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One model across laboratories, panels and countries: a real-world multicenter evaluation of AI-assisted leukocyte population identification in clinical samples

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shared populations with excellent concordance

ρ = 0.93–1.00
for those eight high-agreement populations

0.93–1.13
pooled linear-fit slopes, near unity

Background and study question.

Flow-cytometric leukocyte differentiation is central to hematological diagnostics, but manual analysis is time-consuming and varies between operators. AI-assisted automated gating improves efficiency and reproducibility. Evidence of performance across heterogeneous laboratory environments remains limited.

> Can one AI model, trained predominantly on Western European cohorts, hold its accuracy across different laboratories, panels, workflows, sample types and patient populations?

Study design.

One model was evaluated retrospectively at three laboratories in two countries, each running its own screening panel and analytical workflow. The model was unchanged at every site, with no site-specific retraining and no panel-specific optimization. Peripheral blood at all three; bone marrow contributed by the CCSS cohort.

HpH	Institute of Hematopathology	n = 6,430
	Hamburg, Germany · laboratory-developed panel, BD FACSDiva / FACSuite · reference: routine clinical differential	
HpBB	Pathodiagnostik Berlin (Hämatopathologie Berlin + Brandenburg)	n = 67
	Berlin, Germany · laboratory-developed panel, BD FACSDiva / FACSuite · reference: routine clinical differential	
CCSS	Laboratorio Especializado de Hematología, Hospital Dr. Rafael Ángel Calderón Guardia	n = 542
	Caja Costarricense de Seguro Social, Costa Rica · EuroFlow LST, Infinicyt · reference: expert manual gating	
Total		n = 7,039

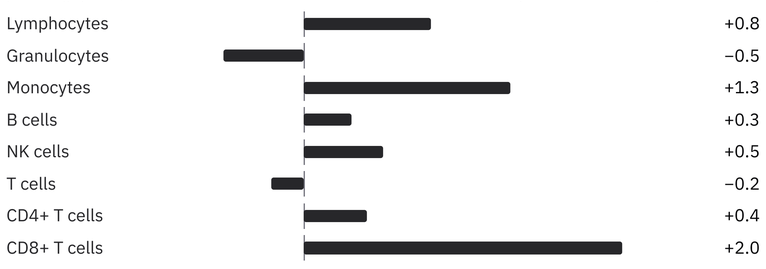
Analysis metrics.

ρ Pearson correlation between reference and model. The headline agreement metric.

Slope of the linear fit. 1.0 means no systematic scaling; below 1.0 the model trends lower than the reference at high values.

Mean bias (reference – model) in percentage points. Positive means the model reports fewer cells.

Pooled mean bias.



All sites pooled, n = 7,039. Scale −1.0 to +2.5 percentage points. CD4/CD8 bias is −0.26 in ratio units and is not plotted here.

Pearson ρ by population and site.

Population	HpH	HpBB	CCSS	0.70 1.00	Pooled ρ
Lymphocytes	0.98	0.96	1.00		0.98
Granulocytes	0.98	0.97	1.00		0.98
Monocytes	0.78	0.74	0.95		0.79
B cells	1.00	1.00	1.00		1.00
NK cells	0.99	0.97	0.97		0.99
T cells	1.00	1.00	1.00		1.00
CD4+ T cells	0.99	1.00	1.00		0.99
CD8+ T cells	0.98	1.00	0.98		0.98
CD4/CD8 ratio	0.93	0.99	0.99		0.93
B cells κ	n/a	n/a	0.99		0.99
B cells λ	n/a	n/a	0.93		0.93

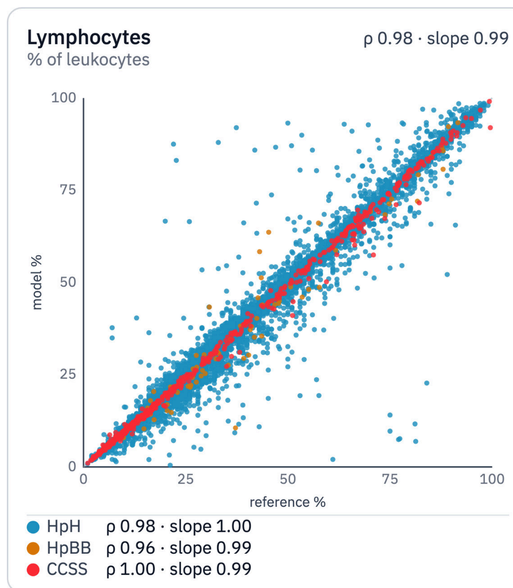
Hollow marker: the one population outside the 0.93–1.00 band. κ and λ are reportable at CCSS only, so their pooled value repeats the CCSS one.

