# SENSITIVITY AND SPECIFICITY TESTS OF HEMOGLOBIN EXAMINATION BETWEEN HEMOGLOBINOMETER AND HEMATOLOGY ANALYZER ON PREGNANT MOTHERS

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## ABSTRACT

This study aimed to determine the sensitivity and specificity test of hemoglobin examination on pregnant women using Hemoglobinometer and Hematology Analyzer devices. The research method used a quantitative approach with the type of research being analytic observational research.

The type of data used was primary data in the form of research results and secondary data in the form of data obtained from literature, books and documents. The sampling technique in this study was a purposive sampling technique, with a total sample of 73 people taken from the Kota Utara Public Health Center and Toto Kabila Regional General Hospital.

The results showed that the hemoglobinometer has a sensitivity of 81% and a specificity of 100%, while the hematology analyzer has a sensitivity of 98% and a specificity of 100%.

**Keywords:** Sensitivity and Specificity, Hemoglobinometer, *Hematology Analyzer*

## INTRODUCTION

Assessment in research facilities, especially laboratories, is a supporting activity that utilizes materials or tests from patients such as blood, urine, mucus, which can help determine infection quickly and accurately by completing other supporting tests, history taking, and assessment which is expected to decide what disease is suffering from. This assessment can also facilitate the determinant history of the disease suffered by the patient [16].

In each laboratory center, to provide the right results, it is based on the Good Laboratory Procedure (GLP), which goes through the stages of preparation, sample processing, and examination results. There are three stages consisting of pre-analytical, analytical, and post-analytic. Pre-analysis is a fundamental stage where at this stage it determines the quality of the sample. Factors that can affect the work process consist of the patient's condition, sampling technique, the time when the sample was taken, and how the sample is treated until the completion of the examination. Analytical is the testing phase so that the results of the examination can be issued. Post-analytic is the last stage in the assessment, issued to convince the patient and their families that the results provided by the officer are correct or substantial [16].

Hematology examinations are in great demand by medical personnel for assisting diagnosis, comparison of diagnoses, and monitoring of a disease. One of the hematological examinations that are often carried out in the laboratory is hemoglobin examination. Hemoglobin (Hb) is a component of erythrocytes that can distribute $O_2$ to all parts of the body. If Hb decreases in the body, then $O_2$ levels also

Submit: Nov 23rd, 2020 Accepted: Dec 15th, 2020 Published: Dec 26th, 2020

decrease. $O_2$ is needed by the body as a metabolic process. Hb can be useful as a medium for transporting $O_2$ from the lungs [2].

According to the World Health Organization (WHO), in 2008 the prevalence of anemia in pregnant women in developed countries was 14%, while in developing countries was 51% [18]. Based on the report of Basic Health Research (2018), the highest prevalence of pregnant women in Indonesia with an age range of 10-54 years was in Southeast Sulawesi by 2,091 people (6.2%) while the lowest was in Papua by 2,648 people (3.0%). The prevalence of pregnant women in Gorontalo Province (2018) reached 980 people (4.03%) where Bone Bolango district contributed to the pregnancy rate reaching 304 people (3.6%) [10].

Examination of Hb levels in pregnant women is a factor that must be considered because iron deficiency is often found during pregnancy. The Hb examination is also one of the tests that is routinely carried out whether at the health centers, antenatal clinics, or in the Patient Care Rooms. The examination is carried out as follow up management of patients with anemia and screening for anemia in pregnant women [2].

There are various methods that can be used to determine Hb Levels, one of which is the cyanmethemoglobin method using a Hematology Analyzer and a hemoglobinometer (POCT). Hospitals usually use a Hematology Analyzer, while lower health service facilities such as sub-health centers or *Polindes* often use a portable hemoglobinometer [2].

*The International Committee for Standardization in Hematology* (ICSH) recommends using an automatic hematology analyzer. This tool calculates Hb levels in erythrocytes. The advantage of a hematology analyzer is a high level of precision and allows a larger number of samples. However, routine maintenance is required such as calibration control, health workers who can operate the tool, and the climatic conditions that must be in a stable condition. In addition, the price of tools and reagents is quite expensive for developing countries [3].

