

## Artificial Intelligence in Hematology Laboratories: Analytical Performance, Clinical Integration, and Implementation Challenges

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### Abstract

### Original Research Article

Hematology analyzers of modern generation produce multidimensional and multiparametric datasets that cannot be effectively interpreted by traditional methods. AI and ML provide advanced computational tools that can help increase diagnostic accuracy and optimize the workflow in laboratories. To critically analyze the use of artificial intelligence in modern clinical hematology laboratories with a focus on automated hematology analyzers, digital morphology, prediction, and hemostasis integration. A structured narrative literature analysis of articles published between 2015 and 2026 was performed. The PubMed and Web of Science databases were used to identify scientific publications studying the application of machine learning and deep learning approaches to hematology. Various AI-based diagnostic models showed good discriminatory ability when classifying leukocytes, detecting blasts, stratifying different types of anemia, and diagnosing malaria. The area under curve of the models frequently exceeded 0.90 in validation datasets. The application of convolutional neural network helped increase the accuracy of digital morphology compared to conventional microscopy. Machine learning algorithms using CBC data allowed predicting sepsis and estimating the risk of malignant diseases. However, the vast majority of the studies used retrospective datasets with little external validation. Artificial intelligence helps optimize and make hematology analysis more accurate. Nevertheless, further research in the form of multicentric prospective validation and regulation is needed before applying the technology in practice.

**Keywords:** Artificial Intelligence, Hematology, Machine Learning, Automated Hematology Analyzers.

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## INTRODUCTION

Hematology is now a data-driven field due to the recent revolution in laboratory medicine's digitization (Topol, 2019; Herman *et al.*, 2021)

Hematological analyzers offer sophisticated data, including cell population data (CPD), reticulocyte features, and CBC profiles. While using these biomarkers increases the sensitivity of diagnosis, it can be difficult to interpret them (Esteva *et al.*, 2019; Nazha *et al.*, 2025). Leukocyte subtyping, smear image analysis, anemia differentiation, machine learning and deep learning-based sepsis and neoplasm prediction are all examples of AI technology in hematology (Gedefaw *et al.*, 2023).

The objective of this paper is to evaluate the practical, clinical, and analytical aspects of using AI in hematology labs.

## METHODS

### Search Strategy

A systematic literature search was carried out in February 2026 on the PubMed and Web of Science databases. This search involved the following MeSH and non-MeSH terms: artificial intelligence, machine learning, deep learning, hematology analyzer, complete blood count, digital morphology, peripheral blood smear, and coagulation.

The search filters included only English language papers published from January 2015 through February 2026.

### Eligibility Criteria

Inclusion criteria for studies were:

- Studies assessing the application of artificial intelligence, machine learning, or deep learning algorithms.

- The exploitation of hematological laboratory datasets, specifically CBC, CPD, digital smear imaging and coagulation analysis.
- Presence of diagnostic or predictive performance measures such as sensitivity, specificity, accuracy and area under the ROC curve (AUC).
- Studies that used human data.
- Sample size
- AI algorithm used (Random Forest, SVM, CNN, etc.)
- Pathology/Analytical objective
- Metrics of performance (sensitivity, specificity, accuracy, AUC)
- Internal cross-validation vs. External validation

The exclusion criteria were:

- Review articles, editorial opinions and conference abstracts.
- Studies that solely considered AI applications in radiology or other non-hematology fields.
- Experimental model studies lacking laboratory dataset.
- Non-English literature.

### Study Selection

- Systematic screening of titles and abstracts was conducted based on pre-specified eligibility criteria.
- Eligibility of full-text articles was then determined based on pre-specified inclusion and exclusion criteria.

### Data Extraction and Synthesis

Variables that were considered during extraction from the eligible articles included:

- The study design (retrospective or prospective study design)

Owing to significant heterogeneity among the various methods used, no meta-analysis could be conducted quantitatively.

Narrative synthesis of results was done based on factors like analytical performance, clinical application, and workflow considerations.

A total of 172 articles were found from searching the databases. Of these, only 67 articles were found suitable after screening titles/abstracts and another 23 articles were finally included.

## RESULTS

### AI in Automated Hematology Analyzers

The use of machine learning classifiers on CPD indices has led to increased distinction of reactive vs. malignant leukocytosis (Ambayya *et al.*, 2021; Gaspar *et al.*, 2019). Models using neural networks and incorporating CBC indices have shown sensitivity more than 90% for blasts (Matek *et al.*, 2019; Virk *et al.*, 2019). Major uses of AI in clinical hematology are shown in Table 1 below.