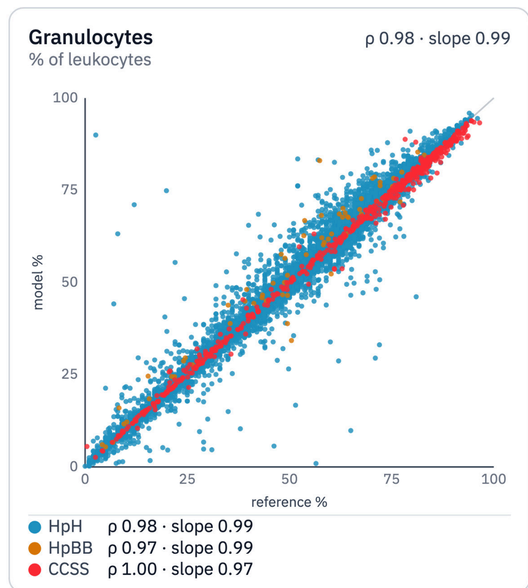
Primary area for refinement.

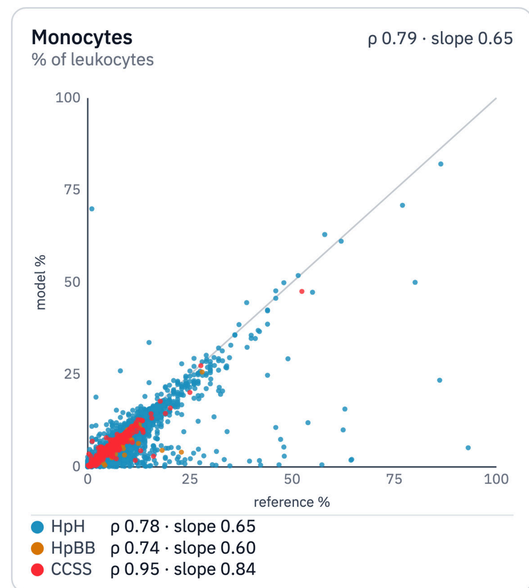
Monocyte identification was the only population with reduced agreement: the model reported lower values than the laboratory reference, most clearly at the German sites (ρ 0.78 and 0.74, slope 0.65 and 0.60). Agreement was substantially stronger against expert manual gating at CCSS (ρ 0.95, slope 0.84). Pooled mean bias was +1.3 percentage points.

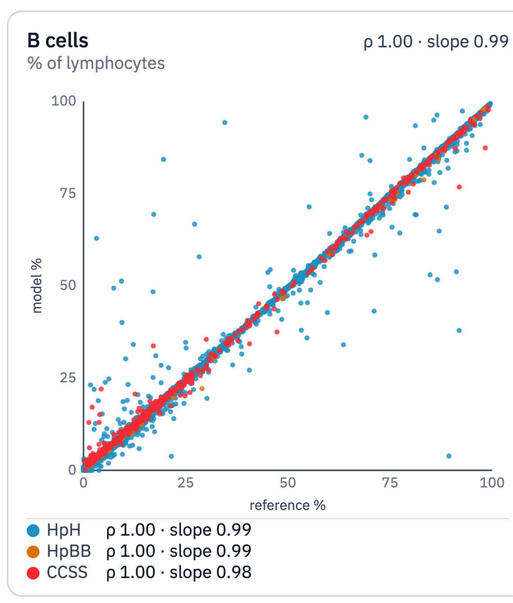
Monocyte identification is sensitive to phenotypic overlap and reference methodology. The stronger CCSS agreement suggests that reference method differences may partly explain the lower performance observed at the German sites (Hauspurg et al. 2025).

