

**pSMILE Minimum Recommended Validation Requirements for
Chemistry Total Allowable Error (TEa)**

Analyte	pSMILE Total Error Limits (whichever is greater)		Precision	
	Percentage	Minimum detectable difference	Short Term 25% TE	Long Term 33% TE
Albumin	± 10% ⁽¹⁾	± 0.2 g/dL ⁽⁴⁾	2.5%	3.3%
Alk. Phos	± 30% ⁽¹⁾	± 5.0 U/L ⁽⁴⁾	7.5%	9.9%
ALT	± 20% ⁽¹⁾	± 5.0 U/L ⁽⁴⁾	5.0%	6.6%
Amylase	± 30% ⁽¹⁾	± 5.0 U/L ⁽⁴⁾	7.5%	9.9%
AST	± 20% ⁽¹⁾	± 5.0 U/L ⁽⁴⁾	5.0%	6.6%
Bilirubin, Direct	± 20% ⁽¹⁾	± 0.4 mg/dL ⁽¹⁾	5.0%	6.6%
Bilirubin, Total	± 20% ⁽¹⁾	± 0.4 mg/dL ⁽¹⁾	5.0%	6.6%
Calcium	± 8% ⁽⁴⁾	± 1.0 mg/dL ⁽¹⁾	2.0%	2.6%
Chloride	± 5% ⁽¹⁾	± 2.0 mmol/L ⁽⁴⁾	1.3%	1.7%
Cholesterol	± 10% ⁽¹⁾	± 3.0 mg/dL ⁽⁴⁾	2.5%	3.3%
CO2	± 20% ⁽⁴⁾	± 0.4 mmol/L ⁽⁴⁾	5.0%	6.6%
Creatinine	± 15% ⁽¹⁾	± 0.3 mg/dL ⁽¹⁾	3.8%	5.0%
Creatine Kinase	± 30% ⁽¹⁾	± 5.0 U/L ⁽⁴⁾	7.5%	9.9%
Estradiol	± 30% ^(3&7)	Not available	7.5%	9.9%
Ferritin	± 20% ⁽⁷⁾	± 4.5 ng/mL ⁽²⁾	5.0%	6.6%
Folate	± 30% ⁽²⁾	± 2.0 ng/mL ⁽²⁾	7.5%	9.9%
GGT	± 25% ⁽⁴⁾	± 5.0 U/L ⁽⁴⁾	6.3%	8.3%
Glucose	± 10% ⁽¹⁾	± 6.0 mg/dL ⁽¹⁾	2.5%	3.3%
hCG Quant	± 18% ^(3&7)	± 3 mIU/mL ^(3&7)	4.5%	5.9%
HDL Cholesterol	± 30% ⁽¹⁾	± 2.0 mg/dL ⁽⁴⁾	7.5%	9.9%
Hemoglobin A1c	± 8% ^(3&8)	Not available	2.0%	2.6%
Iron	± 20% ⁽¹⁾	± 5.0 µg/dL ⁽⁴⁾	5.0%	6.6%
Total Iron Binding Capacity	± 20% ⁽¹⁾	Not available	5.0%	6.6%
Iron Binding, Unsaturated	± 25% ⁽²⁾	Not available	6.3%	8.3%
Lactate	± 10% ⁽³⁾	± 0.4 mmol/L ⁽¹⁾	2.5%	3.3%
Lactate Dehydrogenase	± 20% ⁽¹⁾	± 5.0 U/L ⁽⁴⁾	5.0%	6.6%
LDL-Cholesterol, Calculated	± 20% ⁽⁷⁾	Not available	5.0%	6.6%
LDL-Cholesterol, Measured	± 30% ⁽¹⁾	Not available	7.5%	9.9%
Lipase	± 30% ⁽¹⁾	± 8.0 U/L ⁽⁴⁾	7.5%	9.9%
Magnesium	± 25% ⁽¹⁾	± 0.2 mg/dL ⁽⁴⁾	6.3%	8.3%

Phosphorus	± 10.7% ⁽¹⁾	± 0.3 mg/dL ⁽¹⁾	2.5%	3.3%
Potassium	± 10% ⁽⁴⁾	± 0.5 mmol/L ⁽¹⁾	2.5%	3.3%
Progesterone	± 25% ⁽³⁾	Not available	6.3%	8.3%
Prolactin	± 20% ⁽³⁾	Not available	5.0%	6.6%
Protein, Total (Serum)	± 10% ⁽¹⁾	± 0.2 g/dL ⁽⁴⁾	2.5%	3.3%
Protein, Total (CSF)	± 20% ⁽⁵⁾	Not available	5.0%	6.6%
Sodium	± 5% ⁽⁴⁾	± 4.0 mmol/L ⁽¹⁾	1.3%	1.7%
Transferrin	± 20% ⁽¹⁾	± 0.5 g/L ⁽²⁾	5.0%	6.6%
Testosterone	± 30% ⁽³⁾	± 20 ng/dL ⁽³⁾	7.5%	9.9%
Triglycerides	± 25% ⁽¹⁾	± 13 mg/dL ⁽⁴⁾	6.3%	8.3%
Urea (BUN)	± 9% ⁽¹⁾	± 2.0 mg/dL ⁽¹⁾	2.3%	3.0%
Uric Acid	± 17% ⁽¹⁾	± 0.5 mg/dL ⁽⁴⁾	4.3%	5.6%
Vitamin B-12	± 25% ⁽⁶⁾	± 30 pg/mL ⁽³⁾	6.3%	8.3%
25-OH Vitamin D, Total	± 25% ⁽⁹⁾	± 5.0 ng/mL ⁽⁹⁾	6.3%	8.3%

