



ACCURACY OF HEMOGLOBIN MEASUREMENT USING THE SD BIOSENSOR STANDARD G6PD ANALYZER AS POINT-OF-CARE IN PEDIATRIC POPULATIONS IN MALARIA-ENDEMIC REGIONS

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Malaria remains a significant public health concern, particularly in endemic regions, is frequently associated with anemia in children. Accurate hemoglobin measurement is crucial for diagnosing anemia, especially in resource-limited settings. This study compares the accuracy of SD Biosensor Standard G6PD Analyzer with Hemocue HB301 System for hemoglobin measurement among children in malaria-endemic areas. Objective to determine the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (LR+), negative likelihood ratio (LR-), pretest odds, post-test odds, and overall accuracy of the SD Biosensor Standard G6PD Analyzer compared to the Hemocue HB301 System. This cross-sectional diagnostic study involved 325 children aged 6-18 years in Kualuh Leidong District. Secondary data were obtained from a previous study conducted in August 2024, using a total sampling technique. Hemoglobin levels were measured using both devices. Data obtained then were extracted and analyzed using statistical software. Paired t-tests were used to assess mean differences in hemoglobin value and diagnostic performance indicators were calculated using 2x2 contingency table with p-value < 0.05 was considered as statistically significant. The mean hemoglobin level measured by SD Biosensor Standard G6PD Analyzer (14,22±2,21 mg/dL) was higher than that measured by Hemocue HB301 System (13,45±1,63 mg/dL), with significant difference (p=0,001). The prevalence of anemia detected by SD Biosensor and Hemocue was 12,3% and 11,4%, respectively. The SD Biosensor Standard G6PD Analyzer demonstrated a sensitivity of 70,27%, specificity of 95,14%, PPV of 65%, NPV of 96,14% and an overall accuracy of 92,31%. The SD Biosensor Standard G6PD Analyzer exhibited relatively low sensitivity but high specificity compared to Hemocue HB301 System in measuring hemoglobin levels among children in malaria-endemic areas. Further research is needed to compare both devices against the gold-standard automated hematology analyzer and to identify the factors influencing measurement accuracy.

Keywords: anemia; hemocue HB301 system; hemoglobin; malaria; SD biosensor standard G6PD analyzer

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INTRODUCTION

Malaria is a parasitic infection transmitted by the female *Anopheles* mosquito. The disease is caused by various species of the *Plasmodium* parasite, including *Plasmodium falciparum*, *P. vivax*, *P. ovale*, *P. malariae*, and *P. knowlesi*. According to the World Health Organization (WHO), approximately 249 million malaria cases were reported globally in 2022, resulting in an estimated 608,000 deaths. Despite advancements in healthcare services and the implementation of national and international malaria control and elimination programs, the disease remains one of the leading causes of morbidity and mortality from parasitic infections worldwide (Al-Awadhi et al., 2021; Minhas et al., 2021; World Health Organization, 2023). The clinical manifestations of malaria commonly include fever, chills, and vomiting. On physical examination, findings may include pallor, hepatosplenomegaly, abdominal distension, jaundice, and other systemic signs. While *P. vivax* infection typically presents with milder symptoms than *P. falciparum*, recent decades have seen an increase in reports of severe *P. vivax* malaria, including complications such as cerebral malaria, pulmonary edema, acute respiratory distress syndrome, acute kidney injury, severe anemia, metabolic acidosis, and disseminated intravascular

coagulation (DIC), which can lead to fatal outcomes (Oldenburg et al., 2018; Trivedi and Chakravarty, 2022).

