

# iSED<sup>®</sup> PRO: A Rheology-Based Approach to High-Throughput ESR Testing

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## Abstract

**Title:** iSED PRO: A Rheology-Based Approach to High-Throughput ESR Testing  
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**Introduction:** Erythrocyte sedimentation rate (ESR) is one of the oldest and most common laboratory tests. ESR is a non-specific lab test for assessing or monitoring patients with inflammatory conditions. Traditional ESR testing is done via the manual Westergren method, but many laboratories have adopted automated ESR analyzers to improve workflow. iSED PRO is the latest analyzer in the iSED ESR analyzer family, specifically designed to maximize efficiency for high-throughput labs. Results are available within 20 seconds with minimal hands-on time, significantly reducing time to result and improving patient care. **Method:** The iSED PRO technology is based on syllectometry and utilizes photometric rheology to assess rouleaux formation, the first step of RBC sedimentation. The degree of RBC aggregation is proportional to the degree of sedimentation. RBCs are pumped into the analyzer's flow cell which disaggregates the cells. When the pump stops, an optical sensor detects the changes in light transmission through the flow cell as RBCs aggregate. iSED PRO calculates an ESR value based on light transmission. By measuring RBC aggregation via a fully automated rack-based workflow, iSED PRO can generate a result within 20 seconds without the drawbacks and inconvenience of traditional sedimentation-based ESR testing. With QC scheduling and automated maintenance, iSED PRO further reduces hands-on time needed for routine procedures. Traditional ESR testing is commonly affected by technical and environmental. iSED PRO analyzes samples within seconds in a closed environment, limiting potential impact of environment factors, and the fully automated workflow reduces the potential for human error and improves operator safety. **Results:** Method Correlation (iSED PRO vs Westergren, n=200) was performed according to CLSI Procedure H02-A5 and yielded a regression equation of  $y=1.03x+1.58$ , 95% CI of the slope is 1.000 to 1.093, and 95% CI of intercept is -0.058 to 2.000. CuSum test is >0.05, showing no deviation from linearity. Paired T-Test shows equivalence. Average intrarun precision results are 6.0% for samples 0-30 mm/hr, 2.9% for samples 31-60 mm/hr, 2.4% for samples 61-90 mm/hr, and 2.9% for samples >90 mm/hr. Average interrun precision is 4.3%. **Conclusion:** The iSED PRO's photometric rheology based ESR measurement is comparable with Westergren methodology, and the hands-free workflow and automated maintenance significantly improve laboratory efficiency while patients benefit from results within 20 seconds.