References:

- 1) <https://www.CAP.org>, 2023 Chemistry (C) Participant Summary Evaluation Criteria
- 2) <https://www.datainnovations.com/allowable-total-error-table>
- 3) <http://www.westgard.com/biodatabase1.htm> & <https://www.westgard.com/2019-clia-requirements.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>, 2023 CAP Chemistry (LN2) Linearity and Calibration Verification Participant Summary Evaluation Criteria
- 5) <http://www.CAP.org>, 2023 CAP (M) Cerebrospinal Fluid Chemistry and Oligoclonal Band Participant Summary Evaluation Criteria
- 6) <http://www.CAP.org>, 2023 CAP (VIT-B12) Participant Summary Evaluation Criteria
- 7) <https://1wa.org>, 2023 Chemistry (BCHE) Quantitative Participation Statistics

**pSMILE Minimum Recommended Validation Requirements for
Coagulation Total Allowable Error (TEa)**

Analyte	pSMILE Total Error Limits (whichever is greater)		Precision	
	Percentage	Minimum detectable difference	Short Term 25% TE	Long Term 33% TE
Fibrinogen	± 20% ⁽¹⁾	not available	5.0%	6.6%
Prothrombin Time	± 15% ⁽¹⁾	not available	3.8%	5.0%
Activated Partial Thromboplastin Time	± 15% ⁽¹⁾	not available	3.8%	5.0%

References:

1) <http://www.westgard.com/biodatabase1.htm> & <https://www.westgard.com/2019-clia-requirements.htm>

**pSMILE Minimum Recommended Validation Requirements for
Hematology Total Allowable Error (TEa)**

Analyte	pSMILE Total Error Limits (whichever is greater)		Precision	
	Percentage	Minimum detectable difference	Short Term 25% TE	Long Term 33% TE
WBC	± 15% ⁽¹⁾	± 0.12 x 10 ⁹ /L ⁽³⁾	3.8%	5.0%
RBC	± 6% ⁽¹⁾	± 0.20 x 10 ¹² /L ⁽³⁾	1.5%	2.0%
Hemoglobin	± 7% ⁽¹⁾	± 0.67 g/dL ⁽³⁾	1.8%	2.3%
Hematocrit	± 6% ⁽¹⁾	Not available	1.5%	2.0%
MCV	± 5% ⁽⁴⁾	Not available	1.3%	1.7%
RDW	± 10% ⁽⁴⁾	Not available	2.5%	3.3%
MPV	± 5% ⁽⁴⁾	Not available	1.3%	1.7%
Platelets	± 25% ⁽¹⁾	± 4.5 x 10 ⁹ /L ⁽³⁾	6.3%	8.3%
Neutrophils	± 23.35% ⁽²⁾	± 1.0 ⁽¹⁾	5.8%	7.7%
Lymphocytes	± 17.6% ⁽²⁾	± 1.0 ⁽¹⁾	4.4%	5.8%
Monocytes	± 27.9% ⁽²⁾	± 1.0 ⁽¹⁾	7.0%	9.2%
Eosinophils	± 37.1% ⁽²⁾	± 1.0 ⁽¹⁾	9.3%	12.2%
Basophils	± 38.5% ⁽²⁾	± 1.0 ⁽¹⁾	9.6%	12.7%

References:

- 1) [https://www.CAP, 2023 Hematology \(e.g. FH16\) Participant Summary Evaluation Criteria](https://www.CAP, 2023 Hematology (e.g. FH16) Participant Summary Evaluation Criteria)
- 2) <https://www.westgard.com/minimum-biodatabase1.htm>
- 3) [http://www.cap.org, 2023 CAP Hematology \(LN9\) Linearity and Calibration Verification Participant Summary Evaluation Criteria](http://www.cap.org, 2023 CAP Hematology (LN9) Linearity and Calibration Verification Participant Summary Evaluation Criteria)
- 4) [https://1wa.org. 2023 Hematology \(e.g. HEFA\) Quantitative Participation Statistics](https://1wa.org. 2023 Hematology (e.g. HEFA) Quantitative Participation Statistics)