Malaria can lead to both acute and chronic anemia through several mechanisms, including increased red blood cell destruction in the peripheral circulation, spleen, and bone marrow, as well as impaired erythropoiesis. In addition, antimalarial treatment with primaquine is associated with an elevated risk of hemolysis, particularly in individuals with glucose-6-phosphate dehydrogenase (G6PD) deficiency. These conditions may negatively impact children's cognitive functions—such as attention, memory, visuospatial abilities, language, and executive functioning—which in turn can interfere with academic performance and behavioral development (SSemata et al., 2020). Malaria-infected children are also at increased risk for malnutrition and school absenteeism, both of which can further impair academic achievement (Halliday et al., 2020). Over time, these effects contribute to decreased human capital and may weaken a nation's global competitiveness. Given these significant consequences, accurate hemoglobin measurement is crucial in assessing anemia, particularly among pediatric populations in malaria-endemic regions with limited healthcare resources. The WHO currently recommends the use of automated hematology analyzers (AHA) for comprehensive blood analysis, which includes hemoglobin, hematocrit, leukocyte and platelet counts, and red cell indices—parameters that aid in determining the etiology of anemia. However, AHAs are non-portable, require a stable electricity supply, use proprietary reagents, necessitate skilled personnel, and entail high equipment and per-test costs (World Health Organization, 2023). Moreover, the availability of AHAs in Indonesia is limited, and primary healthcare centers often rely on basic diagnostic tools such as the Sahli method (Ministry of Health of the Republic of Indonesia, 2019).

Due to these constraints, AHAs are often impractical for use in remote or resource-constrained malaria-endemic areas. To overcome these challenges, point-of-care testing (POCT) has emerged as a viable alternative, offering portable and cost-effective diagnostic solutions. In accordance with WHO standards, POCT devices should demonstrate a minimum sensitivity of 80% and specificity of 97%. Hemoglobinometers, a type of POCT device, are compact, easy to operate, and involve lower operational costs compared to AHAs; among these, the Hemocue HB301 System is widely used and recognized for its high accuracy (Kassam et al., 2024). In addition to hemoglobin assessment, evaluating glucose-6-phosphate dehydrogenase (G6PD) enzyme activity is critical in malaria-endemic regions before initiating primaquine therapy, to avoid the risk of drug-induced hemolysis. The SD Biosensor Standard G6PD Analyzer is a POCT device that can simultaneously measure both G6PD activity and hemoglobin concentration, offering a dual-function solution. Given that both the SD Biosensor and the Hemocue HB301 System are viable options for hemoglobin measurement, this study aims to compare the hemoglobin measurement accuracy between the SD Biosensor Standard G6PD Analyzer and the Hemocue HB301 system, and evaluate the potential of the SD Biosensor as a cost-effective, multifunctional alternative in malaria-endemic settings. Establishing such equivalence could enhance operational efficiency and reduce costs associated with anemia screening in the broader context of malaria control efforts in Indonesia.

METHOD

This analytical cross-sectional study was conducted in the malaria-endemic area of Kualuh Leidong District, North Labuhanbatu Regency, Indonesia, utilizing secondary data from a primary study titled “Mapping of Red Blood Cell Abnormalities in the Malaria-Endemic Area of Kualuh Leidong, North Labuhanbatu,” carried out in 2024. Data collection took place in schools within the district in August 2024. The study population included children aged 6–18 years enrolled in elementary to senior high schools who met the inclusion criteria; attendance during data collection and provision of informed consent by parents or guardians and excluded those absent during data collection or with insufficient blood samples for hemoglobin measurement. A total sampling method was applied. Ethical approval was obtained from the Health Research Ethics Committee of Universitas Sumatera Utara (Approval No. 26/KEPK/USU/2025). Collected data comprised demographic variables (age, sex, education level) and hemoglobin concentration measured using SD Biosensor Standard G6PD Analyzer and the HemoCue HB301 System. Statistical analyses were performed using SPSS version 29.0 (SPSS Inc., Chicago, IL), with data presented descriptively in tables. Univariable and bivariable analyses were conducted using dependent sample t-tests, and diagnostic accuracy comparisons between the SD Biosensor Standard G6PD Analyzer and the HemoCue HB301 System were performed.

