Comparison testing of MiniCollect® K2E K_2EDTA Tubes to Microtainer® K2E K_2EDTA Tubes

Background:

Greiner Bio-One has a newly redesigned MiniCollect® tube with an integrated collection scoop and wider opening to facilitate capillary blood collection and sample mixing. The new design no longer requires capillaries or funnels to facilitate blood transfer from the puncture site into the MiniCollect® tube.

The MiniCollect® K2E K_2EDTA capillary blood collection tube also features a co-molded cap which can easily be removed during the collection and sampling process. An audible click ensures proper closure for leakproof transport following sample collection

The interior of the MiniCollect® K2E K_2EDTA tube wall is coated with dipotassium EDTA (K_2EDTA).

MiniCollect® K2E K_2EDTA Blood Collection Tubes are used to collect, transport, store and evaluate capillary blood specimens for hematology tests [1/2].

Study Objective:

A clinical evaluation [3-7] was carried out including both adult and pediatric blood donors at three US sites to compare the performance of the MiniCollect® K2E K_2EDTA tube with new design in comparison to BD Microtainer® K2E K_2EDTA tube. Blood was collected from subjects with both healthy and pathological concentrations of the parameters measured.

Each of the three sites collected at least 60 venous-only specimens, as well as 40 paired venous and capillary specimens, for a total of at least 100 distinct adult donors per site. This design ensured that testing data could be generated from 100 venous specimens and 40 capillary specimens to demonstrate the device performance with all intended sample matrices. In addition, one site collected and tested 10 pediatric heel-stick specimens.

Even though the proposed intended use of this blood collection tube is for the collection of capillary blood, venous collections were included to overcome the sample volume limitations and variations resulting from multiple collections typically associated with obtaining capillary blood samples.

Sample stability was tested by using venous specimens drawn from 25 healthy subjects and stored at room temperature. Initial and replicate testing after 12h was performed on a Sysmex XE 5000 analyzer.

Study design:

The following tube types were used in this study:

Sample ID	Description
A	Microtainer® K2E K_2EDTA 0.25-0.5 ml, (item No.: 365974)
B	MiniCollect® K2E K_2EDTA 0.25-0.5 ml (item No.: 450532)

The study was approved by each site's Institutional Review Board (IRB) prior to beginning any study activities. Informed consent was given by all participants.

Directly after venous blood collection, the tubes were carefully inverted according to the Instructions for Use. The tubes were transported to a laboratory within 6 hours after blood collection. A complete blood count was performed using study site instrumentation:

- DxH 800 from Beckman Coulter
- Sysmex XE-5000

Parameters tested:

- White blood cells (WBC)*
- Red blood cells (RBC)*
- Hemoglobin (HGB)*
- Hematocrit (HCT)*
- Platelets (PLT)*
- Mean corpuscular volume (MCV)
- Mean corpuscular hemoglobin (MCH)
- Mean corpuscular hemoglobin concentration (MCHC)
- Mean platelet volume (MPV)
- Red cell distribution width (RDW)
- Lymphocytes (LYM)
- Neutrophils (NEU)
- Eosinophils (EOS)
- Monocytes (MON)
- Basophils (BAS)

*selected parameters for samples collected from pediatric subjects

Protocol deviations were recorded on a protocol deviation form and subsequently entered into the electronic Case Report Form (eCRF). No adverse events were reported in this study.

Specimens collection:

Site 1: 102 adults (39 venous and capillary, 63 venous)
Site 2: 121 adults (45 venous and capillary, 76 venous)
Site 3: 101 adults (41 venous and capillary, 60 venous) and 10 infants (heel-stick)

All capillary, venous, and heel-stick samples had one measurement from the evaluation tube (B) and one measurement from the control tube (A) for each parameter.

Additional contrived samples were prepared to obtain measurements that were below the lower end of the normal ranges for WBC, RBC, HGB and PLT since few native specimens collected during the conduct of the study had sufficiently low levels of these parameters to cover the medical decision levels.

Statistical evaluation: Outliers were removed using the extreme studentized deviate (ESD) test where up to 5% of the paired samples are allowed to be removed. Outliers may occur as a results of measurement error due to the instrument used. These are removed in the rare case where they exceed the criteria of the ESD test. The estimates and 95% Confidence Intervals for the bias are expressed in terms of the percent difference (CV%) and the difference in values (Abs). The appropriate measure is then compared to the acceptance criteria.

The tables below summarize the **acceptance criteria** for each of the parameters tested in the evaluation.

WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, RDW, LYMPH, NEU, MONO, EO, BASO	**Acceptance criteria**
Correlation for Method Comparison (r)	≥ 0.9
Regression Slope 95% CI Lower Bound	≥ 0.9
Regression Slope 95% CI Upper Bound	≤ 1.1
Regression Intercept 95% CI Lower Bound	≤ 0
Regression Intercept 95% CI Upper Bound	≥ 0

	Acceptance criteria for Overall % Bias
WBC	≤ 15%
RBC	≤ 6%
HGB	≤ 7%
HCT	≤ 6%
MCV	≤ 2.3%
MCH	≤ 2.7%
MCHC	≤ 2.2%
Platelets	≤ 25%
RDW	≤ 4.6%
Lymphocytes	≤ 16%
Neutrophils	≤ 22.4%
Monocytes	≤ 27.9%
Eosinophils	≤ 37.1%
Basophils	≤ 38.5%

Summary of results for method comparison testing:

After removing the outliers, the bias criteria were met at all medical decision levels for all parameters. The regression line criteria were not met in two cases across the data for all three sites. The first case was for Basophils. The values for Basophils are typically in the range of 0.00-0.10, but could only be measured to the nearest 0.01 or 0.1 by the instrumentation. Therefore the difference between the values is either 0 or at least as large as the rounding error leading to a wide 95% CI for the slope that is not contained in the interval 0.9-1.1. The other regression line that failed to meet the criteria was for Eosinophils. The 95% CI for the y-intercept did not include 0, but was very close. Both statistical deviations were minor and did not lead to deviations in the estimated bias of the analytes. Overall, each parameter passed the acceptance criteria for bias demonstrating that there is no difference in parameter values between sample in tubes A and B.

Method Comparison **Regression and Correlation**

Analyte	N	Slope	Intercept	Corr (r)
BAS	440/440	1.015	-0.002	0.7020
EOS	422/441	1.051	-0.005	0.9857
HCT	436/458	1.001	-0.025	0.9928
HGB	436/458	1.000	0.015	0.9942
LYM	431/440	1.010	-0.016	0.9872
MCH	439/446	1.004	-0.106	0.9940
MCHC	438/446	0.995	0.158	0.9547
MCV	445/447	1.004	-0.281	0.9986
MON	434/441	0.993	0.008	0.9618
NEU	427/438	1.001	-0.002	0.9961
PLT	436/458	1.008	0.805	0.9834
RBC	436/458	0.998	0.010	0.9923
RDW	441/446	1.001	-0.009	0.9973
WBC	446/458	0.998	0.024	0.9930