Hb examination using the POCT method with a hemoglobinometer has advantages in terms of being easy and fast to carry out independently, as well as a small number of samples used and the easy sampling [4].

The difference in principle and the advantages and disadvantages of these tools indirectly affect the sensitivity and specificity of measuring Hb levels. Sensitivity is the ability of a test that shows someone who is sick from the whole population that is declared really sick. Specificity is the ability of a test to show someone who is not sick from being really not sick. The role of sensitivity and specificity is very important in the laboratory to indicate accurately (correctly) which one is sick and which is not [16].

In a previous study conducted by Gemilang, et al (2020), a comparison of Hb levels examination with the two methods showed that the hemoglobin level measured using the POCT method of 12.1 (6.2-16.4) g/dL and hemoglobin using a hematology analyzer of 12.6 (5.6-16.5) g/dL differs from the Hb levels tested by hematology analyzer method although there is no significant difference (p value = 0.079) and this POCT tool has the sensitivity value was 85.71%, the specificity value was 84.61% and the accuracy was 85% [6].

## RESEARCH METHOD

The type of research used in this study was observational analytic using a quantitative approach. The sampling technique used was purposive sampling.

The number of samples was 73 samples. Data collection techniques using informed consent and the examination of Hb were measured using a hemoglobinometer and hematology analyzer methods to determine the sensitivity and specificity of these devices.

## RESULTS

Based on the research that has been carried out, the following results were obtained:

1. **Characteristics by ages**

**Table 1.** Distribution based on ages.

| Ages | Frequency | (%) |
|---|---|---|
| <20 years | 6 | 8.2 |
| 20 – 30 years | 44 | 60.3 |
| 31 – 39 years | 23 | 31.5 |
| Total | 73 | 100 |

*Source : Primary Data, 2021*

Table 1 shows that based on age, from 73 respondents, pregnant women aged 20-30 years are 44 people (60.3%), aged 31-39 years are 23 people (31.5%), and the age range under 20 years are 6 people (8.2%).

2. **Characteristics by gestational ages**

**Table 2.** Distribution based on gestational age

| Gestational Age | Frequency | (%) |
|---|---|---|
| 0 – 12 weeks | 73 | 100.0 |
| >12 weeks | 0 | 0.0 |
| Total | 73 | 100 |

*Source : Primary Data, 2021*

Table 2 shows that 73 respondents 100% are in the first trimester or gestational ages are less than 13 weeks.

3. **Characteristics by initial data of hemoglobin (Hb)**

**Table 3.** Distribution based on the initial data of hemoglobin (Hb)

| Initial Hb | Frequency | (%) |
|---|---|---|
| Abnormal | 43 | 58.9 |
| Normal | 30 | 41.1 |
| Total | 73 | 100 |

*Source : Primary Data, 2021*

Table 3 shows that from 73 respondents, 43 people have abnormal Hb levels (58.9%) and 30 people (41.1%) have normal Hb levels.

4. **Characteristics by Hb level using Hb Meter**

**Table 4.** Distribution based on the using of Hb Meter

| Hb Meter | Frequency | (%) |
|---|---|---|
| Abnormal | 35 | 47.9 |
| Normal | 38 | 52.1 |
| Total | 73 | 100 |

*Source: Primary Data, 2021*

Table 4 shows that of the 73 respondents whose Hb levels were examined using an Hb meter, 35 people (47.9%) have abnormal Hb levels and 38 people (52.1%) have normal Hb levels.

5. **Characteristics by Hb level using Hematology Analyzer**

**Table 5.** Distribution based on Hb levels using *Hematology Analyzer*

| ***Hem. Analyzer*** | **Frequency** | **(%)** |
|---|---|---|
| Abnormal | 42 | 57.5 |
| Normal | 31 | 42.5 |
| Total | 73 | 100 |

*Source : Primary Data, 2021*

Table 5 shows that based on examination using hematology analyzer, 42 people (57.5%) have abnormal Hb levels and 31 people (42.5%) have normal Hb levels.

