

**SMILE Minimum Recommended Validation requirements for  
Hematology Total Allowable Error (TEa)**

Analyte	SMILE Total Error Limits (whichever is greater)		Precision	
	Percentage	Minimum detectable difference or absolute	Short Term 25% TE	Long Term 33% TE
<b>WBC</b>	± 15% (1)	0.12 x10 <sup>9</sup> /L (4)	3.75%	5.0%
<b>RBC</b>	± 6% (1)	0.20 x10 <sup>12</sup> /L (4)	1.5%	2.0%
<b>Hemoglobin</b>	± 7% (1)	0.67 g/dL (4)	1.75%	2.33%
<b>Hematocrit</b>	± 6% (1)	2.52% (6)	1.5%	3.0%
<b>MCV</b>	± 5.0% (5)	not available	1.250%	1.65%
<b>RDW</b>	± 10.0% (5)	not available	2.50%	3.33%
<b>MPV</b>	± 5.8% (2,3)	not available	1.45%	1.93%
<b>Platelets</b>	± 25% (1)	4.5 x10 <sup>9</sup> /L (4)	6.25%	8.33%
<b>Neutrophils</b>	± 22.4% (2,3)	1.0 x K/uL (7)	5.6%	7.47%
<b>Lymphocytes</b>	± 16% (2,3)	1.0 x K/uL (7)	4.0%	5.33%
<b>Monocytes</b>	± 27.9% (2,3)	1.0 x K/uL (7)	6.98%	9.30%
<b>Eosinophils</b>	± 37.1% (2,3)	1.0 x K/uL (7)	9.28%	12.40%
<b>Basophils</b>	± 38.5% (2,3)	1.0 x K/uL (7)	9.63%	12.83%

References:

1) <http://www.westgard.com/clia.htm>

2) EP Evaluator version 8, Biological Variation data from Analytical Quality Commission of the Spanish Society of Clinical Chemistry and Molecular Pathology

3) <http://www.westgard.com/biodatabase1.htm> DESIRABLE SPECIFICATIONS FOR TOTAL ERROR, IMPRECISION, AND BIAS, DERIVED FROM BIOLOGIC VARIATION, Ricos C, Alvarez V, et. al "Current databases on biologic variation: pros, cons and progress." Scand J Clin Lab Invest 1999;59:491-500. Annex I, Part I: Within-subject and between-subject CV values of analytes and Desirable Analytical Quality Specifications for imprecision, bias and total error

4) <http://www.cap.org>, CAP2008 LN9-A Hematology Linearity and Calibration Verification Participant Summary Evaluation Criteria

5) <http://www.digitalpt.com>, Digital PT. PT Evaluation Criteria v 1.0, January 2008

6) Clinical and Laboratory Standards Institute (CLSI). Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Proposed Standard - Second Edition. CLSI document H26-P2 (ISBN 1-56238-705-7). CLSI 940 W. Valley Rd., Suite 1400, Wayne, PA 19087

7) <http://www.cap.org>, CAP2010 FH10-B Hematology Participant Summary Evaluation Criteria