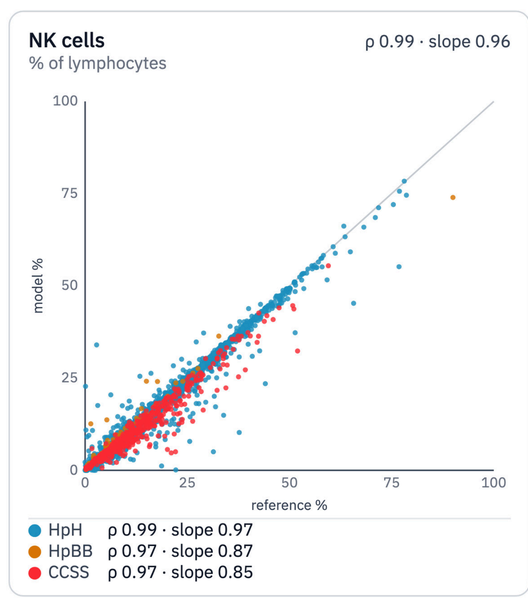
Model output vs laboratory reference.

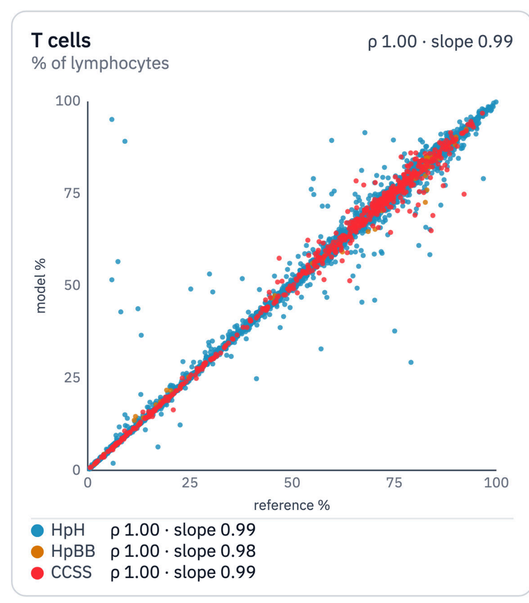


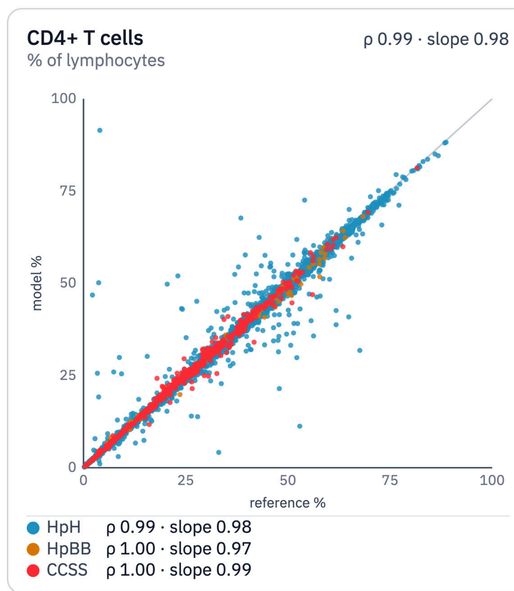


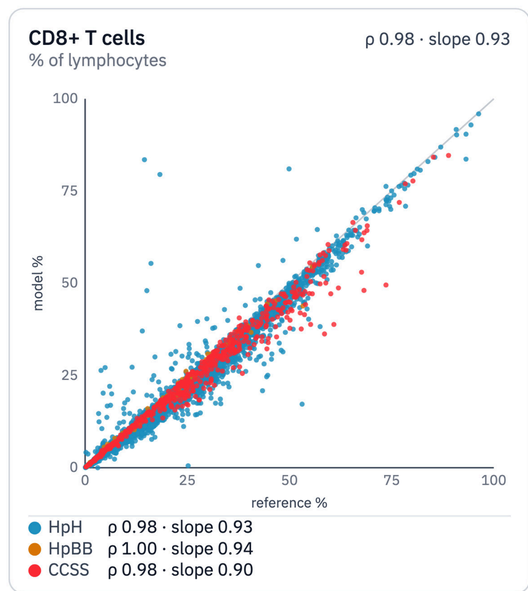


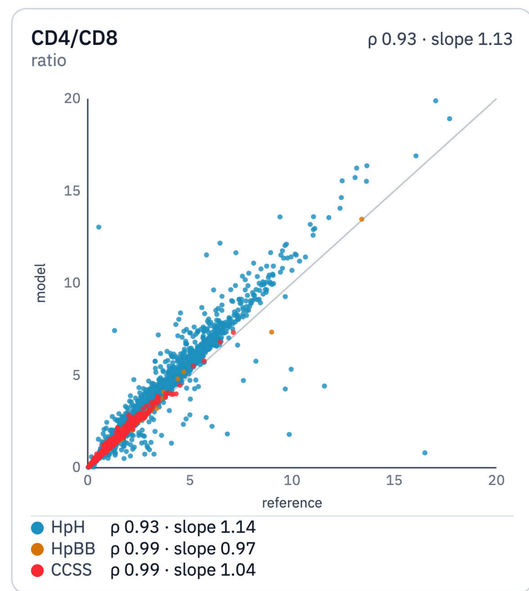


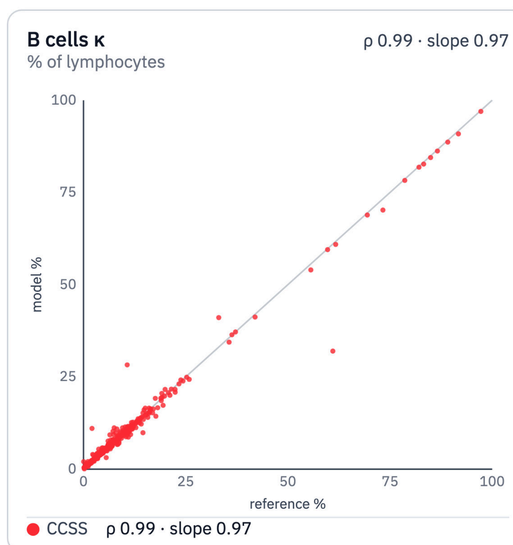


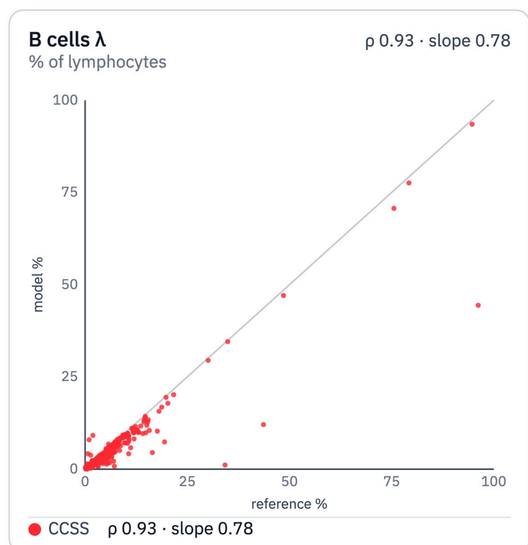












Reading the grid

Nine populations are reportable at all three sites. B-cell κ and λ are reportable at CCSS only, because the German diagnostic-report reference does not carry light chains.

Percentages are of leukocytes or of lymphocytes as labeled; CD4/CD8 is a bare ratio. The value beside each population title is the pooled result; the rows beneath each panel give it per site.

Full-resolution figures, the abstract and contact details
hema.to/escca-2026

Generalization

Consistent agreement across three laboratories, two countries and different panels, workflows and sample types, with one unchanged model. The Costa Rican cohort matched the German sites despite sitting outside the training distribution.

Reference-method independence

High agreement against both routine clinical differential counts and expert manual gating, so the result does not rest on one laboratory's definition of ground truth.

Conclusion

Across three laboratories in two countries, AI-assisted leukocyte differentiation showed excellent agreement with routine laboratory analysis for all major clinically relevant subpopulations, supporting its integration as a reproducible component of routine flow-cytometry workflows in diverse real-world settings.

What that integration looks like (product capability, not evaluated in this study)

The model sits inside a workflow the laboratory keeps control of. CellStudio Connect picks up FCS and LMD files as the cytometer writes them, anonymized on-premise before anything leaves the laboratory. Every prediction stays visible and editable, with four-eyes review and an audit trail. Reports are generated with a human signoff and are written back to the network share or LIS by CellStudio Connect.

Literature: Hauspurg H, Elsner F, Kunzweiler F, Becker M, Pfisterer F, Reufer Y, Plümer P, Fuhrmann S, Schabath R. *A retrospective study comparing the results of leukocyte differentiation between two laboratories and an AI application* (abstract 94P, 2025) — the two-site HpH/HpBB precursor of this study. hema.to/resources/leukocyte-differentiation-study

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AI model: hema.to CellStudio (RUO): a proprietary transformer-based neural network trained from scratch on thousands of expert-annotated flow-cytometry files. Research use only; not for use in diagnostic procedures. · www.hema.to · info@hema.to