Day-Per-Day Maintenance and Six Sigma of the Landwind LW D3600 Hematological Analyzer: Clinical Aspects and Quality Verification

Jeel Moya-Salazar[1,2]*

[1]School of Medicine, Faculties of Health Science, Universidad Privada Norbert Wiener, Lima, Peru.
[2]Hospital Nacional Docente Madre Niño San Bartolomé, Lima, Peru.
jeelms@outlook.com/jeel.moyasalazar@icloud.com

*Corresponding Author: Jeel Moya-Salazar, School of Medicine, Faculties of Health Science, Universidad Privada Norbert Wiener, 440 Arequipa Av., Lima 15046, Peru.

Abstract

Objective: *to verify the functioning and analytical quality of the Landwind LW D3600 hematology analyzer during clinical practice through sigma metrics and power charts, highlighting the importance of daily preventive maintenance.*

Methods: *This prospective cross-sectional study was developed at the University Clinic in Lima, Peru during 2016. Twelve haematological parameters were evaluated - ($\times10^3/\mu L$), RBC ($\times10^6/\mu L$), HB (g/dL), PLT ($\times10^3/\mu L$), HCT (%), and MCV (fL), among others- in two phases: 1) evaluation and estimation of the sigma metric, and 2) 14-day evaluation of the performance of the parameters hematological. In addition, three daily cleaning maintenance systems (electrical, washing, and complete) were compared. Myth-3D control reagents MYTHIC18 of 3 control levels and a single batch were used.*

Results: *In both phases WBC and PLT had a great sigma performance (≥7), and the erythroid parameters (RBC, HB, HCT, and MCV) presented low performance (≤4), where only MCV and RBC (each with Pfr ≤0.6) could be kept under quality with the use of the multi-rule $1_{3s}/2_{2s}/R_{4s}/4_{1s}$ with 4 levels of control. The system of preventative maintenance of complete cleaning improved the quality of analysis showing low imprecision results (p=0.005).*

Conclusion: *the daily evaluation under the sigma metric allowed verifying the quality of the demonstrating a heterogeneous performance and illustrating a process of analytical evaluation in the hematological laboratory.*

Keywords: *verification, hematology analyzer, quality control, complete blood count, maintenance, six sigma*

INTRODUCTION

Nowadays the blood count is essential in clinical practice and in scientific research worldwide. Although hematology has been developed since antiquity, only since 1956 have significant and technological advances been made in search of the current hematological automation that is used in routine clinical care. After four generations, this set of tests that qualitatively and quantitatively evaluate the cellular components of blood, requires an important care to ensure reliable results through stable products of blood control and/ or the use of patient samples as performance controls [1, 2].

Indeed, multiple evaluations have been developed in the hematological analyzers of different systems and hematological magnitudes of complete blood count (CBC), with the goal of establishing their quality requirements, their diagnostic performance and their error detection capacity, as indicated in the main quality-assessment guides [2-8]. To opt for the accreditation path, international certification, and the assurance of the quality of haematological results,

laboratories must comply with certain parameters through quality evaluations that include verification guides for analytical methods such as the sigma metric, the Power function, and the OPSpecs Operational charts [8-12].

Within the quality analysis, the six sigma (6σ) is a systematic method that improves the skills of the institution based on the improvement of the quality system [7, 13]. This system has managed to improve the processes and performance of multiple industrial sectors, as well, since its application within the health systems has been able to provide high quality and effective care.

However, in Peru, very few health centers [8] have included this quality management system or others available as an imperative in their institutional programs, causing onerous deficiencies in the quality of care and difficulties in the management of these centers. Examples of this deplorable quality health-management system are the non-existent quality checks and planning in the clinical analysis centers and the health workers' interest in these [7, 14, 15]. Most of the time, even in high-level hospitals (≥500 beds), they work with what they have and not with what is needed, and the patient is given what can and cannot be required.

We aimed to verify the functioning (6σ) and the analytical quality of the Landwind LW D3600 hematological analyzer during clinical practice. Other objectives, allowed to determine the levels of imprecision and veracity, and their relationship with the daily preventive maintenance of the analyzer and the accuracy of the biological magnitudes.

Materials and Methods

We designed a qualitative, cross-sectional, prospective study in the Clinical Analysis Laboratory of the University Clinic in Lima, Peru during 2016. The Clinic is a Class II Health Center. This center provides health care mainly to patients from the north of Lima (5 districts) with ≥30 beds, and additionally has an agreement with the Social Security of Peru (EsSalud). Approximately 391 medical consultations are made per month.

Inside the laboratory is the Clinical Hematology area that contains a Landwind LW D3600 hematology analyzer (Shenzhen, China), one of the most used in Peruvian clinical laboratories. Approximately 827 samples for CBC are analyzed monthly, and only the altered results are analyzed microscopically.

