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Evaluation of the Quality of Commercial Control Materials and Homemade Lyophilized on Clinical Chemistry Parameters with the Sigma Metric Method

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ABSTRACT

Control materials are used to maintain the accuracy of testing procedures and the quality of laboratory results. However, commercial control materials are often considered less economical, so an alternative is needed, namely lyophilized human serum. Sigma metric helps improve laboratory operational costs efficiency through control settings and *Westgard* rule recommendations involving the Total Error Allowable (TEa) value, bias value (d%), and coefficient of variation (CV%). This study aims to determine the quality of commercial control materials and *homemade* lyophilized materials for blood glucose, uric acid, total cholesterol, and triglyceride parameters based on sigma values. This study used a comparative *cross-sectional* design. The samples included commercial control materials from one of the primary-level laboratories in Bangkalan District and homemade lyophilized samples from human serum collections. Data Analysis was conducted by statistically comparing the bias value and descriptively comparing the sigma value of commercial control material and homemade lyophilized. The results showed no significant difference in bias value between commercial control material and homemade lyophilized material for all parameters (significance value > α 0,05). The sigma values of commercial control material for blood glucose, uric acid, total cholesterol, and triglyceride parameters were 2.81 (poor), 2.41 (poor), 3.10 (marginal), and 2.14 (poor). The sigma values of the homemade lyophilized were 2.12 (poor), 1.76 (unacceptable), 3.36 (marginal), and 2.08 (poor). Based on the sigma values, the homemade lyophilized material was better for total cholesterol parameters, while the commercial control material was better for blood glucose, uric acid, and triglyceride parameters. It can be concluded that homemade lyophilized can be used as an alternative to commercial control materials, especially for total cholesterol parameters. These findings support the cost efficiency of laboratory operations through the development of more economical homemade lyophilized products that are suitable for use in laboratories.

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I. INTRODUCTION

The quality of laboratory test results must be maintained through quality control using internal quality assurance and external quality assurance [1] [2] [3] . Internal Quality Assurance (IQA) is a routine quality control system implemented by laboratories to minimize errors and deviations, thereby ensuring accurate test results [4] [5] [6]. External Quality Assurance (EQA) is a periodic evaluation activity conducted by external parties to monitor a laboratory's performance in conducting specific tests [7] [8] [9].

In this study, control materials are the main issue that needs to be addressed. Control materials are substances used to maintain the accuracy of a testing procedure and monitor the quality of test results in a laboratory [10] [11]. Control materials can be derived from humans or animals and can be found in liquid or powdered (lyophilized) form. Control materials available on the market are sometimes made from bovine serum, which may have components different from human serum [12]. Control materials available on the market also carry a relatively high risk of error due to significant variations in concentration between product lots [13]. In Indonesia, the need to import

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control materials poses a challenge in managing laboratory quality control [14]. The continuous use of commercial control materials is considered economically unfeasible for many countries [15].

These issues can be addressed using alternative control materials from pooled human serum, called pooled sera [16] [17] [18]. However, liquid control materials are less stable and less durable compared to lyophilized forms [19]. The lyophilization process of pooled serum using freeze-drying can result in higher stability [20] [21]. Research by (Handayati, 2022) showed that glucose, uric acid, SGOT, SGPT, creatinine, cholesterol, and triglyceride levels in homemade lyophilized control serum remained stable for 7 months at storage temperatures of 0°C and 2–8°C [14]. Research by (Wulandari *et al*., 2023) also showed that cholesterol and triglyceride levels remained sufficiently stable in the control serum lyophilized after reconstitution for 8 weeks at storage temperatures of −2°C, −4°C, and −20°C [22].

In internal quality control, various types of errors can interfere with the quality and accuracy of test results. Random errors can be caused by temperature, electrical voltage, instability in incubation time, variability in the testing process, and incorrect pipetting techniques. Inappropriate testing methods, inaccurate pipettes, reagent damage, errors in the dissolution process, and imprecise wavelength selection cause systematic errors [23].

Dr. James O. Westgard proposed a rule for evaluating quality control results using the Levey-Jennings chart; however, this method cannot determine the exact error value in the laboratory. Evaluation during the laboratory testing process can utilize the sigma metric method [24]. The sigma metric was first developed in the field of clinical laboratories by Westgard in the 21st century [25]. The sigma metric describes the probability of error in one million tests [26]. Increased demand for testing services will raise laboratory testing costs, but higher testing costs do not always correlate with better test results [27]. Sigma metric helps reduce operational costs by decreasing the amount of quality control materials and reagents used, and reducing the need for recalibration [28] [29].

The achievable sigma levels are as follows: sigma >6 indicates an ideal level, sigma 5–6 indicates a very good level, sigma 4–5 indicates a good level, sigma 3–4 indicates a marginal level, sigma 2–3 indicates a poor level, and sigma <2 indicates a bad level. Sigma metric helps identify and reduce the causes of errors during the testing process [30]. Sigma metrics are more efficient to apply compared to using only Levey-Jennings charts, as they involve selecting the required number of controls, the frequency of controls performed, and the Westgard rules applied [31]. The sigma metric method provides laboratories with the opportunity to achieve the maximum sigma value, indicating world-class performance, meaning that 99.99966% of inspection results are error-free [32].

