Evaluation of Scopio Labs X100 Full Field PBS: The first high-resolution full field viewing of peripheral blood specimens combined with artificial intelligence-based morphological analysis

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Abstract

Background: Current digital cell imaging systems perform peripheral blood smear (PBS) analysis in limited regions of the PBS and require the support of manual microscopy without achieving full digital microscopy. We report a multicenter study that validated the Scopio Labs X100 Full Field PBS, a novel digital imaging system that utilizes a full field view approach for cell recognition and classification, in a decision support system mode.

Methods: We analyzed 335 normal and 310 abnormal PBS from patients with various clinical conditions and compared the performance of Scopio’s Full Field PBS as the test method, with manual PBS analysis as the reference method. Deming regression analysis was utilized for comparisons of WBC and platelet estimates. Measurements of WBC and platelet estimation accuracy along with the agreement on RBC morphology evaluation were performed. Reproducibility and repeatability (R&R) of the system were also evaluated.

Results: Scopio’s Full Field PBS WBC accuracy was evaluated with an efficiency of 96.29%, sensitivity of 87.86%, and specificity of 97.62%. The agreement between the test and reference method for RBC morphology reached 99.77%, and the accuracy for platelet estimation resulted in an efficiency of 94.89%, sensitivity of 90.00%, and specificity of 96.28%, with successful R&R tests. The system enabled a comprehensive review of full field PBS as shown in representative samples.

Conclusions: Scopio’s Full Field PBS showed a high degree of correlation of all tested parameters with manual microscopy. The novel full field view of specimens facilitates the long-expected disengagement between the digital application and the manual microscope.

KEYWORDS
Artificial Intelligence, blood smear, laboratory automation, morphology
1 | INTRODUCTION

Complete blood count (CBC) with peripheral blood smear (PBS) is a rapid common test that serves as a screening tool offering insights into patients’ clinical conditions and guiding further laboratory workup. Despite the good performance of CBC analyzers, their limited capacity to identify morphological variations and abnormalities of blood cellular components led to the establishment of a set of rules to trigger manual blood smear review following the outcome of CBC tests that is specific for each hematology laboratory.

The need to improve and standardize white blood cell (WBC), red blood cell (RBC), and platelet recognition has led to the development of several digital cell imaging systems that utilize various algorithms and methods to automate PBS image analysis, including image segmentation, feature extraction and selection, and pattern classification. To date, a single vendor predominates morphological digital analyzers in hematology laboratories worldwide. While current digital image analyzers are constantly improving and expanding, the main drawback of this field is that only limited fields of view (FOV) from the PBS are analyzed. However, a single vendor predominates morphological digital analyzers in hematology laboratories worldwide. While current digital image analyzers are constantly improving and expanding, the main drawback is that only limited fields of view (FOV) from the PBS are available for review. As a mitigation, many of the digitally analyzed samples are also manually reviewed under a microscope, specifically those that contain cellular abnormalities, as detailed in the ICSH recommendations. Hence, the sometimes-redundant triangle of the PBS, the digital image analyzer, and the manual microscope cannot easily be breached utilizing current technologies.

Our multicenter study evaluated and validated the FDA cleared Scopio Labs X100 Full Field PBS system (Scopio’s Full Field PBS), a novel digital PBS morphological analyzer with full field specimen view as described in Supplementary 1. We analyzed 645 peripheral blood specimens, of which 335 were normal CBC and 310 were abnormal CBC collected from patients with various infectious or neoplastic conditions and compared the WBC differential, RBC morphology evaluation, and platelet estimation performance by the Scopio’s Full Field PBS, with traditional manual PBS analysis performed by experienced medical technologists according to the Clinical and Laboratory Standards Institute H20, 2nd addition (H20-A2). Here, we report a high degree of correlation between the two methods among the WBC classes, RBC morphology evaluation, and platelet estimation, as well as repeatability and reproducibility. In addition, we include representative full field PBS scans for evaluation of the capacity of this novel approach.