6. **Characteristics Based on Hb Levels on the Hb Meter compared with Initial Data**

**Table 6.** Distribution based on Hb levels on the the Hb meter compared with initial data

| Results of Hb Meter | Frequency | (%) |
|---|---|---|
| True Positive | 35 | 47.9 |

| | | |
|---|---|---|
| True Negative | 30 | 41.1 |
| False Negative | 8 | 11.0 |
| Total | 73 | 100 |

*Source : Primary Data, 2021*

Table 6 shows that of the 73 respondents whose Hb levels were measured using an Hb Meter and then compared the results with the initial data, it is obtained that 35 samples are True Positive (47.9%), 30 samples (41.1%) are True Negative and 8 samples are False Negative (11%).

**7. Characteristics Based on Hb Levels on the Hematology Analyzer compared with Initial Data**

**Table 7.** Distribution based on Hb levels on *Hematology Analyzer* compared with initial data

| Results | Frequency | (%) |
|---|---|---|
| True Positive | 42 | 57.5 |
| True Negative | 30 | 41.1 |
| False Negative | 1 | 1.4 |
| Total | 73 | 100 |

*Source : Primary Data, 2021*

Table 7 shows that of the 73 respondents whose Hb levels were measured using an Hematology Analyzer and then compared the results with the initial data, it is obtained that 42 samples are true positive (57,5%), 30 samples are true negative (41,1%), and 1 sample is false negative (1,4%).

**8. Difference/Comparison (%) between the Sensitivity and Specificity of Hb Meter and Hematology Analyzer**

**1. Data of Hemoglobin on Hb Meter**

True Positive : 35
False Positive : 0
True Negative : 30
False Negative : 8

Therefore, the results can be obtained using the following sensitivity and specificity formulas:

a. Sensitivity of Hb Meter

$$\frac{True\ positive}{True\ positive + false\ negative} x\ 100\%$$

$$= \frac{35}{35+8} x\ 100\% = 81\%$$

b. Specificity of Hb Meter

$$\frac{True\ negative}{True\ negative + false\ positive} x\ 100\%$$

$$= \frac{35}{35+0} x\ 100\% = 100\%$$

Based on the results obtained, it can be concluded that the Hb Meter in this study has a sensitivity of 81% and a specificity of 100%.

**2. Data of Hemoglobin on *Hematology Analyzer***

True Positive : 42
False Positive : 0
True Negative : 30
False Negative : 1

Therefore, the results can be obtained using the following sensitivity and specificity formulas:

a. Sensitivity of Hematology Analyzer

$$\frac{True\ positive}{True\ positive + false\ negative} x\ 100\%$$

$$= \frac{42}{42+1} x\ 100\% = 98\%$$

b. Specificity of Hb Meter

$$\frac{True\ negative}{True\ negative + false\ positive} x\ 100\%$$

$$= \frac{30}{30+0} x\ 100\% = 100\%$$

Based on the results obtained, it can be concluded that the Hematology Analyzer in this study has a sensitivity of 98% and a specificity of 100%.

**Table 8.** Difference (%) between the Sensitivity and Specificity of Hb Meter and Hematology Analyzer

| Tools | Sensitivity (%) | Specificity (%) |
|---|---|---|
| **Hb Meter** | **81%** | **100%** |

| | | |
|---|---|---|
| ***Hematology Analyzer*** | **98%** | **100%** |

*Source : Primary Data, 2021*

This result is in line with the statement of Siregar, et al (2018) that a good sensitivity and specificity are close to 100%. Thus, the two devices used in the current study meet the standard.

## DISCUSSION

### 1. Age

Siregar, et al (2018) stated that good sensitivity and specificity were close to 100% so that the two tools used in the current study met the standard because the results were close to 100%.

Pregnant women aged 35 years and over are at risk of experiencing paleness. This is because mothers who are often pregnant are also at risk of experiencing weakness in subsequent pregnancies. Pregnant women must pay attention to food needs, because during pregnancy, supplements are not only needed by the mother but also the embryo. Iron has an important role in the formation of hemoglobin. During pregnancy, the amount of blood in the body of a pregnant woman increases by half compared to normal body conditions so that the mother needs a lot of iron to form hemoglobin and to compensate for the expansion of blood volume [15].