This study aims to compare bias values and evaluate the quality of commercial control materials and homemade lyophilized materials by reviewing the sigma values of the commercial control materials and the homemade lyophilized materials using the Sigma Metric evaluation method. This research is expected to contribute to the development of knowledge regarding quality assurance in clinical chemistry laboratories, provide considerations for selecting control materials in laboratory quality assurance by reviewing the accuracy and precision of control materials, and provide considerations for selecting more effective control materials for internal laboratory quality assurance through the review of sigma values.

This study is structured as follows: Section II discusses the dataset used, the proposed method, and the data processing and analysis methods employed. Section III presents the research results. Section IV compares the results with other studies. Section V concludes with the results and a discussion of the study.

II. MATERIALS AND METHOD

A. Dataset

This study aims to determine the quality of commercial control materials and homemade lyophilized materials on blood glucose, uric acid, total cholesterol, and triglyceride parameters based on sigma values. The study was conducted in one of the primary level laboratories in Bangkalan Regency, East Java. This study used a comparative cross-sectional research design. The independent variables in this study were commercial control materials and homemade lyophilized materials, with the dependent variable being the bias value and sigma value of commercial control materials and homemade lyophilized. The sample population in this study is the type of control material used in laboratory quality assurance. The samples used in this study were commercial control materials and homemade lyophilized control materials.

In the preparation of homemade lyophilized test materials, the inclusion criteria for respondents were set as follows: students of the Surabaya Ministry of Health Polytechnic aged 19–25 years, without dyslipidemia, with normal blood glucose and uric acid levels (checked using POCT/Point of Care Testing), not infected with infectious diseases transmitted through blood transfusion such as HIV, hepatitis, and similar conditions, and willing to participate as respondents by signing an informed consent form. The exclusion criteria for test material respondents were unwillingness to participate, dyslipidemia, and infectious diseases transmitted through blood transfusion, such as HIV, hepatitis, and similar conditions.

Serum that passed the HIV and HbsAg screening tests was then collected in an Erlenmeyer flask and homogenized using a rotator shaker, followed by re-centrifugation to obtain serum completely free of interfering analytes. After the second centrifugation, the serum is recombined in an Erlenmeyer flask and homogenized using a rotator shaker. After homogenization, the serum is divided into vials with a

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volume of 3 mL each and stored in a freezer at 4^0C until frozen. The frozen serum is then subjected to lyophilization at the Laboratory of the Faculty of Technobiology at Surabaya University using a freeze dryer; the lyophilization process takes 48 hours. The serum that has become lyophilized is stored in a freezer at a temperature of 0^0C - 2^0C.

The true value of the homemade lyophilized was determined in a reference laboratory by first reconstituting the homemade lyophilized, then dividing it into 1000 µL microtubes. Next, it was sent to each reference laboratory for testing. The results of the test were then calculated to determine the mean and standard deviation for use in determining the true value.

Blood glucose levels will be examined by the enzymatic method GOD – PAP (Glucose Oxidase – Para Amino Phenazone), uric acid levels will be examined using the colorimetric enzymatic method, total cholesterol levels will be measured by enzymatic CHOD-PAP (Cholesterol Oxidase – Peroxidase Aminoantypirin), and triglyceride levels will be measured by the enzymatic method GPO-PAP (Glycerol Peroxidase Phosphat Acid) [33] [34] [35] [36].

B. Data Collection

This study used primary data and secondary data. Primary data were obtained from the test results on homemade lyophilized samples, while secondary data were obtained from the results of internal quality assurance using commercial control materials used by the research laboratory.

C. Data Processing

Data processing was carried out by grouping the results of the test of commercial control materials and homemade lyophilized materials in a table. Data on each parameter in both types of control materials were calculated for standard deviation, that describes how the data from the control material test was distributed during the research period using the formula shown in Eq. (1).

$$SD = \sqrt{\frac{\Sigma (X - \bar{x})^2}{n-1}} \quad (1)$$

The formula for calculating the Standard Deviation involves several components, including ***X,*** which represents the test results, $\bar{x}$ as the average of all test results, and **n** as the total participants in the laboratory / total replications.

After the standard deviation value is known, the bias value of each parameter in both types of control materials is calculated to describe the degree of inaccuracy, which is the difference between the test results and the target value or actual value. The bias value formula is shown in Eq. (2).

$$d\% = \frac{X - \text{True Value / Target Value}}{\text{True Value / Target Value}} \times 100 \quad (2)$$

The formula for calculating the bias value involves several components, including ***X,*** which is the test result, the **true value,** which is the reference value for homemade lyophilized products, or the **target value,** which is the reference value from commercially available control materials in the control lot.