2 | MATERIAL AND METHODS

2.1 | Scopio labs X100 system

Scopio Labs X100 system is manufactured by Scopio Labs, Tel Aviv, Israel. The system is operated by a browser-based application, namely, the application does not require specific software installed, and may be accessed from any workstation running a browser, inside the secure medical facility network or securely connected to it remotely. The system is based on a computational photography approach, where a series of low-resolution full field images of the specimen are acquired by low power/wide field objective, and reconstructed into a high-resolution full field image based on a physical model (Supplementary 1A). The system includes automated platelet location and pre-estimation, and WBC pre-classification by artificial intelligence (AI) based tools into the following three groups: 1) main WBC classes—neutrophils (including segmented and bands forms), lymphocytes, monocytes, eosinophils, basophils; 2) other WBC classes—immature myeloid cells (promyelocytes, metamyelocytes and myelocytes), blast cells, lymphocyte variant forms, plasma cells; 3) non-WBC classes: nucleated red blood cells and smudge cells. Both WBC and platelet pre-classifications operate as a decision support system (DSS), requiring the operator to review the pre-classified data generated by the system, approve, or correct it. So far, DSS is the only mode cleared by the FDA for such analyzers.

2.2 | Patients and samples

Three clinical sites participated in the multicenter study. These sites included Brigham and Women’s Hospital (BWH), designated site #1; the Hospital of the University of Pennsylvania (HUP), designated site #2; and Tel-Aviv Sourasky Medical Center (TASMC), designated site #3. The study was approved by the corresponding local Institutional Review Boards according to the declaration of the Helsinki accord. The study design was based on the CLSI H20-A2 guidelines.

Specimens were collected and analyzed according to various conditions detailed in Table 1, resulting in a total sample size of 645 specimens. Six slides were prepared from each specimen. The clinically abnormal specimens were collected from patients according to distinct clinical categories, as specified in the CLSI H20-A2. The distribution of samples across sites is shown in Table 1, and the demographics of the patients sampled are summarized in Supplementary 2.

2.3 | Sample preparation

The method of sample preparation depended on site protocols and differed slightly for each site. At site #1, specimens were collected into a spray-coated K2 EDTA 3.6 mL vacuum tube (BD Vacutainer). PBS were prepared, within four hours and at room temperature, by the Sysmex SP-10 which is a fully automated hematology slide preparation and staining system, on glass slides (Micro Slides MS-101; Pre-cleaned, Frosted, Grounded edges. Sysmex America, Inc).

At site #2, specimens were collected into a spray-coated K2 EDTA 3.6 mL vacuum tube (BD Vacutainer). PBS were prepared, within four hours and at room temperature, by the Beckman Coulter Unicell DxH Slidemaker Stainer (Brea, CA, USA), on glass slides (DxH Slides, Beckman Coulter).

At site #3, specimens were collected into a spray-dried K3 EDTA 3.6 mL vacuum tube (Greiner). PBS were prepared, within four hours and...
and at room temperature, by Beckman Coulter Slide Maker Stainer, on glass slides (SP-Slides, Sysmex). Specific staining protocols and sample preparations are detailed in Supplementary 3.

2.4 | PBS analysis area

Scopio’s Full Field PBS locates an optimal analysis area for each PBS to include the monolayer area as well as the feathered edge (Supplementary 1D). On average, the monolayer part of the scan is 0.38 cm², equivalent to 1000 high power fields (100X magnification). The adaptive scan feature contributed to a robust morphological analysis of short and long smears. No restrictions were applied on the analysis area for the manual review.

2.5 | PBS evaluation

Scopio’s Full Field PBS performs WBC analysis by an artificial intelligence-based classifier, in a decision support system (DSS) mode. A total of 645 specimens were analyzed for WBC differentials, RBC morphology and platelets estimation by two independent operators, at three sites, using Scopio’s Full Field PBS (test arm) and manual microscopy (reference arm). All six operators that participated in the study were qualified and certified to perform PBS morphological analysis by their respective site requirements. In addition, each site had an arbitrator in case of disagreement between the two operators in the reference arm only.

200-WBC differentials were evaluated as described in the statistical analysis section. If less than 200 WBC were available for analysis in one PBS (e.g., in the cases of leukopenia), additional slides from the same specimen were analyzed. As a DSS, Scopio’s Full Field PBS results for the WBC differentials were approved (or modified where required) by the operators (Supplementary 1). In the reference arm, the operators performed a manual WBC differential using a manual microscope.

The platelet estimation was derived by automatically locating and counting platelets in 10 FOVs (Supplementary 1E), and multiplying the total count by a constant factor specific to each center and method. As a DSS, platelet detections were approved (or modified where required) by the operators. For the reference method, the operators manually counted platelets in 10 FOVs and calculated a platelet estimation.

Twenty-two parameters of RBC morphology were evaluated by the operators (Supplementary 4). In the test arm, the operators reviewed the digitally scanned PBS with an overlaid grid, with each grid cell proportionally representing a single high-powered manual microscope FOV. For the reference method, the operators manually evaluated the RBC morphology.

