Chemistry Today

2025, Vol. 01 Issue 01
22-25

Research Article

Stability of Lyophilized Serum Control Material for Albumin Parameters During A Two-Month Storage Period Without Preservatives

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ARTICLE INFORMATION

Received: November 30, 2025
Revised: December 4, 2025
Accepted: December 5, 2025
Available online: December 7, 2025

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DOI
https://doi.org/10.68712/emy1de87

A B S T R A C T

The capability of laboratory testing methods must produce a proportional response to the concentration of analytes in samples within the existing range. Quality assurance of data accuracy is obtained through the measurement of control materials at the pre-analytical stage. Control materials greatly influence the results of testing, and the use of unassayed control materials is preferred by many laboratories. The conversion of liquid control materials into powder (lyophilizate) by freeze drying has many advantages and avoids the effects of temperature and light. However, storage time still has the potential to change the structure of the material. Albumin is the main protein in the body that can undergo denaturation at its isoelectric point in liquid. The shelf life of liquid serum albumin is 2 months at a temperature of 15-25°C. Further testing is needed to determine the stability of albumin in lyophilized control material with a shelf life of 2 months at room temperature. This research method is quantitative descriptive with repeated measurements of powdered albumin after freeze drying using Six Sigma Westgard. Research results obtained under high-level conditions were an average albumin activity of 8.99 g/dL, TV 9.01 g/dL, SD: 0,77, CV%: 8,67, d%: 0,33, TE%: 17,01, and a six sigma value of 1.19 with MDC 5.2 g/dL (CLIA). The stability of albumin using the freeze-dry method was tested using the Horwitz CV (2-5 log C) with a value of 1.037 (≤3α, ISO 13528) and an absolute difference |Xr-Yr|= -0.1681 ≤ 0.0198. Conclusion: Freeze-dried albumin as a control material at the high level has good stability and can therefore be used as an alternative control material in the pre-analytical stage.

Keywords: *control material; lyophilized serum; albumin*

1. Introduction

One part of healthcare services is the clinical laboratory, which functions to identify diseases and their sources, support early prevention programs treatment, healthcare, and disease prevention (24, 2023). Accurate and reliable laboratory test results are the responsibility of ATLM personnel. Therefore, it is necessary to implement and improve quality control of laboratory results, laboratory quality monitoring is carried out, starting from sample collection, sample preparation, sample examination, and reporting of laboratory test results to patients. Philip B. Crosby (1926-2001) said that quality is compliance with the requirements of standards. A product is considered to have quality if it is comparable to established standards and quality criteria (Agustina, 2019).

Internal Quality Assurance (IQA) is a preventive and monitoring measure carried out regularly by each laboratory to prevent of minimize errors in obtaining accurate test results. PMI is performed using control materials as test materials for good test results. Control materials are materials used to ensure the accuracy and precision of test results performed in laboratories. (Lestari et al., 2022) These control materials come from commercial control materials and pooled serum control materials.

Pooled serum is a combination of human serum with unassayed values (control material without reference values as a benchmark) used to monitor the quality of test results. (Rahayu et al., 2022) Pooled serum is designed as an alternative for small laboratories at a more affordable price. Pooled serum control materials are made using the freeze-drying method by removing water from the sample through a sublimation process, resulting in a dry product (lyophilization) without damaging the quality and components inside.

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The storage period for lyophilized serum is 2-8°C for short-term storage and -20°C for long-term storage. Lyophilized serum has many advantages, namely that it is protected from temperature and light. However, long-term storage still has the potential to cause changes in the structure of the material. In addition, this control serum can be used for all types of test parameters, one of which is albumin. (Maulidiyanti et al., 2021).

Previous studies have shown that adding ethylene glycol to lyophilized albumin serum can stabilize several analytes present in serum by minimizing microbial growth (Syamsudin et al., 2023). However, there have been few studies on the stability of lyophilized serum in albumin without preservatives when stored at room temperature for long periods of time. Therefore, this study aims to fill that gap.

2. Methods

The study uses a quantitative descriptive analysis design, in which the measurement process involves data processing and analysis, followed by a description of the stability results. (Sugiyono, 2020) The serum obtained from respondents will be processed into lyophilized serum, then stored for two months without the addition of preservatives, and measured periodically to ensure the stability of the albumin parameter.

To monitor stability in detail, lyophilized serum for albumin was measured for 28 days at the Rajawali Health Institute laboratory. Meanwhile, the initial albumin value measured before the lyophilization process will be used as the main reference (True Value) for further analysis of variations in albumin levels during the storage period of lyophilized serum.