**Table 1: Major Applications of Artificial Intelligence in Clinical Hematology**

Domain	AI Model	Target Application	Reported Performance	Clinical Implication
<b>Automated CBC analysis</b>	Random forest, gradient boosting	Leukocytosis classification	AUC 0.85–0.95	Improved discrimination between reactive and malignant leukocytosis
<b>Blast detection</b>	Neural networks	Acute leukemia screening	Sensitivity 92–98%	Reduced false-positive smear review
<b>Digital morphology</b>	CNN	Leukocyte subtype classification	Accuracy >95%	Reduced inter-observer variability
<b>Erythrocyte morphology</b>	CNN segmentation	Anisocytosis, poikilocytosis	Accuracy 88–96%	Improved hemolytic anemia screening
<b>Malaria detection</b>	Deep CNN	Parasitemia identification	Sensitivity 90–99%	Standardized quantification
<b>Sepsis prediction</b>	Ensemble ML	Early risk stratification	AUC 0.80–0.92	Earlier clinical intervention
<b>Hemostasis modeling</b>	Neural networks	Thrombotic risk	AUC 0.78–0.89	Optimized D-dimer utilization

Representative high-impact AI studies in hematology are summarized in Table 2 below.

**Table 2: Representative Artificial Intelligence Studies in Hematology (2015–2026)**

S L	Study (year)	Domain	Dataset	Model	Objective	Performance	DOI
1	Matek <i>et al.</i> ,(2019) (Nature) (Matek <i>et al.</i> , 2019)	Digital morphology	>18,000 annotated leukocytes	CNN	Leukocyte classification and blast detection	High accuracy (expert-level)	10.1038/s42256-019-0101-9
2	Shafique <i>et al.</i> ,(2018) (journals.sagepub.com) (Shafique & Tehsin, 2018)	Digital morphology	Peripheral blood smear images (ALL)	CNN (AlexNet fine-tuning)	ALL detection + subtypes	Sens 100%, Sp 98.11%, Acc 99.50% (detection)	10.1177/1533033818802789
3	Glüge <i>et al.</i> ,(2024) (PubMed) (Glüge <i>et al.</i> , 2024)	Bone marrow morphology	171,374 BM cell images / 945 patients	CNN (RegNet etc.)	Classification of BM cell images	F1 $\approx$ 0.76 (best model)	10.1016/j.cmpb.2023.107924
4	Rajaraman <i>et al.</i> ,(2018)(peerj.com) (Rajaraman <i>et al.</i> , 2018)	Malaria (thin smear)	Peripheral blood smear images	CNN pre-trained	Malaria detection	High performance (compared model)	10.7717/peerj.4568
5	Bibin <i>et al.</i> ,(2017) (Nature) (Bibin <i>et al.</i> , 2017)	Malaria	Peripheral blood smear images	Deep learning (DBN)	Malaria detection	High accuracy	10.1109/ACCESS.2017.2705642
6	Ambayya <i>et al.</i> ,(2021) (PubMed) (Ambayya <i>et al.</i> , 2021)	CBC/CPD (analyzers)	CPD/VCS (routine)	Algorithm-based CPD	Hematologic disorder screening	Rapid screening Malignant vs Non-malignant	10.3390/diagnostics11091652
7	Virk <i>et al.</i> ,(2019) (PubMed) (Virk <i>et al.</i> , 2019)	CBC/CPD (analyzers)	CPD/VCS (limited resources)	CPD-based models	Screening AML	AML screening utility	10.1002/jcla.22679
8	Raess <i>et al.</i> ,(2014) (PubMed) (Raess <i>et al.</i> , 2014)	CBC + CPD	CBC + CPD (routine)	Predictive classification	Screening MDS	Automated MDS screening	10.1002/ajh.23643
9	Campagner <i>et al.</i> ,(2025) (JMIR) (Campagner <i>et al.</i> , 2025)	Sepsis (CBC/MDW)	6 cohortes / 5 hospitals / ~5,344 pts	ML (multimodels)	Early sepsis detection	External multi-center validation	10.2196/55492
10	Steinbach <i>et al.</i> ,(2024) (PubMed) (Steinbach <i>et al.</i> , 2024)	Sepsis (CBC)	External Cohortes	ML on CBC	Sepsis prediction	Robust (external validations)	10.1093/clinchem/hvae001
11	Shashikumar <i>et al.</i> ,(2021) (PubMed) (Shashikumar <i>et al.</i> , 2021)	Sepsis (robust ML)	Multi-centres (EHR)	Deep learning (COMPOSER)	Sepsis + “I don’t know”	Reduction of false positives	10.1038/s41746-021-00504-6
12	Chiu <i>et al.</i> ,(2025) (Nature) (Chiu <i>et al.</i> , 2025)	Bacteremia (ED)	CBC + diff + CPD	ML	Prediction G–bacteremia	AUC $\sim$ 0.76–0.80	10.1038/s43856-025-01200-2
13	Villacorta <i>et al.</i> ,(2022) (PubMed) (Villacorta <i>et al.</i> , 2022)	Hemostasis / D-dimer	PE suspicion	ML (elastic net etc.)	Pulmonary embolism risk stratification	Performance gain vs Non D-dimer model	10.1093/ehjacc/zuab089
14	Komorowski <i>et al.</i> ,(2018) (PubMed) (Komorowski <i>et al.</i> , 2018)	Sepsis (RL)	ICU cohortes	Reinforce ment learning	Sepsis treatment strategy	Associated with lower mortality rate	10.1038/s41591-018-0213-5
15	Loey <i>et al.</i> ,(2020) (MDPI) (Loey <i>et al.</i> , 2020)	Leukemia (imagery)	Peripheral blood smear images	Transfer learning	Leukemia detection	Good performance	10.3390/computers9020029

