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Control Serum Stability Comparison Glutamic Oxaloacetic Transaminase Stored at Temperatures 10ºc And -40ºc in Laboratory Installation Rsup Dr. M Djamil Padang

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ABSTRACT

Strengthening the quality of health laboratories is all activities aimed at ensuring the accuracy and accuracy of laboratory examination results. One of the parameters used for serum control is ASAT (Aspartate Aminotransferase) or GOT (Glutamic Oxaloacetic Transminase) which are very important intracellular body enzymes. This study aims to determine whether there is a significant difference in ASAT examination with control materials stored at 10ºC and -40ºC for 30 days and compare the stability of ASAT parameter control serum tests at storage temperatures of 10ºC and -40ºC. This research was conducted in the laboratory of Dr. RSUP. M Djamil Padang in January 2021, using the analytical descriptive method. Data analysis technique with descriptive test and statistical test by looking for the average value (mean), standard deviation (SD), coefficient of variation (KV) to determine accuracy and then assessed according to Westgard Multirule and Recovery (%R). The results showed that the average value of the ratio of SGOT enzyme levels in control serum stored at 10ºC was 102.4 u/l (±5.43) and -40ºC was 106.7 u/l(±2.33). The results of the analysis at the level of = 0.05 indicate that the result value of t-count = 4.572 and t-table = 2.001 (t-count > t-table). There was a significant difference in the stability of control serum for ASAT examination stored at 10ºC and -40ºC.

Keywords: *Control Serum, Westgard's Rule, Medical Laboratory Technology*

1. INTRODUCTION

Clinical chemistry examination measures changes in biochemical compounds as indicators of health status or disease processes. Assays selected as biochemical markers are used to monitor disease due to non-uniform changes in biochemical compounds in tissues and organs in response to disease. Clinical laboratories aim to report the true value of the concentration or activity of a substance in the body. Clinical laboratories must provide accuracy and precision to examination results, along with reference values for healthy people because laboratory results are important to support diagnosis and therapy. Strengthening the quality of health laboratories is all activities aimed at ensuring the accuracy and accuracy of laboratory examination results. Internal quality control (internal quality control) is a prevention and control activity carried out by each laboratory on an ongoing basis so as not to occur or reduce deviations so that the right examination results are obtained [4].

Before carrying out laboratory examinations, a control serum should be examined, which has known the value of several examination parameters as a reference and the reference value. Control serum is a universal control lyophilized serum made from human or animal serum, with values assayed for all components; this control serum can be used to control the accuracy and precision of manual and automated methods. Most of the control material range values were normal and pathological values. Serum or aliquot materials are influenced by internal and external factors. Internal factors include serum stability, serum physiology, evaporation, contamination of certain substances or dirt and bacteria. While external factors are the tools used, the quality of the reagent , the temperature and the place of storage. Enzyme activity is influenced by the pH of the environment in which the enzyme works, the concentration of the enzyme and substrate, temperature and the presence of enzyme activators or

inhibitors. Temperature has a big effect on enzyme activity. All enzymes work within a certain time span in each type of organism. For every 10ºC increase above the minimum temperature, the enzyme activity will increase twofold until it reaches the optimum condition. An increase in external temperature will generally increase the speed of chemical reactions, but an increase in temperature that is too high will cause denaturation of the enzyme, namely damage to the structure of the enzyme. This causes a decrease in the rate of the reaction catalyzed by the enzyme.[6]

One of the parameters used for serum control is ASAT (Aspartate Aminotransferase) or GOT (Glutamic Oxaloacetic Transminase) which are very important intracellular body enzymes. Serum Glutamic Oxaloacetic Transaminase or SGOT is an enzyme found in the body. SGOT is commonly found in the heart, kidneys, brain, muscles, and liver (liver). This enzyme is responsible for helping to digest protein in the body. To carry out the SGOT examination, the medical team will take a sample of the patient's blood to be tested in the laboratory. In healthy people, this enzyme will look normal,approximately the normal range of 5-40 /L (micro per liter). However, the normal limits for SGOT can vary from person to person. It all depends on the techniques and procedures performed when examining a blood sample. SGOT is indeed found in various organs, but under normal circumstances SGOT is mostly in the liver and cells. However, when the liver is damaged, this enzyme can be released from the liver cells.[7]

Based on the observations made by the researchers at the Dr. RSUP Laboratory. M Djamil, that there are several storages that are carried out above 2ºC, namely the refrigerator temperature of 10ºC. The control serum can still be used in the maintenance process every morning. Although in the laboratory of Dr. M Djamil has set a SOP (Standard Operational Procedure) that the control serum is stored at a temperature of -40ºC, but this treatment is thought to be for the efficiency of the work carried out inside, because if the control serum is taken in the freezer, it is necessary to incubate until the control serum liquid melts and that it takes a long time so that the control serum at the temperature in the ordinary refrigerator is still used. Storage of control serum below 15ºC is still stable for use, but not for more than 24 hours. Not all clinical parameters are commonly applied, especially the examination using the enzymatic method which has stability properties that are sensitive to temperature.