RESULT

A total of 340 children were initially selected using a total sampling method. Fifteen subjects were excluded from the study, including three children with insufficient blood volume for hemoglobin measurement and twelve children who were older than 18 years at the time of the study. Consequently, 325 children who met the inclusion and exclusion criteria were enrolled as study participants. Among the 325 study participants, 159 (48.9%) were male and 166 (51.1%) were female. Based on age group, the majority were aged ≥ 15 –18 years ($n = 115$; 35.4%), followed by those aged 5–11 years ($n = 114$; 35.1%) and 12–14 years ($n = 96$; 29.5%). In terms of educational level, 119 participants (36.6%) were enrolled in senior high school, followed by elementary school ($n = 112$; 34.5%) and junior high school ($n = 94$; 28.9%).

Table 1.
Characteristics of Research Subjects

Characteristics	f (%)
Gender (%)	
Male	159 (48,9%)
Female	166 (51,1%)
Age (%)	
5-11 Years Old	114 (35,1%)
12-14 Years Old	96 (29,5%)
≥ 15 -18 Years Old	115 (35,4%)
Education Level (%)	
Elementary	112 (34,5%)
Junior High School	94 (28,9%)
Senior High School	119 (36,6%)

Hemoglobin measurements in the study population showed that the SD Biosensor Standard G6PD Analyzer produced a higher mean hemoglobin level (14.22 ± 2.21 mg/dL) compared to the Hemocue HB301 System (13.45 ± 1.63 mg/dL). Based on classifications derived from these results, the SD Biosensor identified 40 participants (12.3%) as anemic and 285 (87.7%) as non-anemic, with 23 (7.1%) having mild anemia, 16 (4.9%) moderate anemia, and 1 (0.3%) severe anemia. In contrast, the Hemocue HB301 System reported 37 participants (11.4%) as anemic and 288 (88.6%) as non-anemic, with 20 (6.2%) experiencing mild anemia, 16 (4.9%) moderate anemia, and 1 (0.3%) severe anemia. Overall, the prevalence of anemia was slightly higher when assessed using the SD Biosensor (12.3%) compared to the Hemocue system (11.38%). A paired t-test conducted to evaluate the difference between the two devices yielded a mean measurement difference of 0.762 mg/dL, with a minimum and maximum difference of 0.599 and 0.925 mg/dL, respectively. The result was statistically significant (95% confidence interval, $p = 0.001$), indicating a meaningful discrepancy between hemoglobin values obtained from the SD Biosensor Standard G6PD Analyzer and the Hemocue HB301 System.

Table 2.
Hemoglobin Level and Anemia Status Based on Measurement Using the SD Biosensor Standard G6PD Analyzer and Hemocue HB301 System

Anemia Status	SD Biosensor Standard G6PD Analyzer	Hemocue HB301 System	Mean Difference	Confidence Interval 95		p Value
				Min	Max	
Hemoglobin Level (mean $\pm$ SD, mg/dL)	14,22 $\pm$ 2,21	13,45 $\pm$ 1,63	0,762	0,599	0,925	0,001
Anemia (%)	40 (12,3%)	37 (11,4%)				
Mild Anemia (%)	23 (7,1%)	20 (6,2%)				
Moderate Anemia (%)	16 (4,9%)	16 (4,9%)				
Severe Anemia (%)	1 (0,3%)	1 (0,3%)				
No Anemia (%)	285 (87,7%)	288 (88,6%)				

Further analysis of anemia status revealed that 26 participants (8%) were consistently classified as anemic by both the SD Biosensor Standard G6PD Analyzer and the Hemocue HB301 System. Additionally, 11 participants (3.4%) were identified as anemic by the Hemocue HB301 System but not by the SD Biosensor device, while 14 participants (4.3%) were classified as anemic by the SD Biosensor device but not by the Hemocue system. Meanwhile, 274 participants (84.3%) were consistently categorized as non-anemic by both measurement methods.

Table 3.