Then, the coefficient of variation of each parameter in both types of control materials is also calculated to show the level of imprecision or scale of data distribution converted into percentages using the formula shown in Eq. (3).

$$CV\% = \frac{SD}{X} \times 100\% \quad (3)$$

The formula for calculating the **CV%** or coefficient of variation involves several components, including **SD** or Standard Deviation, and ***x,*** which is the average test results.

After obtaining the coefficient of variation (CV) and bias values, the TEa (Ttotal Error Allowable) value is then determined based on CLIA guidelines. Total Error Allowable is a reference for the error limit in laboratory performance processes [37]. After determining the TEa value, the sigma value can be calculated using the formula listed in Eq. (4).

$$\text{Sigma } (\sigma) = \frac{TEa - d\%}{CV\%} \quad (4)$$

The formula for calculating the sigma value involves several components, including TEa or Total Error Allowable based on CLIA guidelines, d%, which is the bias value, and CV%, which is the coefficient of variation. A sigma value ≥ 6 is considered excellent (world-class), while a value < 3 indicates that the method requires evaluation or improvement. By understanding these components, laboratories can determine appropriate quality control strategies, including the proper application of Westgard rules.

D. Statistical Analysis

Data Analysis was performed by statistically comparing bias values between commercial control materials and homemade lyophilized. Prior to the correlation test, a normality test using the Shapiro-Wilk was performed. If the data is normally distributed, then proceed with parametric statistical tests using the independent t-test. If the data were not normally distributed, the non-parametric *Mann*-Whitney test was used. For comparative analysis of sigma values between commercial control materials and homemade lyophilized materials, descriptive analysis was performed.

III. RESULT

A. Target Value of Commercial Control Material

The target value, standard deviation (SD) value, and range mean ± 2SD of the commercial control material

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have been listed in the product lot of the control material, as presented in Table 1.

Table 1. Target Value, Standard Deviation, Coefficient of Variation, and Range Mean±2SD of Commercial Control Materials.

Parameters	TV (mg/dL)	SD	CV (%)	Rage Mean±2SD (mg/dL)
Blood Glucose	90	7	7,8	76 – 104
Uric Acid	4,5	0,45	10	3,6 – 5,4
Total Cholesterol	137	10	7,3	117 – 157
Triglyceride	118,6	9,5	8	99,6 – 137,6

Based on the table above, the target value of blood glucose is 90 mg/dL with a standard deviation (SD) of 7, the target value of uric acid 4,5 mg/dL with a standard deviation (SD) of 0,45, the target value of total cholesterol is 137 mg/dL with a standard deviation (SD) of 10, and the target value of triglycerides 118,6 mg/dL with a standard deviation (SD) of 9,5.

B. True Value Homemade Lyophilized

The true value of homemade lyophilized was examined during a preliminary period at a reference laboratory. The preliminary period was conducted 10 times in 2 reference laboratories. All test results of the homemade lyophilized during the preliminary period were calculated for target values, standard deviation (SD), and coefficient of variation (CV). The test results for true values of blood glucose, uric acid, total cholesterol, and triglycerides in homemade lyophilized samples are presented in Table 2.

Table 2. True Value, Standard Deviation, Coefficient of Variation, and Range Mean ± 2SD Homemade Lyophilized.

Parameters	TV (mg/dL)	SD	CV (%)	Rage Mean±2SD (mg/dL)
Blood Glucose	82,1	4,48	5,4%	73 – 91
Uric Acid	5,2	0,44	8,4%	4,3 – 6,0
Total Cholesterol	183,2	6,4	3,5%	170,4 – 196
Triglyceride	90	4,2	4,6%	81,6 – 98,4

Based on Table 2 above, the true value for blood glucose parameters is 82,1 mg/dL with a standard deviation (SD) value of 4,48 (range mean ±2SD = 73 – 91 mg/dL), true value for uric acid parameters is 5,2 mg/dL with a standard deviation (SD) value of 0,44 (range mean ±2SD = 4,3 – 6,0 mg/dL), the true value for the total cholesterol parameter is 183,2 mg/dL with a standard deviation (SD) value of 6,4 (range mean ±2SD = 170,4 – 196 mg/dL), and true value for the triglyceride parameter is 90 mg/dL with a standard deviation (SD) value of 4,2 (range mean ±2SD = 81,6 – 98,4 mg/dL).

C. Test Results of Commercial Control Materials

The results of blood glucose, uric acid, total cholesterol, and triglyceride tests on commercial control materials conducted and homemade lyophilized at the research laboratory for 1 month (20 replicates) are presented in Table 3.

Table 3. Results of Blood Glucose, Uric Acid, Total Cholesterol, and Triglycerides Test on Commercial Control Materials and Homemade Lyophilized at the Research Laboratory for 1 Month.