### Digital Morphology and Deep Learning

Convolutional neural networks (CNNs) have revolutionized digital smear interpretation. CNN-based leukocyte classification systems achieved accuracies above 95% in validation cohorts (Matek *et al.*, 2019).

Automated malaria detection models have reported sensitivity between 90–99% (Rajaraman *et al.*, 2018; Bibin *et al.*, 2017). Schematic outline of AI implementation into the process flow of the hematology lab. Data acquired by hematology analyzers and digital

morphology tools are preprocessed and analyzed via machine learning algorithms to enable classification, prediction modeling, intelligent flagging, and LIS integration.

### Predictive Hematology

ML models integrating CBC parameters have improved early sepsis detection compared with conventional biomarkers (Komorowski *et al.*, 2018; Shashikumar *et al.*, 2021; Campagner *et al.*, 2025; Aguirre & Urrechaga, 2022). Predictive algorithms for anemia classification have shown enhanced diagnostic differentiation (Kim *et al.*, 2021).

### AI in Hemostasis

Interpretation of D-dimer and coagulation profiles through AI systems has facilitated better risk stratification of thrombosis and minimized unnecessary diagnostic tests (Villacorta *et al.*, 2022; Ren *et al.*, 2024; Meng *et al.*, 2022).

## DISCUSSION

AI-based methodologies are increasingly changing the analytical paradigm of clinical hematology laboratories. Contrary to conventional rule-based methods, AI technology uses high dimensional data analysis as well as non-linear pattern recognition to improve diagnostic accuracy. This review outlines the accumulating evidence supporting the use of AI in automated hematology, morphology, prediction, and hemostasis.

### Analytical Performance Compared with Conventional Interpretation

Several research studies have found that machine learning and deep learning algorithms perform as good as or better than the expertise of humans in terms of interpretation in validated conditions (Topol, 2019; Esteva *et al.*, 2019; Matek *et al.*, 2019). Leukocyte classifiers based on CNN have been shown to have accuracies higher than 95% with increased consistency compared to manual microscopy (Cheuque *et al.*, 2022; Ahmad *et al.*, 2023; Song & Wang, 2024). The improvement in consistency is one of the most notable features of using such models.

Nevertheless, one must be very careful when evaluating these performance parameters. There are many examples of studies that show very high AUCs during internal validation, potentially indicating overly optimistic performance estimates (Nazha *et al.*, 2025; Chiasakul *et al.*, 2023). Data collected from controlled datasets with an equal distribution of classes does not necessarily correspond to the laboratory case-mix of everyday practice (Herman *et al.*, 2021; Asghar *et al.*, 2024). Consequently, although AI presents considerable promise as a tool for analysis, its translation into clinical practice necessitates external multicenter validation studies (Pozdnyakova, 2026). It should also be noted that

there are relatively few instances where patient outcomes have been improved.

Images taken by digital blood smear devices at high resolutions require pre-processing according to standardized techniques such as segmentation, normalization, and artifact correction (Bamwenda *et al.*, 2025; Shahzad *et al.*, 2024). Convolutional neural networks use hierarchical feature extraction based on the construction of hierarchical feature maps by stacked convolutional layers, then classify features by using fully-connected classification layers with probability scores (Anand *et al.*, 2024). The outputs include leukocyte subclassification, erythrocyte morphometry, and abnormality probability scores (Pozdnyakova, 2026; Wang *et al.*, 2024).

