

Performance Evaluation of a Novel Artificial Intelligence-Assisted Digital Microscopy System for the Routine Analysis of Bone Marrow Aspirates



Multicenter study demonstrates high degree of correlation (82%–93%) between the artificial intelligence-driven decision support system and manual microscopy in BMA analysis.¹

Overview

1. Morphological analysis of BMA is essential for diagnosing, evaluating treatment response, and monitoring neoplastic and benign hematological disorders.
2. At least 500 cells are recommended by numerous guidelines including the ICSH to ensure accurate diagnosis and classification of abnormal cell types.
3. A labor-intensive process, BMA morphology-based diagnosis is done manually through light microscopy, where meeting the 500-cell requirement can be challenging.
4. The lack of standardization in BMA analysis can affect treatment decisions and outcomes.

Reproducibility depends heavily on operator experience and subjective interpretation, which can impact the accuracy of a 500-cell review.

5. ICSH recommended reporting turnaround times are 3 to 24 hours for verbal or written reports, and up to 48 hours for less urgent cases, with some remote labs struggling to meet these timelines.
6. A multicenter study evaluated a novel digital solution. The Scopio Labs X100 Full-Field BMA Application that scans BMA specimens at 100X magnification, using AI to streamline analysis, was compared to traditional manual microscopic methods.



“Considering the complexity of the manual BMA analysis, approaches to increase standardization, sensitivity, and efficiency are needed to improve routine BMA analysis workflow.”¹



Methodology

- A total of **795 BMA specimens** (615 Romanowsky-stained and 180 Prussian blue-stained) from patients with neoplastic and other clinical conditions were analyzed.
- **Phase I:** The whole slide image was scanned for clinically relevant areas, and the number of particles, stripped cells, and hemodilution status, were assessed for adequate sample quality.
- Area selection for digital BMA analysis was performed in **2 phases**.
- **Phase II:** Within clinically relevant areas, a second analysis was performed on ROIs, including a differential of all cells within the prespecified area.



Test method:
Scopio's Full-Field BMA Application



3 clinical centers¹

- Hospital of the University of Pennsylvania
- Oregon Health & Science University
- Tel Aviv Sourasky Medical Center



Reference method:
Manual Full-Field BMA Application microscope

What did the study evaluate?

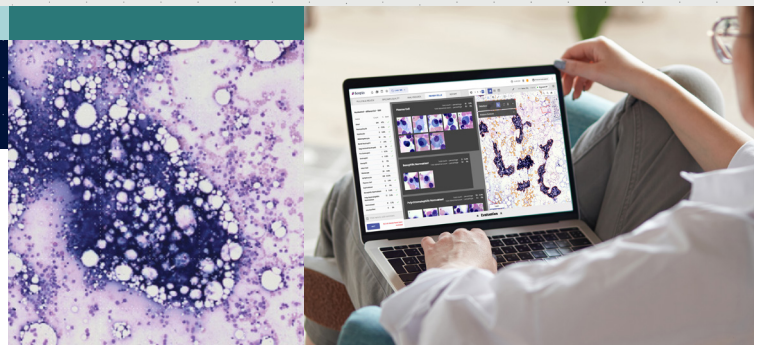
- Efficiency, sensitivity, and specificity of the BMA analysis
- Standardization: Repeatability and reproducibility

About the Technology



Scopio Labs X100 Full-Field BMA Application:

- Combines high resolution with a wide FOV
- Is based on a novel computational imaging approach
- Images the slide at 100x oil-immersion resolution
- **Results in a scan time of less than 5 min/cm².**
- **Has an interactive AI-based DSS** to analyze, pre-classify, and quantify various elements of the BMA specimen and provides ICSH standardized reporting for enhanced diagnosis. ¹ p2 Bagg
- Uses a **browser-based application.** ¹ m p2 Bagg
- Scanned images and reports are stored locally on the device and can be integrated with the Laboratory Information System using HL7 standard or long-time stored using DICOM integration. The average file size of a BMA scan is 4 GB.