Method Comparison Bias at Medical Decision Points

		Bias (CV%)		Bias (Abs)	
Analyte	Level	Estimate	95% CI	Estimate	95% CI
BAS	0.015	-11.6	(-41.4, 18.3)	0.00	(-0.006, 0.002)
	0.05	-2.23	(-13.8, 9.3)	0.00	(-0.007, 0.005)
EOS	0.05	-4.05	(-10.3, 2.2)	0.00	(-0.005, 0.001)
	0.25	3.24	(1.1, 5.4)	0.01	(0.003, 0.014)
HCT	35	0.06	(-0.1, 0.2)	0.02	(-0.048, 0.087)
	50	0.08	(-0.2, 0.3)	0.04	(-0.085, 0.162)
HGB	11.5	0.10	(-0.1, 0.3)	0.01	(-0.010, 0.033)
	16	0.07	(-0.1, 0.3)	0.01	(-0.023, 0.044)
	18	0.05	(-0.2, 0.3)	0.01	(-0.031, 0.051)
LYM	1.5	-0.07	(-0.8, 0.7)	0.00	(-0.012, 0.010)
	3	0.47	(-0.3, 1.3)	0.01	(-0.010, 0.039)
	3.6	0.57	(-0.3, 1.5)	0.02	(-0.013, 0.053)
MCH	28	0.02	(-0.1, 0.1)	0.00	(-0.025, 0.034)
	32	0.06	(-0.1, 0.2)	0.02	(-0.021, 0.062)
	33	0.07	(-0.1, 0.2)	0.02	(-0.024, 0.073)
MCHC	33	0.00	(-0.1, 0.1)	0.00	(-0.036, 0.036)
	36	-0.04	(-0.3, 0.2)	-0.01	(-0.110, 0.081)
	37	-0.05	(-0.4, 0.3)	-0.02	(-0.145, 0.106)

		Bias (CV%)		Bias (Abs)	
Analyte	Level	Estimate	95% CI	Estimate	95% CI
MCV	76	0.00	(-0.1, 0.1)	0.00	(-0.073, 0.066)
	88	0.05	(0.0, 0.1)	0.04	(0.005, 0.076)
	100	0.08	(0.0, 0.2)	0.08	(0.014, 0.154)
MON	0.099	7.21	(-7.7, 22.2)	0.01	(-0.008, 0.023)
	0.28	2.15	(-1.3, 5.6)	0.01	(-0.004, 0.016)
	0.5	0.90	(-0.4, 2.2)	0.00	(-0.002, 0.011)
NEU	3.15	-0.01	(-0.7, 0.7)	0.00	(-0.022, 0.021)
	6.2	0.02	(-0.5, 0.6)	0.00	(-0.032, 0.035)
	8.3	0.03	(-0.6, 0.7)	0.00	(-0.051, 0.057)
PLT	150	1.36	(0.7, 2.1)	2.06	(0.998, 3.118)
	300	1.10	(0.5, 1.7)	3.31	(1.555, 5.068)
	500	0.99	(0.3, 1.7)	4.98	(1.358, 8.607)
RBC	4.1	0.01	(-0.2, 0.2)	0.00	(-0.007, 0.008)
	5.5	-0.05	(-0.3, 0.2)	0.00	(-0.016, 0.010)
	6	-0.07	(-0.3, 0.2)	0.00	(-0.019, 0.011)
RDW	12.9	0.03	(-0.1, 0.1)	0.00	(-0.009, 0.017)
	18.7	0.05	(-0.2, 0.3)	0.01	(-0.033, 0.052)
WBC	4.4	0.35	(-0.4, 1.1)	0.02	(-0.016, 0.047)
	11.3	0.01	(-0.5, 0.6)	0.00	(-0.061, 0.064)
	11.4	0.01	(-0.5, 0.6)	0.00	(-0.062, 0.065)

Summary of results comparing venous to capillary samples (Matrix comparison):

After removing the outliers, the bias criteria were met at all medical decision levels for all parameters. The regression line criteria were not met in five cases (BAS, EOS, MCHC, MCV, and MON) across the data for all three sites. The values for BAS are typically in the range of 0.00-0.10, but can only be measured to the nearest 0.01 or to the nearest 0.1 by the instrumentation causing the differences to be either 0 or at least as large as the rounding error. Though these differences can be relatively large and cause the correlation coefficient to be small, the differences are not clinically significant. Therefore, the correlation was less than 0.9 and the 95% CI for the slope was not contained in the interval 0.9 to 1.1. For EOS, MCHC, and MON, the lower limit of the slope's confidence intervals were below 0.9 (0.89, 0.89, and 0.88, respectively) due to slight systematic shifts. Each of these are minor statistical deviations. Slight systematic shifts may be attributed to small variations in reference ranges for venous and capillary blood [8/9] Published literature studies do not indicate equivalent results as it depends on the patient collective investigated e.g. healthy or oncology patients. However, SD is comparable. All RBC parameters (MCV, MCH, MCHC, HCT) correlated well (r= 0.9971, 0.9943, 0.9325, and 0.9691 respectively). Lastly, the 95% CI for the y-intercept does not contain 0 for MCHC and MCV. However, the observed ranges for these parameters (30.2-36.9 for MCHC and 60.3-103.2 for MCV) are not in the vicinity of the Y intercept, (0), and therefore this is not clinically meaningful.

Matrix Comparison Regression and Correlation:

Analyte	N	Slope	Intercept	Corr (r)
BAS	246/246	0.960	-0.009	0.5784
EOS	241/248	0.927	0.003	0.9842
HCT	242/249	0.982	0.484	0.9691
HGB	241/249	0.962	0.346	0.9749
LYM	244/248	0.972	-0.017	0.9699
MCH	244/248	0.996	0.089	0.9943
MCHC	244/248	0.934	2.001	0.9325
MCV	244/249	1.026	-1.789	0.9971
MON	248/248	0.946	0.009	0.9370
NEU	240/246	0.964	-0.001	0.9919
PLT	237/249	0.993	11.587	0.9364
RBC	244/249	0.955	0.150	0.9683
RDW	243/249	1.001	0.005	0.9964
WBC	243/249	0.959	0.013	0.9850

Matrix Comparison Bias at Medical Decision Points

		Bias (CV%)		Bias (Abs)	
Analyte	Level	Estimate	95% CI	Estimate	95% CI
BAS	0.015	-91.4	(-226.9, 44.0)	-0.01	(-0.020, 0.002)
	0.05	-24.3	(-40.0, -8.5)	-0.01	(-0.017, -0.005)
EOS	0.05	-1.49	(-9.6, 6.7)	0.00	(-0.005, 0.003)
	0.25	-6.29	(-8.9, -3.7)	-0.02	(-0.021, -0.009)
HCT	35	-0.44	(-1.0, 0.1)	-0.15	(-0.346, 0.042)
	50	-0.85	(-1.8, 0.0)	-0.43	(-0.871, 0.021)
HGB	11.5	-0.84	(-1.4, -0.2)	-0.10	(-0.164, -0.028)
	16	-1.70	(-2.5, -0.9)	-0.27	(-0.390, -0.148)
	18	-1.94	(-3.0, -0.9)	-0.35	(-0.526, -0.165)
LYM	1.5	-4.02	(-5.6, -2.4)	-0.06	(-0.082, -0.036)
	3	-3.42	(-5.1, -1.7)	-0.10	(-0.151, -0.051)
	3.6	-3.32	(-5.3, -1.3)	-0.12	(-0.186, -0.049)
MCH	28	-0.06	(-0.2, 0.1)	-0.02	(-0.058, 0.023)
	32	-0.10	(-0.3, 0.1)	-0.03	(-0.094, 0.029)
	33	-0.11	(-0.3, 0.1)	-0.04	(-0.108, 0.035)
MCHC	33	-0.52	(-0.7, -0.4)	-0.17	(-0.226, -0.115)
	36	-1.03	(-1.4, -0.6)	-0.37	(-0.510, -0.226)
	37	-1.18	(-1.7, -0.7)	-0.43	(-0.619, -0.249)

