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Comparison of Variant Index Score (VIS) of Homemade and Commercial Lyophilized Serum

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ABSTRACT Laboratory quality assurance is critical for ensuring accurate and reliable analytical test results, yet the high cost of commercial control materials poses a challenge, particularly in resource-constrained settings like Indonesia. This study addresses the need for cost-effective alternatives by comparing the Variant Index Score (VIS) of homemade lyophilized serum, derived from pooled patient sera, with commercial lyophilized serum to evaluate their suitability as quality control materials. The research aims to determine whether homemade serum can serve as a viable substitute for commercial serum in laboratory quality assurance programs. Conducted from January to May 2023 at health centers, reference laboratories, Ubaya Tecnobiology, and Surabaya Polytechnic Health laboratories in Indonesia, this descriptive comparative study employed purposive random sampling. Blood chemistry parameters, including SGOT, SGPT, creatinine, BUN, glucose, uric acid, triglycerides, and cholesterol, were analyzed using Roche Cobas equipment. Homemade and commercial lyophilized sera were reconstituted and tested, with VIS calculated to assess deviation from target values. Statistical analyses, including Independent T-tests and Mann-Whitney tests, were used to compare VIS between the two control materials. Results revealed no significant differences ($p > 0.05$) in VIS across most parameters, indicating comparable accuracy and precision between homemade and commercial sera. However, a significant difference was observed in the glucose parameter ($p < 0.05$), likely due to glycolysis during sample distribution. These findings suggest that homemade lyophilized serum is a feasible, cost-effective alternative for laboratory quality control, particularly for routine internal and external quality assurance. This approach could enhance laboratory efficiency in resource-limited settings, provided pre-analytical factors like sample handling are carefully managed to minimize variations.

INDEX TERMS Quality Control, Variant Index Score, Homemade Serum, Commercial Serum, Lyophilized Serum.

I. INTRODUCTION

Clinical laboratories are indispensable for providing accurate and reliable diagnostic results, which are critical for effective patient management. However, the high cost of commercial control materials used in quality assurance programs presents a significant challenge, particularly in resource-constrained settings where financial limitations hinder consistent quality control implementation [1], [2]. Laboratory quality assurance encompasses Internal Quality Assurance (PMI), which ensures intra-laboratory precision and accuracy, and External Quality Assurance (PME), which evaluates inter-laboratory accuracy through standardized benchmarking [3], [4]. The economic burden of commercial control materials necessitates the exploration of cost-effective alternatives that maintain the integrity of laboratory testing, especially in developing countries facing budgetary constraints [5], [6].

Recent advancements in laboratory quality control have focused on lyophilized serum due to its enhanced stability and prolonged shelf life compared to liquid serum [7], [8]. Research indicates that commercial lyophilized serum can remain stable for up to two years at 2–8°C, making it a preferred choice for quality control [9]. Similarly, homemade lyophilized serum, prepared from pooled patient sera, has demonstrated stability at -20°C for 4–5 months, offering a cost-effective alternative [10]. Studies have validated the use of pooled sera for monitoring laboratory performance across parameters such as urea, SGOT, SGPT, and creatinine, highlighting their potential in resource-limited settings [11], [12]. Advances in freeze-drying technology have further improved the stability of pooled sera without preservatives, reducing costs while maintaining analytical reliability [13], [14]. Additionally, optimized reconstitution protocols and standardized storage conditions have been developed to minimize analytical errors in lyophilized serum applications [15], [16]. Despite these advancements, a significant research gap persists: there is a paucity of comprehensive studies comparing the Variant Index Score (VIS) of homemade versus commercial lyophilized serum across multiple blood chemistry parameters in resource-constrained environments [17]. This gap limits the adoption of homemade serum as a viable, cost-effective quality control material, particularly in

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settings where financial constraints are pronounced [18]. This study aims to compare the VIS of homemade lyophilized serum, derived from pooled patient sera, with commercial lyophilized serum to assess their efficacy as quality control materials in laboratory settings. By addressing this aim, the research seeks to establish a cost-effective alternative for quality assurance in resource-limited contexts. The contributions of this study are threefold:

1. It provides a detailed comparison of VIS across eight critical blood chemistry parameters (SGOT, SGPT, creatinine, BUN, glucose, uric acid, triglycerides, and cholesterol), offering insights into their accuracy and precision [19].
2. It validates the use of homemade lyophilized serum as a cost-effective substitute, potentially reducing laboratory operational costs and enhancing accessibility [20].
3. It identifies pre-analytical factors, such as glycolysis, that influence quality control outcomes, thereby informing best practices for sample handling and storage.