## Introduction

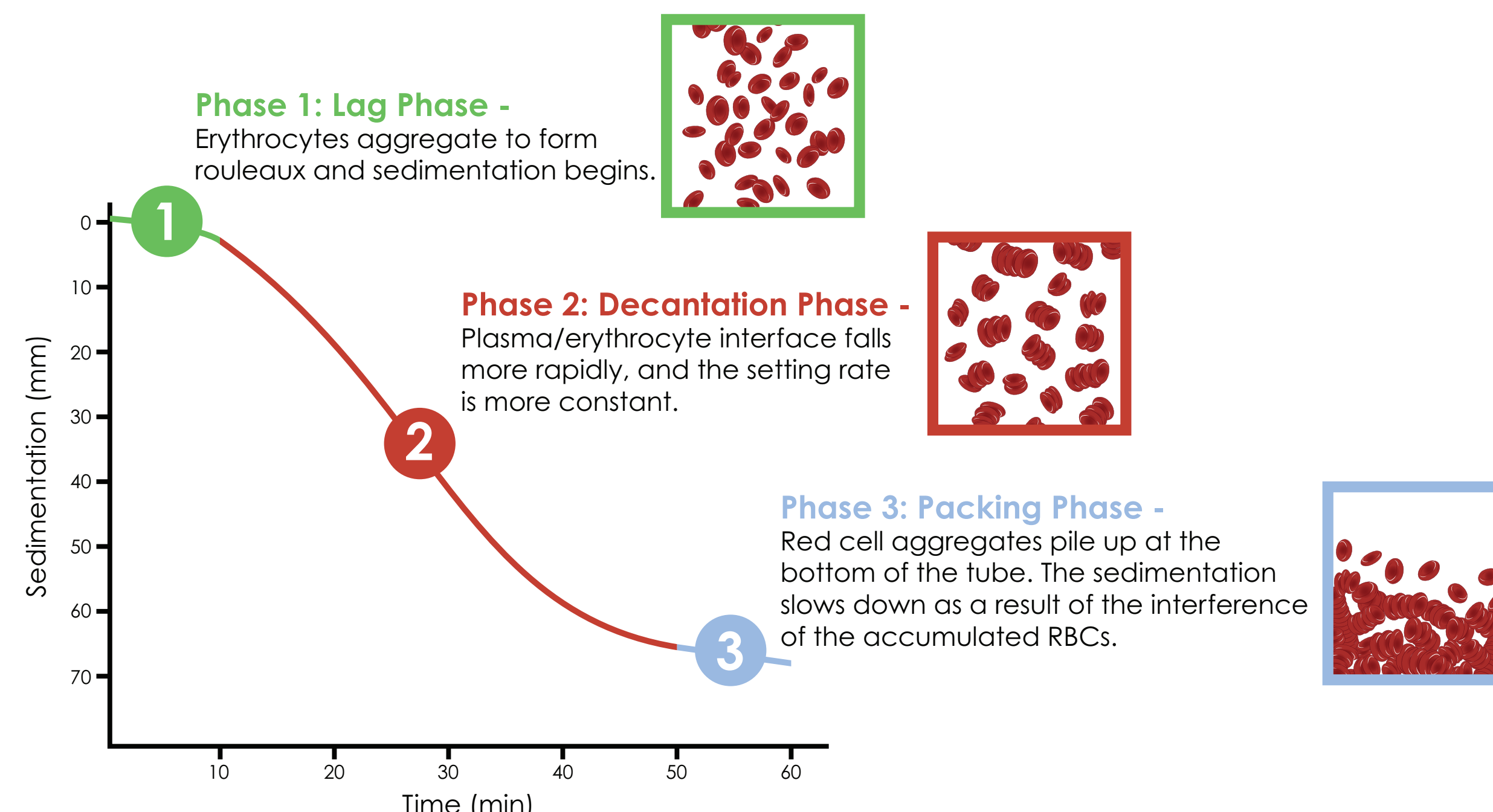
ESR, one of the oldest and most common laboratory tests, is a non-specific lab test for assessing or monitoring patients with inflammatory conditions. Traditional ESR testing is done via the manual Westergren method, but many laboratories have adopted automated ESR analyzers to improve workflow. iSED PRO is the latest analyzer in the iSED ESR analyzer family, specifically designed to maximize efficiency for high-throughput labs. iSED PRO is compatible with common hematology racks. Results are available within 20 seconds with minimal hands-on time, significantly reducing time to result and improving patient care. New automated features, such as QC scheduling, further minimize operator interactions. As labs are faced with critical shortages of personnel, efficiency enhancements of routine lab tests are more important than ever for maintaining productivity.



## Method

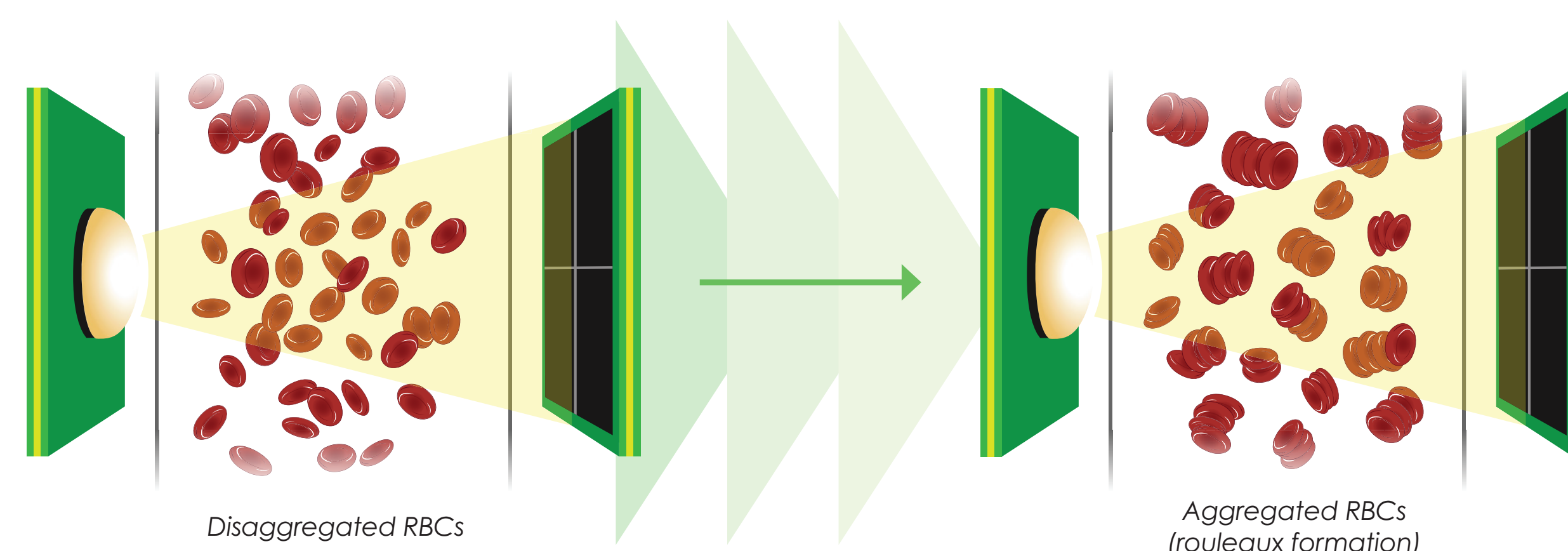
The iSED PRO technology is based on syllectometry and utilizes photometric rheology to assess rouleaux formation, the first step of RBC sedimentation.

