Southern African Journal of Anaesthesia and Analgesia. 2021;27(2):99-103
https://doi.org/10.36303/SAJAA.2021.27.2.2379

South Afr J Anaesth Analg
ISSN 2220-1181 EISSN 2220-1173

ORIGINAL RESEARCH

Comparison of point-of-care device DiaSpect against the HemoCue and laboratory analyser in an ICU population

B Salmond,[1] RN Rodseth,[1] Z Farina,[1] RP von Rahden[2]

[1] *Discipline of Anaesthesiology & Critical Care, College of Health Sciences, University of KwaZulu-Natal, South Africa*
[2] *Private Practice, South Africa*
Corresponding author, email: *belindamerrifield@yahoo.com*

Background: Haemoglobin levels guide many diagnostic and therapeutic interventions. They form part of the basic daily management of ICU patients. Laboratory results are frequently delayed. This can have important clinical consequences, including withholding potentially life-saving interventions. Point-of-care devices, if accurate, provide a solution to this problem. Inaccurate devices may provide misleading results leading to unnecessary and hazardous blood transfusions or under-estimation of disease severity. The aim was to compare the accuracy and reliability of the DiaSpect Hemoglobin T (DiaSpect. Medical GmbH, Sailauf, Germany) haemoglobinometer with the HemoCue (HemoCue AB, Ängelholm Sweden) haemoglobinometer and the gold standard laboratory analyser for this trial (XT-200i Sysmex/Coulter LH750).

Methods: Venous blood samples were collected via a central venous line from Intensive Care Unit (ICU) patients (n = 265) for determination of haemoglobin (Hb) concentration by DiaSpect as well as the HemoCue, and the automated haemoglobin analysers: XT-200i Sysmex or the Coulter LH750. Agreement between the methods was tested using Bland–Altman plots. A Hb variation of 0.5 g/dl was considered clinically significant. There were a significant number of wasted samples with the DiaSpect, as a total of 350 cuvettes were used but only 214 complete samples obtained. This wastage was attributed to errors in sampling, cuvette shortage, lack of experience with the device and lack of 'user-friendliness'.

Results: A total of 265 samples were obtained, of which 207 had complete data sets and were analysed further in the study. There were 58 incomplete samples, of which 51 were DiaSpect samples. Mean haemoglobin was 9.11 (standard deviation ± 1.74), 9.07 (standard deviation ± 1.96) and 9.02 (standard deviation ± 2.06) using the laboratory analyser, HemoCue and DiaSpect respectively. Laboratory and HemoCue: the mean difference between the two readings was -0.04 (95% limits of agreement -2.15 to 2.07 g/dl) with an average between 5.00 g/dl and 15.10 g/dl. Laboratory and DiaSpect: the mean difference between the readings was -0.09 (95% limits of agreement -2.64 to 2.46 g/dl) with an average between 5.10 g/dl and 14.9 g/dl. HemoCue and DiaSpect: the mean difference between the two haemoglobin levels was 0.04 (95% limits of agreement 2.73 to -2.64 g/dl). Both methods returned measurements within the pre-defined clinical acceptable limits of ± 0.5 g/dl.

Conclusion: The haemoglobin concentration assessment by the HemoCue and DiaSpect showed an acceptable limit of agreement when compared against the laboratory analyser. There were a significant number of wasted samples when using the DiaSpect.

Keywords: Diaspect, Hemocue, point-of-care testing, haemoglobin, comparison

Introduction

Haemoglobin levels guide many clinical diagnoses and therapeutic interventions including detection and diagnosis of anaemia, efficacy of therapies, serial assessments to track disease progression and blood loss.[1] Point-of-care (POC) testing offers rapid diagnosis at the patient bedside.[2] Devices need to be sufficiently reliable and accurate for clinical purposes.[3] The ideal Hb screening method for blood collection centres should have high specificity and sensitivity, with low false failure (deferral) rates and low false pass rates, and lie within 0.5 g/dl of the gold standard.[4] There are several invasive POC devices available for haemoglobin estimation which use absorption photometry. These include reagent (HemoCue), non-reagent (DiaSpect), and conductivity-based (i-Stat) analysis methods.[5]