3. Results and Discussion

Table 1. Result of Accuracy and Precision Tests of Control Material Stability Measurements For Albumin Parameters During a Two-Month Storage Period Without Preservatives

Parameter	Mean(U/L)	SD (U/L)	CV (%)
Albumin	8,99	0,77	8,67

Parameter	Tru Velue (%)	Mean	d (%)
Albumin	9	8,99	0,33%

Based on Table 1, the results of precision and accuracy testing for the albumin parameter show an average value (Mean) of 8.99% with a standard deviation (SD) of 0.77 U/L. The coefficient of variation (CV) value obtained is 8.67%. Meanwhile, the accuracy test using the true value of 9% and the relative deviation (bias) percentage (d%) obtained was 0.33%.

Table 2. Six Sigma Results of Lyophilized Serum Control Material Stability Measurement for Albumin Parameters During a Two-Month Storage Period Without Preservatives

Parameter	Tea %	Six Sigma
Albumin	17,01	1.19

In Table 2, the total error (TEA) calculation resulted in 17.01% and a Six Sigma value of 1.19. According to analytical quality criteria, a method must achieve at least 3α to be considered reliable for routine operations. This value is well below the minimum clinical threshold (3,0α), indicating that the method is not yet suitable for efficient routine testing due to the high risk of analytical failure.

Table 3. Results of Homogeneity and Stability Data for Lyophilized Serum According to ISO: 13528

Measurement on day	Albumin Value
1	1.4158
2	1.3168
3	1.4732
4	1.5078
5	1.5362
6	1.07
7	1.6474
Mean Xr	1.4239

Measurement Result of Lyophilized Serum Control Albumin Parameter		Yt Rata-Rata
Ya	Yb	Ya Yb
1.6474	1.6474	1.6474
1.5078	1.4158	1.5362
1.3168	1.5362	1.5078
Yr		1.5292

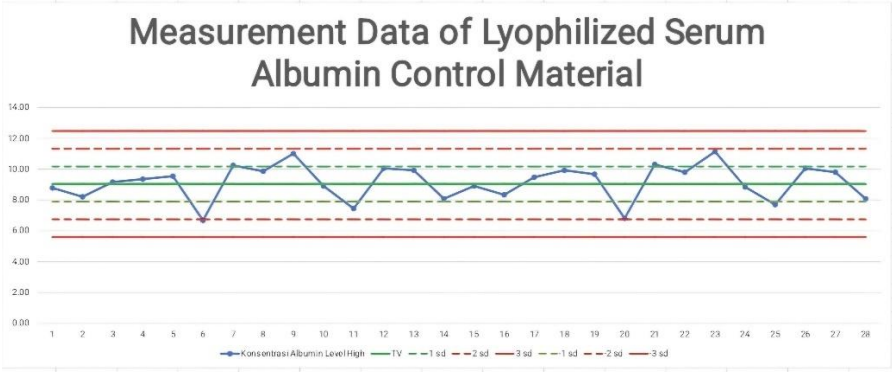
Table 3 shows the testing in accordance with ISO 13528:2008, the Xr homogeneity test and Yr stability test with results of Xr= 1.4329 and Yr= 1.5292. However, on day 6, there was a value of 1.07 that deviated from the mean (Mean Xr) of 1.4239 and also deviated from the results of other days. This deviation indicates a problem with the homogeneity of the sample or instability at one testing point.

Table 4. Horwitz CV Data Results for Measuring the Stability of Lyophilized Control Materials for Albumin Parameters During a Two-Month Storage Period Without Preservatives

CV Horwitz	2'1-0,5 Log C
Mean Concentration	1,4239
Unit	Persen
Fractional Concentration (C)	0,002
Log C	-2,698
0,5 Log C	-1,349
1-0,5 Log C	2,349
2'1-0,5 Log C	4,698
CV Horwitz	**4,698**

Based on Table 4, the Horwitz coefficient of variation (CV Horwitz) value for this analysis was calculated using a fractional concentration (C) of 0.002, resulting in a value of 4.698%. However, in comparison, the actual coefficient of variation (CV) obtained was 8.67%. The analysis shows that the actual CV (8.67%) far exceeds the Horwitz CV (4.698%), so it is considered not to meet the precision standards set by the Horwitz model.

Figure 1. Levey-Jennings Graph Based on Serum Stability Values of Lyophilisate for The Albumin Parameter With a Two-Month Shelf Life Without Preservatives.



The results of the Levey-Jennings graph confirm that the albumin analysis method is generally under control. It is just, there were two significant incidents in the 6th and 20th measurements, with results falling outside the ± 2SD limit and nearly violating the ± 3SD limit.

4. Conclusion

Overall, albumin in freeze-dried serum without preservatives showed adequate stability for two months, making this material a viable alternative as a control material in the pre-analytical stage in clinical laboratories. Control materials in the form of freeze-dried serum without preservatives can be an alternative for the pre-analytical stage in albumin measurement, especially for small laboratories. However, its use must be accompanied by routine monitoring to identify any errors.

Acknowledgement

The researcher would like to express his deepest gratitude to his parents, friends, supervisors, the Rajawali Health Institute, and all parties who have been involved in this research process.

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