Automated Analyzer

To make the determinations, we was used the Landwind LW D3600 hematological analyzer with three differentials, 20 parameters, and 3 histograms. The amount of venous blood sample used for each measurement was 9.6 μl. The biological magnitudes of measurement were: WBC (leukocyte count), RBC (erythrocyte count), HB (hemoglobin dose), HCT (calculated computerized hematocrit), MCV (Middle Corpuscular Volume), PLT (platelet count), MCH (Mean Corpuscular Hemoglobin), MCHC (Mean Corpuscular Hemoglobin Concentration), LYM # (number of lymphocytes), MID # (number of monocytes), GRAN # (number of granulocytes), LYM% (percentage value of lymphocytes), MID% (percentage value of monocytes), GRAN% (percentage value of granulocytes), PCT (Plateletcrit), RDW-CV (Red Blood Distribution Width - Coefficient of variation), RDW-SD (Red Blood Distribution Width - Standard deviation), MPV (Mean Platelet Volume), PDW (Platelet Distribution Width) and P-LCR (Platelet- Large Cell Ratio). In this study, we included only the first six biological parameters indicated by availability of quality data for interpretation.

Reagents

The Landwind system has an open system for reagents. The reagents used for the hematological analyzes were: Diluent for Hematology Analyzer (Lot 2016121001) presentation of 20 L, Lyser for Hematology Analyzer (Lot 20160707) presentation of 0.5 L, and Cleaner for Hematology Analyzer (Lot 2016121601), presentation of 1 L (all from COMING, Sozhou, China).

The control haematological reagents (internal controls) were Myt-3D MYTHIC 18 (Orpée SA, Geneva, Switzerland) of lot B0816 of three levels of control (low, medium and high) of open system and for the evaluation of 18 biological magnitudes. These controls were analyzed according with the operational requirements and Standardized Operational Procedures (SOPs) of the institution (**Figure 1**).
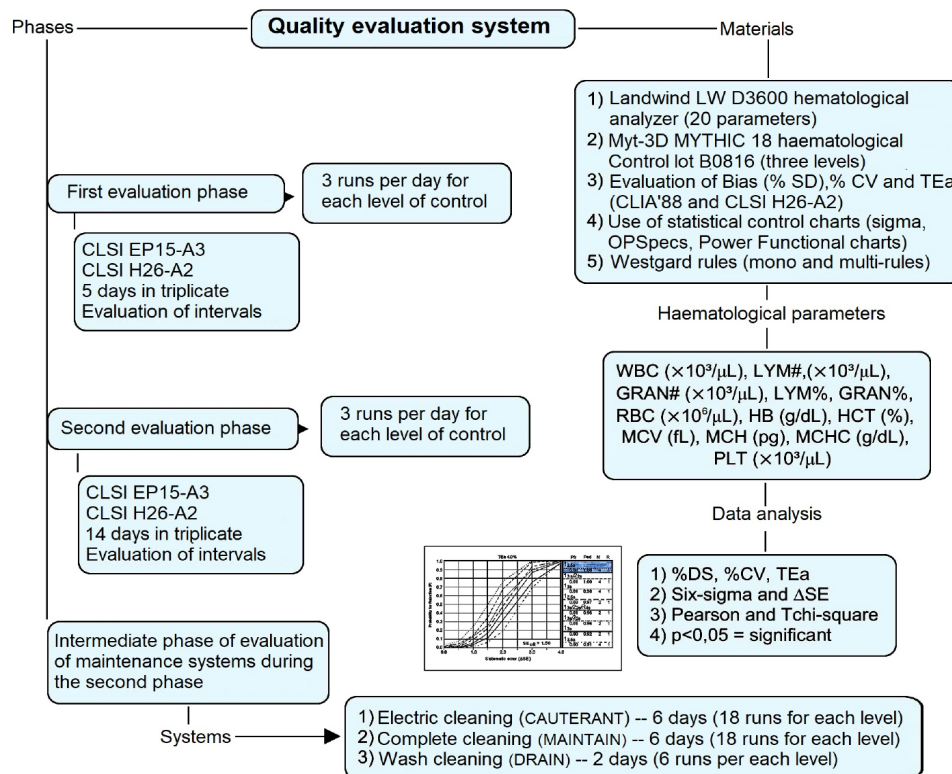
Fig 1. *Flowchart of the quality assessment system of the Landwind LW D3600 hematology analyzer for six sigma. The manufacturer's technical specifications are described for the twelve main haematological parameters.*

Maintenance System

The Landwind maintenance system has five options for daily maintenance and efficiency assurance. Two types of assigned daily maintenance have been considered:

a) Electric cleaning (CAUTERANT) followed by two washes (duration ≤40 seconds), which involves electric shocks to the sample reception system, detaching the "agglutinated" cells within the channel that may cause analysis errors.

b) The complete cleaning (MAINTAIN) that implies a general washing of the system, electrical distribution for channel cleaning and suction of remains within the circuit.

