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Evaluation of the accuracy and precision of the microlab 300 device for total cholesterol test on the CHOD-PAP method

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Abstract

Internal quality assurance (PMI) is a routine preventive and monitoring activity in the laboratory to minimize errors and produce accurate tests. Quality accuracy and precision are important indicators in assessing PMI. Accuracy indicates the closeness of the test results to the true value, while precision describes the closeness of the results of repeated tests on the same sample. Total cholesterol examination using a spectrophotometer, especially the CHOD-PAP method, is often carried out at the Clinical Laboratory of the Poltekkes Kemenkes Pontianak due to its stability. This observational study aims to evaluate the accuracy and precision of the Microlab 300 tool for total cholesterol examination using the CHOD-PAP method at the Integrated Laboratory of the Poltekkes Kemenkes Pontianak. The study population was the assayed control serum solution, with samples in the form of normal control serum solution dialab which was divided into 100 vials containing 50 µL. A total of 30 vials were used for the preliminary period and 30 vials for the control period. The parameter examined was total cholesterol by CHOD-PAP method. The results showed the average accuracy of the Microlab 300 tool was 96.08% and precision was 99.21%. The daily graph using Westgard's rule shows that the control material is within the control limits. Thus, it can be concluded that the Microlab 300 tool shows good accuracy and precision in the examination of total cholesterol CHOD-PAP method in the laboratory.

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INTRODUCTION

Laboratories are part of health services that are needed to support health improvement efforts (Milne, & Milne, 2010; Alemnji, et al., 2014; Swanson, et al., 2014). As an important component in health services, laboratory examination results are used to determine the diagnosis and monitor treatment results (McPherson, & Pincus, 2021; Olver, Bohn, & Adeli, 2023). Therefore, the quality of laboratory examination results must be guaranteed (Pamungkas, Handayati, & Woelansari, 2019) .

Strengthening the quality of health laboratories is all activities aimed at ensuring the accuracy and accuracy of the examination results from a laboratory (Pamungkas, Handayati, & Woelansari, 2019). Internal quality assurance is a preventive and supervisory activity carried out by each laboratory on a regular basis so as not to occur or reduce errors / deviations so that the right examination results are obtained.

Internal quality assurance is important in a laboratory to control laboratory examination results, minimize deviations from inaccurate results to support the diagnosis of a disease. One of the indicators to assess the internal quality of the laboratory is the quality of accuracy and precision (Wijayanti, Yansen, and Nurcahyanti 2022). Accuracy is to show the closeness of the examination results to the true value (true value) that has been determined by standard methods, while precision is to determine how close an examination result is when done repeatedly with the same sample (Lebo, Merkel, & Knight, 2024).

The implementation of accuracy and precision requires control materials that are used every day for routine examinations. Control materials for clinical chemistry examinations are generally in the form of liquids depending on the examination to be carried out and the tools to be used. One tool that is often used in laboratories for clinical chemistry examinations is a spectrophotometer (Nabilla et al. 2022) .

Spectrophotometers have several advantages, namely having high sensitivity and selectivity, easy measurement, fast spectrophotometer performance. The disadvantages of spectrophotometers are that they are dependent on reagents that require a special place and are quite expensive. One of the parameters that can be examined using a spectrophotometer is the examination of total cholesterol.

Examination of cholesterol levels in several clinical pathology laboratories generally uses a spectrophotometer. High cholesterol levels can cause various diseases, especially those related to coronary heart disease and cardiovascular (Nabilla et al. 2022) . According to WHO (World Health Organization) every year there are deaths from cardiovascular disease reaching more than 17.8 million. While data from the Ministry of Health of the Republic of Indonesia in 2023 in Indonesia the death rate from this disease reached 650,000 people per year. Therefore, the results of clinical pathology laboratory examinations must be precise and accurate so that the examination results can be reported validly. Examination of total cholesterol levels is often carried out at the Pontianak Poltekkes Kemenkes clinical laboratory. One of the advantages of this parameter is that it has better durability and stability compared to other parameters. The examination of total cholesterol levels can be examined using the enzymatic method CHOD-PAP (Cholesterol Hydrolysis and Oxidation Determination from Para Aminoantipyrine) which forms quinoneimine so as to produce a pink complex compound which is measured using a microlab 300 brand spectrophotometer.