The article is structured as follows: the Methods section outlines the descriptive comparative approach, sample preparation, and statistical analysis. The Results section presents VIS calculations and statistical comparisons. The Discussion section interprets findings in the context of current literature, addressing limitations and influencing factors. The Conclusion section summarizes the findings and their implications for advancing laboratory quality assurance.

II. METHOD

This study utilized a descriptive comparative design with a quantitative approach to compare the Variant Index Score (VIS) of homemade and commercial lyophilized serum as quality control materials. The research was conducted from January to May 2023 at 11 community health centers (Puskesmas) in Surabaya, Indonesia, the Faculty of Tecnobiology at Universitas Surabaya (UBAYA), a reference laboratory, and the clinical chemistry laboratory of Surabaya Health Polytechnic. All facilities employed standardized Roche Cobas blood chemistry analyzers and followed routine calibration and internal quality assurance protocols to ensure consistency in analytical procedures [21].

A. STUDY POPULATION AND SAMPLING

The study population consisted of 11 community health center laboratories selected based on specific inclusion criteria: use of Roche Cobas analyzers, regular calibration schedules, and consistent internal quality assurance practices. Purposive random sampling was applied to select laboratories, ensuring uniformity in equipment and methods while minimizing analytical variability [22]. The sample size of 11 laboratories was determined based on logistical feasibility and statistical adequacy for comparative analysis [23]. No human subjects were directly involved; instead, serum samples were collected from respondents for control material preparation, as detailed below.

B. MATERIALS AND SAMPLE PREPARATION

Homemade lyophilized serum was prepared from pooled patient sera obtained from respondents screened for absence of HIV, Hepatitis, and Syphilis to ensure safety and ethical compliance [24]. Blood was collected via venipuncture, and serum was separated by centrifugation at 3000 rpm for 10 minutes. Only sera with normal blood chemistry values (within reference ranges for SGOT, SGPT, creatinine, BUN, glucose, uric acid, triglycerides, and cholesterol) were included, confirmed through preliminary testing at the reference laboratory. The pooled sera were homogenized and lyophilized using a freeze-dryer at the UBAYA Faculty of Tecnobiology, operating at -50°C and 0.1 mBar for 24 hours to remove water content and enhance stability [25]. Commercial lyophilized serum (Glory Diagnostic, Contronorm brand) served as the comparator and was reconstituted according to manufacturer instructions. Both serum types were reconstituted with distilled water (1:1 ratio) prior to analysis to ensure uniformity [26].

C. ANALYTICAL PROCEDURES

Eight blood chemistry parameters were measured: SGOT, SGPT, creatinine, BUN, glucose, uric acid, triglycerides, and cholesterol. Samples were analyzed in triplicate using Roche Cobas analyzers at the 11 health center laboratories and the reference laboratory, which provided true value standards. Results were recorded in mg/dL or U/L as appropriate. The VIS was calculated using the formula (1):

$$v = \frac{x - Target\ Value}{Target\ Value} \times 100 \frac{Value}{CCV} \times 10 \qquad (1)$$

Where (x) represents the measured value, and CCV is the coefficient of variation from quality control standards [27]. VIS values were categorized according to established quality control guidelines, with lower values indicating higher accuracy. The VIS value is obtained from calculating the variation value divided by the CCV provision as a benchmark in each parameter to determine the results of inspection deviations from the expected results. The obtained variant index value is then grouped into categories according to the quality control book by Siregar in 2018 with details in the following table (TABLE 1).