The current gold standard for POC technology for haemoglobinometry is the HemoCue, and has been validated in multiple studies.[2,3,6] The HemoCue B-Hemoglobin system (HemoCue AB, Ängelholm Sweden) analyses haemolysed blood using spectrophotometric detection and makes use of a disposable microcuvette containing nitrite azide reagent.[3] The reaction is a modified azide-methaemoglobin reaction, and its absorbance is measured at two wavelengths (570 nm and 880 nm) to compensate for turbidity.[3]

Recently introduced to the KwaZulu-Natal Public Health Sector is the DiaSpect Hemoglobin T (DiaSpect. Medical GmbH, Sailauf, Germany). It measures total Hb in unaltered whole blood with a special cuvette that also serves as the sampling device.[3] A broad-spectrum, multichromatic sensor measures the absorbance of unaltered whole blood in reagent-free cuvettes over a wide spectral range (wavelengths between 400 and 800 nm).[3,4] The reagent-free polystyrene cuvettes are not affected by the wide range of temperatures (10–40 °C) and humidity and they do not require special storage conditions.[7] There is limited literature on the accuracy and reliability of the DiaSpect. This study aimed to compare it to the HemoCue using laboratory-obtained values as a reference.

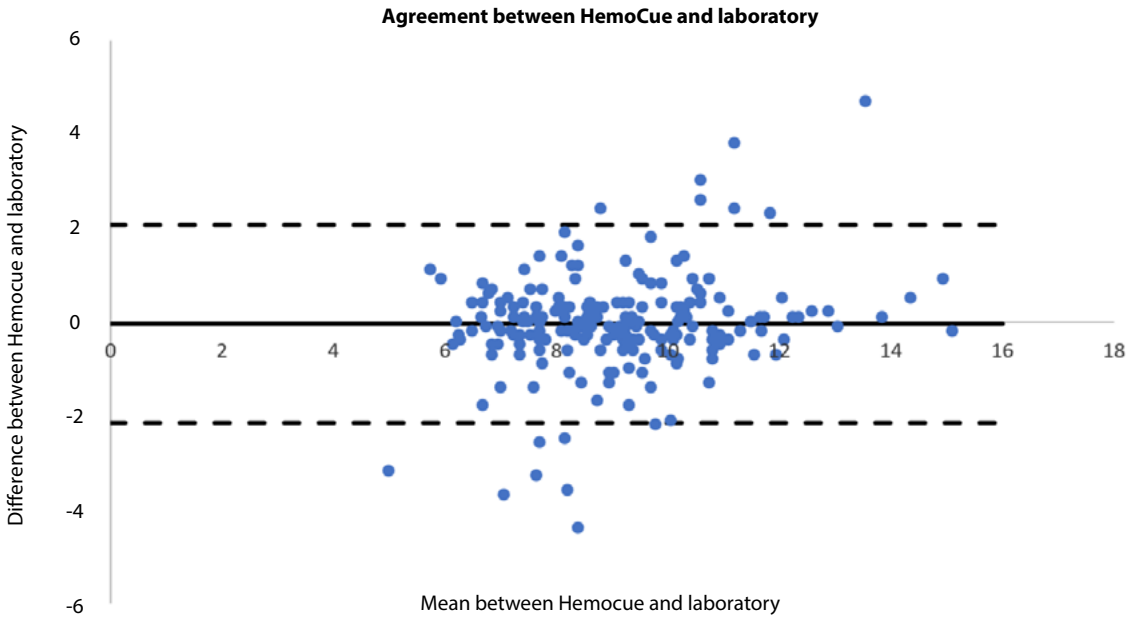

Figure 1: Comparison of HemoCue and laboratory

Table I: Lost sample data sets

Incomplete samples					**58**
	Total	**Unknown**	**No cuvette**	**Clotted**	**Other**
Diaspect	51	33	18		
Haemocue	10	10			
Laboratory	3			2	1
Complete samples					**207**
Total number					**265**