In addition, during the study, two washings were performed on the ejection systems of the equipment called wash cleaning (DRAIN) on the last day of each week during the 14 days of evaluation in the second evaluation phase (see below). No daily maintenance was carried out during the first phase.

Quality Assessment, Analytical Record Series, and Statistical Control Charts

Following the manufacturer's recommendations on the use of the daily controls in each evaluation level, two consecutive evaluation phases were developed: 1) Evaluation and estimation phase of the sigma metric and 2) 14-days evaluation of the Hematological parameters performance.

Each daily analysis of individually haematological control level had three simultaneous analytical series, with inter-serial analytical needle cleaning, from these readings the average was established as the estimated daily value. The controls were analyzed at room temperature (77±2 °F).

Before each analysis, all tubes were mixed by inversion at least 30 times [16]. The analytical series were not repeated. The haematological analyzer was stabilized for 30 minutes before the analytical series. The daily quality assessment lasted approximately 30 ± 7 minutes. All analysis was made by the laboratory staff at the clinic early in the morning, and was validated by the Pathologist before their coding.

First Evaluation Phase

During the first phase, 15 analytical series were developed of each biological quantity. Three series were made daily for 5 days. With these values, we estimated the standard deviation (SD) that was considered as bias of each parameter, and the coefficient of variation (% CV).

The systematic error and imprecision were determined respectively with the DS and %CV as previously detailed [9, 13, 14]. The accuracy of each test was determined with the total error (TEa) of the laboratory method to establish the 6σ of each biological variable, according to: $(6\sigma = (TEa - Bias\ observed)/(\%CV\ observed))$.

The lines and operative points were established in each statistical control chart and the critical systematic error (ΔSE). The values of TEa were taken from the CLIA'88 guide [17] and the CLSI H26-A3 guide (only for MCV, since CLIA'88 did not indicate the quality requirement for this magnitude) [18]. During this phase the methods with other internal controls were validated at the start of the trial.

Second Evaluation Phase

In the second phase, we were alternated the three cleaning systems per day, each system was executed before the quality evaluation. The sigma level was monitored during the evaluation time and the performance and statistical control applied on the same biological magnitudes were evaluated [13, 14, 18].

We evaluate that the analysis value of each parameter is within the manufacturer's range after nine days of evaluation. We consider mean values as those established daily for the daily-control-chart of the Landwind data system. The estimation of 6σ and ΔSE metrics was performed as in the first phase of the study. Finally, in this phase, the methods were validated with other internal controls at the beginning of the trial **(Figure 1)**.

Data Analysis Strategy

We developed the quality matrix in the MS-Excel 2010 system where all the daily values obtained in the two phases of quality assessment were included. Each format contained DS, %CV, TEa, 6σ, and ΔSE of each parameter. Furthermore, the Probability of False Rejection (Pfr) and the Probability of Error Detection (Ped) values were estimated in each statistical control sheet. We considered as desirable sigma ≥5, which we considered acceptable was 4, and sigma ≤3 were considered inadmissible.

Likewise, we used the Pearson test to evaluate the possibility of a relationship among the three system maintenance systems and the global sigma of the analyzer. The averages of each marker level were compared with the Chi-squared with the means determined statistically. The data were compared in each phase and the significant difference between runs was noted considering a value of p<0.05 as statistically significant. Data analysis was performed on the IBM SPSS v21.0 statistical analyzer (Armonk, USA) for Chrome® (Google, CA, USA).

Ethical Aspects

This research was subject to compliance with the international ethical standards of research in Health Sciences. Furthermore, this study had the approval and conformity of the Heads and Administrators of the Health Committee of the institution.

RESULTS

During the first phase a sigma of 7.4 was determined for WBC, a sigma of 3 for RBC, 2.5 for HB, 9.8 for PLT, a sigma of 2.7 for HCT, and 3.1 for MCV, indicating a heterogeneous performance of the key haematological components of the Landwind LW D3600 analyzer. At the Low Level we determined that the values of RBC (≥1 DS), HB (≤2 DS), and PLT (≤2 DS), were outside the range defined by the manufacturer. In the Normal Level, the HB had ≥1 DS. In the High Level we determined that HCT presented values ≤1 DS **(Table 1)**. A significant difference was found between the values of imprecision and bias (sigma) of the haematological parameters evaluated (p <0.01).