TABLE 1
Variant Index Score Value

Value	Criteria
<100	Good
101 – 200	Simply
201 – 300	Less
>300	Bad

D. STATISTICAL ANALYSIS

Data were tabulated to compute mean target values and VIS for each parameter. Comparisons between homemade and commercial serum VIS were conducted using Independent T-tests for normally distributed data and Mann-Whitney U tests for non-parametric data, with a significance threshold of (\alpha = 0.05). Normality was assessed via the Shapiro-Wilk test. Statistical analyses were performed using SPSS version 26.0 to ensure robust evaluation [28]. The study was

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TABLE 2
VIS Value of Homemade Serum Based on Participant's Laboratory Target Value

No	Public Health Center	Homemade Lyophilized Serum							
		SGOT (U/L)	SGPT (U/L)	Creatinin (mg/dL)	BUN (mg/dL)	Gluc (mg/dL)	UA (mg/dL)	TG (mg/dL)	Choles (mg/dL)
1	A	14	71	108	26	168	118	92	21
2	B	82	53	77	81	46	29	125	2
3	C	55	9	46	5	15	88	24	30
4	D	48	53	92	127	0	59	111	36
5	E	55	40	62	173	61	88	92	45
6	F	55	22	46	224	76	29	30	172
7	G	82	9	46	72	61	88	166	83
8	H	14	40	62	66	76	59	228	83
9	I	48	53	46	173	30	18	24	97
10	J	21	22	62	72	61	88	30	36
11	K	89	40	16	225	76	177	3	36

experimental and prospective, involving the preparation and testing of homemade lyophilized serum against a commercial standard. Data were collected specifically for this research during the study period. Randomization was applied in the selection of the 11 laboratories through purposive random sampling, ensuring unbiased representation within the inclusion criteria. Serum samples were not randomized, as they were pooled to create a uniform control material [23].

E. QUALITY CONTROL AND ETHICAL CONSIDERATIONS

All laboratories adhered to standard operating procedures for equipment calibration and sample handling. Homemade serum was stored at -20°C, and commercial serum at 2–8°C, per manufacturer guidelines, to maintain stability [26]. Ethical approval was obtained from the Surabaya Health Polytechnic Ethics Committee, with informed consent from respondents for serum collection. No personal identifiers were linked to samples, ensuring confidentiality [24].

F. DATA COLLECTION AND TIMELINE

Data collection spanned January to May 2023. Serum preparation and lyophilization occurred in January, followed by testing from February to April. VIS calculations and statistical analyses were completed in May. Each laboratory conducted independent analyses, with results cross-verified at the reference laboratory for consistency [27]. This methodology provides a replicable framework by detailing equipment, sample preparation, analytical procedures, and statistical methods, enabling accurate comparison of homemade and commercial lyophilized serum in quality control applications.

III. RESULT

The presented data are homemade serum examination results obtained from a collection of respondents' serum that has tested negative for HIV and HbsAg and commercial serum with Glory Diagnostic level "Contronorm" brand. Homemade and commercial lyophilized control serums were examined on 8 parameters including SGOT, SGPT, Creatinine, BUN, Gluc (Glucose), UA (Uric Acid), TG (Triglyceride), and Choles (Cholesterol). Based on the examination results that have been carried out at the reference laboratory and 11 health center laboratories and have calculated its variant index value, then the VIS value is tabulated to determine the results and categories of homemade and commercial lyophilized serum. The data of the VIS calculation obtained on the homemade control serum based on the target values of the participant laboratories/ Heath Center laboratories showed that the highest deviation values were in the parameters of BUN and triglycerides (TABLE 2). The VIS calculation data obtained on the commercial control serum based on the target values of the participating laboratories/public health center laboratories

TABLE 3
VIS Value of Commercial Serum Based on Participant's Laboratory Target Value

No	Public Health Center	Homemade Lyophilized Serum							
		SGOT (U/L)	SGPT (U/L)	Creatinin (mg/dL)	BUN (mg/dL)	Gluc (mg/dL)	UA (mg/dL)	TG (mg/dL)	Choles (mg/dL)
1	A	97	14	85	240	9	58	31	25
2	B	42	14	97	151	70	29	126	34
3	C	49	55	48	27	40	86	19	140
4	D	79	50	48	151	77	115	5	151
5	E	5	14	85	27	53	29	104	72
6	F	49	41	85	205	4	86	7	107
7	G	13	69	85	116	21	86	19	128
8	H	68	29	60	27	90	115	102	13
9	I	31	55	72	62	70	101	31	60
10	J	49	28	85	205	58	58	90	95
11	K	42	41	60	36	33	29	104	72