According to Rizky who stored SGPT levels at a temperature of 20º-25ºC for 5 days showed that there was no difference but decreased successively due to the use of room temperature in this study. Room temperature tends to change every hour, causing a decrease in SGPT levels in serum and plasma. ASAT parameter is an enzymatic test. However, in several maintenance and control treatments, laboratory practitioners use control serum at normal cooling temperatures. although at some time the resulting parameter control values remain within the reference range, but if placed on the graph of the Westgard rule calculation later, a significant bias is found. This is presumably due to the maintenance and control of the equipment that uses a bad temperature.[7]

From this phenomenon, the author needs to provide an overview that can be used as a later reference, especially for laboratory practitioners. By using the Cobas 6000i Architect Plus' Automatic Spectrophotometry tool, the researchers conducted a study entitled "comparison of the stability of serum glutamic oxaloacetic transaminase control which was stored at 10ºC and -40ºC in the laboratory installation of Dr. RSUP. M Djamil Padang"

2. MATERIAL AND METHODS

This study used a descriptive analytic method which aims to compare the stability of the ASAT parameter control serum examination at storage temperatures of -10ºC and -40ºC. This research has been carried out in the laboratory of RSUP Dr. M Djamil Padang in January 2021. The population is all ASAT parameters for clinical chemistry examination carried out internal quality assurance in the laboratory of Dr. RSUP. M Djamil Padang. The sample in this study was a sample taken by one ASAT parameter which was examined for 30 days in the laboratory of Dr. RSUP. M Djamil Padang. In this study the authors use quantitative research, because the data obtained in the form of numbers. The figures obtained were further analyzed in data analysis. The type of data in this study is special data because the data can only be obtained in clinical laboratories in the field of clinical chemistry.

3. RESULTS

3.1. Univariate Analysis

3.1.1 SGOT Enzyme ActivityTemperature10°C

SGOT enzyme activity at 10°C is shown in table 4.1.

Table 1. Table of Average SGOT Enzyme Activity at 10°C

N	Mean Suhu 10^0C (u/L)	Verifikasi (Mean)
30	102.4	-0,67

The table above is the control value obtained in the 30-day experiment with SGOT parameters for a temperature of 10ºC. From this experiment, the average control serum value was 102.4 u/L.

3.1.2 SGOT Enzyme Activity Temperature -40ºC

The enzyme activity at -40oC is shown in Table 4.1.

Table 2. Table of Average SGOT Enzyme Activity at -40°C

N	Mean Suhu -40^0C (u/L)	Verifikasi (Mean)
30	107.4	-0,27

The table above is the control value obtained in the experiment during 30 days SGOT parameter for -40ºC temperature. From the research conducted, the average control serum value was 107.4 u/L.

3.1.3 Precision Test

Table 3. Comparison of serum values of SGOT enzyme activity and precision test results of ASAT examination stored at 10ºC and -40ºC

Store Temperature	**Mean**	**SD**	**KV**
10ºC	102,4 u/l	5,43	5,30
-40ºC	107,4 u/l	2,33	2,17

Based on the table above, it can be seen that the average value of the comparison of SGOT enzyme levels in control serum stored at 10ºC is 102.4 u/l and -40ºC is 106.7 u/l. Meanwhile, the standard deviation value at 10ºC is 5.43 and -40ºC is 2.33 and the coefficient of variation at 10ºC is 5.30 and -40ºC is 2.17

3.2 Bivariate Analysis

Table 4. Normality test

Data Normality Test Kolmogorov-Smirnov	
Store Temperature	Results
10ºC	0,528
-40ºC	0,608

In the calculation of the normality test that has been carried out using the help of Microsoft Excel. Then the results of the normality test at both storage temperatures were normally distributed because the results were more than the significance value of 5% or 0.05. So for the test used is the t test because the data is normally distributed.

3.3 Differences in SGOT Enzyme Activity Temperature 10°C with a temperature of -10°C

By using the SPSS data processing program with the independent t-test method, the t-count result is 4.572. Furthermore, the t-count value is compared with the t-table with db = (N-2) = (30-2) = 28 at a significant level of 5% = 2.001, or the results of t-count = 4.572 > t-table = 2.001 at 5% significance level. This is based on decision making based on the significance level of t-count < t-table, which means H1 is accepted. These differences can be seen through the test table below:

Table 5. Research Hypothesis Test

Store Temperature	**N**	**t-count**	**t-table**	**Decision**
10ºC	60	4,572	2,001	t-count > t-table then H0 is rejected
-40ºC				

From the table above, it can be concluded that there are differences in the stability of control serum for ASAT examination stored at 10ºC and -40ºC.