### Erythrocyte sedimentation phases



The degree of RBC aggregation determines the degree of sedimentation. RBCs are pumped into the analyzer's flow cell which disaggregates the cells. When the pump stops, an optical sensor detects the changes in light transmission through the flow cell as RBCs aggregate. iSED PRO calculates an ESR value based on light transmission.

### iSED PRO Flow Cell



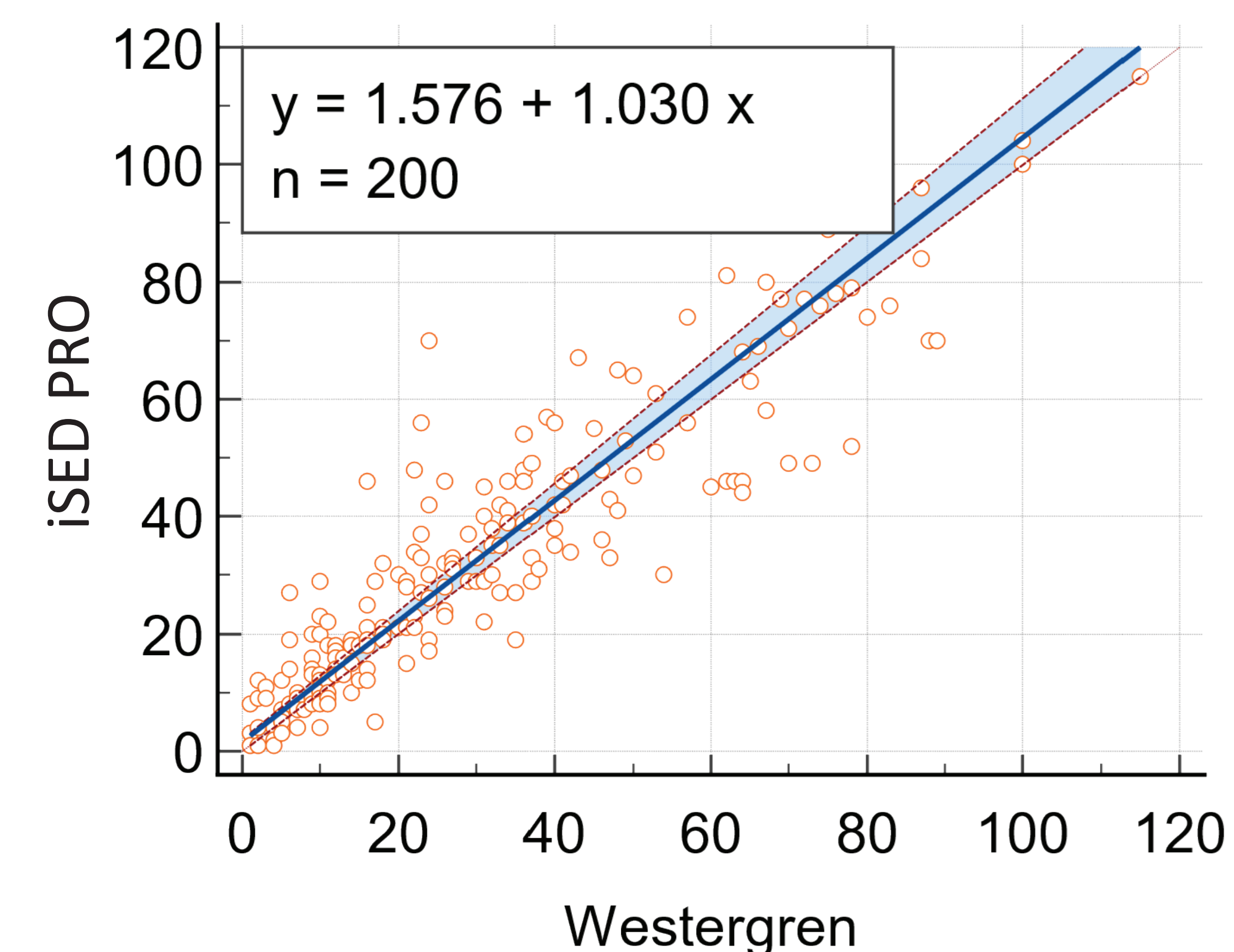
By measuring RBC aggregation via a fully automated rack-based workflow, iSED PRO can generate an ESR result within 20 seconds without the drawbacks and inconveniences of traditional sedimentation-based ESR testing. With QC scheduling and automated maintenance, iSED PRO further reduces hands-on time needed for routine procedures. Traditional ESR testing is commonly affected by technical and environmental factors. iSED PRO analyzes samples within seconds in a closed environment, limiting the ability of environmental factors like temperature to influence results, and the fully automated workflow reduces the potential for human error. Operator safety is improved compared to traditional ESR testing as capped, primary EDTA samples can be used without the need to uncapped or dilute samples. iSED PRO was correlated to the Westergren method using fresh samples. Passing-Bablok regression analysis was used to determine if the methods correlated, and precision and carryover were also assessed.