Cross-Tabulation of Anemia Categories Based on Hemoglobin Measurements Obtained Using The SD Biosensor Standard G6PD Analyzer and The Hemocue HB301 System

Hemoglobin Measurement	Anemia Status	Hemocue HB301 System		Total
		Anemia	No Anemia	
SD Biosensor Standard G6PD Analyzer	Anemia	26 (8%)	14 (4,3%)	40 (12,3%)
	Tidak Anemia	11 (3,4%)	274 (84,3%)	285 (87,7%)
	Total	37 (11,4%)	288 (88,6%)	325 (100%)

Based on the data obtained from the cross-tabulation, calculations were performed to determine the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (LR+), negative likelihood ratio (LR-), pretest odds, post-test odds, and accuracy of the SD Biosensor Standard G6PD Analyzer compared to the Hemocue HB301 System. The sensitivity of the SD Biosensor Standard G6PD Analyzer was 70.27%, with a specificity of 95.14%. The PPV, NPV, LR+, and LR- values were 65%, 96.14%, 14.4, and 0.31, respectively. The pretest odds and post-test odds were 0.128 and 1.858, respectively. The overall accuracy of the SD Biosensor Standard G6PD Analyzer was 92.31%.

Table 4.

The Sensitivity, Specificity, PPV, NPV, LR+, LR-, Pretest Odds, Post Test Odds, and Accuracy of SD Biosensor Standard G6PD Analyzer

Parameter	Value
Sensitivity	70,27%
Spesificity	95,14%
Positive predictive value (PPV)	65%
Negative predictive value (NPV)	96,14%
Likelihood ratio + (LR+)	14,4
Likelihood ratio – (LR-)	0,31
Pretest odds	0,128
Post-test odds	1,858
Accuracy	92,31%

DISCUSSION

The majority of study participants were female (51.1%), aged 15–18 years (35.4%), and had completed senior high school (36.6%). According to demographic data from the Central Bureau of Statistics, the population of girls aged 5–19 years in Kualuh Leidong Subdistrict was 5,538, slightly lower than the number of boys in the same age group, which was 5,748. Age-group analysis showed minimal variability: 3,592 children were aged 5–9 years, 3,879 were aged 10–14 years, and 3,815 were aged 15–19 years. In terms of educational level, most school-aged children in Kualuh Leidong were enrolled in elementary school (4,180 children), followed by junior high school (1,188 children), and senior high school (852 children) (North Labuhanbatu Regency Statistics Agency, 2022). This demographic pattern indicates a decline in school enrollment as education level increases. Several factors may contribute to this trend. Economic factors, such as family income, education costs, and poverty, can pose significant barriers. Family-related factors—including parental education level, cultural background, parental involvement, and number of children—also play a critical role in shaping children's attitudes toward education. Environmental influences, including family social status, peer influence, and early marriage, may affect the decision to continue schooling. In addition, teacher and school quality, regional development, and child health status also influence children's participation in higher levels of education (Shanty et. al., 2024; Winoto et al., 2022).

In this study, the prevalence of anemia based on measurements using the SD Biosensor Standard G6PD Analyzer was 12.3%, slightly higher than that recorded with the Hemocue HB301 System, which was 11.4%. Globally, approximately 1.3 billion individuals are affected by anemia across both developed and developing countries, with an estimated 9.6 million of them being children with severe anemia (Aliyo and Jibril, 2022). In 2017, an estimated 293.1 million (47.4%) children under five years of age were anemic worldwide, with 67.6% residing in Africa. In Indonesia, the overall prevalence of anemia is 16.2%, with prevalence rates of 16.3% among individuals aged 5–14 years and 15.5% among those aged 15–24 years (Ministry of Health of The Republic of Indonesia Health Development Agency, 2023). The anemia prevalence found in this study, based on both devices, is lower than global

and national estimates. This discrepancy may be attributed to the geographic location of the study area—coastal regions with easier access to nutritious seafood—or to sample collection bias, as the study was conducted in a school located in the subdistrict capital, where residents may have better socioeconomic status compared to other villages. Further classification of hemoglobin levels measured by the SD Biosensor Standard G6PD Analyzer showed that 23 participants (7.1%) had mild anemia, 16 (4.9%) had moderate anemia, and 1 participant (0.3%) had severe anemia. Results from the Hemocue HB301 System were comparable, with 20 participants (6.2%) classified as having mild anemia, 16 (4.9%) as moderate anemia, and 1 (0.3%) as severe anemia. Data from a 2019 study reported anemia prevalence among children as 21% for mild anemia, 18% for moderate anemia, and 1% for severe anemia—figures that closely align with the findings of the present study (Stevens et al., 2022).