In the second phase, an optimal sigma value was determined for WBC (7,4) and PLT (10), acceptable for MCV (3,2), and unacceptable for RBC (3), HB (2,2), and HCT (2.6) **(Table 2)**. Significant difference was found between the sigma values of the haematological parameters evaluated (p <0.01). From the range of values indicated by the Low Level haematological control, the PLT had ≥2 DS, the HCT was within the upper-limit of 1 DS, the MCV within the range but close to the low-limit, and alarmingly HB presented values of ≥1 DS . In the Normal Level, the alteration

was evidenced only in HB (> 1 DS). Finally, at the High Level the HCT had ≥1DS. No-significant difference was found between the sigma values during the first and second phases in all parameters evaluated (p = 0.415).

Table 1. *Results of the first phase of quality assessment of the Landwind LW D3600 haematology analyzer. The values of the sigma and ΔSE metrics were determined with the CLSI guide EP15-A3. Only the Quality Requirement indicated in CLIA'88 and CLSI have been considered for six parameters.*

Levels	Analysis	WBC ($\times 10^3$/μL)	RBC ($\times 10^6$/μL)	HB (g/dL)	PLT ($\times 10^3$/μL)	HCT (%)	MCV (fL)**
Low	SD	0.29	0.33	7.81	31.62	2.62	0.97
	Mean	2.0	2.5	54.7	131.3	18.5	73.8
	%CV	14.9	13.4	14.3	24.1	14.2	1.3
	Sigma	7.5	3.0	3.0	11.2	2.8	3.3
Medium	SD	0.73	0.23	7.47	57.62	2.20	0.74
	Mean	7.5	4.6	124.3	274.3	38.9	84.8
	%CV	9.8	5.1	6.0	21.0	5.7	0.9
	Sigma	7.4	3.0	2.3	9.8	2.6	3.2
High	SD	4.01	0.12	2.85	21.05	1.44	0.74
	Mean	17.3	5.8	178.4	540.9	55.0	95.7
	%CV	23.2	2.1	1.6	3.9	2.6	0.8
	Sigma	7.3	2.9	1.7	7.1	2.4	3.0
Total	%CV$_{MEAN}$	38.0	11.6	12.4	32.9	13.0	2.1
	Bias	4.8	0.5	12.9	89.2	4.5	1.8
	TEa*	7.5	3.0	3.5	12.5	3.0	4.0
	Sigma	7.4	3.0	2.5	9.8	2.7	3.1
	ΔSE	5.7	1.3	0.8	8.1	1.0	1.5

*Indicates the adjustment of the quality requirements according to CLIA 88 (see ref 17). ** Value of TEa indicated in the CLSI guide H26-A3. Abbreviations: CV%$_{MEAN}$: Average coefficient of variation; ΔSE: critical systematic error; TEa: quality requirement; SD: standard deviation; %CV: coefficient of variation.

Table 2. *Results of the second phase of quality assessment of the Landwind LW D3600 haematology analyzer. The CLSI EP15-A3 guide was used to determine and evaluate the sigma and ΔSE values during the 14 days of evaluation. The Quality Requirement indicated in CLIA'88 and CLSI have been considered for six parameters.*

Levels	Analysis	WBC ($\times 10^3$/μL)	RBC ($\times 10^6$/μL)	HB (g/dL)	PLT ($\times 10^3$/μL)	HCT (%)	MCV (fL)**
Low	SD	0.14	0.20	5.53	35.55	1.69	1.12
	Mean	1.9	2.4	52.8	108.1	16.8	71.0
	%CV	7.4	8.6	10.5	32.9	10.0	1.6
	Sigma	7.5	3.0	3.0	11.4	2.8	3.3
Medium	SD	0.66	0.37	13.87	22.19	3.51	1.14
	Mean	6.9	4.3	120.6	253.1	35.7	82.2
	%CV	9.5	8.6	11.5	8.8	9.8	1.4
	Sigma	7.4	3.0	2.3	10.0	2.6	3.2
High	SD	1.02	0.43	18.28	31.25	4.48	1.07
	Mean	16.6	5.2	163.4	505.2	47.8	91.6
	%CV	6.1	8.3	11.2	6.2	9.4	1.2
	Sigma	7.3	2.9	1.9	7.4	2.5	3.1
Total	%CV$_{MEAN}$	18.1	19.7	26.2	25.9	22.5	3.1
	Bias	1.7	0.9	34.0	65.3	8.6	2.6
	TEa*	7.5	3.0	3.5	12.5	3.0	4.0
	Sigma	7.4	3.0	2.2	10.0	2.6	3.2
	ΔSE	5.8	1.3	0.6	8.3	1.0	1.5

*Indicates the adjustment of the quality requirements according to CLIA 88 (see ref 17). ** Value of TEa indicated in the CLSI H26-A3 guide. Abbreviations: CV%MEAN: Average coefficient of variation; ΔSE: critical systematic error; TEa: quality requirement; SD: standard deviation; %CV: coefficient of variation.