		Bias (CV%)		Bias (Abs)	
Analyte	Level	Estimate	95% CI	Estimate	95% CI
MCV	76	0.20	(0.1, 0.3)	0.15	(0.051, 0.255)
	88	0.52	(0.4, 0.6)	0.46	(0.384, 0.535)
	100	0.76	(0.6, 0.9)	0.77	(0.624, 0.909)
MON	0.099	3.85	(-22.2, 29.8)	0.00	(-0.023, 0.031)
	0.28	-2.14	(-8.2, 4.0)	-0.01	(-0.023, 0.011)
	0.5	-3.63	(-5.8, -1.5)	-0.02	(-0.028, -0.007)
NEU	3.15	-3.67	(-4.8, -2.5)	-0.11	(-0.148, -0.079)
	6.2	-3.65	(-4.7, -2.6)	-0.22	(-0.287, -0.158)
	8.3	-3.65	(-4.9, -2.4)	-0.30	(-0.395, -0.200)
PLT	150	6.83	(3.6, 10.1)	10.60	(5.442, 15.760)
	300	3.15	(1.1, 5.2)	9.62	(3.383, 15.849)
	500	1.65	(-2.0, 5.3)	8.30	(-10.537, 27.141)
RBC	4.1	-0.82	(-1.4, -0.3)	-0.03	(-0.056, -0.011)
	5.5	-1.76	(-2.6, -0.9)	-0.10	(-0.142, -0.050)
	6	-1.99	(-3.1, -0.9)	-0.12	(-0.182, -0.055)
RDW	12.9	0.10	(-0.1, 0.3)	0.01	(-0.007, 0.033)
	18.7	0.09	(-0.4, 0.6)	0.02	(-0.083, 0.117)
WBC	4.4	-3.87	(-6.1, -1.7)	-0.17	(-0.260, -0.073)
	11.3	-4.06	(-5.4, -2.8)	-0.45	(-0.590, -0.309)
	11.4	-4.06	(-5.4, -2.8)	-0.45	(-0.597, -0.311)

Sample Stability

Venous specimens from healthy adult subjects were drawn to evaluate the equivalence of hematology results in specimens collected in MiniCollect® K2E K_2EDTA tubes (sample B) and Microtainer® K2E K_2EDTA tubes (sample A) when the tubes were stored at room temperature.

All tubes were tested for each parameter according to the acceptance criteria listed above.

The stability results of blood specimens at room temperature tested at 0h and retested after 12h are shown in the following table. Mean, minimum and maximum values, and SD of the 25 specimens tested are indicated for each parameter at each time point.

	Valid N	Mean	Minimum	Maximum	Std.Dev.
SAMPLE B WBC 0h	25	8.25	4.11	12.51	2.32
SAMPLE B WBC 12h	25	8.28	4.02	12.60	2.32
SAMPLE A WBC 0h	25	8.28	4.02	12.56	2.33
SAMPLE A WBC 12h	25	8.22	3.94	12.77	2.33
SAMPLE B RBC 0h	25	4.60	3.76	5.20	0.35
SAMPLE B RBC 12h	25	4.59	3.75	5.22	0.35
SAMPLE A RBC 0h	25	4.60	3.76	5.14	0.34
SAMPLE A RBC 12h	25	4.61	3.78	5.22	0.36
SAMPLE B Hbg 0h	25	13.60	11.70	16.00	1.05
SAMPLE B Hgb 12h	25	13.62	11.50	15.90	1.06
SAMPLE A Hgb 0h	25	13.60	11.40	15.90	1.05
SAMPLE A Hgb 12h	25	13.62	11.60	16.00	1.05
SAMPLE B Hct 0h	25	41.10	35.10	46.50	2.61
SAMPLE B Hct 12h	25	41.96	35.60	47.50	2.67
SAMPLE A Hct 0h	25	41.08	35.00	45.80	2.58
SAMPLE A Hct 12h	25	42.12	35.80	47.40	2.62
SAMPLE B MCV 0h	25	89.62	77.20	98.20	5.04
SAMPLE B MCV 12h	25	91.56	79.20	99.80	5.06
SAMPLE A MCV 0h	25	89.59	77.40	98.00	4.92
SAMPLE A MCV 12h	25	91.61	79.20	99.80	5.03
SAMPLE B MCH 0h	25	29.63	24.40	31.80	1.76
SAMPLE B MCH 12h	25	29.71	24.40	31.90	1.76
SAMPLE A MCH 0h	25	29.64	24.30	31.90	1.77
SAMPLE A MCH 12h	25	29.60	24.50	32.20	1.76
SAMPLE B MCHC 0h	25	33.07	30.60	35.00	0.97
SAMPLE B MCHC 12h	25	32.45	30.00	34.70	1.02
SAMPLE A MCHC 0h	25	33.08	30.80	34.80	0.99
SAMPLE A MCHC 12h	25	32.32	29.90	34.10	1.00
SAMPLE B PLT 0h	25	264.48	201.00	373.00	44.60
SAMPLE B PLT 12h	25	266.60	190.00	369.00	42.42
SAMPLE A PLT 0h	25	266.72	207.00	378.00	44.37
SAMPLE A PLT 12h	25	268.56	196.00	371.00	45.29
SAMPLE B RDW 0h	25	13.12	12.10	15.60	0.84
SAMPLE B RDW 12h	25	13.56	12.40	16.10	0.90
SAMPLE A RDW 0h	25	13.13	12.10	15.70	0.86

SAMPLE A RDW 12h	25	13.54	12.40	16.10	0.92
SAMPLE B LYM 0h	25	2.65	1.14	4.25	0.80
SAMPLE B LYM 12h	25	2.64	1.09	4.09	0.79
SAMPLE A LYM 0h	25	2.65	1.11	4.13	0.83
SAMPLE A LYM 12h	25	2.63	1.09	4.14	0.81
SAMPLE B NEU 0h	25	4.81	1.74	7.56	1.66
SAMPLE B NEU 12h	25	4.85	1.78	7.63	1.68
SAMPLE A NEU 0h	25	4.84	1.72	7.73	1.67
SAMPLE A NEU 12h	25	4.82	1.70	8.04	1.66
SAMPLE B MONO 0h	25	0.58	0.29	0.98	0.19
SAMPLE B MONO 12h	25	0.58	0.30	1.10	0.20
SAMPLE A MONO 0h	25	0.57	0.28	1.03	0.18
SAMPLE A MONO 12h	25	0.56	0.30	1.05	0.21
SAMPLE B EO 0h	25	0.16	0.03	0.51	0.11
SAMPLE B EO 12h	25	0.17	0.04	0.44	0.10
SAMPLE A EO 0h	25	0.17	0.02	0.46	0.10
SAMPLE A EO 12h	25	0.16	0.00	0.48	0.11
SAMPLE B BAS 0h	25	0.03	0.01	0.07	0.01
SAMPLE B BAS 12h	25	0.03	0.01	0.08	0.01
SAMPLE A BAS 0h	25	0.03	0.01	0.07	0.01
SAMPLE A BAS 12h	25	0.03	0.01	0.11	0.02

Summary of results for stability testing:

All evaluation tube (B) samples (25/25) met stability acceptance criteria for WBC, RBC, HGB, HCT, MCH, PLT, LYM, and NEU at 12 hours. For the MiniCollect® K2E K_2EDTA tubes, stability acceptance criteria were met in 24/25 samples at 12 hours for MON and in 23/25 samples at 12 hours for EOS. For RDW, 20/25 samples met the acceptance criteria at 12 hours. The acceptance criteria were met in 18/25 samples at 12 hours for BAS. For MCHC, 16/25 tubes met the criterion at 12 hours. Lastly, 15/25 evaluation tubes met the criterion at 12 hours for MCV.
For WBC, RBC, HGB, HCT, MCH, PLT, LYM and NEU, the control tube (A) samples met acceptance criteria for all 25 patients included at 12 hours. All six parameters that failed to meet the acceptance criteria for the MiniCollect® K2E K_2EDTA tubes also failed to meet the criteria in the Microtainer® K2E K_2EDTA tubes. Specifically, for the control tubes, the stability acceptance criteria were met in 23/25 samples at 12 hours for MON and in 22/25 samples at 12 hours for EOS. For RDW, 21/25 samples met the acceptance criterion at 12 hours. The acceptance criterion was met in 19/25 samples at 12 hours for BAS. For MCHC, 11/25 tubes met the criterion at 12 hours. Lastly, 15/25 control tubes met the criterion at 12 hours for MCV.