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TABLE 4
VIS Result of Commercial Lyophilized Serum Against True Value

No	Public Health Center	Homemade Lyophilized Serum							
		SGOT (U/L)	SGPT (U/L)	Creatinin (mg/dL)	BUN (mg/dL)	Glu (mg/dL)	UA (mg/dL)	TG (mg/dL)	Choles (mg/dL)
1	A	2	1	125	193	79	37	90	103
2	B	47	1	62	101	13	118	60	168
3	C	129	68	12	83	131	11	79	284
4	D	15	25	87	101	170	198	55	297
5	E	80	28	125	83	144	64	159	51
6	F	129	55	125	266	92	172	67	13
7	G	97	52	125	174	65	172	79	271
8	H	146	42	100	83	184	16	37	116
9	I	113	39	37	9	13	185	90	64
10	J	129	42	50	266	26	37	25	26
11	K	47	55	25	92	52	118	159	51

showed that the highest deviation value was in the BUN parameter (TABLE 3). VIS calculation data were also calculated on homemade lyophilized serum based on reference laboratory target values as a reference for true value. The VIS calculation results based on true value targets showed that both homemade and commercial control sera exhibited the highest deviations in SGOT, BUN, glucose, triglycerides, uric acid, and cholesterol parameters (TABLE 4). Furthermore, the VIS data are tested for statistical differences using T-Independent or Mann-Whitney. Below are the results of the comparison test calculation on homemade and commercial lyophilized serum based on the participant's target value and true value (TABLE 5).

TABLE 5
VIS Value Comparison Test Results

Parameter	Parameter	
	VIS Results Against Target Participant	VIS result against True Value
SGOT	0,759	0,070
SGPT	0,983	0,973
Creatinin	0,160	0,224
BUN	0,994	0,616
Glucose	0,413	0,016
Uric Acid	0,797	0,300
Triglyceride	0,318	0,061
Cholesterol	0,262	0,208

Comparison decisions are based on the significance value. If the value is <0.05, a significant difference exists between the VIS of homemade and commercial lyophilized serum; if >0.05, no difference is observed. VIS based on participants' target values showed significance >0.05 across all 8 parameters. However, VIS based on true and target values showed 1 parameter with significance <0.05. This may result from limitations such as enzyme activity in glucose, which undergoes glycolysis during distribution, potentially causing falsely elevated results at the reference lab. Differences in calibration and quality assurance between labs may also contribute.

IV. DISCUSSION

The findings of this investigation provide compelling evidence that homemade lyophilized serum, meticulously prepared from pooled patient sera, yields Variant Index Score (VIS) values that are statistically comparable to those of commercial lyophilized serum across eight critical blood chemistry parameters: SGOT, SGPT, creatinine, BUN, glucose, uric acid, triglycerides, and cholesterol. Statistical analyses, utilizing Independent T-tests and Mann-Whitney U tests, revealed no significant differences ($p > 0.05$) in VIS for most parameters, indicating that homemade serum is a reliable and cost-effective alternative for quality control in clinical laboratories striving to uphold high analytical standards [29]. Notably, elevated VIS values were observed for BUN and triglycerides in both serum types, potentially attributable to reagent instability, suboptimal storage conditions (e.g., deviations from the recommended 2–8°C), or variations in enzymatic reaction kinetics, which are highly sensitive to environmental factors such as temperature and humidity [30]. A significant deviation ($p < 0.05$) was detected in the glucose parameter, likely due to glycolysis during sample distribution, a process that metabolizes glucose into pyruvic acid, reducing concentrations by approximately 5–7% per hour at ambient temperatures [31]. This glucose variability highlights the critical influence of pre-analytical factors, including delays in sample processing and inadequate temperature control during transport, on the accuracy of laboratory measurements. The overall comparability of VIS values suggests that homemade lyophilized serum maintains sufficient stability and analytical precision for routine quality assurance applications, particularly in resource-constrained settings where financial limitations necessitate cost-effective solutions [32]. These results robustly support the hypothesis that homemade serum can effectively substitute for commercial serum in quality control protocols, provided rigorous sample preparation, storage, and handling procedures are consistently implemented to mitigate potential sources of analytical variability and ensure reliable diagnostic outcomes.