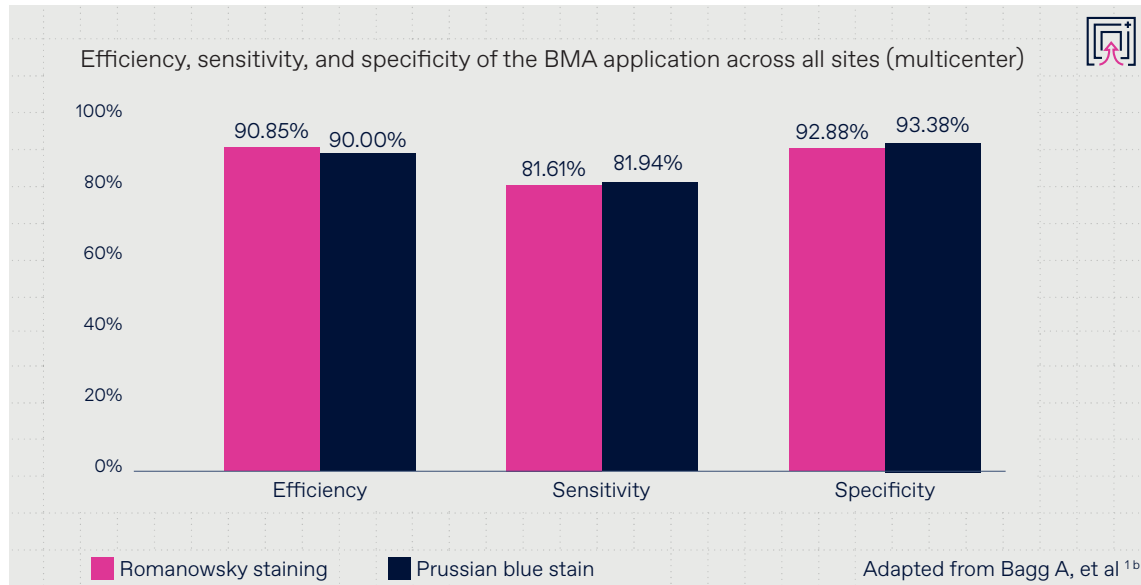


Results

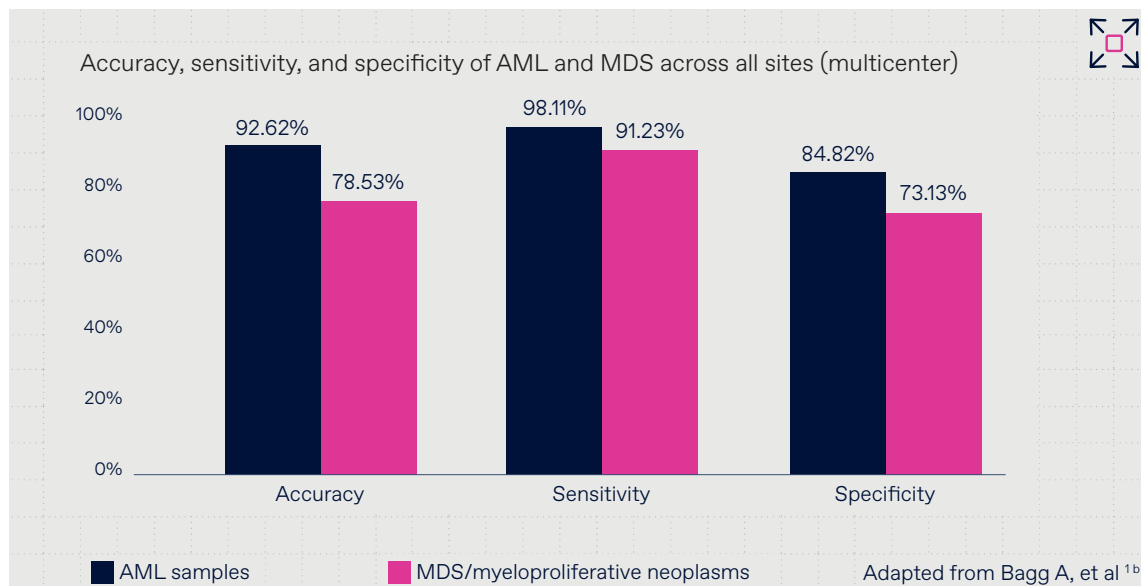
Efficiency, Sensitivity and Specificity

The test method showed a high correlation with the reference method for comprehensive BMA evaluation*

- Romanowsky samples: 90.85% efficiency, 81.61% sensitivity, and 92.88% specificity
- Prussian blue-stained samples: 90.00% efficiency, 81.94% sensitivity, and 93.38% specificity



There was high accuracy, sensitivity, and specificity for blast counts in AML and MDS/myeloproliferative samples.