Samples collected in both the MiniCollect® tube and the Microtainer® tube met the acceptance criteria for eight of the parameters measured at 12h but demonstrated results where a percentage of samples for the remaining six parameters did not meet these criteria at 12h. Because the stability results for both tubes are comparable, the failures are most likely attributed to stability of the sample itself rather than some component of tubes.

Conclusion:

The performance of the MiniCollect® K2E K_2EDTA tube has been demonstrated to be substantially equivalent to the BD Microtainer® K2E K_2EDTA tube on both instruments when blood collected in each tube was tested for representative hematology parameters. Each parameter tested passed the acceptance criteria for bias. Results indicate that there is no interference from the MiniCollect® K2E K_2EDTA tube with either the assay methodologies or the instruments used in this study.

Comparing venous to capillary samples, the results generated in the study demonstrate expected differences as reported in the literature studies as indicated above, and are therefore, acceptable. Each parameter tested passed the acceptance criteria for bias. The results support method comparison results showing lack of interference by the MiniCollect® K2E K_2EDTA tube with the parameters measured and instrument methods used in this study.

Study results demonstrated a minimum stability of 12 hours for samples collected in the MiniCollect® K2E K2EDTA Tubes for 8 of the 14 parameters. Both tubes met the stability requirements for WBC, RBC, HGB, HCT, MCH, PLT, LYM and NEU but did not meet the stability requirements for MCV, MCHC, MON, BAS, EOS and RDW at 12h. Since the stability results obtained for MiniCollect® K2E K_2EDTA and Microtainer® K2E K_2EDTA are comparable, the deviations are likely due to specimen handling and/or degradation of the sample rather than to properties of the collection tubes.

In summary, the newly designed MiniCollect® K2E K_2EDTA tube is substantially equivalent to the BD Microtainer® K2E K_2EDTA tube.

References:

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[3] ISO 6710: *Single-use containers for venous blood specimen collection*. International Standard. 2017

[4] EP25-A: *Evaluation of Stability of in Vitro Diagnostic Reagents*; Approved Guideline – Second Edition. CLSI 2011.

[5] EP09-A3: *Measurement Procedure Comparison and Bias Estimation Using Patient Samples*; Approved Guideline — Second Edition (Interim Revision). CLSI 2011.

[6] GP39-A6: *Tubes and Additives for Venous and Capillary Blood Specimen Collection*; Approved Standard – Sixth Edition CLSI 2011

[7] GP42-A6: *Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens* – Approved Standard – Sixth Edition CLSI 2011

[8] C. Preeti. B. Vivek. T. Manikchandra. G. Umakant. P. Sanjay Kumar. Comparison of complete count parameters between venous and capillary blood in oncology patients. J. Lab Physicians 2016 8(1) 65-66

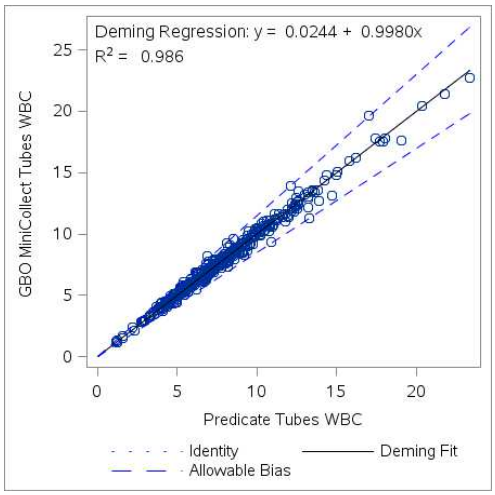
[9] E. Schalk. MU Heim. M Koenigsmann. K. Jentsch-Ullrich. Use of capillary blood count parameters in adults. Vox Sang 2007)3(4). 348-53

Results in detail: Method Comparison (both instruments included)

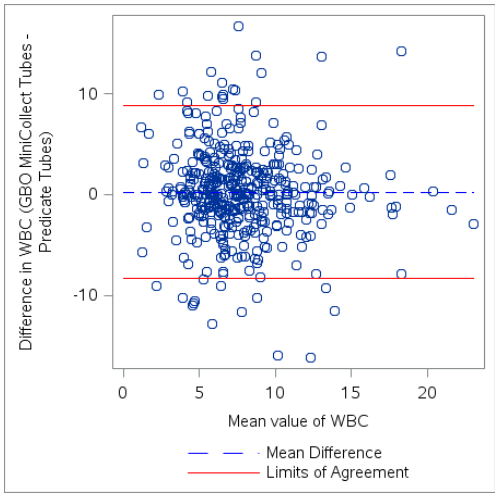
White Blood Cells (WBC)

Normal range: 3.6 -11.2 x 10^3/µl

Deming Regression - WBC - 10^3/uL



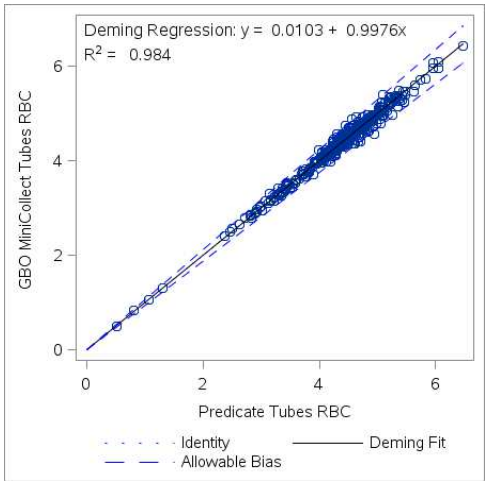
Bland-Altman Plot - WBC - 10^3/uL



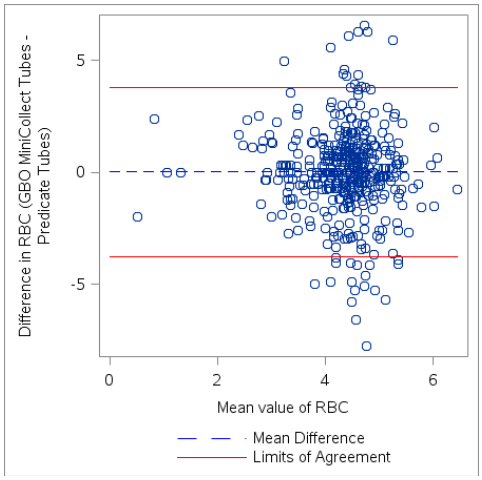
Red Blood Cells (RBC)

Normal range: 3.73 - 5.5 x 10^6/µl

Deming Regression - RBC - 10^6/uL



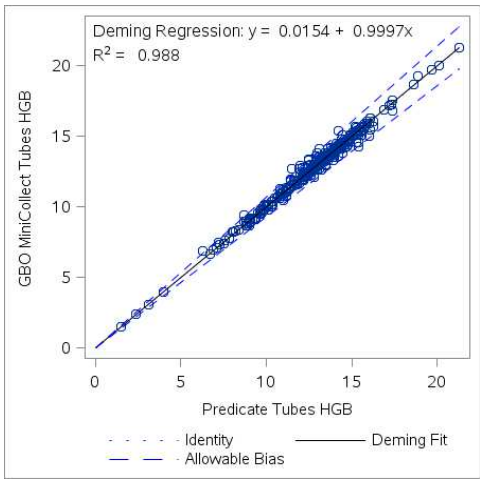
Bland-Altman Plot - RBC - 10^6/uL



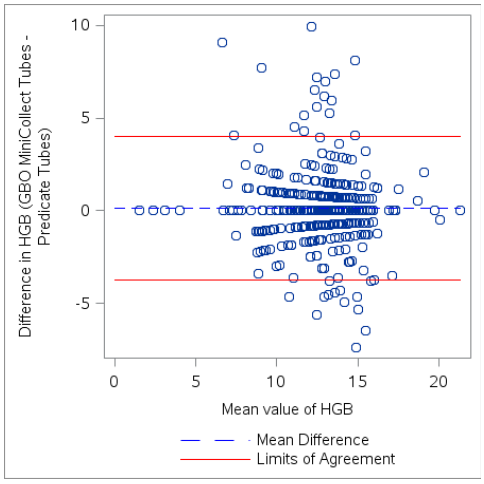
Hemoglobin (HGB)