The Integrated Laboratory of Pontianak Health Polytechnic has a spectrophotometer brand microlab 300 which was purchased around 2010 and is still in use today (Inventory Report of the Integrated Laboratory of Pontianak Health Polytechnic, 2023). This semi-automatic tool, used for blood chemistry examination, has the principle of being able to decompose light into a light spectrum with a narrow wavelength region. Measurement of light absorption due to the interaction of light that has a certain wavelength with a solution or dye microlab tool has a photometric absorbance range of -0.1 to 2.3. Regarding the precision test and accuracy test of the Microlab 300 and Rayto RT-1904C tools for the GOD-

PAP method glucose test. It was obtained that the accuracy value of the microlab 300 spectrophotomer was 96.48% then for the precision value of the microlab 300 spectrophotometer of 99.59%.

The reliability of the Microlab 300 brand spectrophotometer will decrease over time. One of the factors that causes the reliability of this microlab 300 to decrease is that it has never been calibrated from the first purchase. Calibration is the process of verifying that a measuring instrument accuracy is in accordance with its design. Calibration is needed to ensure that the results of measuring sample levels are accurate and consistent. If the measurement results are not accurate and consistent, it will affect the quality of laboratory quality.This observational study aims to evaluate the accuracy and precision of the Microlab 300 tool for total cholesterol examination using the CHOD-PAP method at the Integrated Laboratory of the Poltekkes Kemenkes Pontianak.

METHOD

This research is an observational study, namely research that makes a picture or description of a situation objectively using numbers, starting from data collection, interpretation of data, and appearance and results. This type of research uses an observational research design to see a description of the phenomenon, where activities are carried out systematically and emphasize more on factual data (Siregar et al. 2022) .

The data used in this study are primary data, namely data taken directly from an object (Sujarweni 2014). Primary data in this study are data obtained from the observation of the CHOD-PAP method of cholesterol examination using the Microlab 300 tool. Data collection in this study was carried out after obtaining the results of the examination of cholesterol levels using a spectrophotometer and entered into the examination results table (Sudaryono 2017).

RESULTS AND DISCUSSION

Evaluation of the accuracy and precision of the Microlab 300 tool for the examination of total cholesterol levels by the CHOD-PAP method, this study used a sample of 30 normal control serum solutions for the preliminary period. In this study, sampling was carried out randomly, the preliminary period was carried out for 6 days in 1 working day a sample of 5 control sera was examined. The preliminary period in this study was carried out to determine the average value and standard deviation. the value will be used as a reference value in the control period. The following results were obtained.

Table 1. Cholesterol Level Values in the Preliminary Period Using the Microlab 300 Tool.

Average	Standard Deviation	Value Range
134.33	4.96	119.45-149.21

Based on the value of the preliminary period in table 1, the average value of cholesterol levels is 134.33, the standard deviation value is 4.96 with a range value obtained of 119.45-149.21. After obtaining the results in the preliminary period, the next stage is the control period to determine the accuracy and precision of the tool. This study used a sample of 30 normal control serum solutions for the control period. In this study, sampling was carried out randomly, the control period was carried out for 6 days in 1 working day, 5 control serum samples were examined. The following results were obtained.

Table 2. Cholesterol Level Values in the Control Period using *Microlab 300* Device.

No.	Sample Code	Cholesterol Levels
1.	6	131
2.	37	139
3.	35	134

4.	62	142
5.	4	127
6.	78	130
7.	65	143
8.	28	129
9.	14	139
10.	67	143
11.	10	141
12.	57	128
13.	75	132
14.	80	127
15.	22	139
16.	68	127
17.	77	135
18.	85	142
19.	94	128
20.	100	142
21.	55	143
22.	88	138
23.	92	130
24.	97	135
25.	99	132
26.	3	127
27.	86	138
28.	42	142
29.	74	140
30.	7	136
Average		**135.3**

Based on the control values in table 2, the average cholesterol level is 135.3 mg/dl.

Table 3. Accuracy value of the Microlab 300 device for checking cholesterol levels using the CHOD-PAP method.

No.	Sample Code	Cholesterol Levels	Accuracy (%)
1.	6	131	97.52%
2.	37	139	96.52%
3.	35	134	99.75%
4.	62	142	94.29%
5.	4	127	94.54%
6.	78	130	96.77%
7.	65	143	93.54%
8.	28	129	96.03%
9.	14	139	96.52%
10.	67	143	93.54%
11.	10	141	95.03%
12.	57	128	95.28%
13.	75	132	98.26%
14.	80	127	94.54%
15.	22	139	96.52%
16.	68	127	94.54%

17.	77	135	99.50%
18.	85	142	94.29%
19.	94	128	95.28%
20.	100	142	94.29%
21.	55	143	93.54%
22.	88	138	97.26%
23.	92	130	96.77%
24.	97	135	99.50%
25.	99	132	98.26%
26.	3	127	94.54%
27.	86	138	97.26%
28.	42	142	94.29%
29.	74	140	95.77%
30.	7	136	98.75%
Average			96.08 %

Based on the accuracy value in table 3, the average accuracy value of the *Microlab* 300 tool is 96.08%.