Anemia remains a significant public health concern, associated with substantial health and economic burdens. Among children, it is estimated to result in an annual economic loss of approximately US\$161 billion due to reduced productivity, and US\$113 billion annually for adolescent girls and adult women (Jain et al., 2024). According to data from the World Bank, childhood anemia is associated with a decline in gross domestic product (GDP) of US\$2.32 per person due to lost productivity, and an increase in cost of living by 4.05% due to associated cognitive impairments (Horton and Ross, 2003). In children, anemia can lead to chronic and irreversible cognitive deficits, impairing academic performance and reducing future work capacity, with long-term societal consequences (Msinde, 2023). Among adolescents, particularly girls, the anemia prevalence in Indonesia is estimated at 27.1%. In this population, anemia not only impairs cognitive and physical development but also increases susceptibility to infections and reproductive health issues, including risks of preterm birth and low birth weight (Maryam and Susilawati, 2024). Given the significant impact of anemia on the pediatric population, understanding its pathophysiology, identifying risk factors, and ensuring early detection are essential components of effective anemia management in children (Martinez-Torres. Et al., 2023).

The gold standard modality for hemoglobin measurement remains the use of automated hematology analyzers (An et al., 2019). However, due to limited human resources and laboratory infrastructure in the study location, AHA testing could not be utilized. As an alternative, hemoglobin levels were measured using two available point-of-care testing (POCT) devices: the SD Biosensor Standard G6PD Analyzer and the Hemocue HB301 System. The SD Biosensor Standard G6PD Analyzer quantitatively measures hemoglobin concentration and G6PD enzyme activity via reflectometry, a feature crucial for evaluating primaquine safety in malaria patients to prevent hemolytic complications (Pal et al., 2018). The Hemocue HB301 System is a minimally invasive hemoglobinometer that is simple to operate and more cost-effective than AHA, making it widely used in blood transfusion units and healthcare facilities (Adam et. al., 2012). Previous studies report that the Hemocue HB301 System has a sensitivity of 90% and specificity of 80% for detecting anemia, compared to AHA (Yadav et al., 2020). A study involving 553 blood donors found the device's sensitivity to be 99.3% in males and 98.9% in females when benchmarked against AHA (Ran et al., 2021). Research from South Africa comparing three POCT hemoglobinometers—Hemocue HB301, STAT-Site MHgb, and URIT-12—showed that the Hemocue HB301 had superior diagnostic performance, with 70% sensitivity, 70% specificity, a positive predictive value (PPV) of 61%, and a negative predictive value (NPV) of 78% (Jaggernath, et al., 2016). Based on these findings and the unavailability of AHA at the study site, the Hemocue HB301 System was used as the reference standard in this study. However, some studies have reported differing results. A study of 1,487 children in Laos reported higher hemoglobin levels using the Hemocue HB301 System (10.84 ± 1.03 g/dL) compared to AHA (10.23 ± 1.31 g/dL), yielding a sensitivity of 68.7% and specificity of 85.8% (Hinnouho, et al., 2018). Similarly, research conducted in India with 108 children showed a significant difference in hemoglobin measurements between the Hemocue HB301 (11.697 ± 1.312 g/dL) and AHA (11.965 ± 1.012 g/dL) (Kumar and Ramalingam, 2020).