### Dataset Bias and Generalizability

One of the key limitations noted in the literature is the dominance of retrospective and single-center databases. Training algorithms on homogeneous cohorts can cause demographic, ethnic, and device-based biases (Kelly *et al.*, 2019; Vasey *et al.*, 2022). Parameters measured by hematology analyzers differ based on the manufacturer, calibration methods, and demographics.

Moreover, image-based deep learning models trained using carefully curated digital smear images could fail to generalize to smears with different staining characteristics or other artifacts, or even smears that have been prepared improperly.

### Overfitting and Model Robustness

Overfitting is an issue that continues to plague AI-assisted hematology research. Although internal cross-validation is effective in preventing overfitting, this does not preclude the need for external validation. Only a small number of research papers have employed prospective validation. Also, most of the diagnostic accuracy reported results from highly curated data.

The deployment of models calls for clear documentation of test-training data splits, accuracy confidence intervals, and calibration measures (Bossuyt *et al.*, 2015; Norgeot *et al.*, 2020). Further studies will need to focus on replication, algorithmic transparency, and reporting guidelines consistent with TRIPOD-AI and CONSORT-AI principles.

### Explainability and Clinical Integration

"Black box" properties of some deep learning systems pose obstacles to their use in medicine (Wang *et al.*, 2024; Srisuwananukorn *et al.*, 2023). The practice of hematology is performed under controlled conditions where audit trail is important. Explainable artificial intelligence can improve transparency of decisions and facilitate regulatory approval (Pozdnyakova, 2026).

The inclusion of artificial intelligence software in LIS and other middleware environments is another

important implementation challenge. The results generated by artificial intelligence software should be easily integrated into standard laboratory reports without adding any burden to the cognitive abilities of lab staff (Hu *et al.*, 2022).

### Impact on Workflow and Operational Efficiency

In addition to performance, artificial intelligence-powered solutions also present considerable promise for optimizing laboratory procedures. An intelligent flagging system would minimize the need for unnecessary smear examinations, especially on samples presenting minimal risk (Lewis & Pozdnyakova, 2023). Manual examination may be reduced by up to 30–40% using this method in some studies.

Automated triaging and prioritization algorithms could potentially improve patient safety in a tertiary hospital environment where there are larger sample sizes and fluctuating staffing numbers (Hu *et al.*, 2022).

Nevertheless, economic analysis is still lacking. Studies regarding the cost-effectiveness of the necessary hardware, digital slide scanners, and computational needs should be considered (Wang *et al.*, 2024).

### Applications in Predictive Hematology and Precision Medicine

AI-driven models that incorporate complete blood count variables are not limited to static classification. Risk assessment models for sepsis, blood cancers, and thrombosis hold promise for future research (Komorowski *et al.*, 2018; Singer *et al.*, 2016; Angus & van der Poll, 2013). Longitudinal blood test results incorporated into an electronic medical record may lead to earlier detection of illness progression (Walter *et al.*, 2021).

Nevertheless, predictive algorithms require prospective validation to demonstrate tangible improvement in patient outcomes. Analytical accuracy does not necessarily translate into improved morbidity or mortality metrics (Nazha *et al.*, 2025).

### Regulatory and Ethical Considerations

The incorporation of AI within hematology laboratories is subject to the requirements set out by regulatory bodies in relation to *in vitro* diagnostics and medical software. Changes in algorithms, patient confidentiality, and cyber security present further issues (Cheuque *et al.*, 2022; Vasey *et al.*, 2022).

Issues surrounding ethics involve the openness of the algorithm, prevention of biases, and equal performance within different communities (Rösler *et al.*, 2023). Multi-center collaboration could assist in resolving these issues.

### Future Directions

Some of the future priorities for research include multicentric validation studies, harmonization between platforms on hematological analyzers, development of standard digital smears database, cost-effectiveness evaluation, and AI integration with molecular/omics data (Shahzad *et al.*, 2024; Ghete *et al.*, 2024).

The use of hybrid approaches combining rule-based reasoning with adaptive machine learning algorithms could be a reasonable compromise approach (Dehkharghanian *et al.*, 2023).

### Strengths and Limitations of This Review

This systematic review represents an organized summary of the available literature on applications of artificial intelligence within the hematology laboratory. Nevertheless, limitations associated with the narrative nature of this analysis and the heterogeneity of included research should be noted. In addition, the lack of meta-analysis does not allow estimating overall performance parameters.

## CONCLUSION

Artificial intelligence has the potential to transform the paradigm of analysis in hematology laboratories through improved accuracy, consistency, and efficiency. Nonetheless, rigorous external validation, regulatory control, and practical application are crucial for successful implementation in the clinical setting.

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