Table 4. Precision value of *Microlab* 300 device for cholesterol level examination by CHOD-PAP method.

No.	Sample Code	Cholesterol Level	Precision
1.	6	13	99.50%
2.	37	13	99.30%
3.	35	13	99.95%
4.	62	14	98.85%
5.	4	12	98.90%
6.	78	13	99.35%
7	65	14	98.70%
8.	28	12	99.20%
9.	14	13	99.30%
10.	67	14	98.70%
11.	10	14	99.00%
12.	57	12	99.05%
13.	75	13	99.65%
14.	80	12	98.90%
15.	22	13	99.30%
16.	68	12	98.90%
17.	77	13	99.90%
18.	85	14	98.85%
19.	94	12	99.05%
20.	100	14	98.85%
21.	55	14	98.70%
22.	88	13	99.45%
23.	92	13	99.35%
24.	97	13	99.90%
25.	99	13	99.65%
26.	3	12	98.90%
27.	86	13	99.45%
28.	42	14	98.85%

29.	74	14	99.15%
30.		13	99.75%
Average			99.21%

Based on the accuracy value in Table 4, the average precision value of the Microlab 300 tool is 99.21%.

Table 5. Descriptive Analysis of Research Results

	Accuracy (%)	Precision (%)
Standard	≥90%	≥94%
Microlab 300	96.08%	99.21%

Based on the measurement results of the control material, the average accuracy value of the *Microlab* 300 tool is 96.08% and the average precision value of the *Microlab* 300 tool is 99.21% with accuracy standards ≥90% and precision standards ≥94%.

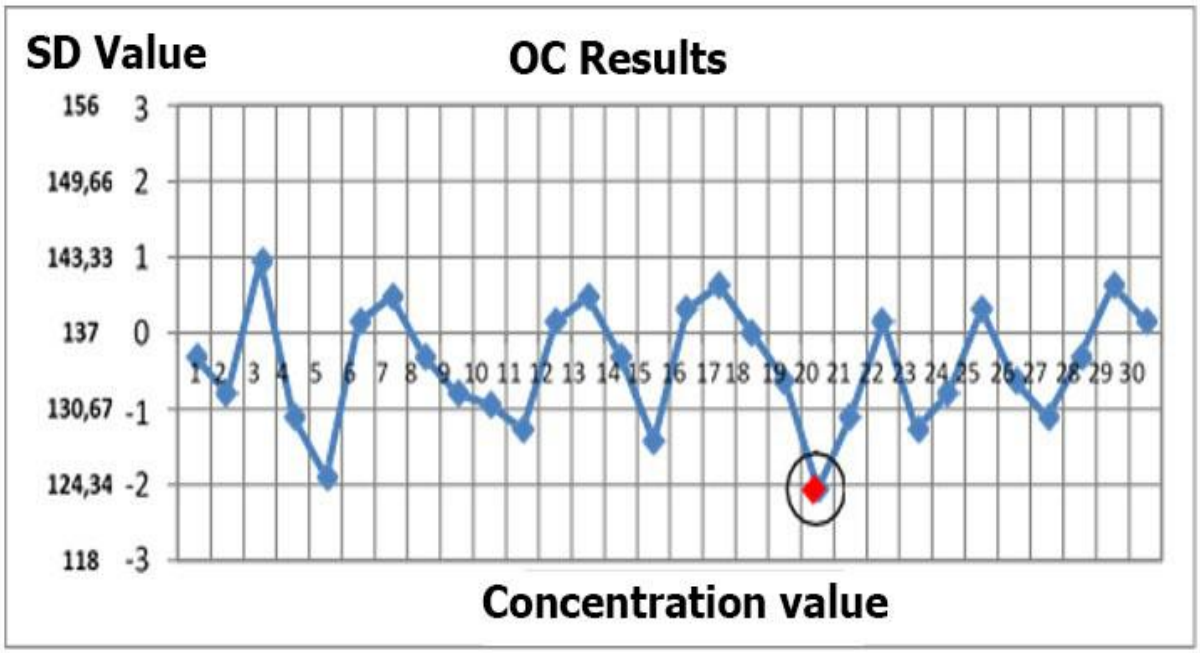

Figure 1. Daily Graph Results of the Preliminary Period

Based on the measurement results of the control material after being plotted into a daily graph using the Wesrgard rule, the results in the preliminary period, namely one control material outside the mean value of ±2s (1-2s) on the 20th control material, but these results are still acceptable according to the Westgard rule.