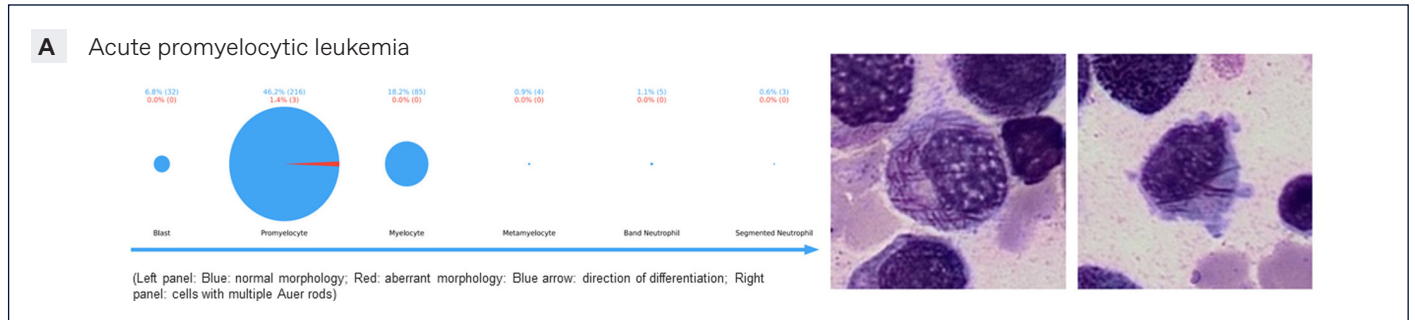


*Primary and secondary marrow aspirate characteristics (maturation, morphology, and count assessment), as well as overall inter-user agreement, were evaluated. Primary characteristics were differentiated as abnormal or normal, adequate or inadequate e.g. sample adequacy, type of cell (e.g,blast, plasma cell estimate). Secondary characteristics once differentiated as abnormal need a degree of abnormal (for e.g. plasma cell increased in percentage grades 3-10% ; , 11-30% etc. The same applies for percentage of cells decreased.)