2.6 | Repeatability

Following CLSI’s EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures, 3rd Edition (CLSI’s EP05-A3), standard-ardized “20 × 2 × 2” (20 days, 2 runs, 2 replicas) repeatability experiment was conducted for 15 test samples (8 normal, 7 abnormal)
which were randomly selected from within each clinical group. For each test sample, WBC pre-classification and platelet estimation results were analyzed with a two-way nested ANOVA, and standard deviation (SD) estimates with 95% confidence interval (CI) for the repeatability, between-run (within-day), between-day, and within-laboratory variance components were calculated.

### 2.7 Reproducibility

Following CLSI’s EP05-A3, a standardized “3 × 5 × 5” (3 devices, 5 days, 5 replicas) reproducibility experiment was conducted for 10 test samples (5 normal and 5 abnormal), which were randomly selected from within each clinical group. For each test sample, WBC pre-classification and platelet estimation results were analyzed with a two-way nested ANOVA, and SD estimates with 95% CI for the between-day (within-site), between-site, within-laboratory variance, and reproducibility components were calculated.

### 2.8 Statistical analyses

To account for operator-related differences between the test and reference methods, the CLSI H20-A2 technique of averaging the two operators’ measurements in the reference arm and the test arm was employed, with a complementary bootstrap method using operator’s individual data (ie, without averaging two operators’ measurements). These two statistical techniques, that yielded comparable results, were used with the Deming regression analysis for WBC and platelet estimates, calculations of efficiency (agreement), sensitivity and specificity of WBC abnormality grading and platelet estimations.

Deming regression analysis was performed on WBC differential results for neutrophils, lymphocytes, monocytes and eosinophils, and platelet estimates, with a complementary Bland-Altman analysis for method bias.

Following the CLSI H20-A2 guidance, for accuracy measurements in terms of efficiency (agreement), sensitivity and specificity of WBC abnormality grading, a distributional WBC group and a morphological WBC group were defined. The distributional WBC groups and the morphological WBC groups are detailed in Table 2. In both reference and test methods, WBC cell types with a count outside their defined normal ranges were marked as abnormal. Sequentially, each result from the test arm was given a label of true negative (TN), when no abnormality was detected in neither the test nor reference arm, true positive (TP) when an abnormality was detected in both the test arm and reference arm, false negative (FN) when no abnormality was detected in the test arm, but was detected in the reference arm, or false positive (FP), when an abnormality was detected in the test arm, but not in the reference arm. The TP, TN, FP, and FN values were summarized for all specimens, by groups, and efficiency, sensitivity, and specificity were calculated.

Platelet estimation accuracy measurements for efficiency (agreement), sensitivity, and specificity calculations were conducted similar to the WBC groups.

For the RBC analysis, 22 RBC characteristics were subdivided into 5 groups: color (chromasia), shape, size, inclusions, and arrangement (Supplementary 4). A four-by-four contingency table for each RBC group was calculated by summing all the grades given (0, +1, +2, +3) in the two methods, including results from both operators, and overall agreement between grades given in both methods was measured.

### 3 RESULTS

The correlation coefficients for neutrophils, lymphocytes, monocytes and eosinophils, were 0.98, 0.96, 0.95, and 0.98, respectively; the slope values of 1, 0.99, 0.94, and 0.89, respectively, and the intercept values of 0.39, −0.51, −0.15, and −0.004, respectively (Figure 1A). A low number of basophils (up to 5%) did not allow for a meaningful statistical analysis (data not shown). Additionally, a Bland-Altman analysis was performed on the WBC differentials and demonstrated no test method bias (Supplementary 5). Normal WBC reference ranges were calculated based on 335 normal CBC samples (Table 1). The measurements of the major WBCs normal ranges are shown in Table 2. The normal ranges were comparable between the two methods and between the three sites. The accuracy of the morphological abnormalities, distributional abnormalities, and total accuracy were 96.82%, 95.75%, and 96.29% (with 95% confidence intervals of 96.12% to 97.43%, 94.95% to 96.46%, and 95.77% to 96.76%), respectively. The sensitivity of the same groups was 85.46%, 88.83%, and 87.86% (with intervals of 80.19% to 89.78%, 85.94% to 91.31%, and 85.38% to 90.06%), respectively. The specificity of the same groups was 97.79%, 97.43%, and 97.62% (with intervals of 97.16% to 98.31%, 96.70% to 98.03%, and 97.16% to 98.02%), respectively. The results above are after the corrections/ approvals by the operators in the DSS mode. The performance of the pre-classified outcome and its improvement by the operators (the DSS stage) are detailed in Supplementary 6.