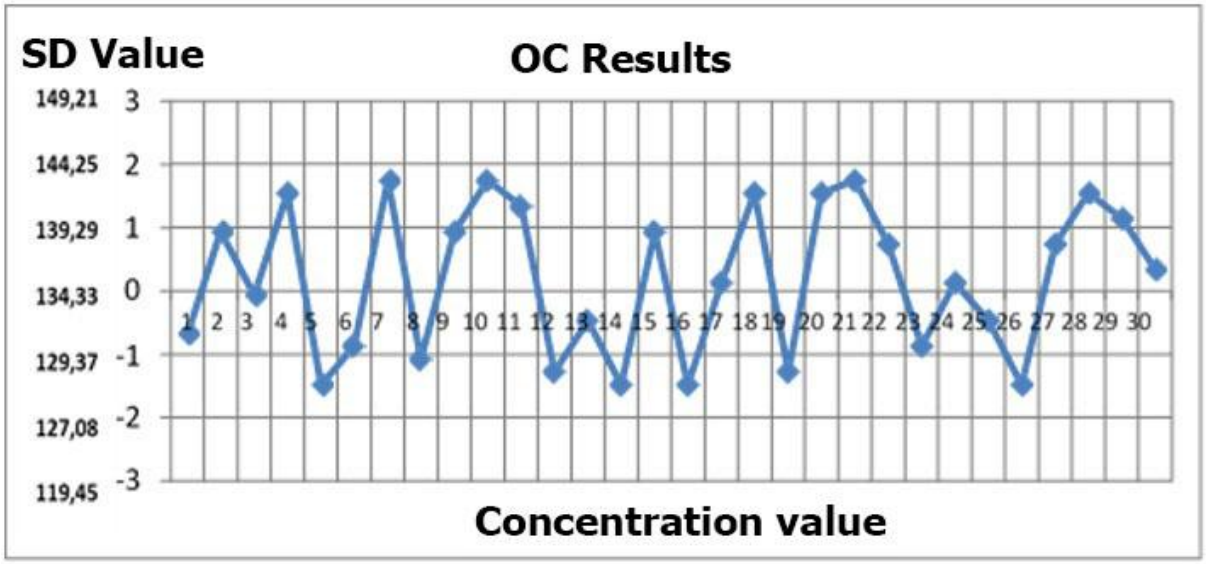

Figure 2. Daily Graph Results of Control Period

Based on the measurement results of the control material after being plotted into a daily graph using the wesrgard rule, the results obtained in the control period were not found in the six basic westgard rules, namely 1-2s, 1-3s, 2-2s, R4s, 3-1s, 4-1s, and 10x, meaning that all control materials in the graph are within the control limits (within the control limits).

DISCUSSION

Laboratories are required to maintain equipment as needed so that in carrying out the examination of patient specimens, there are no obstacles or disturbances originating from laboratory equipment. Damage to equipment can hamper laboratory activities, so that it can interfere with laboratory performance. Therefore, the laboratory must periodically carry out internal quality assurance to ensure that the examination results are valid and reliable. One of the indicators to assess internal quality assurance is accuracy.

Accuracy is to show the closeness of the examination results to the true value determined by the standard method. The accuracy test carried out on the microlab 300 tool aims to determine how the accuracy value of the tool on the cholesterol examination of the CHOD-PAP method (Cholesterol Hydrolysis and Oxidation Determination from Para Aminoantipyrine).

In this study, the accuracy value is obtained by measuring the inaccuracy value (d%). After the inaccuracy value (d%) is obtained, then the inaccuracy value is reduced by 100%. So that the accuracy value of the Microlab 300 tool for cholesterol examination is 96.08%. According to Clinical Laboratory Improvement Amendments (CLIA), the accuracy of total cholesterol examination is said to be good if the accuracy value is ≥ 90%. Based on the results of the study when compared with the minimum accuracy standard, the Microlab 300 tool in the Clinical Chemistry Laboratory of the Poltekkes Kemenkes Pontianak tool is categorized as having good accuracy because it is worth 96.08%.

Good accuracy indicates that the device is performing well and there is no systematic error. Systematic error is a measurement error that leads to one direction where the result is too high or too low from the value that should be. This error can be caused by instrumentation (tools) that is not calibrated so that it gives inappropriate results (Chackartchi, et al., 2022; Del Olmo, et al., 2022; Cheng,et al., 2023).