The mean sigma overall of both phases was 4.7 considering the sum of all the parameters analyzed, all control levels for each phase, and the mean estimate using the three levels. The sigma averages for the white series was 7.4 (WBC), and for PLT was 9.9. For the erythroid series it was 3, 2.3, 2.6, and 3.1 for RBC, HB, PLT, HCT, and MCV, respectively.

The evaluation of the three cleaning/maintenance systems, shown significant differences among all the systems (p = 0.005). When the results of the quality evaluations were grouped according to the type of cleaning system, we found that the DRAIN system presented a sigma of 9.8 for PLT that differs from the other two systems (**Table 3**).

Table 3. *Quality assessment of Landwind LW D3600 haematological analyzer according to the types of daily maintenance (electrical, complete, and wash cleaning systems). The values of the sigma metric, Bias% and ΔSE according to the CLSI guide EP15-A3 have been determined. The Quality Requirement indicated in CLIA'88 and CLSI have been considered for six parameters.*

Maintenance System	Levels	Analysis	WBC ($\times 10^3$/µL)	RBC ($\times 10^6$/µL)	HB (g/dL)	PLT ($\times 10^3$/µL)	HCT (%)	MCV (fL)**
a) Electric cleaning (CAUTERANT)	Low	SD	0.11	0.16	5.31	36.93	1.37	1.19
		Mean	1.9	2.3	51.6	117.1	16.2	70.7
		%CV	5.8	6.9	10.3	31.5	8.4	1.7
	Medium	SD	0.52	0.30	12.27	22.79	2.87	1.12
		Mean	6.7	4.3	118.4	251.1	35.0	82.0
		%CV	7.7	6.9	10.4	9.1	8.2	1.4
	High	SD	0.75	0.36	16.85	26.40	3.79	1.00
		Mean	16.5	5.2	161.8	509.3	47.1	91.2
		%CV	4.5	6.9	10.4	5.2	8.0	1.1
	Total	%CV$_{MEAN}$	14.2	16.1	24.2	24.8	19.1	3.0
		Bias	1.3	0.7	30.9	61.5	7.1	2.5
		TEa*	7.5	3.0	3.5	12.5	3.0	4.0
		Sigma	7.4	3.0	2.2	10.0	2.6	3.2
		ΔSE	5.8	1.3	0.6	8.4	1.0	1.5
b) Complete cleaning (MAINTAIN)	Low	SD	0.13	0.21	5.89	37.94	1.73	1.04
		Mean	2.0	2.5	54.9	100.5	17.8	71.5
		%CV	6.5	8.4	10.7	37.7	9.7	1.4
	Medium	SD	0.79	0.45	16.49	19.01	4.25	1.27
		Mean	7.2	4.5	124.8	260.7	37.0	82.6
		%CV	11.1	10.2	13.2	7.3	11.5	1.5
	High	SD	1.28	0.53	21.44	35.32	5.46	1.12
		Mean	16.9	5.3	167.7	508.7	49.0	92.0
		%CV	7.6	10.0	12.8	6.9	11.1	1.2
	Total	%CV$_{MEAN}$	20.9	23.0	29.6	26.8	25.9	3.2
		Bias	2.1	1.1	39.9	67.0	10.3	2.7
		TEa*	7.5	3.0	3.5	12.5	3.0	4.0
		Sigma	7.4	3.0	2.2	10.0	2.6	3.2
		ΔSE	5.7	1.3	0.5	8.4	1.0	1.5
c) Wash cleaning (DRAIN)	Low	SD	0.05	0.10	2.04	17.56	0.76	0.68
		Mean	1.8	2.2	49.8	103.7	15.8	70.7
		%CV	3.1	4.4	4.1	16.9	4.8	1.0
	Medium	SD	0.12	0.10	3.13	21.65	0.88	0.41
		Mean	6.6	4.2	114.2	236.0	34.2	82.2
		%CV	1.8	2.3	2.7	9.2	2.6	0.5
	High	SD	0.61	0.18	7.21	26.29	1.90	0.71
		Mean	16.1	5.0	155.0	482.8	46.0	91.5
		%CV	3.8	3.6	4.7	5.4	4.1	0.8
	Total	%CV$_{MEAN}$	6.7	7.4	8.8	20.3	8.3	1.6
		Bias	0.7	0.3	11.0	53.8	3.0	1.3
		TEa*	7.5	3.0	3.5	12.5	3.0	4.0
		Sigma	7.4	3.0	2.2	9.8[‡]	2.6	3.2
		ΔSE	5.7	1.3	0.6	8.2	1.0	1.5

*Indicates the adjustment of the quality requirements according to CLIA 88 (see ref 17). ** Value of TEa indicated in the CLSI H26-A3 guide. We found a non-significant value among the maintenance systems (p = 0.363). Abbreviations: CV%$_{MEAN}$: Average coefficient of variation; ΔSE: critical systematic error; TEa: quality requirement; SD: standard deviation; %CV: coefficient of variation.