Control Type	Parameters	Mean (mg/dL)	Standard Deviation
Commercial	Blood Glucose	90	3
	Uric Acid	4,5	0,2
	Total Cholesterol	138,3	4,04
	Triglyceride	123,6	6,24
Homemade lyophilized	Blood Glucose	82	3
	Uric Acid	5,2	0,3
	Total Cholesterol	178	3,8
	Triglyceride	87,75	5,3

Based on Table 3 above, the average test results for the blood glucose parameter from all commercial control samples were 90 mg/dL with a standard deviation (SD) of 3, for uric acid parameters 4,5 mg/dL with a standard deviation (SD) of 0,2, for cholesterol parameters 138,3 mg/dL with a standard deviation (SD) of 4,04, and for triglyceride parameters 123,6 mg/dL with a standard deviation (SD) of 6,24. Meanwhile, the results of the homemade lyophilized test for blood glucose parameters were 82 mg/dL with a standard deviation SD of 3, for uric acid parameters, the value was 5,2 mg/dL with an SD of 0,3, for cholesterol parameters, the value was 178 mg/dL with an SD of 3,8, and for triglyceride parameters, the value was 87,75 mg/dL with an SD of 5,3.

All the test results of blood glucose, uric acid, cholesterol, and triglycerides in commercial control materials did not exceed the target range ±2SD, and all test results for blood glucose, uric acid, cholesterol, and triglycerides in homemade lyophilized did not exceed the true value range ±2SD of the homemade lyophilized. Based on the Levey-Jennings control chart rules, all test results for the commercial control material and the homemade lyophilized can be stated to be “in control”.

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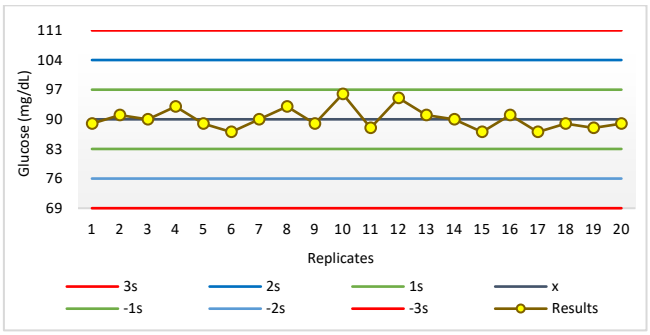