Table II: Mean haemoglobin levels

Method of measurement	**Mean ± SD**	**Median**	**(min; max)**
Laboratory	9.11 ± 1.74	9.1	(5.2; 15.2)
HemoCue	9.07 ± 1.96	8.9	(3.4; 15.9)
DiaSpect	9.02 ± 2.06	9	(3; 14.6)

Table III: Mean haemoglobin difference between devices

Comparison methods	**Bias ± SD**	**Limits of agreement**
Laboratory vs HemoCue	-0.04 ± 1.08	-2.15–2.07
Laboratory vs DiaSpect	-0.09 ± 1.30	-2.64–2.46
HemoCue vs DiaSpect	0.04 ± 1.37	-2.64–2.73

Methodology

We undertook a quantitative analysis to determine the agreement between the DiaSpect, the HemoCue (currently being used in Grey's Hospital Intensive Care Unit) and the laboratory analyser (gold-standard). The study was conducted amongst patients admitted to Greys' ICU, Pietermaritzburg, KwaZulu-Natal, South Africa from 1 October to 31 December 2018. Convenience sampling was used, in which all patients over the age of 18 years admitted to Grey's hospital ICU for the duration of the study were sampled until the sample size was achieved. Patients were excluded if:

- they did not require central venous catheters,
- they did not require routine blood tests,
- blood samples were not taken from a central venous line, or
- insufficient blood volume was available to conduct analysis on all three machines.

As all samples were collected as part of routine clinical care, a waiver of consent was requested from the Biomedical Research Ethics Committee (BREC) of the University of KwaZulu-Natal. This, together with full ethical approval, was granted on 11 July 2018 (BE037/18).

All blood samples were collected at midnight from a central venous line using an aseptic technique. The first sample was collected in a blood specimen tube and sent for laboratory analysis. The automated haemoglobin analysers used by the laboratory were the XT-2000i Sysmex and Coulter LH 750. The second and third samples were immediately evaluated using the HemoCue and DiaSpect. The values measured by all three devices were captured on a data sheet and then entered onto an Excel spreadsheet. Each of the readings from the HemoCue and DiaSpect were compared to the gold standard (laboratory analyser), and then the HemoCue and DiaSpect readings were compared to each other.

A sample size of 150–200 patients was calculated to measure clinical agreement with a confidence interval of 95%, with a Hb variation of 0.5 g/d being defined as significant. Pairs of haemoglobin samples were compared as follows: HemoCue and laboratory analyser, DiaSpect and laboratory analyser, and HemoCue and DiaSpect. The mean of differences (bias), standard deviation of differences (SD) and limits of agreement (average difference ± 1.96 standard deviation of the difference) were