Of the variability evaluation by test our findings show that in the high-level control of WBC with DRAIN system presented values ≤1 DS, and that the MAINTAIN system improved the values keeping them close-to-the-standard average, as well as with the RBC values for all control levels. For HB, a heterogeneous behavior was found for each maintenance system, where with DRAIN system all the evaluation levels reported values ≥ 2 DS, the other two systems (CAUTERANT and MAINTAIN) had ≤1 DS.

For the HCT the DRAIN system showed values ≥1 DS for the Low and Normal control levels, and the other two systems (CAUTERANT and MAINTAIN) presented ≥1 DS values in the High-control level. The MCV evaluation showed that the CAUTERANT and DRAIN systems had values ≥1 DS for the Low-Level of control. The three maintenance systems had values ≥2 DS for the Low-Level of control in all the haematological parameters evaluated.

Figure 2 and **3** show the main rules of statistical quality control under the sigma metric and power charts. For the erythroid parameters we found a sigma level <4, where only MCV (Pfr = 0.6) and RBC (Pfr = 0.3) could be kept in the quality range the use of the multi-rule $1_{3s}/2_{2s}/R_{4s}/4_{1s}$, with 100% Ped, and 4 levels of controls. In the Power functional charts only MCV had access to the selection of Westgard rules (single-rule: $1_{2.5s}$ with 4 levels of control and 100% of Ped) with a Pfr of 0.5.

In addition, both PLT and WBC demonstrated high sigma values during the evaluation in all phases and each maintenance systems. If we consider the rule $1_{3.5s}$ of daily use for all the haematological parameters (based on the selection of control rules with WBC and/or PLT for its high sigma), in **Figure 3**, we propose how it would work HB and HCT.
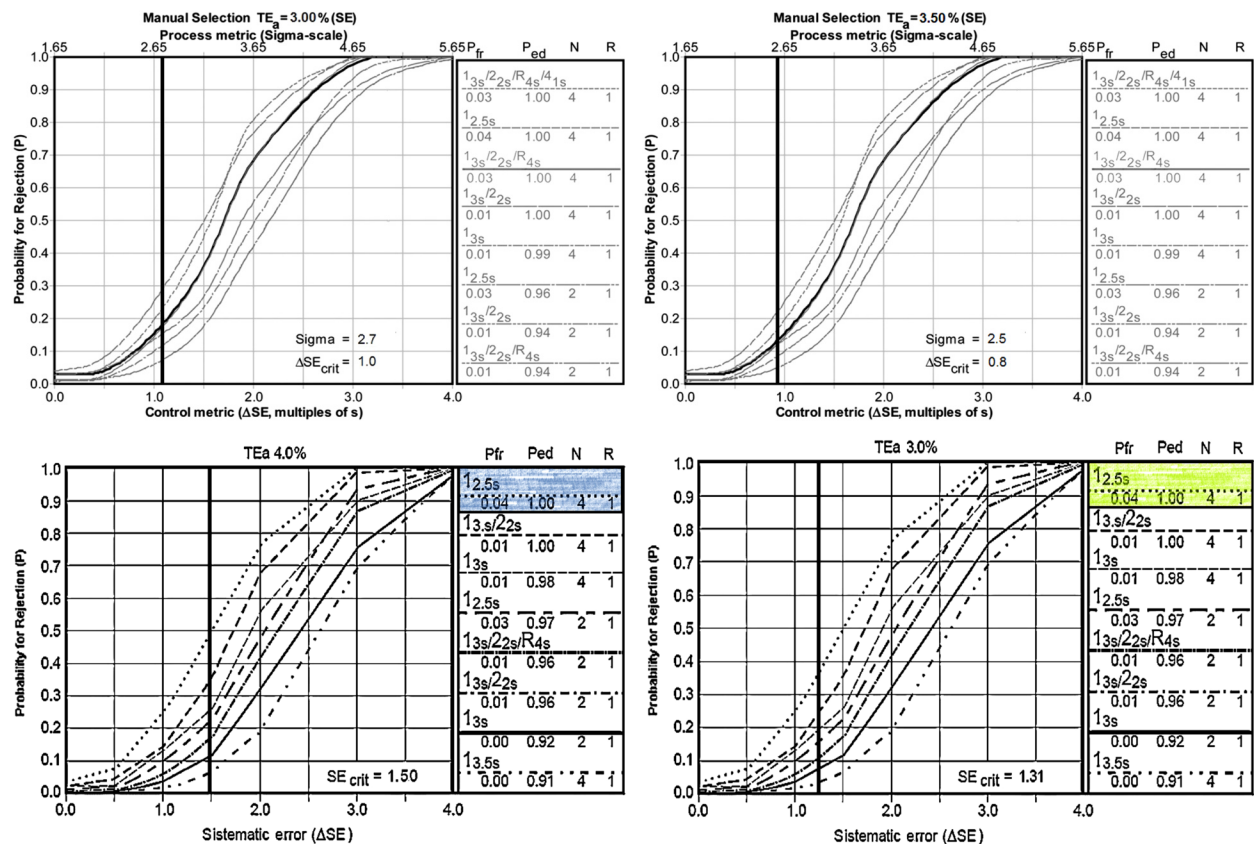