Fig 1.(a) Levey-Jennings Graph of Glucose on Commercial Control

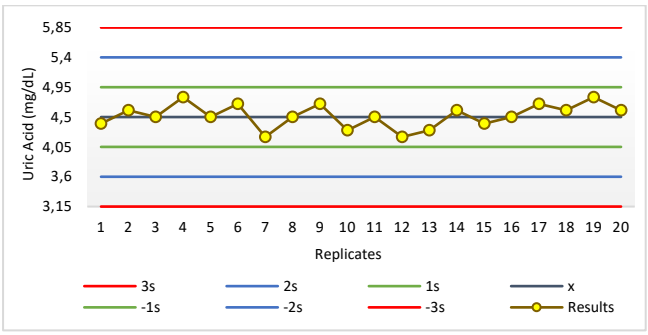

Fig 1. (b) Levey-Jennings Graph of Uric Acid on Commercial Control

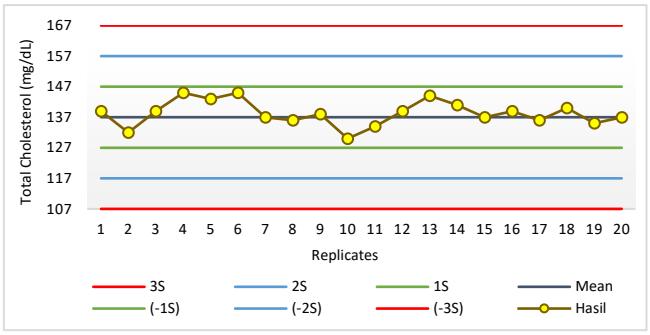

Fig 1 (c) Levey-Jennings Graph of Total Cholesterol on Commercial Control

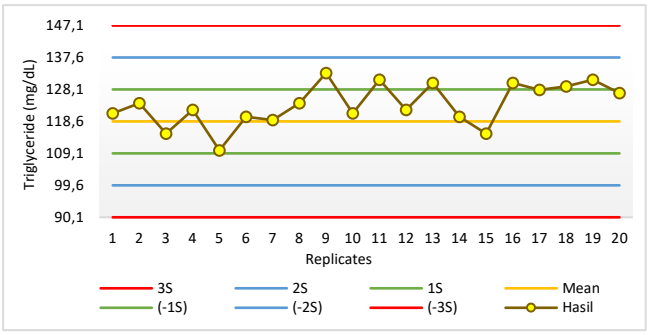

Fig 1 (d) Levey-Jennings Graph of Triglyceride on Commercial Control

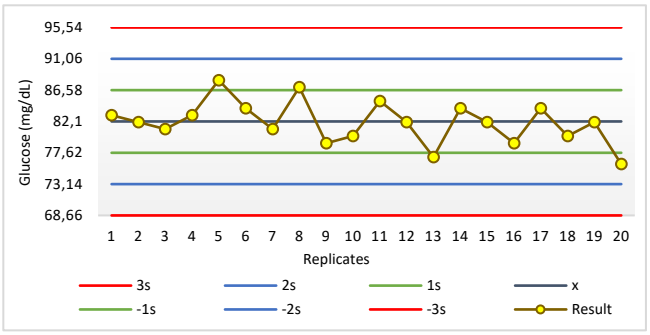

Fig 1 (e) Levey-Jennings Graph of Glucose on Homemade Lyophilized

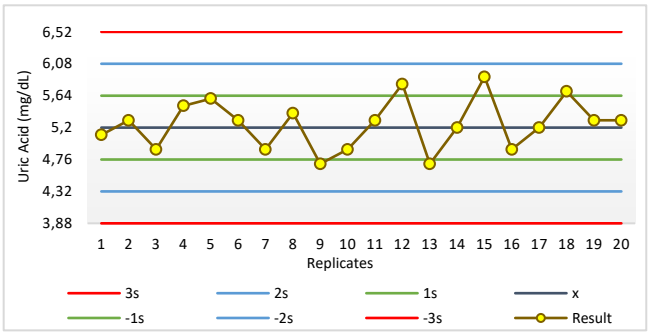

Fig 1 (f) Levey-Jennings Graph of Uric Acid on Homemade Lyophilized

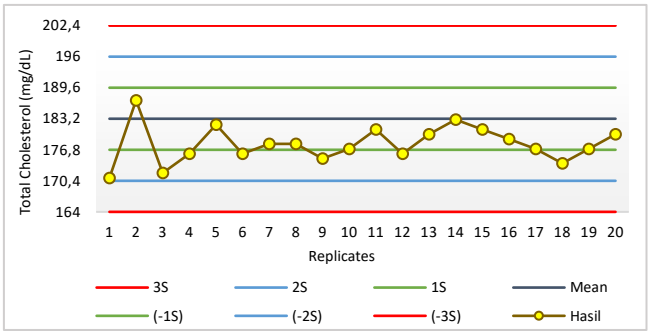

Fig 1 (g) Levey-Jennings Graph of Total Cholesterol on Homemade Lyophilized

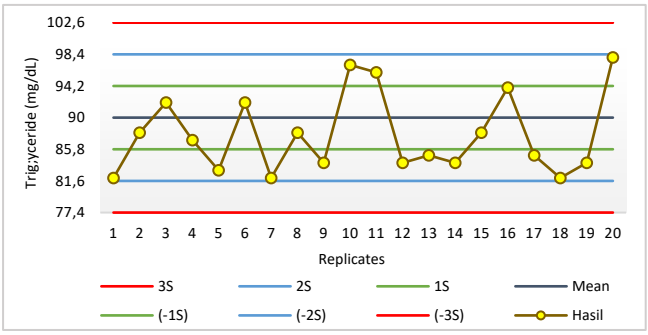

Fig 1 (h) Levey-Jennings Graph of Triglyceride on Homemade Lyophilized

Fig. 1 Levey-Jennings Graph of Blood Glucose, Asam Urat, Total Cholesterol, and Triglyceride Results Test on Commercial Control Materials and Homemade Lyophilized.

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E. Bias Value of Each Test Result

Each blood glucose, uric acid, total cholesterol, and triglyceride test result on commercial control materials and homemade lyophilized materials conducted at the research laboratory was calculated.

Based on the true value or target value. The bias value and comparative test results of each blood glucose, uric acid, total cholesterol, and triglyceride test results in commercial control and homemade lyophilized can be observed in Table 4.

Table 4. Bias Value of Each Test Results of Blood Glucose, Uric Acid, Total Cholesterol, and Triglyceride on Commercial Control and Homemade Lyophilized.

Day to	Blood Glucose		Uric Acid		Total Cholesterol		Triglyceride	
	Commercial (%)	Homemade (%)	Commercial (%)	Homemade (%)	Commercial (%)	Homemade (%)	Commercial (%)	Homemade (%)
1.	1.1%	1.2%	2.2%	1.9%	1.5%	6.7%	2%	8.9%
2.	1.1%	0%	2.3%	1.9%	3.6%	2.1%	4.6%	2.2%
3.	0%	1.2%	0%	5.7%	1.5%	6.1%	3%	2.2%
4.	3.3%	1.2%	6.6%	5.7%	5.8%	3.9%	2.9%	3.3%
5.	1.1%	7.3%	0%	7.7%	4.4%	0.7%	7.3%	7.8%
6.	3.3%	2.4%	4.4%	1.9%	5.8%	3.9%	1.2%	2.2%
7.	0%	1.2%	6.6%	5.7%	0%	2.8%	0.3%	8.9%
8.	3.3%	6.1%	0%	3.8%	0.7%	2.8%	4.6%	2.2%
9.	1.1%	3.6%	4.4%	9.6%	0.7%	4.5%	12.1%	6.7%
10.	6.6%	2.4%	4.4%	5.7%	5.1%	3.4%	2%	7.8%
11.	2.2%	3.6%	0%	1.9%	2.2%	1.2%	10.5%	6.7%
12.	5.5%	0%	6.6%	11.5%	1.5%	3.9%	2.9%	6.7%
13.	1.1%	6.1%	4.4%	9.6%	5.1%	1.7%	9.6%	5.6%
14.	0	2.4%	2.3%	0%	2.9%	0.1%	1.2%	6.7%
15.	3.3%	0%	2.2%	13.5%	0%	1.2%	3%	2.2%
16.	1.1%	3.6%	0%	5.7%	1.5%	2.3%	9.6%	4.4%
17.	3.3%	2.4%	4.4%	0%	0.7%	3.4%	7.9%	5.6%
18.	1.1%	2.4%	2.3%	9.6%	2.2%	5%	8.8%	8.9%
19.	2.2%	0%	6.6%	1.9%	1.5%	3.4%	10.5%	6.7%
20.	1.1%	7.2%	2.3%	1.9%	0%	1.7%	7.1%	8.9%
Sig.	**0.199**		**0.210**		**0.171**		**0.865**	