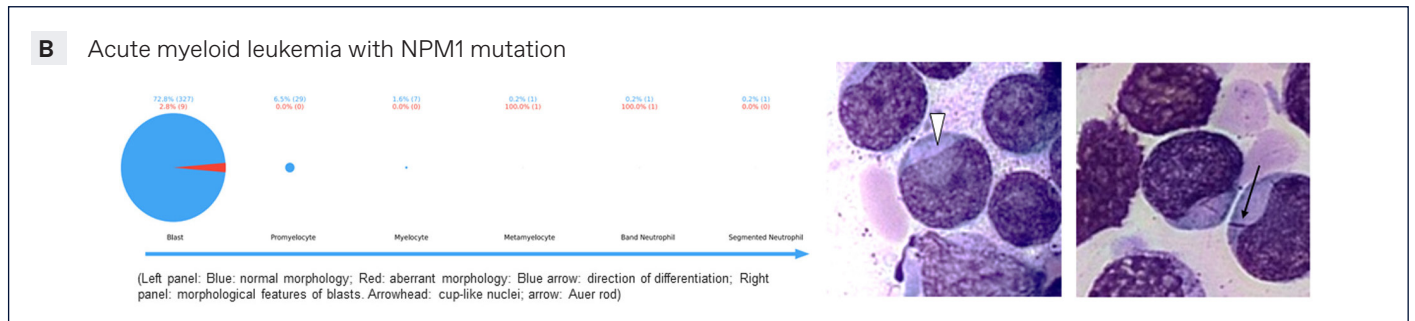
Lineage assessment

Representative cells demonstrated lineage presentations based on the quantitative analysis of individual clinical samples.

A clear maturation arrest at the pro-myelocyte stage is observed in a case of acute promyelocytic leukemia with a PML:RARA fusion, with 3% of the cells displaying bundles of Auer rods (A).

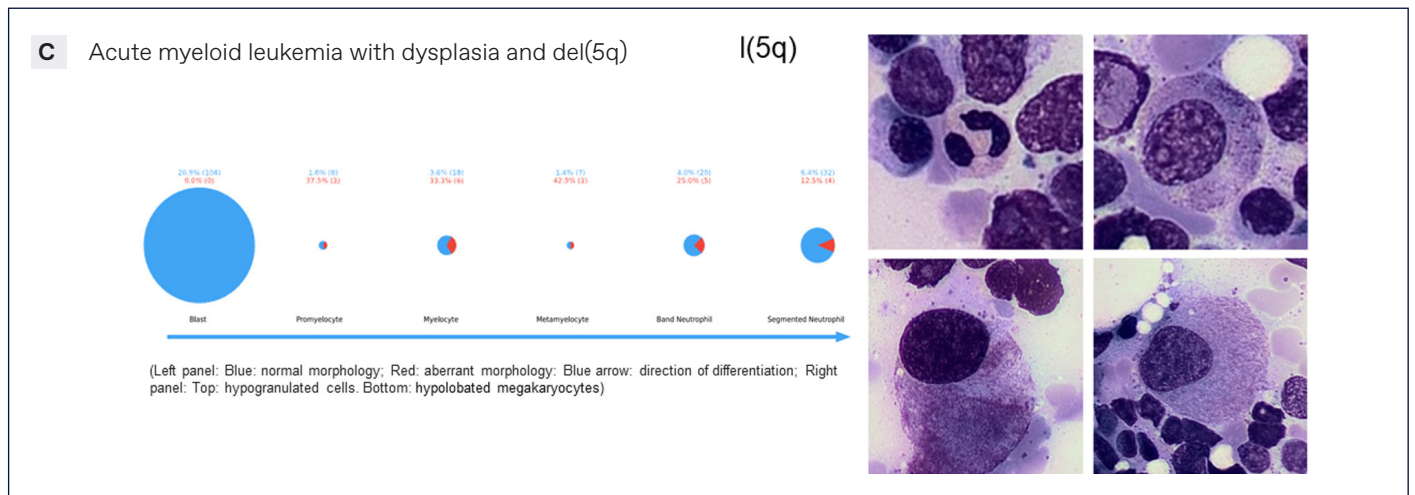


In contrast, **maturation arrest at the blast stage**, with no further maturation of the myeloid lineage, is shown in an AML case (B).



In this case, solitary Auer rods as well as cup-like nuclear invagination in some of the blasts, were observed, consistent with the presence of an *NPM1* mutation in this case.