Fig 2. *Quality control procedures with sigma metrics (A and B) and Power functional chart (C and D). In both cases (A and B) none of the Westgard rules are applicable for statistical quality control (Probability of error detection -Ped- 0.90). In C and D were considered respectively 0.4 and 0.3 of Pfr for the selection of control rules (shaded box above-right of each)A. HCT (%) (First phase), B. HB (g/dL) (First phase), C. MCV (fL) (Second phase), D. RBC (×10⁶/ μL) (First phase). Abbreviations: HB: hemoglobin dosage, HCT: automated hematocrit calculated, MCV: mean cell volume, RBC: Red Blood Corpuscles.*
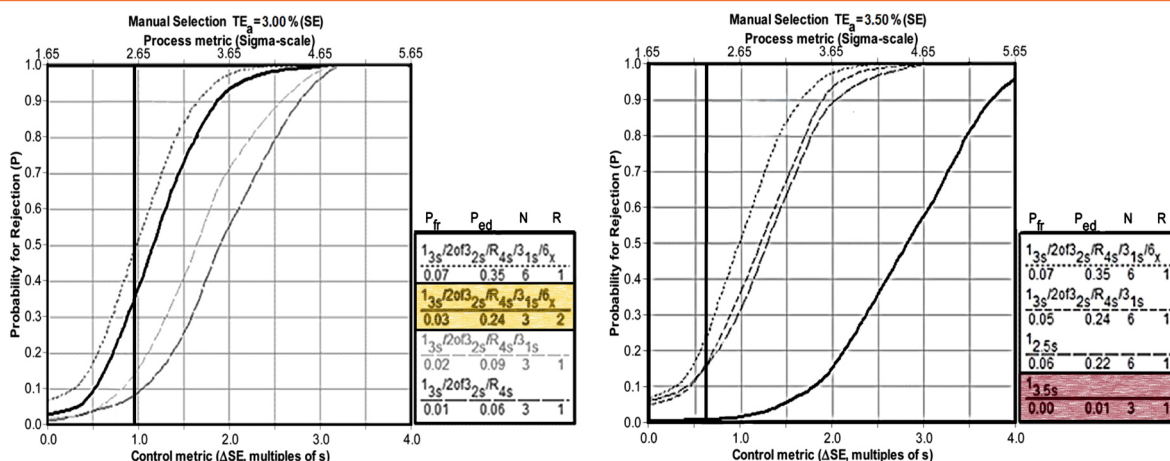
Fig 3. *Selection of the quality control procedure based on the $1_{3.5s}$ control rule established for WBC/PLT. For both cases, the control rules have been selected with a lower Prf and number of control levels (shaded boxes on the right side of each graph). Global rule for analysis $1_{3s}/2of3_{2s}/R_{4s}/3_{1s}/6_x$ with 3 levels of control. A. HCT (%), B. HB (g/dL) (both of the second phase). Abbreviations: HB: hemoglobin dosage, HCT: automated hematocrit calculated.*

Discussion

In this study of quality verification and application in the hematology laboratory, the analytical quality of the Landwind LW D3600 analyzer had a great sigma performance for WBC and PLT, and low performance for the erythroid parameters. These results improved with the system of daily preventive maintenance of DRAIN system showing low imprecision results during clinical practice.

In Peru, the Landwind LW D3600 hematology analyzer is widely used by health centers from level I to III, due to its low cost per test, to the facilities of the providers for its sale (per lending) and installation in the clinical laboratory, for being a semi-automated system, and for having an open-analysis-system that allows the use of hematological reagents, controls and calibrators according to the availability of each institution. However, and during the study period, no validation and / or verification studies have been found in the health care centers of Peru, under the conditions and biological variability of the users.