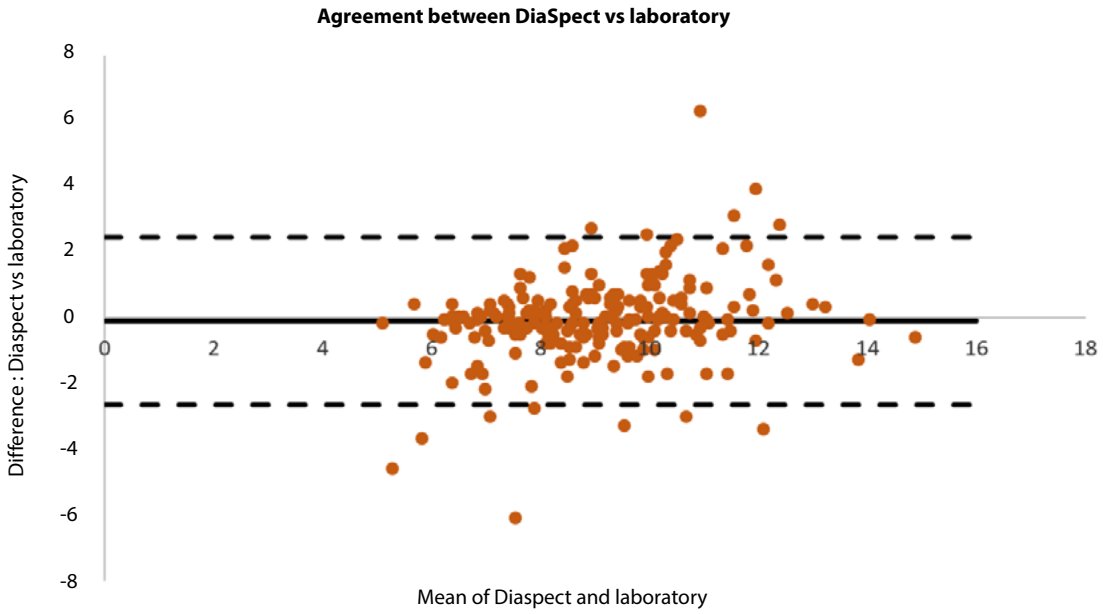

Figure 2: Comparison of DiaSpect and laboratory

calculated according to the Bland–Altman method. A difference of ± 0.5 g/dl was considered to be clinically significant and was used as the limits of agreement. All analyses were performed using STATA (StataCorp. 2017. Stata Statistical Software: Release 15. College Station, TX: StataCorp LLC).

Results

A total number of 265 samples were obtained, of which 207 had complete data sets. The 58 incomplete data sets were comprised of 51 from the DiaSpect, 10 from the HemoCue, and three from the laboratory (Table I). Mean haemoglobin level was 9.11 (SD ± 1.74), 9.07 (SD ± 1.96) and 9.02 (SD ± 2.06) using the laboratory analyser, HemoCue and DiaSpect respectively (Table II).

When comparing the laboratory and HemoCue measurements, the difference between the two readings was -0.04 (limits of agreement -2.15; 2.07 g/dl). The average recorded haemoglobin was between 5.00 g/dl and 15.10 g/dl (Figure 1; Table III). When comparing the laboratory and the DiaSpect measurements, the mean difference between the haemoglobin levels was -0.09 (limits of agreement -2.64 to 2.46 g/dl) and the average lay between 5.10 g/dl and 14.9 g/dl (Figure 2; Table III). When comparing the HemoCue and the DiaSpect, the mean difference between the two haemoglobin levels was 0.04 (limits of agreement -2.64 to 2.73 g/dl) (Figure 3; Table III). All three methods fell within the pre-defined clinical acceptable limits of ± 0.5 g/dl.

Discussion

Numerous comparison studies have been conducted to assess the accuracy of POC technologies compared to laboratory-based methods.[5] A summary of published studies revealed a significantly larger difference in Hb measurement between POC and laboratory devices, and that Hb POC devices offered reduced