Another hypothesis that supports the consequences of this review is that presented by Manuaba (2016), that in young women where the conception organs are not fully ready and with a mindset that is not ready to become a parent, the pregnancy is at risk of miscarriage, or the baby is born with low birth weight. The ideal age for the first pregnancy for a woman is 20 years because at that age the woman's uterus is ready to conceive [13].

Various theories about a safe ages for a woman to undergo pregnancy as well as findings in the field that are in line with these theories indicate that indirectly most pregnant women in the Kota Utara Health Center area and in the Bone Bolango Regency have implemented one of the Government's programs, namely Planned Parenthood. It was stated that one of the great benefits of participating in this program is reducing the maternal mortality rate (MMR), which is based on collaboration data of Central Statistics Agency (BPS) and UNICEF Indonesia (2020). It shows that girls aged 10-14 years are five times more likely to die during pregnancy or during delivery due to complications compared to women aged 20 years and over.

### 2. Gestational Age

Researchers took respondents with the first trimester of pregnancy in order to make the sampling process easy and faster. If the researcher took respondents with a third trimester of pregnancy, it was feared that the respondent would not meet with researchers in the field anymore because this gestational age is close to the puerperium (birth) period. For the gestational age in the second trimester, it was feared that this gestational age had become the third trimester when the researchers conducted the study.

Another reason the researchers took respondents with the first trimester of pregnancy was because at this time pregnant women would experience a number of major changes in their bodies. This is in line with the theory put forward by Zumrotun, et al (2018) that in early pregnancy, pregnant women often experience continuous nausea and vomiting that

can lead to lack of fluids or called dehydration. This causes the extracellular fluid and plasma of pregnant women to decrease so that the volume of fluid in the blood vessels decreases and as a result, blood flow to the tissues decreases [20].

This causes the amount of nutrients including iron and oxygen delivered to the tissues to decrease. Usually pregnant women are reluctant to eat fish, meat, liver or foods that contain iron, resulting in anemia whereas at this time, pregnant women are advised to consume lots of nutritious food, vitamins and iron because it will affect the results of measuring hemoglobin (Hb) levels, either using an Hb Meter or using a Hematology Analyzer [20].

**3. Initial Data of Hemoglobin (Hb)**

The basis for calculating sensitivity and specificity is someone whose condition is known [16]. Therefore, in determining the sensitivity and specificity of the Hb meter and Hematology Analyzer in this study, the researchers first took initial data on Hb levels recorded in the medical records of the Kota Utara Health Center and the Laboratory of Toto Kabila Hospital in Bone Bolango.

The prevalence of pregnant women with Hb levels less than normal or being in an anemic condition is high. This review is in accordance with the theory put forward by Astutik (2018) that pregnancy can provide significant changes to a pregnant woman's body. One of the significant changes is in the hematological system. Pregnant women often experience a decrease in Hb levels during pregnancy [1].

The initial data of this study are in line with the research of Irdayanti (2017) which examined Hb levels in pregnant women in the first trimester, second trimester, and third trimester where it was obtained that from 7 pregnant women studied, there were 3 pregnant women who had normal Hb levels and 4 pregnant women had abnormal Hb levels [9].

**4. Hb Levels by Hb Meter**

Siregar, et al (2018) stated that in determining sensitivity and specificity, the first thing to do is collecting initial data. The next step is to measure the concentration of the sample using proper devices to determine its sensitivity and specificity [16]. In this study, the tools used to determine Hb levels were Hb Meter and Hematology Analyzer devices.

After being compared with the initial data, there are differences in the results between the Hb levels in the initial data and the Hb levels tested using the Hb Meter where in the initial data, 43 people (58.9%) had abnormal Hb levels and 30 people (41 ,1%) had normal Hb levels. This difference in results can be caused by various things, including the disadvantages of the hemoglobinometer itself.