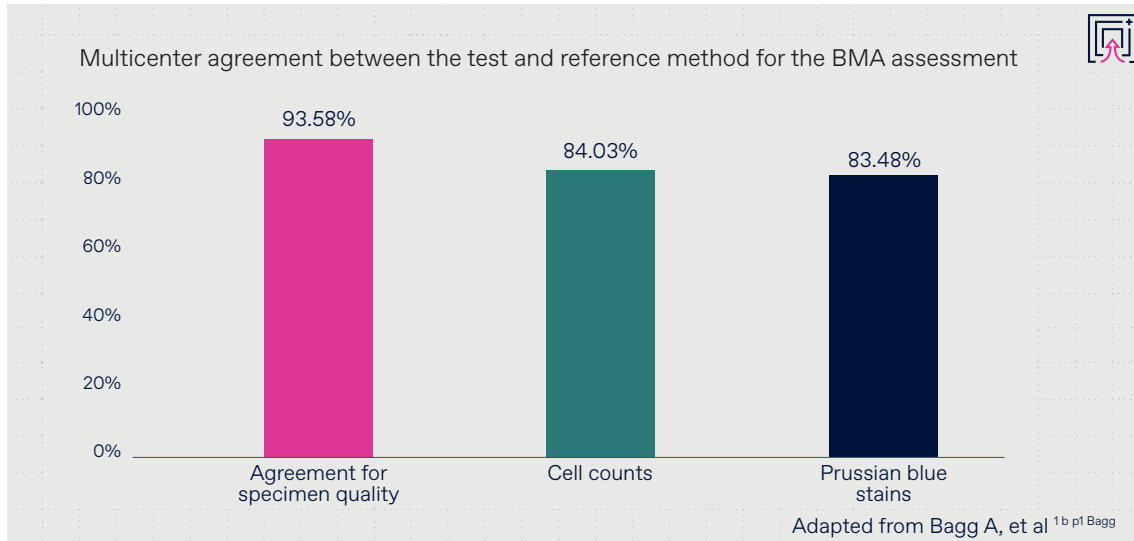
A hypogranulated neutrophil was seen in a case of AML (C).



In addition, hypolobated megakaryocytes were found in the sample, as is typically seen with the presence of del(5q) in this case. ^{1 d p8 Bagg}

Standardization

The overall agreement between the test and reference methods for BMA assessment was 91.1%. ^{1 f p1 Bagg}



Specimen Analysis

The AI-decision support system

- Analyzed an average of **1,385 ± 536 cells per specimen** selecting 39.98 ± 19.64 fields of view, with $87\% \pm 21\%$ accepted by operators as qualifying for analysis.
- Resulted in **17.62 ± 7.24 ROI** per specimen.

Standardization: Repeatability and Reproducibility

For repeatability and reproducibility, all standard deviations and coefficients of variation values were below the predefined acceptance criteria both for discrete measurements (coefficient of variation below 20%) and **differential measurements (SD below 5%)**.

Conclusions

Scopio Labs X100 Full-Field BMA Application:

- Represents a high-quality, accurate digital Full-Field BMA Application analysis
- Demonstrates a high degree of correlation between the digital DSS and gold standard manual microscopy
- Thereby expedites expert review and diagnosis of BMA specimens
- Has the potential to provide practical applications including remote BMA evaluation and possibly new opportunities for the research of normal and neoplastic hematopoiesis



Read the full publication

Reference:

1. Bagg A, Raess PW, Rund D, Bhattacharyya S, Wiszniewska J, Horowitz A, et al. Performance Evaluation of a Novel Artificial Intelligence-Assisted Digital Microscopy System for the Routine Analysis of Bone Marrow Aspirates. *Mod Pathol*. 2024 Sep;37(9):100542. doi: 10.1016/j.modpat.2024.100542

Disclaimers:

1. Scopio's Full-Field Bone Marrow Aspirate Application is CE-marked and cleared for sale in CE count additional regions. Not commercially available in the US for in vitro diagnostic procedures
2. Scopio's Full-Field remote capabilities are available through the secure hospital network

Acronyms and Abbreviations:

BMA: Bone Marrow Aspirate; **ICSH:** International Council for Standardization in Haematology **MDS:** Myelodysplastic syndromes **ROIs:** Regions of Interest
AI: Artificially intelligence **DICOM:** Digital Imaging and Communications in Medicine **DSS:** Decision Support System **FOV:** Field of View