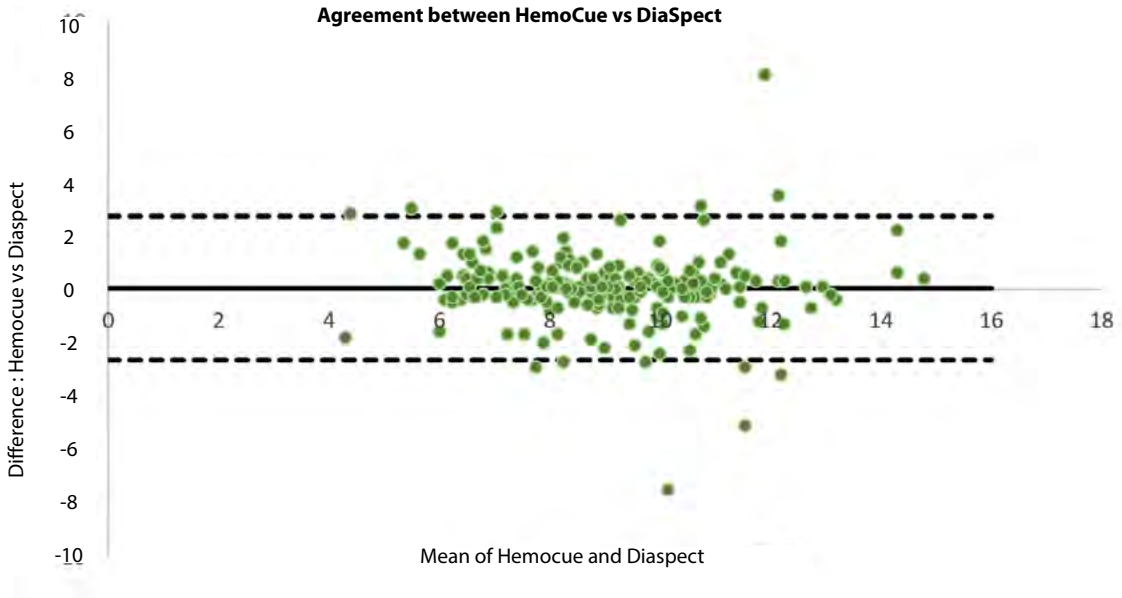

Figure 3: Comparison of HemoCue and DiaSpect

accuracy compared to laboratory analysers.[8] Hb measurement from capillary blood in POC devices varies 0.5–2.3 g/dL from reference standards,[2,9-12] and some POC devices have shown up to 10 times the variability in Hb measurement compared to a laboratory CO-Oximeter device.[13]

A meta-analysis by Hiscock et al. concluded that HemoCue 201+ provides unbiased estimates of laboratory haemoglobin, and that the HemoCue had a higher precision vs an alternate POC (Masimo).[5] This greater accuracy came at a greater, recurrent cost for the disposable microcuvettes containing nitrite azide (ZAR:US R12.5:$0.75/test), and their deterioration in adverse climates.[3,14] Readings must also be taken within 10 minutes of filling the cuvettes to prevent inaccurate readings.[7] High humidity has been shown to bias the function and Hb measurements by nitrite – azide systems, where an Australian study has reported that cuvettes exposed to a high humidity for ≥ 4 days may underestimate Hb by as much as 2 g/dL.[7]

One of the potential advantages of DiaSpect over the HemoCue is that its plastic cuvettes do not contain any reagents and are therefore not affected by temperature or humidity and require no special storage conditions. In addition, the length of time to results with the HemoCue is approximately 5 minutes in contrast to the DiaSpect which displays results within 2–5 seconds.[3,4,7,13]

In this study the HemoCue graph showed narrower limits of agreement than that of the DiaSpect and greater agreement with laboratory values. However, it did contain more outliers and the graph showed greater dispersal at Hbs > 10 g/dl and < 7 g/dl. By contrast the DiaSpect had wider limits of agreement and only started demonstrating dispersal at readings > 11g/dl. Both machines showed greater scatter with higher Hb averages possibly indicating limited accuracy at these levels.

This study has shown that three methods (HemoCue, DiaSpect and the laboratory analyser) can be used interchangeably, as the limits of agreement fell within the clinically accepted predefined limits of ± 0.5 g/dl. This concurs with a study conducted by Singh et al. where the DiaSpect was found to be the most sensitive method of POC testing for Hb (sensitivity 98.1%), was significantly quicker (1.9 seconds) and had a bias of -0.18 g/dL.[4]

This assertion/finding is also supported by a study conducted by Malukani et al. where they found that haemoglobin values by HemoCue and DiaSpect showed quite similar results against the reference. The mean Hb value of HemoCue (13.8 ± 1.7 g/dl) was higher by 0.26 when compared to their reference (13.54 ± 1.53 g/dl) and the DiaSpect was found to be the most accurate technique (sensitivity 98.8%; specificity 97.14%). They concluded that the DiaSpect system compared well with established methods of blood donor screening and had the highest sensitivity, specificity and likelihood ratio, and as such was the best method for donor screening out of the various methods tests.[15] Lastly, these findings also concur with a study conducted by Canadian blood services evaluating the DiaSpect, where they found its precision to be excellent, and that it was faster and easier to use than alternative POC devices available to them.[13]

A large proportion of rural hospitals in KwaZulu-Natal have prolonged turn-around laboratory times, and many do not have after-hours facilities. A reliable and accurate POC device can aid in rapid assessment and monitoring of haemoglobin, and lead to accelerated decision-making regarding blood transfusions and the ordering of blood. Additional value of the POC device is found in patients with active haemorrhage or bleeding diathesis where immediate quantification of the patient's haemoglobin is of decision-making value. An accurate POC testing Hb is a useful addition to laboratory testing in the bleeding patient where haemoglobin trends can be rapidly and economically followed at the bedside. Having a POC device that is reliable allows for swift response to dynamic clinical situations.

