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COMPARING THE ACCURACY OF THE POINT-OF-CARE BLOOD COUNT WITH A CONVENTIONAL LABORATORY ANALYSIS METHOD

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Abstract: Complete blood count is one of the most commonly requested tests and is highly relevant for diagnosis, treatment and clinical monitoring. However, the conventional analysis method requires collection by venipuncture and requires more time, as well as specialized equipment and personnel. Point-of-care (POC) technology has made great advances and revolutionized diagnostic methods, presenting diverse applications and the possibility of faster, more accessible and minimally invasive tests. The objective of this study is to compare the accuracy of POC technology for blood count analysis, using only a drop of blood, with the conventional analysis method. Adult patients (over 18 years old) from the Canoas Emergency Hospital who underwent complete blood count were selected. The POC device for this study was the RevDx system developed by EfA Technologies and the results obtained were compared with those generated by the automated hematology analyzer model Pentra XL 80. To assess the agreement and accuracy between the two methods, Pearson's correlation coefficient was used. A high level of agreement was observed between the two methods, especially for parameters such as WBC, HGB and NEU_%, indicating that RevDx performs well compared to the conventional method for these parameters. The parameters HGB and NEU_abs presented a Bias close to zero, indicating that there is no significant systematic difference between the two methods. The results of this study demonstrated high agreement between CBC measurements obtained by the traditional method (Pentra XL 80) and by the RevDx device through strong correlations that indicate a significant accuracy of the POC technology. This study validates the effectiveness of RevDx and highlights the importance of implementing innovative technologies at the point of care to optimize healthcare.

INTRODUCTION

In recent years, advances in point-of-care (POC) technology have revolutionized the field of clinical diagnostics, offering the possibility of rapid, affordable, and minimally invasive tests[1,2]. Among the various applications of POC technology, laboratory analysis using a drop of blood presents a significant leap in the efficiency of patient care[3]. The complete blood count (CBC), is the most commonly ordered test and an essential tool in clinical medicine used to assess health status, diagnose diseases, and monitor responses to treatment[4]. CBC usually requires blood collection by venipuncture[5]. This conventional method involves more invasive procedures, can be time-consuming, and often requires specialized equipment and personnel. POC technology for blood analysis aims to address these challenges by enabling rapid examinations performed anywhere with minimal discomfort and immediate results. This innovation has the potential to transform patient care, particularly in remote or resource-constrained settings where laboratory facilities are not available. However, despite its advantages, the accuracy and concordance of laboratory test analyses performed by POC technology continue to be studied for validation and adoption in clinical practice[6].

OBJECTIVES

This study aims to compare the accuracy of POC technology for CBC analysis, using a drop of blood, with the conventional method of venous blood collection. Specifically, we sought to determine the concordance of the results between these two approaches to validate the use of CBC analysis in clinical practice. By evaluating the reliability and accuracy of POC technology, this research contributes to the body of evidence needed to support its integration into routine clinical diagnostics and patient care strategies. We evaluate the concordance between the results obtained by the traditionally performed venipuncture with the results obtained with the use of a new POC technology. Specifically, we sought to verify that the POC method can identify the same hematological alterations found by the traditional method. In addition, we assessed the feasibility and efficiency of the POC method in terms of processing time and costs. In this study, the following parameters will be analyzed:

- White blood cells (WBC)
- Hemoglobin (HGB)
- Hematocrit (HCT)
- Red Blood Cells (RBC)
- Breakdown of 5 types of white blood cells in percentage and absolute numbers:

Neutrophils (NEU), Monocytes (MONO), Lymphocytes (LYMPH), Eosinophils (EOS) and Basophils (Baso).

MATERIAL AND METHODS

SAMPLE SELECTION

Adult patients (over 18 years of age) undergoing a complete blood count as part of their clinical evaluation. The participants were selected consecutively during the collection of tests at the Hospital de Pronto Socorro de Canoas (HPSC). This study was evaluated and approved by the Research Ethics Committee of the HPSC.