The selection of these quality specifications depends on the requirements of the laboratory, these specifications are described and recommended by different institutions such as the Spanish Society of Laboratory Medicine, CLIA, Tonks, Aspen, among others, and offer different levels of demand (based on the maximum allowed error) [19].

Our data show a desirable global performance (σ = 4.7) discordant with other studies of hematological evaluation with the sigma model [20-22]. This discrepancy may be due to the different selection and use of specifications that present more permissible or narrower "quality limits "as the case may be. We do not believe err if we consider the requirements indicated in the CLSI H26 guide to be recommendable, since it represents the quality guide for clinical laboratories based on long-term evaluations with high efficiency [18].

As in previous reports [20,21], we observed that in the Low-level control the imprecision values were outside the permissible range and therefore low levels of sigma were obtained, mainly in the biological erythroid parameters. The erythroid pathological estimate depends on the reliability of the laboratory results, and these in turn on their accuracy levels diagnose. For example, the MCV presented a low performance with two levels of control, which could interfere in the sigma and final inaccuracy result of the HCT (σ≥2.6), which is calculated using the MCV and RBC [23].

In addition, the PLT showed a σ≥10 despite a range of inaccuracy beyond the manufacturer limit. We consider that these characteristics can be similar to PDW, MPV, P-LCR, which serve, for example, as a key tool for the monitoring, rapid diagnosis and treatment of delayed renal graft function and kidney transplantation [24]. These result, therefore, are a permanent requirement for quality management systems. The global rule for

quality maintenance of the Landwind analyzer was $1_{3s}/2$of $3_{2s}/R_{4s}/3_{1s}/6_x$ with 3 levels of control, however, there probably are not enough rules to provide the necessary error detection.

For the quality control procedure for HB (Ped = 0.24) and HCT (Ped = 0.01), in practical terms, we can derive the Average Run Length estimation, obtaining respectively 4.16 and 100 analytical series to the error detection. This means that for HB more than 4 analytical series will be required before the detection of the problem for each suspected case of error, whilst for HCT the problems will not be detected within the analytical series where the problems occur.

When we compare our results with the database of the American College of Pathologists that provide five-commercial-brands data (Abbott, Horiba ABX, Bayer, Beckman and Sysmex) for 4 biological magnitudes analyzed, we found that for RBC, all the analyzers from Abbott, Bayer and Sysmex had higher sigma levels ($\sigma \geq 3.33$), and systems such as Horiba ABX and the Beckman Coulter LH500 and Coulter HMX had identical sigma levels ($\sigma = 3$). For WBC ($\sigma = 7.4$) all the equipment analyzed by Abott, Sysmex, and the Bayer Advia 120 and Advia 2120 presented lower sigma levels than reported in this study ($\sigma \leq 6.25$), whilst Horiba ABX, Beckman and Bayer Advia 70 had equal or higher levels. For HB, all the equipment evaluated showed better sigma levels ($\sigma \geq 2.93$), conversely to what we observed with PLT where all the values of the were below our report ($\sigma = 9.9$), and only the Bayer Advia 120 analyzer showed a close value ($\sigma = 8.53$) [23.25,26].

Our two-phase manual evaluation scheme allowed us to verify the performance of the analysis system and subsequently its evaluation based on previous results for sigma monitoring in haematology. Thus, we emphasize the importance of *a priori* day-by-day preventive maintenance to the analysis. The MAINTAIN system demonstrated an adequate daily functioning in the variability of quality over the manufacturer's ranges (**Table 3**), therefore, we recommend this maintenance system for routine use.

Our results should be interpreted under the following limitations. First, we only analyzed a batch of Myt-3D hematological control MYTHIC 18 (lot B0816). After the ninth day of the study we found that the values of all the hematological parameters were within the manufacturer's range and was established as a new mean, however, according to the CLSI guide H26-A3, neither an historical% CV nor the complete batch was established [18]. Second, we did not compare the results with external quality control or with other automated hematological systems such as SYSMEX, Beckman Coulter, or Abbott used in several national hospitals and private clinics in Peru [4]. Finally, as far as possible, we store and use the control reagents according to the manufacturer's recommendations, however faults in the conservation or stability could have occurred by the commercial distributors of the brand; these could be cause of erroneous results [14]. Despite these limitations, this study developed for the first time an evaluation of the performance and quality of haematological analyzes related to the daily maintenance of the Landwind LW D3600 analyzer at Class II Health Center.

In summary, the daily evaluation under the sigma metric allowed to verify the quality of the Landwind LW D3600 analyzer demonstrating a heterogeneous performance. The quality control procedures proposed here illustrate how the verification and analytical evaluation could be carried out in the hematological laboratory that detects errors that could affect the medical decision levels of each parameter.

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