RBC morphology evaluation results are shown in Table 3. The agreement of the RBC groups (color, shape, size, inclusions, arrangement and overall) was 99.49%, 99.77%, 99.61%, 100.00%, 96.65%, and 99.77% (with 95% confidence intervals of 99.14% to 99.73%, 99.68% to 99.84%, 99.36% to 99.78%, 99.93% to 100.00%, 95.52% to 97.57% and 99.71% to 99.83%), respectively, with no statistical significance between the sites.

For platelets estimations, the slope, correlation, and intercept between the test and reference methods were 1.03, 0.94, and −10.31, respectively, and between the test method and CBC were 0.998, 0.91, and −20.83, respectively (Figure 1B). The comparison between the test and reference method resulted in an accuracy of 94.89%, sensitivity of 90.00%, and specificity of 96.28% (with 95% confidence intervals of 92.78% to 96.53%, 83.51% to 94.57%, and 94.11% to 97.82%, respectively). A Bland-Altman analysis was
performed on the platelet estimations and demonstrated no bias between the test and reference methods (Supplementary 7).

The repeatability and reproducibility study supported high levels of repeatability and reproducibility regarding both WBC and platelets measurements of the Scopio’s Full Field PBS. A representative layout for the repeatability measurement of a normal sample is shown in Figure 2A. Standard deviation (SD) and 95% confidence intervals (CI) estimates were constructed for each WBC subclass. Upper bound of the SD’s 95% CI values for within-laboratory precision component were plotted for the different WBC types in the tested samples. All values were below the pre-defined acceptance criteria of 5% (Figure 2B). For platelets, Figure 2C plots the mean platelet values for each tested sample, with the vertical error segments representing SD within-laboratory precision component. All SD values were below the pre-defined acceptance criteria of 50 platelets. The WBC reproducibility results are shown in Figure 2D, with SD values of the reproducibility component, for the different WBC types in the tested samples. All SD values were below the pre-defined acceptance criteria of 5% (Figure 2D). For platelets, the results are shown in Figure 2E, with the mean platelets value for each tested sample plotted with the vertical error segments representing SD values of the reproducibility component. All SD values were below the pre-defined acceptance criteria of 50 platelets.

In order to assess the capacity of the system to identify platelets clumps, we analyzed ten samples with confirmed pseudothrombocytopenia. We detected platelets clumps in 10/10 of the samples, including two samples with clumps located at the feathered edge of the smear. Representative samples are shown in Supplementary 8.

The revolutionary full field capability of the system, that includes the PBS monolayer and feathered edge, enables experts to gain general slide context, which is critical for proper clinical decision-making. We included several full field PBS scans of several clinical examples (Figure 1, representative samples; Table 1, representative samples links; Supplementary 8).

### TABLE 2

Comparison of distributional normal ranges (%) and morphological normal ranges (%) between the manual and digital methods across three sites

| Cell type           | HUP Manual microscope | HUP Full Field microscope | TASMC Manual microscope | TASMC Full Field microscope | BWH Manual microscope | BWH Full Field microscope |
|---------------------|-----------------------|---------------------------|-------------------------|-----------------------------|-----------------------|---------------------------|
| Neutrophils         | 47.50-84.50           | 45.33-84.50               | 46.00-76.50             | 42.00-75.00                 | 53.06-81.00           | 51.50-79.94               |
| Lymphocytes         | 8.50-46.23            | 7.00-45.82                | 10.00-39.50             | 11.00-37.00                 | 8.50-29.26            | 7.00-30.07                |
| Monocytes           | 1.00-10.00            | 0.90-11.00                | 2.00-12.00              | 1.41-11.50                  | 2.06-8.94             | 1.06-8.50                 |
| Eosinophils         | 0.00-5.50             | 0.00-5.50                 | 0.00-8.00               | 0.00-6.50                   | 0.00-4.00             | 0.00-4.44                 |
| Basophils           | 0.00-2.00             | 0.00-2.01                 | 0.00-2.00               | 0.00-2.50                   | 0.00-1.52             | 0.00-1.97                 |

Note: Comparison of distributional normal ranges (%) and morphological normal ranges (%) between the manual and digital methods across three sites. Immature myeloid cells include metamyelocytes, myelocytes, and promyelocytes. Variant lymphoid cells include atypical lymphocytes, aberrant lymphocytes, and large granular lymphocytes. HUP, Hospital of the University of Pennsylvania Hospital; TASMC, Tel Aviv Sourasky Medical Center; BWH, Brigham and Women’s Hospital.