Inclusion criteria:

- HGB: Range: greater than 7 [g/dl].
- WBC: Interval: between 3500 and 15000 / uL
- NEU, LYMPH, MONO Intervals:
- NEUT between 30% and 90%.
- LYMPHS between 5% and 70%.
- MONO greater than 1.5%,

Exclusion Criteria:

- Large Immature Cells (LIC) > 4% of the total leukocyte count.
- Samples that raised critical warnings and flags in the Pentra XL 80 were excluded due to unreliable results of the Pentra.
- Samples with a significant deviation between the two reference tests (Pentra XL 80 test before RevDx sampling vs Pentra XL 80 test after RevDx sampling)

During the evaluation, each blood sample was tested with the laboratory analysis equipment available at the hospital (**Pentra XL 80),** then with the Point of Care (**RevDx Device)**, and then again with the laboratory analysis equipment (Pentra XL 80). The second Pentra XL 80 test was used as a reference value for the statistical analysis. As part of the RevDx equipment chip preparation procedure, a manual (visual) inspection was performed prior to loading it into the device and after the test was finished to validate that the loading was carried out correctly.

According to the RevDx manual, specimens suspected to contain nucleated red blood cells may skew the results of the analysis. Therefore, as a guideline, specimens with Pentra XL 80 flags that might indicate abnormal values of nucleated red blood cells were excluded from the study.

BLOOD COLLECTION PROCEDURES

The collection method was peripheral venipuncture containing an adequate volume of blood for the completion of the complete blood count. The sample for the Point of Care (POC) test was a drop of blood (50 µL) extracted by the pipetting technique from the tube itself collected for the routine test.

POINT OF CARE TECHNOLOGY

The POC device for this study was the RevDx system developed by EfA Technologies (**Figure 1**). RevDx is a portable laboratory equipment that incorporates multi-channel technology, focused on complete blood counts using a drop of blood. The sample is placed in a microfluidic cartridge and inserted into the RevDx device to identify and count different types of blood cells.

The process involves automatic optical-mechanical microscopy, which is battery-operated and connectivity-independent, making it suitable for use in remote or resource-limited environments. The system uses image processing and AI software to enable accurate blood counts, including hemoglobin levels and differential counts, offering results in just a few minutes.

Figure 1. Point of Care device and test cartridge to complete the CBC analysis.

LABORATORY ANALYSIS

Blood samples collected by the traditional method were processed by the clinical laboratory using the automated hematology analyzer model Pentra XL 80 (**Figure 2**). The results were recorded. The Point of Care method was analyzed by RevDX using a drop of blood (50 µL) extracted from the main sample.

The objective of this study was to perform a comparative analysis between blood count results obtained by traditional laboratory methods and those acquired from RevDX technology.

Data blinding and privacy were ensured through unique records for the study with sequential collection numbers.

Figure 2. Pentra XL 80 in the HPSC Hematology Laboratory.

STATISTICAL ANALYSIS

The results obtained by the two methods were compared using Pearson's correlation coefficient to evaluate the diagnostic accuracy and concordance between the two methods, providing a quantitative measure of the strength and direction of the relationship. Another perspective on the same result could be obtained by, Bland-Altman plots. This analysis offers a visual assessment of the agreement with the gold-standard but also visualizes the confidence interval of the deviation from it.

RESULTS

Table I provides a statistical analysis comparing the results of the CBC measurements. The table includes a Pearson's correlation coefficient that indicates the linear correlation between the methods – values closer to 1 suggest a stronger correlation. The Mean Absolute Error (MAE) and the Bias are used to determine the magnitude of the mean error and the systematic deviation between the measurements of the two methods, respectively. Table 2 shows the proportion of results for HGB, #NEU, and WBC within *1 g/dl, 500 cell/m, 1000 cell/ml* (accordingly) of the gold standard. In general, lower MAE and a bias close to zero are preferable, as they indicate greater accuracy and less systematic deviation. The slope and the intercept in table 1, provided with 95% confidence intervals (CI), help to understand the relationship between the measurements obtained by the two methods. A slope close to 1 and an intercept close to 0 indicate that the methods have very similar readings.

HGB	0.21
NEU	0.55
WBC	0.44

Table 2: shows the proportion of samples where the differences between Penta and RevDx in HGB, #NEU, and WBC exceed the range of 1 g/dl, 500 cell/m, 1000 cell/ml (accordingly).

The Bland-Altman graph series in **Figure 3** compares the measurements of the different blood parameters obtained from the Pentra XL 80 and RevDx systems. Each chart represents a different parameter, such as white blood cells WBC, RBC, HGB, etc.