The Hb Meter was used in this study because the Hb meter is a device designed to check hemoglobinlevels using the Point of Care Testing (POCT) method which adheres to the principle of Amperometric Detection considering the change of potential electric to be formed for a moment is influenced by electrochemical reactions.

This tool is used in several health facilities because of the several advantages including the consequences of this examination that are very helpful for specialists in checking the progress of the condition of patients, making further/advanced treatment steps, and the results are needed in communicating with patients and their families. Hb Meter does not require test

treatments such as centrifugation. The use of the hemoglobinometer does not have to be staffed by a specialized researcher as it can be done by health workers. However, it does not mean that the tool does not have any disadvantages[4].

The disadvantages of a Hb Meter is the simplicity and rapidity in testing that can lead to inaccurate assessments. The use of fewer blood samples and the difficulty of knowing the quality (nature) of the sample can affect the accuracy of the side effects of its examination such as hemolysis, lipemia and drugs. In utilizing the device by non-lab workers, it is necessary to carry out quality control so that the inspection results are guaranteed and in accordance with the guidelines. It is important to direct and know who fulfills the needs as a Hb Meter user [4].

These advantages and disadvantages became the topic for researchers to compare the Hb Meter with Hematology Analyzer in the terms of sensitivity and specificity in reading Hb levels of pregnant women. Moreover, based on the facts in the field, some health services such as health centers use a Hb Meter as another alternative in conducting Hb checks so that even though it has some disadvantages, the Hb meter can still be used.

Examination of Hb levels must pay attention to pre-analytical, analytical to post-analytical to minimize errors that will occur during the examination because there may be factors that affect the results of the examination such as the wrong way of taking blood samples, the wrong way of storing specimens where the sample is delayed too long leading to a change in the shape of the blood cells, or before the examination the blood sample is not homogenized properly [2].

**5. Hb levels by *Hematology Analyzer***

In addition to the Hb meter that carries the principle of the Point of Care Testing (POCT) method, Hb measurements can also be carried out using a Hematology Analyzer or an automatic blood cell measurement tool that carries the principles of electrical impedance, photometry, flow cytometry and histogram (calculation).

The principle of measuring Hb levels using a hematology analyzer is that the heme (ferrous) is specifically oxidized by potassium ferricyanide to (ferric) methemoglobin. Methemoglobin then responds with cyanide particles to form cyanmethemoglobin which is brown in color. The absorbance was estimated by a colorimeter or spectrophotometer at 540 nm [12].

The choice of the automatic method or the Hematology Analyzer tool in determining the sensitivity and specificity in this study is because this automatic method is the best method in measuring Hb levels. This is in accordance with Atmaja's (2018) explanation that this strategy is the best level of quality and is recommended by ICSH. Examination of Hb levels with a hematology analyzer is not difficult to do and the side effects of the examination are more precise. The cyanmethemoglobin strategy is the reference technique for hemoglobin assays. Various hemoglobins can be estimated with sulfhemoglobin as an exception. The error factor is about ±2%. This technique is commonly used in some medical clinics or health facilities [2].

In addition, in conducting sample inspections, attention must be paid to things that can affect the results.

According to Atmaja (2018), the things that affect the results are not doing regular calibration and the blood being controlled has expired but is still being used to save operational costs [2].

Another theory that supports the results of this study was also mentioned by Yuli (2017) that the examination of Hb levels in pregnant women is an important factor because iron deficiency conditions are often found during pregnancy. Hemoglobin test is also the most frequently performed test in health centers, antenatal clinics, as well as in the Patient Care Room and is also needed for follow-up management of patients with anemia and screening for anemia in pregnant women [19].

It is in line with research from Selesfina, et al. (2020), who examined Hb levels in third trimester pregnant women at Robert Wolter Mongisidi Hospital Manado showed that of the 39 samples examined, there were 25 samples (64.1%) had low Hb levels and 14 subjects (35.9 %) have normal Hb levels [15].