Based on Table 4 above, it shows the results of the bias value comparison test between commercial control materials and homemade lyophilized. The significance of glucose parameter is 0.199, the significance of uric acid parameter is 0.210, the significance of total cholesterol parameter is 0.171, and the significance of triglyceride parameter is 0.865. The significance values of all parameters showed more than 0.05, indicating that there was no significant difference in bias values between commercial control materials and homemade lyophilized control materials for blood glucose, uric acid, total cholesterol, and triglyceride parameters.

F. Bias Value, CV, & Sigma Value of All Test Results

The average of all blood glucose, uric acid, total cholesterol, and triglyceride test results for 1 month in commercial control materials and homemade lyophilized was calculated for the bias value and coefficient of variation (CV) against the target value or true value. After obtaining the bias value and coefficient of variation (CV), the sigma value was calculated. The results of the calculation of the bias value, coefficient of variation (CV), and sigma value of the target value of all test results on commercial control materials and homemade lyophilized materials are shown in Table 5.

Table 5. Bias Value, Coefficient Variation (CV), and Sigma Value of All Blood Glucose, Total Cholesterol, and Triglyceride Test Results on Commercial Control Material and Homemade Lyophilized.

Control Type	Parameters	Bias Value (%)	CV (%)	Sigma Value
Commercial	Blood Glucose	0.11	2.81	2.81
	Uric Acid	0.44	3.97	2.41
	Total Cholesterol	0.95	2.92	3.10
	Triglyceride	4.22	5.05	2.14
Homemade Lyophilized	Blood Glucose	0.18	3.68	2.12
	Uric Acid	1.06	6.59	1.76
	Total Cholesterol	2.84	2.13	3.36
	Triglyceride	2.5	6.01	2.08

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Based on Table 5 above, it is known that the sigma values of commercial control materials for blood glucose, uric acid, total cholesterol, and triglyceride parameters are 2.81 (poor), 2.41 (poor), 3.10 (marginal), and 2.14 (poor), while those of homemade lyophilized are 2.12 (poor), 1.76 (unacceptable), 3.36 (marginal), dan 2.08 (poor).

IV. DISCUSSION

A. Target Value or True Value

The target value of the commercial control material for blood glucose parameter is 90 mg/dL with a standard deviation (SD) of 7, for uric acid parameter is 4.5 mg/dL with a standard deviation (SD) of 0.45, for total cholesterol parameter is 137 mg/dL with a standard deviation (SD) of 10, and for triglyceride parameter is 118.6 mg/dL with a standard deviation (SD) of 9.5.

To determine the true value of homemade lyophilized, it is necessary to calculate the average of at least 10 replicates on 10 different days carried out in a reference laboratory [36]. In this study, the true value of the homemade lyophilized for glucose parameter was 82.1 mg/dL with a standard deviation (SD) of 4.48, for uric acid parameter was 5.2 mg/dL with a standard deviation (SD) of 0.44, for total cholesterol parameter was 183.2 mg/dL with a standard deviation (SD) of 6.4. For triglyceride parameter was 90 mg/dL with a standard deviation (SD) of 4.2. Most of the parameters produced small standard deviation values, which indicates that the true value test results carried out in the reference laboratory are in the good category, meaning that the homemade lyophilized test material studied has good quality.

Based on the target values of commercial control materials and the true values of the homemade lyophilized test material, all parameters are within the normal range. The standard deviation (SD) of commercial control materials is higher than that of the homemade lyophilized test material. The cause of the high standard deviation (SD) value is the duration of the preliminary period in determining the true value/target value, as explained by Westgard [38], a longer preliminary period will collect more variation between laboratories, including more operators and method changes, such as performance before and after maintenance, changes in reagent lot numbers, sample probes, or pipettes, and others. Meanwhile, the preliminary period for determining the true value for homemade lyophilized was only conducted for 10 days, during which variations in reagent lots, operators, and method changes were minimized, resulting in a smaller standard deviation (SD) for homemade lyophilization control materials.