In Bland-Altman plots, the percentage differences between the Pentra and RevDx readings (y-axis) are plotted against the measurements of the gold-standard method-the Pentra (x-axis). The center line in each

Parameter	n	Pearson's correlation	MAE [units of measurement]	Bias [units measured]	slope (95%CI)	interception (95%CI)
WBC	100	0.89	0.98	-0.03	0.93 (0.84,1.03)	0.61 (-0.31,1.54)
RBC	100	0.85	0.34	0.24	0.86 (0.75,0.97)	0.80 (0.34,1.25)
HGB	100	0.91	0.64	-0.13	0.95 (0.86,1.03)	0.54 (-0.54,1.63)
HCT	100	0.89	2.44	1.67	0.96 (0.86,1.06)	3.12 (-0.69,6.93)
NEU_%	98	0.93	3.04	1.07	0.99 (0.91,1.07)	1.68 (-4.04,7.41)
LYM_%	100	0.89	3.19	-1.75	0.85 (0.76,0.94)	1.30 (-0.67,3.26)
MON_%	99	0.74	1.70	-0.57	0.92 (0.75,1.09)	0.17 (-1.43,1.78)
EOS_%	99	0.95	0.80	-0.62	0.96 (0.89,1.02)	-0.52 (-0.73,-0.31)
BAS_%	100	0.09	0.25	0.21	0.18 (-0.23,0.58)	0.30 (0.23,0.38)
NEU_abs	98	0.93	0.77	0.10	0.99 (0.91,1.08)	0.15 (-0.43,0.74)
LYM_abs	100	0.83	0.34	-0.15	0.85 (0.74,0.97)	0.11 (-0.11,0.34)
MON_abs	99	0.80	0.16	-0.07	0.78 (0.66,0.90)	0.11 (0.01,0.22)
EOS_abs	99	0.77	0.08	-0.06	0.74 (0.61,0.87)	-0.01 (-0.04,0.02)
BAS_abs	100	0.13	0.02	0.02	0.18 (-0.10,0.46)	0.03 (0.02,0.03)

Table 1: shows the statistical analysis of CBC measurements on Pentra 80 vs RevDx results.