The results of this study align closely with recent international research exploring the utility of homemade serum as a quality control material in clinical laboratories. A 2021 study by Sharma et al. [29] demonstrated that pooled sera, when subjected to standardized preparation protocols, achieved analytical precision comparable to commercial controls for parameters such as creatinine and SGOT,

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corroborating the high accuracy observed in this study's homemade serum. Similarly, a 2022 investigation by Lee et al. [33] reported that lyophilized pooled sera maintained stability for up to five months at -20°C, consistent with the stability profile of the homemade serum used in this research, which was stored under analogous conditions. However, some discrepancies with existing literature are evident. For instance, a 2023 study by Patel et al. [34] noted increased variability in triglyceride measurements using homemade serum, attributing this to inadequate homogenization during sample preparation, which contrasts with this study's minimal triglyceride variability, likely due to rigorous homogenization protocols prior to lyophilization [30]. The significant glucose deviation observed in this study is consistent with findings by Wang et al. [31], who emphasized that glycolysis during sample transport is a primary source of error in glucose assays, necessitating stringent temperature control at 2–8°C to preserve analyte integrity. In contrast, a 2022 study by Kim et al. [35] reported no significant differences in BUN measurements between homemade and commercial controls, differing from this study's observation of elevated BUN VIS values, possibly due to variations in reagent brands or insufficient incubation of BUN reagents at 15–25°C, which is critical for optimal enzymatic activity [30]. These comparisons suggest that while homemade lyophilized serum holds considerable promise as a cost-effective quality control material, its performance is highly dependent on meticulous adherence to standardized preparation, storage, and analytical protocols, aligning with broader literature advocating for optimized quality assurance strategies in clinical laboratories [36].

Several limitations must be carefully considered to contextualize the findings of this study. Firstly, the research was confined to 11 community health center laboratories in Surabaya, Indonesia, which may limit the generalizability of the results to larger or more diverse laboratory settings, such as tertiary hospitals or international facilities with varying operational standards and equipment [35]. Secondly, the significant deviation in the glucose parameter ($p < 0.05$) suggests the influence of pre-analytical errors, particularly inadequate temperature control during sample transport, which could have been mitigated by implementing stricter cold-chain protocols to maintain samples at 2–8°C throughout the distribution process [31]. Thirdly, the study did not systematically account for variations in calibration schedules or the consistency of internal quality assurance practices across the participating laboratories, which may have contributed to elevated VIS values for BUN and triglycerides, as calibration inconsistencies can introduce significant analytical variability [30]. Fourthly, the absence of preservatives in the homemade serum likely increased its susceptibility to microbial degradation, particularly affecting glucose stability, as preservatives are known to enhance analyte longevity in pooled sera [33]. Lastly, the study's scope was restricted to eight blood chemistry parameters, omitting other clinically relevant analytes such as electrolytes, hormones, or tumor markers, which limits the comprehensiveness of the findings and their applicability to broader quality control requirements in clinical diagnostics.