B. Accuracy of Commercial Control Material and Homemade Lyophilized

Accuracy shows the accuracy of the test results with the target value or true value. The accuracy of the test results is measured by calculating the inaccuracy, or what is called the bias value (d%) [26]. The bias value of all test results on commercial control materials were as follows: blood glucose, 0.11%; uric acid, 0.44%; total cholesterol, 0.95%; and triglycerides, 4.22%. In comparison, the bias values of test results using homemade lyophilized controls were: blood glucose, 0.18%; uric acid, 1.06%; total cholesterol, 2.84%; and triglycerides, 2.50%.

The results of the bias value comparison test of each test result between commercial control materials and homemade lyophilized showed a significance value > 0.05 for all parameters. This result shows that H0 is accepted, meaning that there is no significant difference in bias value between commercial control material and homemade lyophilized material in all parameters. Therefore, homemade lyophilized material can be used as an alternative to commercial control material.

Although there is still a high bias value, the inspection results are considered to have good accuracy because the are in the range of ±2SD. Bias values define a deviation from the true value, so the smaller the bias value, the higher the accuracy [19]. Small bias values they indicate that the instruments and methods used in the tests are quite accurate, but they tend to have the potential for differences in results from the target value or true value [25]. The difference in results is influenced by error factors during the test process, in line with research conducted by (Khotimah, 2022, Wulandari, 2023), stating that the level of accuracy of laboratory test results is related to errors that occur during the test process [22] [39] [40]. During the research process, there may be errors such as improper pipetting due to being conducted by more than one person, insufficient homogenisation leading to uneven mixing of the analyte, which impacts the instability of test results. According to (Siregar et al., 2018), bias may arise from several factors, including control materials derived from animals, variations in the production process, variations in packaging, and reconstruction errors [19] [41]. In this study, the commercial control materials used have been formulated in such a way as to resemble human serum. During the one-month study, the commercial control used remained in the same packaging. This resulted in the majority of parameters for the commercial control being generally lower than those of the homemade lyophilisate [19] [41].

The bias value of commercial control materials, which is higher on the triglyceride parameters, aligns with Westgard's statement, which mentions that a large ± 2SD value range also causes a high bias value; thus even if the examination results deviate significantly from the target value but still fall within the ± 2SD range, it is still considered acceptable. The sufficiently large SD value of the commercial control material results in a ± 2SD range that is also quite wide; thus control results that deviate significantly from the target value but fall within the ± 2SD limits are still accepted. This leads to a high bias value.

C. Precision of Commercial Control Materials and Homemade Lyophilized

Precision or accuracy of a laboratory result is obtained through measurement of imprecision or coefficient of variation (Coefficient of Variation) [42]. The results showed that the coefficient of variation (CV) of all

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commercial control results for blood glucose parameters was 2.81%, for uric acid parameters was 2.97%, for total cholesterol parameters was 2.92%, and for triglyceride parameters was 5.05%. While the coefficient of variation (CV) value of all homemade lyophilized results for blood glucose parameters is 3.68%, for uric acid parameters is 6.59%, for total cholesterol parameters is 2.13%, and for triglyceride parameters is 6.01%.

The lower the CV value, the more precise the test results [43]. Precision indicates random error is caused by unstable instruments, temperature variations, reagent variations, calibration, variations in test procedure techniques (pipetting, mixing, incubation time), and operator competence variations [19] [44]. The results showed that all parameters in the commercial control material did not exceed the maximum limit of the CV value. Whereas, in the homemade lyophilized, the CV value of the uric acid parameter exceeded the maximum CV value limit.

The coefficient of variation value that does not exceed the maximum limit of CV shows good stability, in line with (Siregar *et al*., 2018), which states that the control material in lyophilized form is more stable and durable than the liquid form [19]. Research (Kusmiati *et al*., 2022) shows that the results of the CV value of blood glucose do not exceed the maximum limit [23]. Research (Kulkarni *et al*., 2020), showed most clinical chemistry parameters, including total cholesterol and triglycerides in commercial control materials, were stable for up to 12 weeks, as indicated by the coefficient of variation (CV) value not exceeding the CCV limit [15]. The coefficient of variation (CV) of homemade lyophilized in this study is in line with research (Rahayu, 2023), which shows that serum lyophilized made by ourselves using freeze-dry technique stored at 2-8°C can be an alternative to commercial control materials in cholesterol and triglyceride testing. This is indicated by good precision values for eight weeks [12]. This is consistent with research results showing that the CV values for glucose, total cholesterol, and triglycerides do not exceed the maximum CV limits, due to the specimen handling during the research process being in accordance with the recommendations. Research (Widyaningtias *et al*., 2024) showed that the CV value of uric acid in the control material for 3 months did not exceed the maximum CV limit [26]. However, in contrast to the results of this study, which show that the CV value for uric acid tends to exceed the maximum CV limit.

The high coefficient of variation is influenced by temperature stability. Improper specimen shipping and storage temperatures will cause specimen evaporation, which will affect specimen stability [45]. In this study, although the specimen storage followed the recommended standards, the temperature was not consistently maintained, resulting in the CV value of uric acid in the homemade lyophilisate exceeding the maximum CV limit. This was due to the degradation of uric acid compounds caused by temperature influences, leading to unstable test results.