Normal range: 11.4-15.9 g/dL

Deming Regression - HGB - g/dL



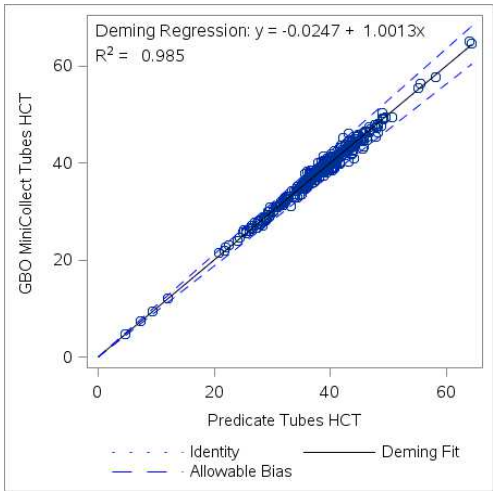
Bland-Altman Plot - HGB - g/dL



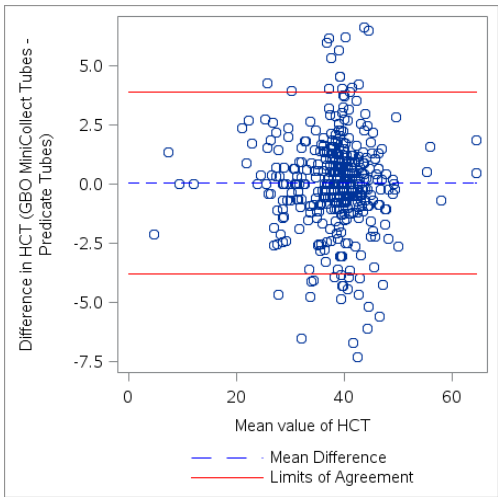
Hematocrit (HCT)

Normal range: 33.3-45.7 %

Deming Regression - HCT - %



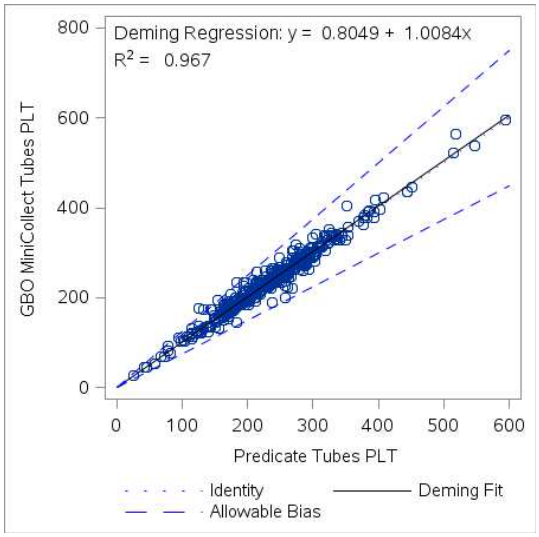
Bland-Altman Plot - HCT - %



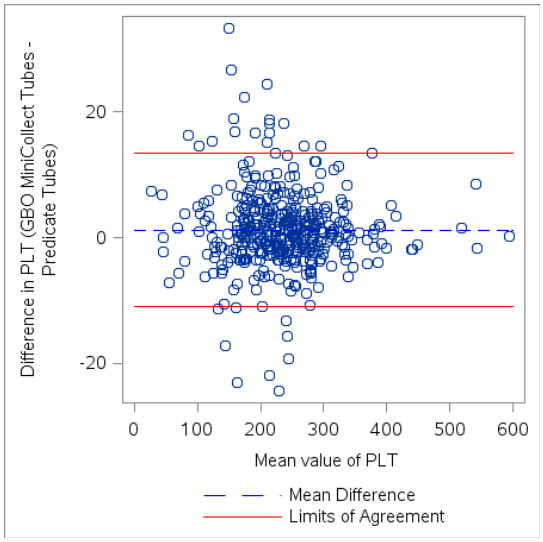
Platelets (PLT)

Normal range: 159-386 x 10^3/µL

Deming Regression - PLT - 10^3/uL



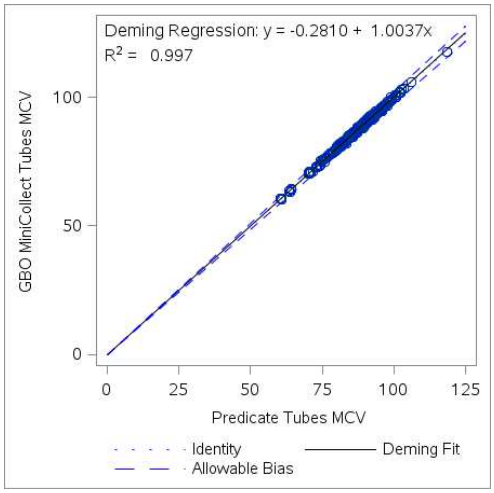
Bland-Altman Plot - PLT - 10^3/uL



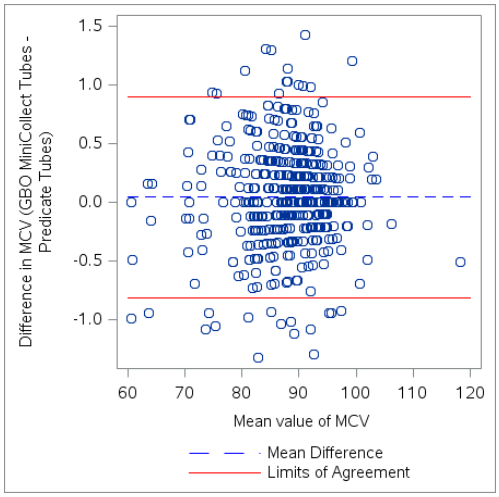
Mean Corpuscular Volume (MCV)

Normal range: 73.7-95.5 - 96 fL

Deming Regression - MCV - fL



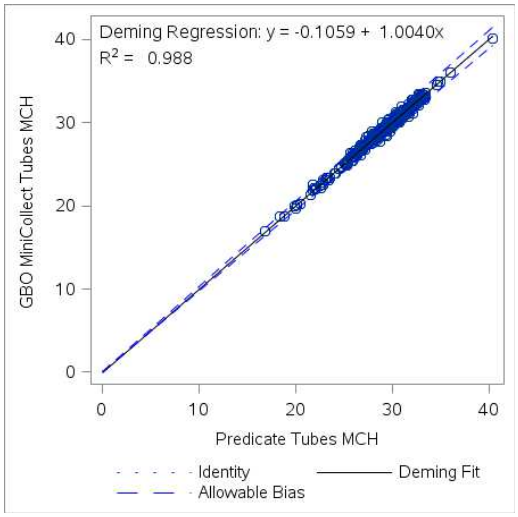
Bland-Altman Plot - MCV – fL



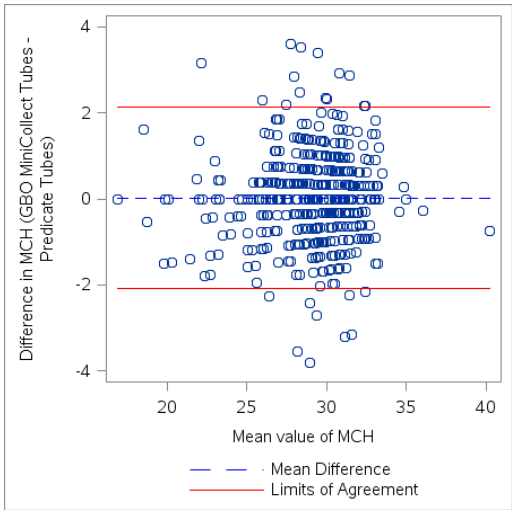
Mean Corpuscular Hemoglobin (MCH)

