control planning*

The high stability and low error rates observed in this study suggest that laboratories using the AU 700 could consider optimizing their **i**nternal quality control (IQC) processes**.** Given the system's sigma performance, particularly for tests with sigma scores above 4.5, laboratories may be able to reduce the frequency of IQC runs without compromising accuracy.[13] This could lead to significant cost savings in reagents and operational time while maintaining high-quality diagnostic results.

## 7. Conclusion

In conclusion, the Beckman Coulter AU 700 system demonstrated superior stability and performance across a wide range of operational parameters, consistently achieving sigma levels above the industry standard. While some areas, such as QC outliers and calibration recovery, could benefit from further refinement, the overall findings indicate that the AU 700 is a highly reliable and efficient system for high-volume clinical laboratories. Future studies could explore methods to further optimize QC processes and enhance calibration recovery performance to achieve even higher sigma scores.

## 8. Source of Funding

None.

## 9. Conflict of Interest

None.

## References

1. Beckman Coulter Inc. Beckman Coulter AU 700 Clinical Chemistry Analyzer—Operator's Manual. Beckman Coulter Inc.; 2023. Available from: [https://www.beckmancoulter.com/].
2. Miller JJ, Gammie AJ. A Novel Approach for Routinely Assessing Laboratory Sigma Metrics for a Broad Range of Automated Assays. *J Appl Lab Med*. 2024;9(3):477–92.
3. Westgard JO, Westgard SA. The importance of Six Sigma Quality in laboratory testing. *Clin Biochem*. 2014;47(12):663-4.
4. CLSI EP25-A, Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline, September 2009.
5. Ebrahim A, DeVore K, Fischer T. Limitations of Accelerated Stability Model Based on the Arrhenius Equation for Shelf Life Estimation of In Vitro Diagnostic Products. *Clin Chem.* 2021;67(4):684–8
6. Ahmed El-Neanaey W, Mahmoud AbdEllatif N, Abdel Haleem Abo Elwafa R. Evaluation of Sigma metric approach for monitoring the performance of automated analyzers in hematology unit of Alexandria Main University Hospital. *Int J Lab Hematol*. 2021;43(6):1388–93.
7. Suneetha R, Krishnappa J, Dinesh K, Zeanath CJ. Seamless Care, Seamless Operations: Mitigating Medical Equipment Downtime and Maintenance Costs for Uninterrupted Patient Care. *J Res Med Dent Sci.* 2024;12(2):6–14.
8. Tan R, Yilmaz M, Kurtulmuş Y. A practical approach example to measurement uncertainty: Evaluation of 26 immunoassay parameters. *Biochem Med (Zagreb)*. 2022;32(3):030705.
9. Abdel GMT, El-Masry MI. Verification of quantitative analytical methods in medical laboratories. *J Med Biochem*. 2021;40(3):225–36.
10. Armbruster D. Accuracy controls: assessing trueness (bias). *Clin Lab Med*. 2013;33(1):125–37.
11. Moosavi SM, Ghassabian S. Linearity of Calibration Curves for Analytical Methods: A Review of Criteria for Assessment of Method Reliability [Internet]. Calibration and Validation of Analytical Methods - A Sampling of Current Approaches. InTech; 2018.
12. Kyle PB. Beware of carryover in modern chemistry analyzers. *Clin Chem Lab Med*. 2010;48(4):519–21.
13. David A. Armbruster, Debra B. Alexander, Sample to sample carryover: A source of analytical laboratory error and its relevance to integrated clinical chemistry/immunoassay systems. *Clinica Chimica Acta*. 2006;373(1-2):37–43.
14. Saleh N, Gamal O, Eldosoky MAA, Shaaban AR. An integrative approach to medical laboratory equipment risk management. *Sci Rep*. 2024;14:4045.
15. Zhang Y, Wu AH, Bender CJ. Evaluation of the performance of clinical chemistry analyzers: a comparison of analytical quality based on Six Sigma metrics. *Clin Chim Acta*. 2015;448:77–82.

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