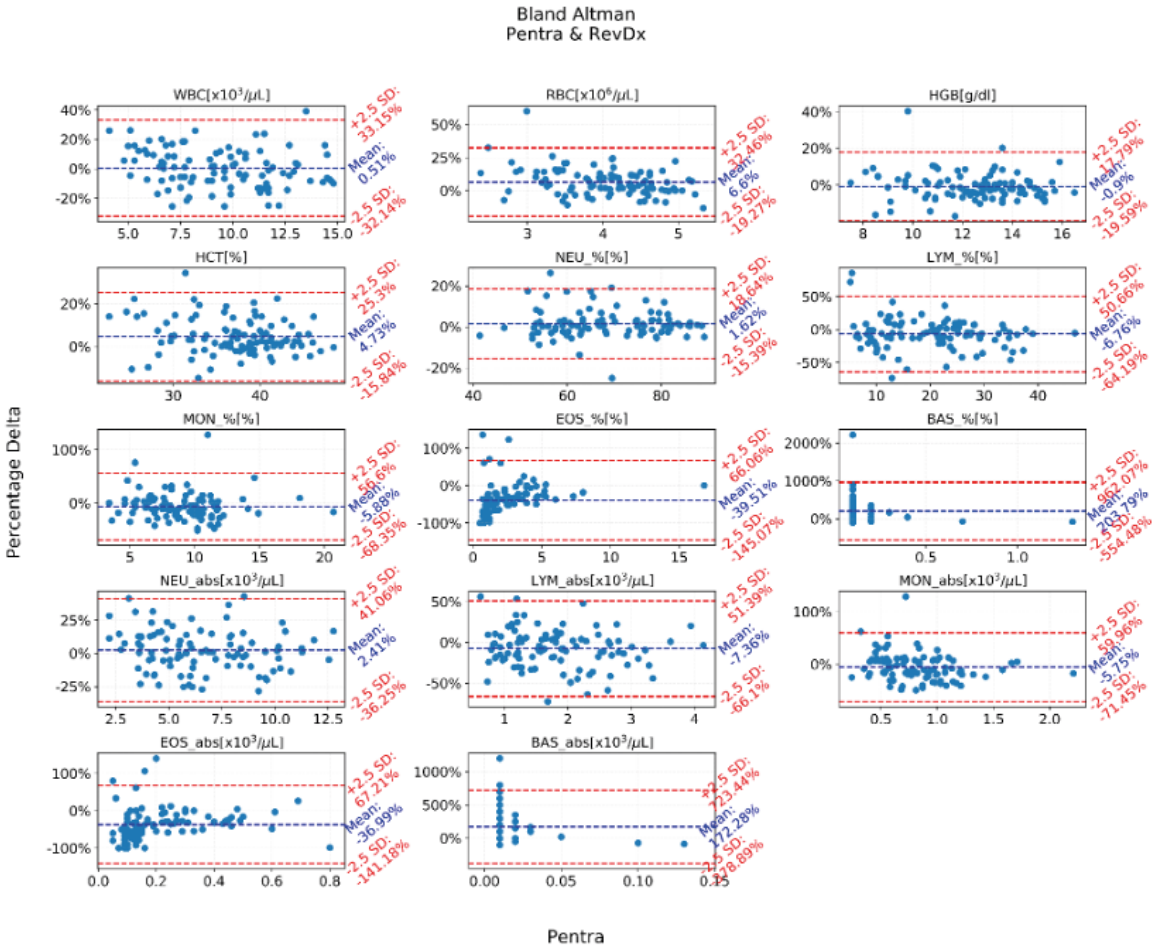


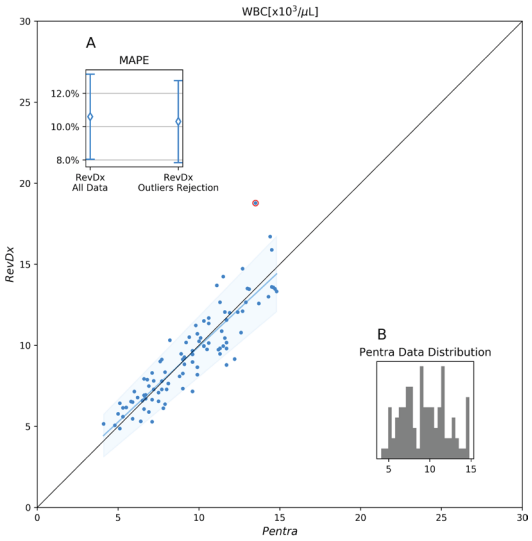
Figure 3. Bland-Altman graphs comparing measurements of different blood parameters.

graph represents the mean difference, and the top and bottom lines represent the limits of agreement (±2.5 standard deviations), indicating where most of the expected results should be. Points outside these lines are considered outliers. This is presented for each parameter within the range specified for percentage analysis.

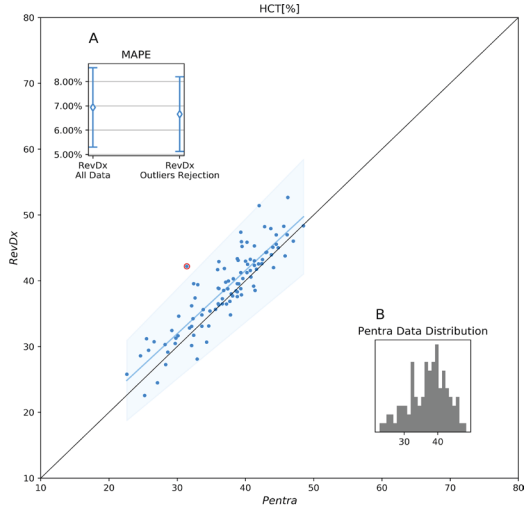
This graphical analysis is valuable to assess the agreement between RevDx and Pentra XL 80 system on different blood parameters.

In graphics **1, 2,** and **3**, we provide the results for the WBC, Hematocrit, and HGB, respectively. We compare the results obtained by the **RevDx** versus the results obtained by the **Pentra XL 80** equipment. The X-axis represents the values of the Pentra XL 80 (gold standard), and the Y-axis shows the RevDx handset score. The blue line shows the regression line between the Pentra and RevDx results, and the shaded area represents the 95% confidence interval of the regression*; the black line shows the identity line. Subjects marked as outliers (2.5σ) are marked with red circles. Subplot 'A' shows the MAPE (Mean Absolute Percentage Error) with a confidence interval (95%) of all data and the remaining data after excluding outliers. Subplot 'B' shows the distribution of the data evaluated by the Pentra device.