Normal range: 24.3 – 33.2 pg

Deming Regression - MCH - pg



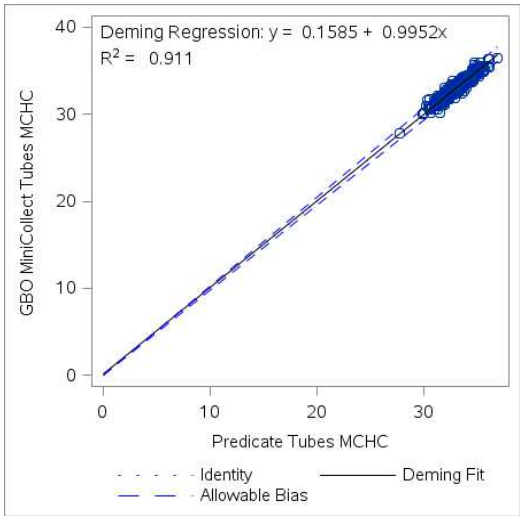
Bland-Altman Plot - MCH – pg



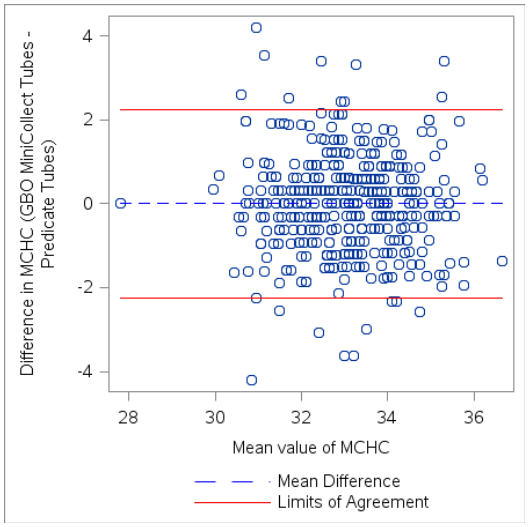
Mean Corpuscular Hemoglobin Concentration (MCHC)

Normal range: 32.5-35.8 g/dl

Deming Regression - MCHC - g/dL



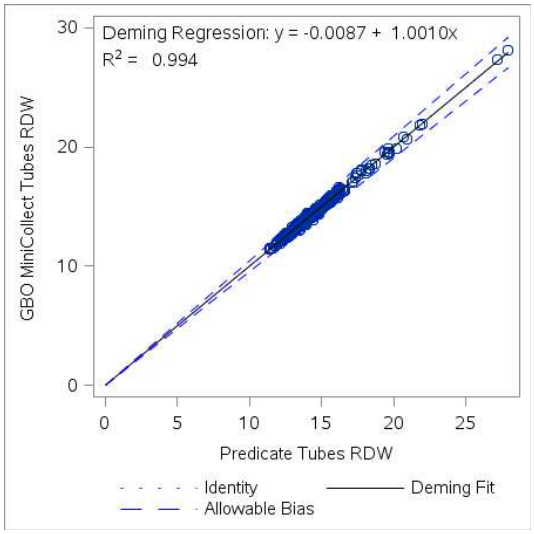
Bland-Altman Plot - MCHC - g/dL



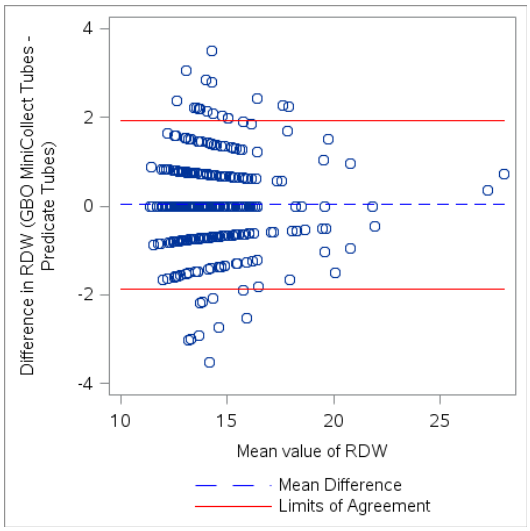
Red Cell Distribution Width (RDW)

Normal range: 12.3-17.0 %

Deming Regression - RDW - %



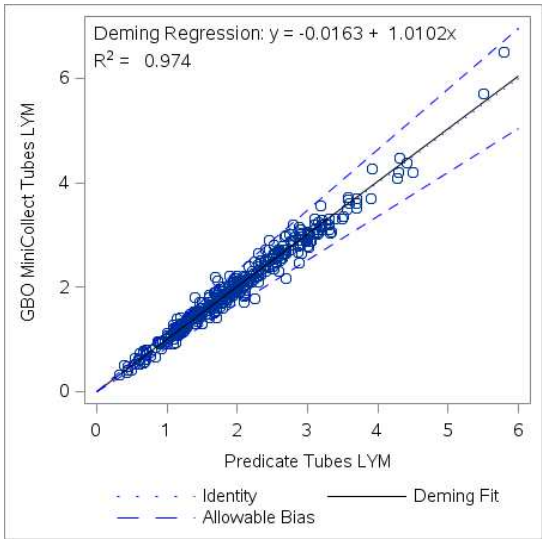
Bland-Altman Plot - RDW - %



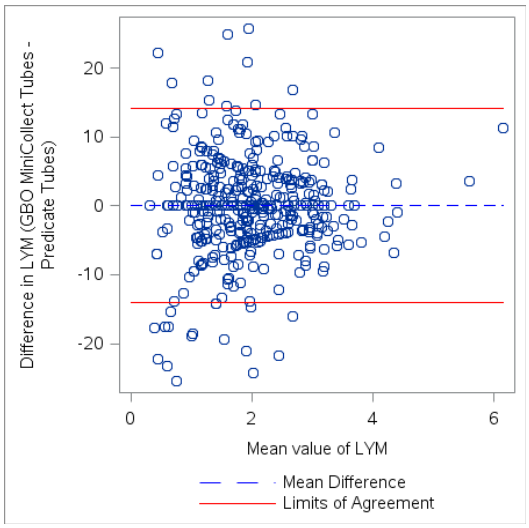
Lymphocytes (LYM)

Normal range: 1.0-3.0 x 10^3/µL

Deming Regression - LYM - 10^3/uL



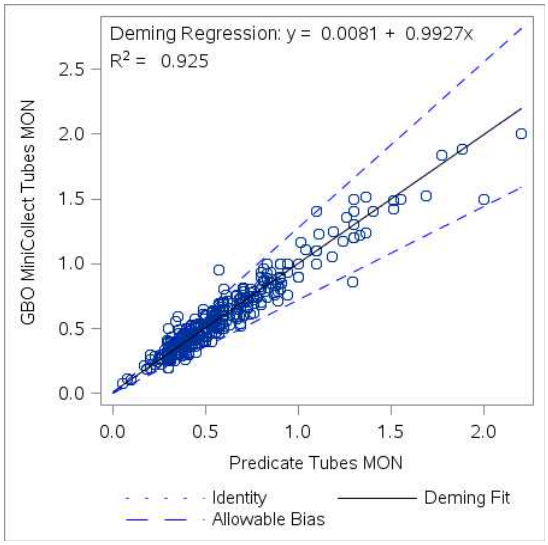
Bland-Altman Plot - LYM - 10^3/Ul



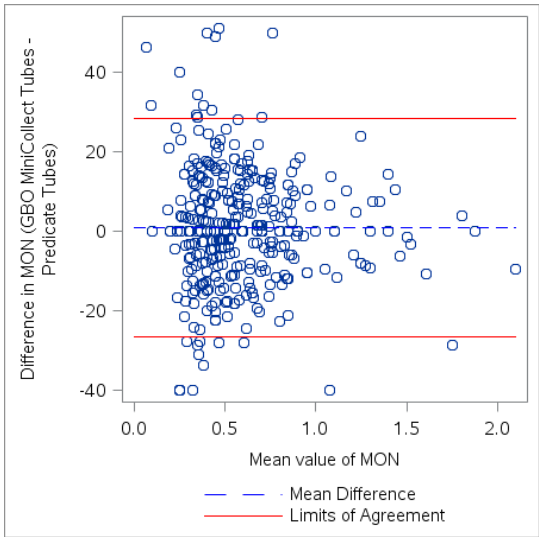
Monocytes (MON)