Regarding the incomplete data sets due to the missing samples: three laboratory samples were not recorded, and this was due to two blood samples clotting and not being processed, and one patient who demised and thus the sample was not processed. Fifty-one DiaSpect samples were omitted, eighteen of which were attributed to cuvette shortage, whilst the remainder were unaccounted for. The study started with 350 DiaSpect cuvettes, but only 214 samples were obtained, and nil cuvettes remained at the end of the study. This raises the question of user-friendliness and financial feasibility regarding the DiaSpect if only 63% of cuvettes will yield results. It could also reflect a lack of familiarity with the DiaSpect versus the HemoCue, despite in-service training. The reasons for this wastage need to be elucidated, whether they are the result of cuvette failure or training shortcomings. This study was not designed to do this but may represent an area for further research.

A disadvantage of POC testing is a lack of training, poor standardisation in obtaining blood samples and insufficient internal/external quality assessment. Considering the reasonable expectation that POC testing use will increase in all pathology disciplines, it is imperative that systems are put in place to oversee these issues.[16]

Limitations

To ensure reliability of results and enable uniform sampling this study was conducted in an ICU population, thereby possibly limiting the generalisability of these results. However, by only sampling from a central venous line at a specific time in a specific quantity the possible confounders related to sampling were eliminated.[7,8] The study was also limited in that samples were measured by two makes of laboratory automated haemoglobin analysers; however, previous studies have found them comparable.[17,18] Further, due to ICU patients having on average a lower haemoglobin than normal each POC unit was only tested within a narrow measurement range. Thus, the upper spectrum validity cannot be deduced accurately. Finally, there was also no distinction made between which patients were actively bleeding or whether blood transfusions had been received**.** Multiple personnel were involved in the collection of samples, which could have introduced error or incorrect sampling. To minimise

this all ICU staff participating in this study received in-service training and training in strict protocol adherence.

Conclusion

POC testing may become the standard of practice, but there is a further need for research on its utility within the ICU.[8] It is prudent to evaluate a POC testing device against a reference method before introducing it into practice.[3] The DiaSpect is comparable in regard to accuracy and reliability to the HemoCue, and has the added advantage of being faster and cheaper. However, factoring in the need for multiple samples being wasted negates its cost benefit of R9.90/test. Therefore, this study does not recommend replacing the HemoCue POC with DiaSpect. Further research into the reasons for cuvette wastage is recommended as it may help support the economic advantage of the DiaSpect. In the meantime, the use of POC tests in the ICU should not be viewed as a replacement for conventional laboratory services but as a supplement.

Conflict of interest

All authors have no conflicts of interest to declare.

Funding source

Solely funded by departmental resources.

Ethical approval

The Biomedical Research Ethics Committee (BREC) of the University of KwaZulu-Natal. This, together with full ethical approval, was granted on 11 July 2018 (BE037/18).

ORCID

B Salmond https://orcid.org/0000-0003-1864-996X
RN Rodseth https://orcid.org/0000-0002-3779-7805
Z Farina https://orcid.org/0000-0002-0522-2062
RP von Rahden https://orcid.org/0000-0002-6673-4221