D. Sigma Value of Commercial Control Materials and Homemade Lyophilized

The sigma value is calculated from the difference between the Total Allowable Error (TEa) and the bias value of the target value of all test results, then divided by the CV (Coefficient of Variation) value of all test results. The TEa value limit set by the Clinical Laboratory Improvement Amendment (CLIA) for blood glucose parameters is 8%, for uric acid parameters is 10%, for total cholesterol parameters is 10%, and for triglyceride parameters is 15% [46].

The results obtained the sigma value of commercial control materials for blood glucose parameters is 2.81 (poor), for uric acid parameters is 2.41 (poor), for total cholesterol parameters is 3.10 (marginal), and for triglyceride parameters is 2. 14 (poor). The sigma value of homemade lyophilized for blood glucose parameter is 2 12 (poor), for uric acid parameter is 1.76 (unacceptable), for total cholesterol parameter is 3.36 (marginal), and for triglyceride parameter is 2.08 (poor). Based on the sigma level grouping, the homemade lyophilized is equivalent to the commercial control material for blood glucose, total cholesterol, and triglyceride parameters, but not equivalent for uric acid parameters Based on the sigma value, the homemade lyophilized is better for total cholesterol parameter, while the commercial control material is better for blood glucose, uric acid, and triglyceride parameters.

The difference in sigma values in this study may be attributed to the lack of temperature stability during the research process, as a digital thermometer was not used to monitor temperature stability. In line with (Siregar et al., 2018), storage temperature affects the stability of control materials, metabolism by living cells in the specimens is also a confounding factor that can affect inaccurate results. Additionally, commercial control materials made from non-human serum sources may contain other substances that will affect the test results [19]. The sigma value of the uric acid parameter, classified as unacceptable (1.76), was caused by pre-analytical factors. In line with (Wulandari *et al*., 2023, Nabilah *et al*., 2023), which shows that errors in pre-analytics include improper specimen reconstitution processes, such as improper pipetting, and contaminated specimen storage [22] [47]. During the pre-analytical phase of the study, reconstitution was performed using a volume pipette rather than a more accurate micropipette, which likely contributed to variability in results. Moreover, uneven homogenisation also leads to unstable control results due to poorly mixed analytes.

Systematic errors can also lead to poor result accuracy. Systematic errors include low-quality reagents, weaknesses in testing methods, lack of accuracy from blank samples and reagent blanks, poor calibration reagent quality, inaccurate equipment performance (pipettes), use of inappropriate wavelengths, and incorrect reagent dissolution procedures. During the research process, the equipment encountered issues that required calibration and replacement of reagents; these factors led

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to high bias values and coefficient of variation values, resulting in a low sigma value, which would require more quality control procedures [19].

According to (Aggarwal *et al.*, 2019), evaluation of total cholesterol parameters with a sigma value of 3 requires quality controlonce every 45 samples, while for blood glucose, uric acid, and triglyceride parameters with a sigma value of ≤ 2 is the frequency of control carried out once every 10 samples. In this evaluation, the laboratory can use 3 levels of control material (Checked 1 time in duplo or done 2 times testing), by applying all Westgard rules [48]. The sigma value describes the validation of an inspection method, so if there are parameters in a method with a sigma value < 3, then the method cannot be used as a routine method and must be evaluated [50].

This finding has practical implications for clinical laboratories, especially in primary facilities with budget constraints for the use of commercial control materials. Homemade lyophilised control materials can be implemented for total cholesterol parameters, noting that initial validation for stability and precision of results is necessary. Implementation should include routine testing with scheduled control frequencies, along with regular monitoring using Levey-Jennings charts and sigma value evaluation. This approach has the potential to enhance operational cost efficiency while maintaining the quality of testing results.

V. CONCLUSION

This study aims to compare bias values and evaluate the quality of commercial control materials and homemade lyophilized controls by reviewing the sigma values of the Sigma Metric evaluation method. Based on the analysis of bias values, no significant difference in bias values was found between the commercial control material and the homemade lyophilized material. This study shows that commercial control materials have poor performance for blood glucose parameters (2.81), uric acid (2.41), and triglycerides (2.14), but marginal performance for the total cholesterol parameter (3.10). Meanwhile, homemade lyophilized materials have unacceptable performance for uric acid parameter (1.76), poor performance for blood glucose parameter (2.12) and triglycerides (2.08), but have marginal performance for total cholesterol parameter (3.36). Only the total cholesterol parameter indicates acceptable performance in the freeze-dried control material.

Further research is needed to optimise the lyophilisation, reconstitution, and stability processes of homemade lyophilised products, particularly for parameters that show low sigma values. Evaluating the stability of storage temperature, solvent composition, well-calibrated instruments, and improved drying techniques can help enhance the quality of homemade control materials, thereby expanding their use as an alternative to commercial control materials in clinical laboratory testing.

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