Normal range: 0.2-1.0 x 10^3/µL

Deming Regression - MON - 10^3/uL



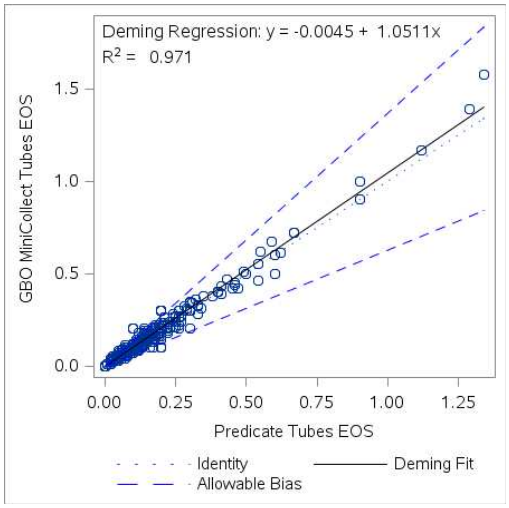
Bland-Altman Plot - MON - 10^3/uL



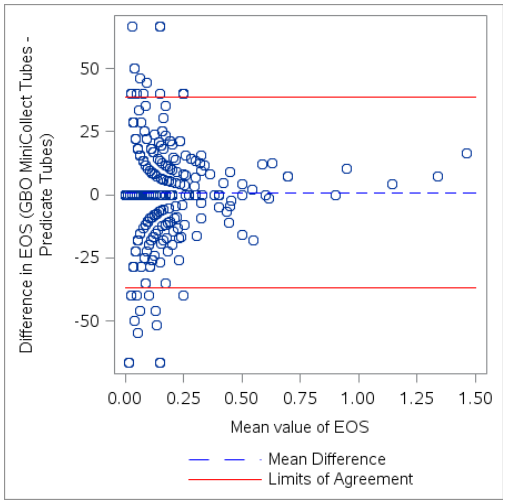
Eosinophils (EOS)

Normal range: 0.02-0.5 x 10^3/µL

Deming Regression - EOS - 10^3/uL



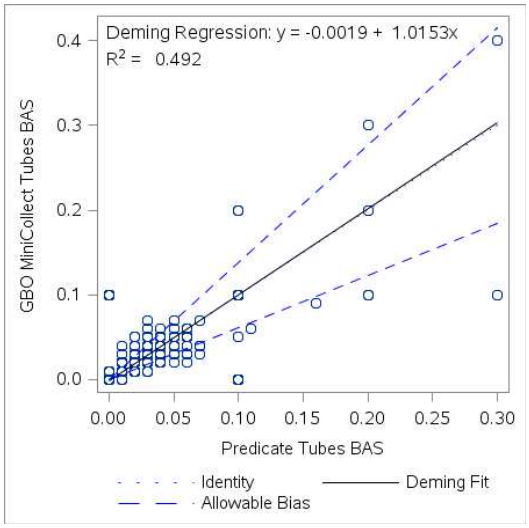
Bland-Altman Plot - EOS - 10^3/uL



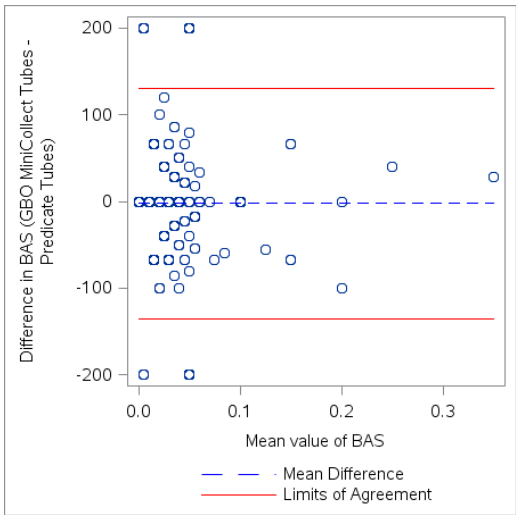
Basophils (BAS)

Normal range: 0.02-0.1 x 10^3/µL

Deming Regression - BAS - 10^3/uL



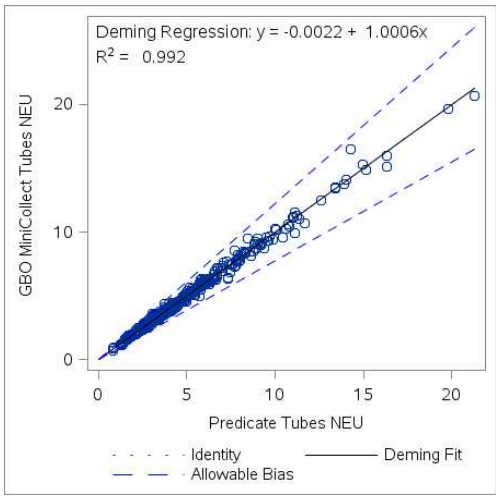
Bland-Altman Plot - BAS - 10^3/uL



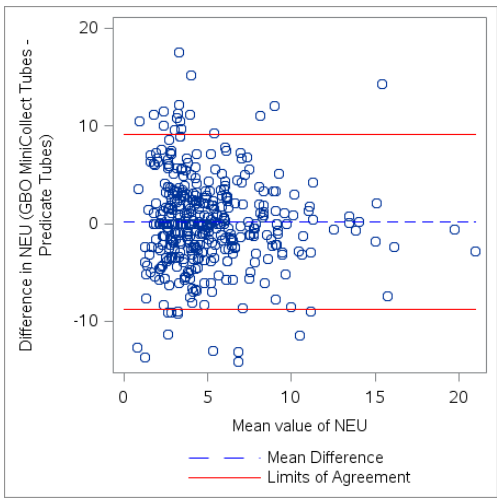
Neutrophils (NEU)

Normal range: 2.0-7.0 x 10^3/µl

Deming Regression - NEU - 10^3/uL



Bland-Altman Plot - NEU - 10^3/uL

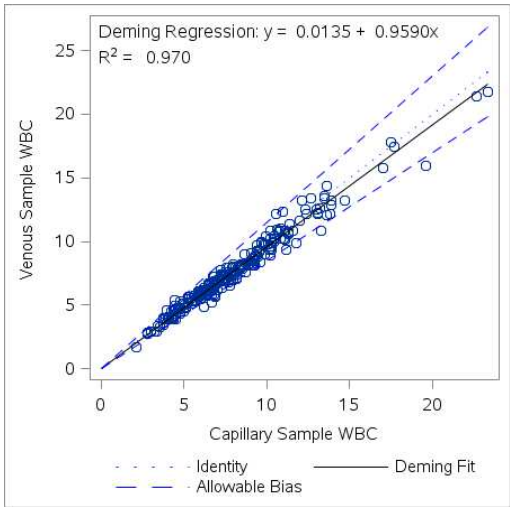


Results in detail: Matrix Comparison of Capillary to Venous Blood

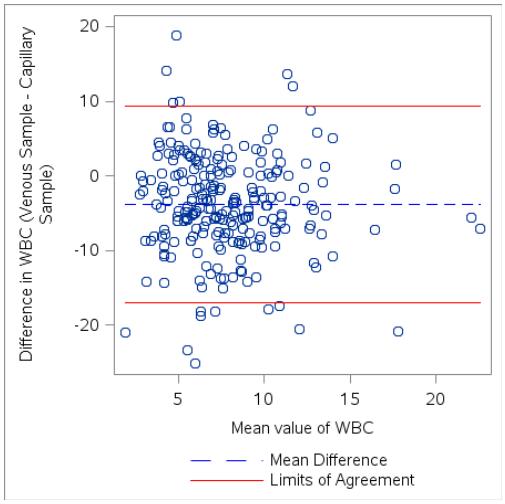
White Blood Cells (WBC)