References

1. Ray J, Post J, Hamielec C. Use of rapid arterial blood gas analyser to estimate blood haemoglobin concentration among critically ill adults. Crit Care. 2002 February 6;6(1):72. https://doi.org/10.1186/cc1456.
2. Gehring H, Hornberger C, Dibbelt L, et al. Accuracy of point-of-care-testing (POCT) for determining haemoglobin concentrations. Acta Anaesthesiol Scand. 2002 Sep;46(8):980-6. https://doi.org/10.1034/j.1399-6576.2002.460809.x.
3. Robertson L, Lewis D, Osei-Bimpong A. Utility of the diaspect haemoglobinometry system as a point-of-care analyzer. Point of Care. 2011;10(1):17-21.
4. Singh A, Dubey A, Sonker A, Chaudhary R. Evaluation of various methods of point-of-care testing of haemoglobin concentration in blood donors. Blood transfus. 2015;13:233-9.
5. Hiscock R, Kumar D, Simmons S. Systematic review and meta-analysis of method comparison studies of Masimo pulse co-oximeters and HemoCue absorption spectrometers with laboratory haemoglobin estimation. Anaesth Intensive Care 2015; 43(3):341-50. https://doi.org/10.1177%2F0310057X1504300310.
6. Kim S-H, Lilot M, Murphy LS-L, et al. Accuracy of continuous non-invasive haemoglobin monitoring: A systematic review and meta-analysis. Anaesthesia and Analgesia. August 2014;119(2):332-46. https://doi.org/10.1213/ANE.0000000000000272.
7. Chaudhary R, Dubey A, Sonker A. Techniques used for the screening of haemoglobin levels in blood donors: current insights and future directions. Journal of Blood Medicine. 2017;8:75-88. https://doi.org/10.2147/JBM.S103788.
8. Masimo. Total haemoglobin measurements: Accuracy of laboratory devices and impact on physiological variation. 2009. Available from: https://www.masimo.co.jp/pdf/SpHb/LAB5527A.pdf. Accessed 31 Aug 2020.
9. Gómez-Simón A, Navarro-Núnez L, Pérez-Ceballos E, et al. Evaluation of four rapid methods for haemoglobin screening of whole blood donors in mobile collection settings. Transfusion and Apheresis Science. 2007 Jun;36(3):235-42. https://doi.org/10.1016/j.transci.2007.01.010.
10. Patel KP, Hay GW, Cheteri MK, Holt DW. Haemoglobin test result variability and cost analysis of eight different analysers during open heart surgery. J Extra Corpor Technol. 2007;39(1):10-17.
11. Van de Louw A, Lasserre N, Drouhin F, et al. Reliability of HemoCue in patients with gastrointestinal bleeding. Intensive Care Med. 2007 Feb;33(2):355-8. https://doi.org/10.1007/s00134-006-0461-6.
12. Argawal R, Heinz T. Bedside haemoglobinometery in haemodialysis patients: Lessons from point of care testing. ASAIO J. 2001.47(3):240-3. https://doi.org/10.1097/00002480-200105000-00016.
13. Goldman M, Uzicanin S, Yi Q-L, Acker J, Ramirez-Arcos S. Validation and implementation of a new haemoglobinometer for donor screening at Canadian blood services. Transfuison. 2012 July;52(7):1607-13. https://doi.org/10.1111/j.1537-2995.2012.03757.x.
14. Lara A, Mundy C, Kandulu J, Chisuwo L, Bates I. Evaluation and costs of different haemoglobin methods for use in district hospitals in Malawi. J Clin Pathol. 2005 Jan;58(1):56-60. https://doi.org/10.1136/jcp.2004.018366.
15. Malukani P, Gajjar MD, Gonsai RN, Bhatnagar N, Goswami HM. Study of newer invasive and non-invasive methods of haemoglobin estimation in blood donor screening – A study on 200 donors. IRR. 2014;6(4):26-30.
16. Briggs C, Kimber S, Green L. Where are we at with point-of-care testing in haematology? British Journal of Haematology. 2012;158:679-690. https://doi.org/10.1111/j.1365-2141.2012.09207.x.
17. Bruegel M, Nagel D, Funk M, et al. Comparison of five automated hematology analyzers in a university hospital setting: Abbott Cell-Dyn Sapphire, Beckman Coulter DxH 800, Siemens Advia 2120i, Sysmex XE-5000, and Sysmex XN-2000. Clin Chem Lab Med. 2015 January 13;53(7):1057-71. https://doi.org/10.1515/cclm-2014-0945.
18. Kang S-H, Kim HK, Ham CK, Lee DS, Cho H-I. Comparison of four hematology analyzers, CELL-DYN Sapphire, ADVIA 120, Coulter LH 750, and Sysmex XE-2100, in terms of clinical usefulness. International Journal of Laboratory Haematology. 2008 October 29;30(6):480-6. https://doi.org/10.1111/j.1751-553X.2007.00981.x.