**DISCUSSION**

The goal of our study was to assess and validate the Scopio Labs X100 Full Field PBS application. In addition to demonstrating a high degree of correlation with the manual method for WBC classification, RBC morphology evaluation, and platelet estimation, Scopio’s Full Field breakthrough technology enables viewing of whole blood smears via a modern browser-based application, accompanied by pre-classification of WBC and platelets estimation (links in Table 1 and Figure 1). While the performance of existing digital microscopic systems in classification of WBC is generally adequate in a decision support system (DSS) mode, the option of full field specimen viewing during PBS analysis is an unmet need. The correct RBC morphological classification is problematic, and the automated identification of highly informative RBC forms such as schistocytes or teardrop cells need to be significantly reviewed.

As noted by the ICSH recommendations, abnormal leukocytes may be under-represented in limited-area digital smear analyses of
FIGURE 1  A, Comparison between manual differential count and Scopio Labs Full Field PBS system for neutrophils, lymphocytes, monocytes, and eosinophils. Correlation coefficients ($R^2$) are indicated for each cell type. Representative samples from the correlation curves (green dots) are indicated in Roman letters and can be viewed in the links indicated herein: I – Neutrophils: https://demo.scopiolabs.com/#/view_scan/65e8a4bd-4fa2-4447-a6dd-9cf977df22; II – Lymphocytes: https://demo.scopiolabs.com/#/view_scan/507d01a1-f4a1-44e-e1b7-e663f6fde3; III – Monocytes: https://demo.scopiolabs.com/#/view_scan/df67545-e517-43e1-895f-03e04ab07e5; IV – Eosinophils: https://demo.scopiolabs.com/#/view_scan/65da1b1c-5211-466f-83e7-aa7b20854e01. B, Comparison between CBC-derived platelet count (left) and manual microscopy platelet estimation (right) to Scopio Labs Full Field PBS system platelet estimation. Correlation coefficients ($R^2$) are indicated for each comparison. Representative samples from the correlation curves (green dots) are indicated in Roman letters and can be viewed in the links indicated herein: V – CBC comparison: https://demo.scopiolabs.com/#/view_scan/687ca7f-728a-4435-807c-b782aea96cb9; VI – manual microscopy estimation comparison: https://demo.scopiolabs.com/#/view_scan/47ced5c4-cda2-4837-aa99-71296fa4cd37
flagged-CBC samples. Scopio’s Full Field PBS enables full screening of the PBS, allowing the correct identification of the problematic cases, as demonstrated in the links provided in the manuscript. For example, in the case with viral infection, reactive lymphocytes as well as numerous apoptotic lymphocytes are clearly observed. In the case of a patient on chemotherapy, abnormalities of RBC are present, including microcytosis, hypochromia and occasional teardrop cells and schistocytes, apart from the profound leukenopenia and thrombocytopenia. In the specimen with acute leukemia, anisocytosis, frequent teardrop cells, and ovalocytes are evident, the appearance of the blasts is myelomonocytic accompanied by immature/aberrant monocytes, and aberrant giant platelets are found, suggesting that the acute myeloid leukemia may have evolved from a myeloproliferative neoplasm or chronic myelomonocytic leukemia.

The degree of RBC abnormalities, such as the prevalence of schistocytes or malarial trophozoites can be evaluated from a full field view of the PBS, allowing the correct identification of the problematic cases, as demonstrated in the links provided in the manuscript. For example, in the case with viral infection, reactive lymphocytes as well as numerous apoptotic lymphocytes are clearly observed. In the case of a patient on chemotherapy, abnormalities of RBC are present, including microcytosis, hypochromia and occasional teardrop cells and schistocytes, apart from the profound leukenopenia and thrombocytopenia. In the specimen with acute leukemia, anisocytosis, frequent teardrop cells, and ovalocytes are evident, the appearance of the blasts is myelomonocytic accompanied by immature/aberrant monocytes, and aberrant giant platelets are found, suggesting that the acute myeloid leukemia may have evolved from a myeloproliferative neoplasm or chronic myelomonocytic leukemia.