In this study, the mean hemoglobin concentrations measured by the SD Biosensor Standard G6PD Analyzer and the Hemocue HB301 System were 14.22 ± 2.21 g/dL and 13.45 ± 1.63 g/dL, respectively. The mean difference was 0.762 g/dL (range: 0.599–0.925 g/dL). Paired t-test analysis indicated a statistically significant difference between the two devices, with higher values consistently

obtained from the SD Biosensor. Similar findings have been reported in a study conducted in Indonesia with 60 subjects, where the SD Biosensor yielded significantly higher hemoglobin readings (Sadhewa, et al., 2024). Conversely, a multi-center study involving 643 participants in the United States and Thailand reported a smaller discrepancy of less than 0.4 g/dL between the two devices (Pal et al., 2018). Diagnostic analysis showed that the SD Biosensor Standard G6PD Analyzer had a sensitivity of 70.27%, meaning it correctly identified 70.27% of anemic individuals, but missed 29.73% (false negatives), making it less optimal for initial screening compared to the Hemocue HB301. The device's specificity was 95.14%, indicating strong ability to correctly identify non-anemic individuals, with only 5% false positives—thus minimizing overdiagnosis. The PPV was 65%, indicating that 65% of positive results correctly identified anemia, while 35% were false positives—below the ideal threshold of $\geq 80\%$, posing a risk of overtreatment. The NPV was 96.14%, reflecting high reliability in ruling out anemia when the test result was negative. This highlights the device's strength in confirming true negatives, despite lower performance in detecting true positives. The positive likelihood ratio (LR+) was 14.4, suggesting that a positive test result with the SD Biosensor significantly increases the likelihood of anemia. The negative likelihood ratio (LR-) was 0.31, indicating a fair capacity to rule out anemia, although not conclusively. Ideally, LR- should be < 0.1 for strong exclusion power. The LR values suggest that while the device is highly effective for confirming anemia, it is less reliable for excluding it. The pretest odds (the probability of anemia before testing) was 0.128, indicating that, prior to testing, approximately 1 in 9 participants was expected to be anemic. The post-test odds following a positive result was 1.843, consistent with the PPV of 65%, while the post-test odds after a negative result was 0.004, aligning with the NPV of 96.14%. These metrics aid in determining whether further diagnostic evaluation is warranted following initial testing.

Diagnostic accuracy—defined as the proportion of true results (both positive and negative) out of all test results—was 92.31%, categorizing the SD Biosensor as a highly accurate tool (accuracy $> 90\%$ is considered excellent). Its high specificity supports its use for confirming anemia, though its lower sensitivity limits its utility as a screening tool. POCT devices are increasingly used outside laboratory settings due to their ability to provide rapid and reliable results. An ideal POCT device should meet the ASSURED criteria—Affordable, Sensitive, Specific, User-friendly, Rapid, Equipment-free, and Deliverable to end-users. The World Health Organization (WHO) recommends a minimum sensitivity of $\geq 80\%$ and specificity of $\geq 97\%$ for POCT devices (Khan et al, 2024; Gavina, 2023). In this study, the SD Biosensor Standard G6PD Analyzer demonstrated a sensitivity of 70.27% and specificity of 95.14%, falling short of WHO's standards. Therefore, this device cannot yet replace the Hemocue HB301 System as a reliable POCT for hemoglobin assessment. The strength of this study lies in its provision of comparative accuracy data between two POCT devices—SD Biosensor and Hemocue HB301—for hemoglobin measurement, an area with limited existing literature. The study's relatively large sample size ($n = 325$) adds robustness, and comprehensive diagnostic performance metrics were evaluated, including sensitivity, specificity, PPV, NPV, LR+, LR-, pretest odds, post-test odds, and accuracy. These findings may inform the selection of appropriate hemoglobin testing modalities in malaria-endemic regions. However, this study has limitations. Hemoglobin measurements from the two devices were not benchmarked against the gold standard AHA, which may limit interpretation of diagnostic accuracy. The cross-sectional, single-center study design also restricts generalizability and fails to capture temporal variability in hemoglobin levels. Additionally, external factors such as nutritional status, infections, comorbidities, and cost-effectiveness of each device were not considered, which may influence hemoglobin levels and diagnostic decision-making.

CONCLUSION

The SD Biosensor Standard G6PD Analyzer demonstrated high specificity and good overall accuracy; however, its sensitivity in measuring hemoglobin concentration was inferior compared to the HemoCue HB301 System.

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