**6. Sensitivity and Specificity of Hb Meter**

Although the sensitivity value in this study did not reach 100%, the results shown were high (81%) which means that this device is fairly accurate because it can still detect more than 50% of the population who are really sick. Siregar, et al (2018), stated that sensitivity is the ability of the test to show which one is sick from all who are sick [16]. In addition, Hurip (2021) stated that high sensitivity and specificity can indicate a high level of accuracy [7].

The findings of this laboratory result are supported by the theory of Siregar, et al (2018) which reveals that good sensitivity is close to 100%. Sensitivity is often referred to as the detection limit, i.e. an analyte that has the lowest concentration when detected by various methods. Examination for screening purposes is required with a high sensitivity examination [16].

These results are in accordance with the research of Gemilang et al. (2017) which determined the value of sensitivity, specificity and accuracy on the POCT and hematology analyzer where it was suspected that there was no critical contrast ($p = 0.079$) and the POCT sensitivity value was 85.71%, while the specificity was 84.61%, and accuracy was 85% [6].

This specificity value of 100% indicates that the Hb Meter used in this study is very specific and is able to show healthy individuals from those who are not really sick. This result is supported by the theory of Siregar, et al (2018) which states that specificity is the ability of the test to show which individuals are not sick from those who are really not sick [16].

The findings of this laboratory result are supported by the theory of Siregar et al (2018), which reveals that a good specificity is close to 100%. Analytical specificity is often referred to the limit of detection, i.e. the lowest level of an analyte that can be detected by a method. Examination with high specificity is especially required in examinations for screening purposes [16]. Another theory that supports it is said by Hurip (2021) that a high level of validity of a diagnostic test is indicated by a high sensitivity and specificity value [7].

This result is also in line with research by Nurhidayat and Sunarti (2015) which obtained a specificity value (64.61%) higher than the sensitivity value (45.45%). From these laboratory findings, as well as

supporting theories and research that are in line, the researcher concludes that measuring hemoglobin using the Hb Meter can be used as an alternative [14].

**7. Sensitivity and Specificity of *Hematology Analyzer***

The results obtained from this study indicate the sensitivity of the Hematology Analyzer is very high because it almost reaches 100%. The high value, according to the researchers, is inseparable from the advantages possessed by this electronic device where the reaction of hemoglobin is oxidized by potassium ferrocyanide to methemoglobin to frame cyanmethemoglobin with a red color. The strength of the image is checked with a photometer and contrasted normally [12]. According to Siregar, et al (2018), compared to other methods, this automatic method has the smallest error factor, which is only about ±2%.

The results of this study indicate that the Hb levels in the Hb Meter is lower than the Hematology Analyzer [16]. The results of this study are in line with research by Atmaja (2018), which examined Hb levels using the Point-Of-Care-Testing tool by 13.1 g/dl and the Hematology Analyzer by 14.4 g/dl. The results showed a lower value than the Hematology Analyzer tool. This result can be caused by the disadvantages of the Hb Meter which can only use a small amount of blood samples. In addition, it is difficult to know the quality (quality) of samples that can affect the accuracy of the results of the Hb Meter examination, such as hemolyzed and lipemic samples [2].

The specificity value of 100% on the Hematology Analyzer is the same as the specificity value on the Hb Meter. This indicates that the two devices are very specific and able to show healthy individuals from those who do not experience illness. The results of the study and the conclusions drawn by the researcher are supported by the theory which states that specificity is the ability of a test to show someone is not sick from those who are not said to be sick [16].

The value of 100% in this study also shows that the levels of validity of these devices are very high because according to theory, a high level of validity of a test is indicated by the high sensitivity and specificity of a diagnostic test [7].

There is no difference in the specificity values of the two devices hence it is in line with the research conducted by Gemilang, et al. (2017) that there is no significant difference on the results (p value = 0.079) and the POCT tool has a sensitivity value of 85.71%, a specificity value of 84.61%, and an accuracy rate of 85% [6].

## CONCLUSION

Based on this research, it can be concluded that:

1. The Hemoglobinometer in this study has a sensitivity of 81% and a specificity of 100%.
2. The hematology analyzer in this study has a sensitivity of 98% and a specificity of 100%.

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