## Results

Method Correlation (iSED PRO vs Westergren, n=200) was performed according to CLSI Procedure H02-A5:

### Results of Passing-Bablok Regression Analysis

Variable X	Westergren
Variable Y	iSED PRO
Sample Size	200
Regression Equation	$y=1.03x + 1.58$
Slope 95% Confidence Interval	1.000 to 1.093
Intercept 95% Confidence Interval	-0.058 to 2.000
Cusum Test for Linearity	No significant deviation from linearity (P=0.57)



### Intrarun Precision

Ten replicates of a sample from each quartile of the analytical range were tested, and the process was repeated in 4 separate runs.

	Quartile 1 (0-30 mm/hr)				Quartile 2 (31-60 mm/hr)			
	Sample 1	Sample 2	Sample 3	Sample 4	Sample 1	Sample 2	Sample 3	Sample 4
Mean (mm/hr)	9.8	16.4	27.6	27.7	36.7	46.3	55.7	53.5
SD (mm/hr)	1.2	0.7	0.7	1.3	0.7	1.5	1.6	2.0
CV	12.5%	4.3%	2.5%	4.5%	1.8%	3.2%	2.9%	3.8%
Average CV	6.0%				2.9%			
	Quartile 3 (61-90 mm/hr)				Quartile 4 (>90 mm/hr)			
	Sample 1	Sample 2	Sample 3	Sample 4	Sample 1	Sample 2	Sample 3	Sample 4
Mean (mm/hr)	75.2	86.6	78.7	72.6	109.5	100.4	91.0	104.8
SD (mm/hr)	1.5	1.3	2.1	2.5	2.6	2.6	2.9	3.5
CV	2.0%	1.6%	2.6%	3.5%	2.4%	2.6%	3.2%	3.3%
Average CV	2.4%				2.9%			

### Interrun Precision

SEDiTROL<sup>®</sup> ESR Quality Controls Levels 1 and 2 were run 3 times a day over a period of 5 consecutive days. Stabilized quality control material was used to minimize the effect of sample age on results.

	Run 1		Run 2		Run 3		Overall % CV
	Level 1	Level 2	Level 1	Level 2	Level 1	Level 2	
Average (mm/hr)	10.8	68.0	10.8	67.4	10.2	68.2	4.3%
SD	0.8	0.7	0.4	0.5	1.1	0.8	
%CV	7.7	1.0	4.1	0.8	10.7	1.2	

### Carryover

Carryover testing was performed to demonstrate the sequence of sample testing does not affect measured values. High target value and low target value samples were selected for each run, and each sample was run in triplicate. Samples with high ESR values were run ahead of the samples with lower ESR values, and % carryover was calculated for each run.

	Run A	Run B	Run C	Overall
Carryover	1.96%	3.53%	0.00%	1.83%

## Conclusion

The iSED PRO's photometric rheology based ESR measurement is comparable with results generated via the traditional Westergren while demonstrating acceptable precision and carryover. The hands-free workflow and automated maintenance significantly help conserve scarce laboratory resources while improving patient management with <20 second ESR turnaround time.