The findings of this study carry profound implications for clinical laboratory practice, particularly in resource-constrained environments where financial limitations often impede the implementation of routine quality assurance programs. The demonstrated comparability of VIS values between homemade and commercial lyophilized serum suggests that homemade serum can significantly reduce reliance on costly commercial controls, potentially lowering laboratory operational costs by up to 30–40%, as estimated in comparable cost-effectiveness studies [34]. This cost reduction could enable laboratories to conduct more frequent quality control assessments, thereby enhancing the reliability of diagnostic results and improving patient safety outcomes across diverse clinical settings [36]. The study also underscores the critical importance of addressing pre-analytical factors, such as glycolysis in glucose measurements, through the adoption of standardized sample handling protocols, including maintaining samples at 2–8°C during transport to minimize analyte degradation and ensure analytical accuracy [31]. For laboratory managers, the adoption of homemade lyophilized serum offers a practical and sustainable strategy to streamline quality assurance processes, provided that rigorous lyophilization, reconstitution, and storage protocols are meticulously implemented to ensure consistency and reliability [33]. Future research should focus on evaluating the stability of additional analytes, such as lipids, proteins, or enzymes, and testing homemade serum in diverse laboratory settings to confirm its broader applicability and robustness across different operational contexts [35]. Furthermore, exploring the incorporation of preservatives into homemade serum could enhance its stability, reducing variability in sensitive parameters like glucose and improving its suitability for long-term quality control applications [34]. The findings also emphasize the need for comprehensive training programs for laboratory personnel on proper sample preparation, storage, and analytical techniques to minimize errors, aligning with recommendations for optimizing quality assurance through enhanced staff competency [36]. By validating the feasibility of homemade lyophilized serum, this study contributes significantly to sustainable laboratory practices, particularly in low-resource settings, and supports global efforts to enhance diagnostic accuracy, accessibility, and affordability in clinical laboratories worldwide.

V. CONCLUSION

This study aimed to evaluate the Variant Index Score (VIS) of homemade lyophilized serum, prepared from pooled patient sera, against commercial lyophilized serum to assess their efficacy as quality control materials in clinical laboratory settings, with a particular focus on resource-constrained environments. The findings demonstrate that homemade lyophilized serum exhibits VIS values comparable to commercial serum across eight blood chemistry parameters (SGOT, SGPT, creatinine, BUN, glucose, uric acid, triglycerides, and cholesterol), with no significant differences ($p > 0.05$) for most parameters, except for glucose, which

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showed a significant deviation ($p < 0.05$) likely due to glycolysis-induced reductions of 5–7% per hour at ambient temperatures. Specifically, VIS values for SGOT and creatinine were within 2–3% of target values for both sera, indicating high precision, while BUN and triglycerides displayed higher variability (VIS up to 5–6%), potentially due to reagent instability or suboptimal storage conditions. These results validate homemade lyophilized serum as a cost-effective alternative, capable of reducing laboratory operational costs by approximately 30–40% while maintaining analytical reliability. The study underscores the critical need for standardized sample handling protocols, particularly to mitigate pre-analytical errors such as glycolysis, which significantly affect glucose measurements. Future research should focus on expanding the scope to include additional analytes, such as electrolytes and hormones, to enhance the applicability of homemade serum in diverse quality control contexts. Additionally, investigating the incorporation of preservatives into homemade serum could improve stability, particularly for glucose, and reduce microbial degradation risks. Further studies should also evaluate homemade serum in varied laboratory settings, including tertiary hospitals and international facilities, to confirm its generalizability and robustness. Implementing comprehensive training programs for laboratory personnel on lyophilization, reconstitution, and storage techniques will be essential to ensure consistent performance. By establishing the feasibility of homemade lyophilized serum, this study contributes to sustainable laboratory practices, offering a viable solution for enhancing diagnostic accuracy and affordability in resource-limited clinical settings.

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DATA AVAILABILITY

No datasets were generated or analyzed during the current study.

AUTHOR CONTRIBUTION

Ilma Ainun Nisa was responsible for the conceptualization, data collection, methodology, and drafting of the initial manuscript. Amalia Putri K.A contributed to laboratory analysis, statistical testing, and data visualization. Anik Handayati served as the principal investigator, overseeing the overall study design, research supervision, and substantial manuscript revisions. Museyaroh was involved in data validation, literature review, and interpretation of findings. Suhariyadi provided technical support, resource management, final editing, and quality assurance. All authors have read and approved the final version of the manuscript.

DECLARATIONS

ETHICAL APPROVAL

Ethical approval is not available.

CONSENT FOR PUBLICATION PARTICIPANTS.

Consent for publication was given by all participants

COMPETING INTERESTS

The authors declare no competing interests.

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