4. DISCUSSION

4.1 Univariate Analysis

4.1.1. Enzyme activity storage temperature 10ºC

In experiments conducted at a storage temperature of 10ºC the values obtained every day look very different. As on the first day the value obtained is 98 then on the second day the value obtained increases, namely 103. Then there was also a very large decrease in value as in the 8th experiment with 108 results and surprisingly on the 9th day the value obtained actually decreased very much, namely 98. Furthermore, the graph began to stabilize in the 11th experiment until the next experiment. -24, it can be seen that the increase or decrease in the results is not too much different. In the 25th experiment the value fell back to 89 and from the 26th day to the 30th day the graph returned to normal, although there was an increase or decrease but not too significant.

The values that have been verified and entered into the westgard graph are not against the rules because none of the graphs exceeds 2 SD. Although there are several experiments that are close to 2 SD but are still acceptable, if there are scores that pass 2 SD but are not sequential then the value is still acceptable [3].

Rahayu research 2015 The results of research on vitamin C levels in red, green, fried and curly chilies that were stored for 7 days showed that vitamin C levels in chilies stored at room temperature had high levels of the average vitamin C is 1.1 mg gram/100 grams and stored at a temperature of 10 an average of 1.44 mg gram/100 grams, the results of the Independent T-Test statistical test obtained p=0.011, which indicates that the results are p<0, 05. Based on the results of the study, it was concluded that there was an effect of storage temperature on vitamin C levels in various types of chili. Based on the research above, the equation with the research that the researchers did was both using the storage temperature 10. According to the assumption of the researcher, that at a storage temperature of 10ºC, yield instability often occurs which results in several very significant decreases and increases.

4.1.2 Enzyme activity storage temperature -40ºC

From the ASAT examination of control materials stored at 10ºC and -40ºC if adjusted according to Westgard's rules, it can be concluded that for inspections at 10ºC there was no error at all but almost on the warning criteria because there were several experiments that were close to -1SD. Furthermore, for the storage temperature of -40ºC, it can almost be said that there is no error at all because seen from the graph, nothing goes up too far or down, they are almost always on the same line in every experiment. Woro Wirasti (2016) showed that there was a significant effect of storage for one month of lyophilized universal control serum or commercial control serum that had been dissolved on the decrease in serum stability for parameters of serum glucose levels and SGOT enzyme activity, although the values at the end of the study were still in the range stated in serum packaging. Similar to the research that the researchers did, there was a difference between the storage temperature of 10ºC and -40ºC for one month and the results were that none of them violated Westgard's rules. In the experiments carried out for a storage temperature of -40ºC, it was declared normal because none of the lines on the graph crossed -1SD or +1SD four times in a row. As in the 25th to 29th experiments, although five times in a row with the same result, but because they did not pass -1SD, it was still acceptable [4].

Sukmana (2016) said that storage of xylanase enzymes at storage temperatures of 30ºC, 40ºC, 50ºC, 60ºC and 70ºC concluded that generally the stability of the enzyme would be more stable at lower temperatures and also the length of storage carried out would greatly affect the activity of the xylanase enzyme. The Minister of Health (2017) said that the guidelines for using the Westgard rule were firstly considered whether the low control value or high control value crossed the 12S control limit, if not, it means that the control check on that day went well. It also means that all checks on the same day went well. On the other hand, if one of the controls exceeds the 12S control limit, it is noticed whether there are other control rules that are violated (the limit is crossed). If it turns out that no control rules have been violated, it means that the inspection on that day is good (in control, accept run). If it turns out that there are control rules that are violated, then the inspection on that day is disturbed (out of control, reject run).

According to the researcher's assumption that to see the stability of an enzyme, it is better to do it at a low temperature and also not to store it for too long so that the activity of the enzyme is not affected.

4.2 Bivariate Analysis

Bivariate analysis in this study was conducted to prove the hypothesis that had been made previously. This study aims to compare the stability of ASAT control serum that was stored at 10ºC and -40ºC.

From experiments conducted 30 times for each storage temperature, then data analysis was carried out with the Westgard rule as a reference, it can be concluded that the best ASAT control serum examination in this study was at a storage temperature of -40ºC. Even so, there can be some drawbacks that lead to a temperature of -40oC, namely if the control serum does not match the pre-analytic treatment, freezing occurs in the control fluid which results in the instrument not being able to read properly, so it is necessary to do temperature stability again and of course it takes a long time. In the preanalytic process. Furthermore, storage that is too long can cause enzyme activity to be affected.

5. CONCLUSION

1. The activity of the AST enzyme on the control material stored at 10ºC obtained the mean of 102.4 u/l, the standard deviation of 5.43 while the coefficient of variation was 5.30.
2. The activity of AST enzyme on the control material stored at -40ºC, the mean is 106.7 u/l, the standard deviation is 2.33 while the coefficient of variation is 2.17.
3. By using independent t-test, it can be concluded that there is a difference in the stability of control serum for ASAT examination stored at 10ºC and -40ºC.

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