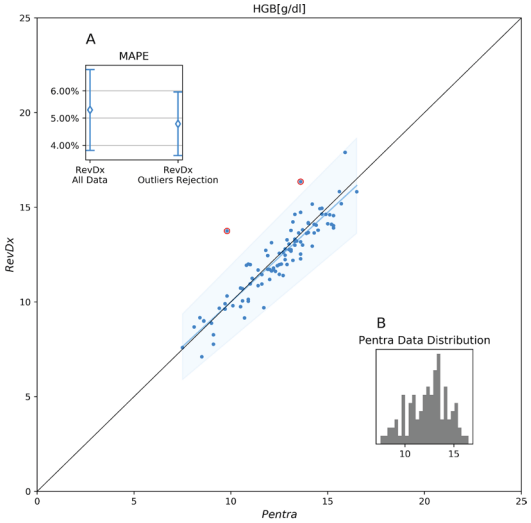
* The boundaries of the shaded area are (1) the upper boundary of the slope together with the upper limit of the intercept (with a 95% confidence interval each) (2) the lower limit of the slope together with the lower limit of the intercept (with a 95% confidence interval each)



Graph 1. Leukocyte Cell (WBC) results by the the Pentra X RevDx



Graph 2. Pentra Hematocrit X RevDx



Graph 3. Pentra Hemoglobin X RevDx

DISCUSSION

Pearson's correlation coefficients indicated a high level of agreement between the two methods, especially for parameters such as leukocytes (WBC), hemoglobin (HGB), and neutrophil percentage (NEU_%). These strong correlations (0.89, 0.91, and 0.93, respectively) suggest that the RevDx device performs well compared to the conventional method for these parameters. The MAE and Bias values for most parameters were low, pointing to the ability of RevDx to reproduce Pentra XL 80 results with minimal systematic errors.

In particular, the HGB and NEU_abs parameters showed a bias close to zero, indicating no significant systematic difference between the measurements of the two devices. When considering the Mean Absolute Percent Error (MAPE) before and after excluding the outliers group, it was observed that for several parameters, such as leukocytes (WBC), erythrocytes (RBC), and hemoglobin (HGB), the errors remained consistently low (ranging between approximately 5-10%), which demonstrates a good correlation between RevDx and standard results in these measurements. However, for parameters such as the percentage of Basophils (BAS_%), the MAPE was remarkably high even after excluding the outliers group, reaching more than 195%. As WBC, RBC, and HGB measurements are clinically important, while basophil percentage is used only rarely, the RevDx system would probably be useful in clinical practice. The implementation of Point of Care technology in laboratory tests can significantly reshape clinical practice in various healthcare settings[7]. In remote areas, where access to large-scale laboratories is limited, POC devices provide critical information that can lead to immediate decision-making and early initiation of treatment. This can be particularly transformative in infectious disease management, chronic disease monitoring, and emergency care. The results of the RevDx system can be integrated with digital health records and telemedicine platforms for a more agile and responsive healthcare ecosystem.

CONCLUSION

This study demonstrated high agreement between the blood count measurements obtained by the traditional laboratory method (Pentra XL 80) and by the RevDx device. Critical parameters such as leukocytes, hematocrit, and hemoglobin showed strong correlations between traditional and POC testing, demonstrating the accuracy of the POC technology.

Although some parameters, such as the percentage of basophils, presented higher errors, most of the parameters analyzed showed bias close to zero, indicating the absence of significant systematic differences. The results suggest that for many clinical cases RevDx is a viable and efficient alternative for laboratory testing, especially in remote or resource-constrained settings, providing rapid and accurate diagnosis. Implementing POC technology can reduce operational costs[8], improve access to healthcare, and enable faster clinical decisions. In chronic and infectious disease contexts, the use of POC devices can lead to more efficient monitoring and timely therapeutic interventions, improving clinical outcomes and patients' quality of life[9,10].

This study validates the effectiveness of RevDx and highlights the importance of adopting innovative technologies at the point of care to optimize healthcare.

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