Precision is to determine how close an examination result is when done repeatedly with the same sample. The precision test carried out on the microlab 300 tool aims to

determine how the precision value of the tool for the CHOD-PAP method cholesterol examination.

In this study, the precision value was obtained by measuring the impression value expressed as the coefficient of variation expressed in units of percent (CV%). After the coefficient of variation is obtained, it is then reduced by 100%. So that the precision value obtained on the Microlab 300 tool for total cholesterol examination is 99.21%.

The results of the study were then compared with the precision standard obtained from the limit of deviation of the examination of the imprecision (inaccuracy) value (CV%) for total cholesterol of 6, where precision is said to be good for total cholesterol examination if ≥94%. So it can be stated that the precision of the microlab 300 tool for total cholesterol examination of the CHOD-PAP method has good precision.

Good precision indicates that the performance of the Microlab 300 tool in the Pontianak Poltekkes Kemenkes clinical laboratory is good and there is no random error. Random error is any deviation from the expected result. This error is an error with a pattern that is not fixed due to instability such as reagents, pipettes, and instruments used (Siregar et al. 2018) .

The preliminary period is a period to determine the mean and standard deviation values to be plotted onto a graph using the westgard rule as a reference for evaluating the control serum used every day. The mean and SD values are used as baseline values which are reference values for subsequent examinations (control period). This reference value applies to control materials with the same lot number if the lot number is different, it must start with the preliminary period again to determine the reference value (Kementerian Kesehatan Republik Indonesia, 2013).

The control period is a period to determine whether the daily inspection is good or not. This period is carried out to determine the accuracy value and precision value of the microlab 300 device. In the control period, the bias value (d%) and the value (%CV) are calculated as in appendix 9.

Furthermore, the measurement results of the control material are plotted into a daily graph, the assessment is carried out using the westgard rule for the preliminary period, the 1-2s rule is obtained, meaning that one control material is outside the mean ±2s value on the 20th control material of 3%, however, these results are still acceptable, the norm is 4.5%. According to the Westgard rule, the 1-2 rule is an in-control provision (warning limit) In this case, the control value is still acceptable and the inspection results can still be issued, the possibility of random errors (random) This error is usually caused by instability such as reagents, pipettes, and incubation time. Then, in the control period, the results obtained in the control period did not find 6 basic westgard rules, namely 1-2s, 1-3s, 2-2s, R4s, 3-1s, 4-1s, and 10x, meaning that all control materials in the graph are within the control limits (within control limits). This shows that the implementation of quality assurance quality with accuracy and precision indicators is good.

Good accuracy and precision indicate that the homogeneity and stability of the control materials used are good. In this study, the control material used was homogeneous because the results of cholesterol levels obtained were still within the control limits. Homogeneity is a property or condition that shows a homogeneous material or sample, if analyzed gives precise and thorough results. Homogeneity is very important in the manufacture of control materials, because of homogeneity, showing the control material is the same in all vials.

The stability of the control material is critical for accuracy and precision as the presence of stability, indicates that the control material should have the same or similar composition as the specimen being examined. The control material must be proven to be stable enough to ensure that it does not change during storage in the freezer. One of the causes of unstable control material is the presence of sparks in the refrigerator during storage of the control material, so that the components in the control material change their

composition during the storage period. However, before this study was conducted, the freezer in the refrigerator in the integrated clinical laboratory was turned off overnight so that at the time of the study, the storage of control materials no longer had ice. This was done to anticipate the control material to remain stable. Stable control materials will give results that tend to be the same when tested in different time spans.

CONCLUSION

Based on the results of research on the evaluation of the accuracy and precision of the Microlab 300 tool for the examination of total cholesterol CHOD-PAP method (Cholesterol Hydrolysis and Oxidation Determination from Para Aminoantipyrine). It was concluded that the accuracy of the Microlab 300 tool on the total cholesterol examination of the CHOD-PAP method was 96.08%, the precision of the Microlab 300 tool on the total cholesterol examination of the CHOD-PAP method was 99.21%, based on the daily evaluation chart using the Westgard rule the control material was within the control limits (within the control limits), the accuracy and precision of cholesterol examination using the Microlab 300 tool was good. It is recommended to further researchers to evaluate the accuracy and precision of the same tool with different parameters to ensure that the tool also has good accuracy and precision for examination with other parameters such as uric acid, creatinine, and glucose.

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