The ICSH recommendations raised concerns about possible differences between digital cellular images and the manual observation practice of laboratory specialists. However, in a full field digital setting, our study points to a good comparison between methodologies, both with respect to the classification of WBC types in a DSS mode, and to the recognition of aberrant cell types. With respect to platelet estimation, Scopio’s Full Field PBS automatically identifies and produces platelet concentration estimates in a DSS mode, with performance similar to both CBC analyzers and to manual platelet estimates, and no significant bias. These performances were demonstrated here in a multi-center study involving multiple qualified operators, utilizing various slide-makers and staining protocols. Notably, case review times were documented throughout the study, in both the reference arm (manual microscopy) and test arm (Scopio’s Full Field PBS). Under clinical study settings, where each examiner reported on a 200-WBC differential, complete RBC morphology evaluation and platelet estimation based on 10 FOVs, the median time for manual review was 20:00 minutes per case, and the median time for Scopio’s Full Field

### Table 3

| RBC morphology group | Multi-center | HUP | TASMC | BWH |
|----------------------|-------------|-----|-------|-----|
| Color                | 99.49%      | 98.88% | 100.00% | 99.63% |
|                      | 99.14%-99.73% | 97.96%-99.46% | 99.57%-100.00% | 98.92%-99.92% |
| Shape                | 99.77%      | 99.94% | 99.96% | 99.36% |
|                      | 99.68%-99.84% | 99.84%-99.99% | 99.86%-100.00% | 99.09%-99.57% |
| Size                 | 99.61%      | 99.11% | 99.92% | 99.83% |
|                      | 99.36%-99.78% | 98.45%-99.54% | 99.57%-100.00% | 99.41%-99.98% |
| Inclusions           | 100.00%     | 100.00% | 100.00% | 100.00% |
|                      | 99.93%-100.00% | 99.79%-100.00% | 99.79%-100.00% | 99.77%-100.00% |
| Arrangement          | 96.65%      | 99.11% | 90.97% | 100.00% |
|                      | 95.52%-97.57% | 97.73%-99.76% | 87.87%-93.50% | 99.09%-100.00% |
| Overall              | 99.77%      | 99.75% | 99.97% | 99.59% |
|                      | 99.71%-99.83% | 99.63%-99.84% | 99.91%-99.99% | 99.44%-99.72% |

Note: Comparison between manual RBC analysis of microscopy (reference) and Scopio Labs Full Field PBS (test). The range and average agreement between reference and test methods in 5 morphological groups across the three sites are presented (%). HUP, Hospital of the University of Pennsylvania Hospital; TASMC, Tel-Aviv Sourasky Medical Center; BWH, Brigham and Women’s Hospital.
PBS review was 7.46 minutes, a 60% improvement of workflow efficiency.

Scopio Labs X100 Full Field PBS adaptive scanning area of the slide, meant to locate the feathered edge and the monolayer in short and long smears is fully automated, without the user being able to override it. While the automatic scanned area was suitable throughout the study, enabling override option seemed reasonable. On average, scan and pre-classification times were 4 minutes per slide, but were up to 7 minutes for long smears. Also, the AI-based tools were available for the pre-classification of 16 WBC classes and platelets detection only. RBC morphology evaluation remains a completely manual workflow but is based on more than 1000 FOVs images of the full field. Pre-classification of the leukocytes did not include all types of aberrant cells (e.g., various types of lymphoma cells). User manual reclassification of the WBCs, specifically in the aberrant cases, was required to achieve higher level of sensitivity (7% average increase, Supplementary 6). For platelet estimations, reclassification did not yield notable improvement in accuracy.

Scopio Labs Full Field PBS application may help to bridge the gap between the manual and digital microscopic PBS review, especially in cases where the context of the slide is important in making a
diagnosis, and in settings when a member of the clinician and diagnostic team is not present on site and/or at a laboratory performing the test. Additionally, the browser-based solution presented herein can be integrated into external quality assessment (EQA) schemes, and to wide scale remote training programs, to simulate real-life blood smear comprehensive morphological analysis. There are thus numerous avenues in which this technology may be employed for the benefit of hematology-based health care.

CONFLICT OF INTEREST
Ben-Zion Katz is a consultant to Scopio Labs.

AUTHORS CONTRIBUTIONS
B-Z K, I A, M D F, and O P involved in conceptualization; B-Z K, A B, and O P involved in methodology; M T, D B, G S T, A A, B S, F M P, J E, and D J analyzed and investigated the study; B-Z K and O P wrote the original draft; B-Z K, M D F, A B, I A, and O P wrote, reviewed, and edited the article; I A and M D F supervised the study. All authors read and approved the final manuscript.

DATA AVAILABILITY STATEMENT
The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION
Additional supporting information may be found online in the Supporting Information section.

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