Normal range: 3.6 -11.2 x 10^3/µl

Deming Regression - WBC - 10^3/uL



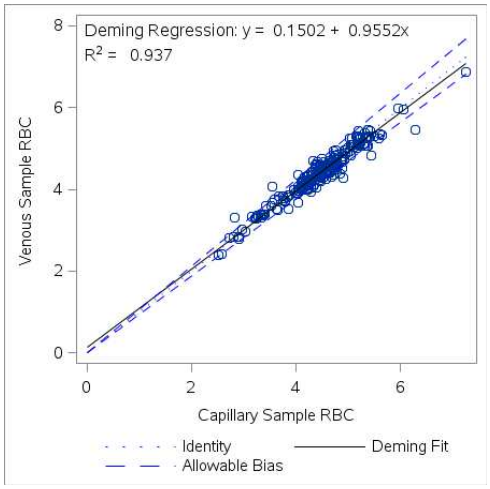
Bland-Altman Plot - WBC - 10^3/uL



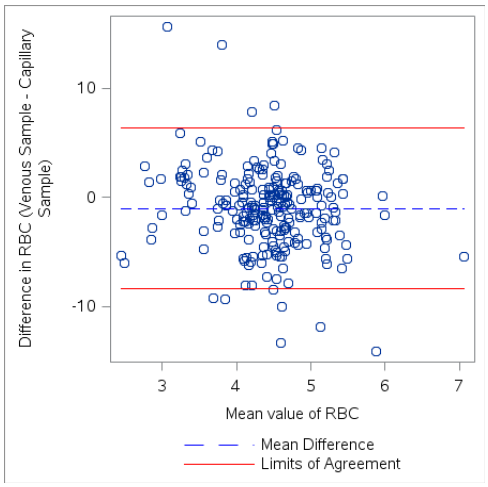
Red Blood Cells (RBC)

Normal range: 3.73 - 5.5 x 10^6/µl

Deming Regression - RBC - 10^6/uL



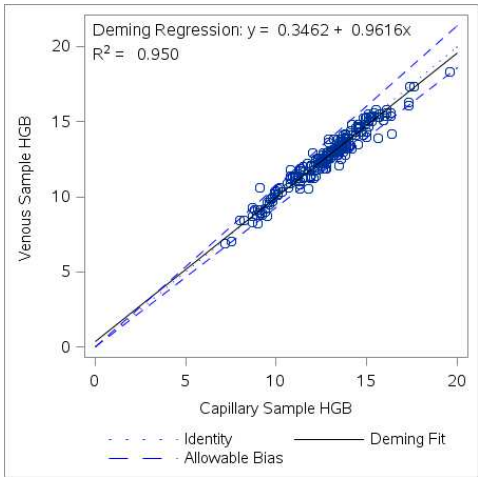
Bland-Altman Plot - RBC - 10^6/uL



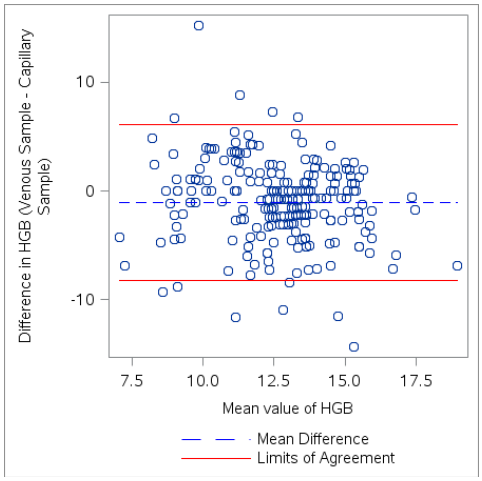
Hemoglobin (HGB)

Normal range: 11.4-15.9 g/dL

Deming Regression - HGB - g/dL



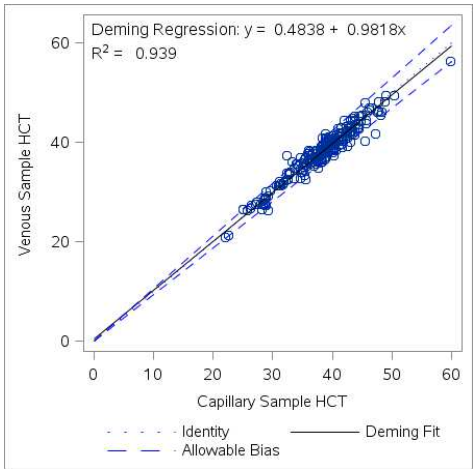
Bland-Altman Plot - HGB - g/dL



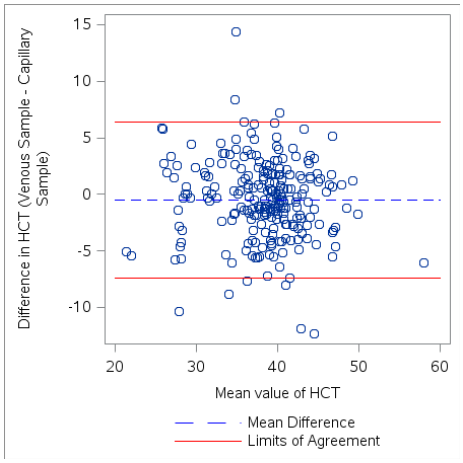
Hematocrit (HCT)

Normal range: 33.3-45.7 %

Deming Regression - HCT - %



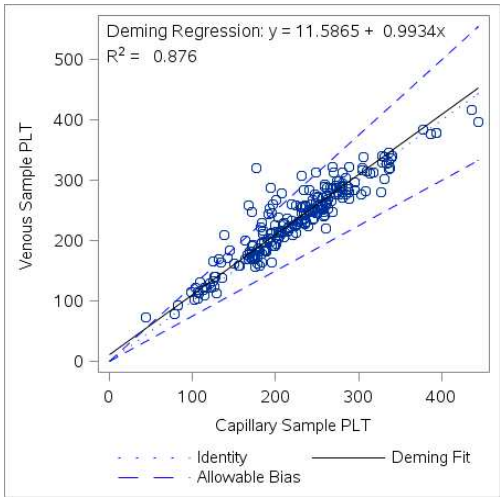
Bland-Altman Plot - HCT - %



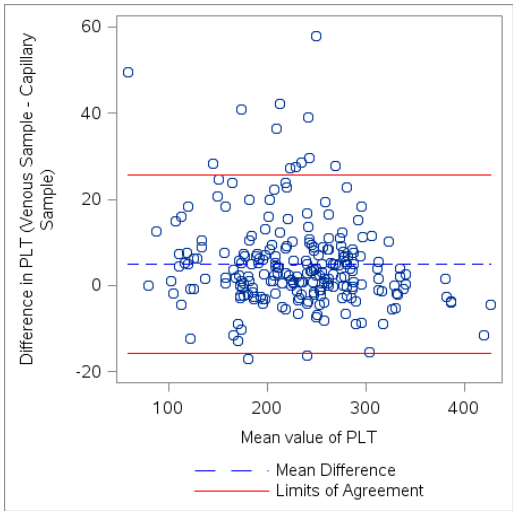
Platelets (PLT)

Normal range: 159-386 x 10^3/µL

Deming Regression - PLT - 10^3/uL



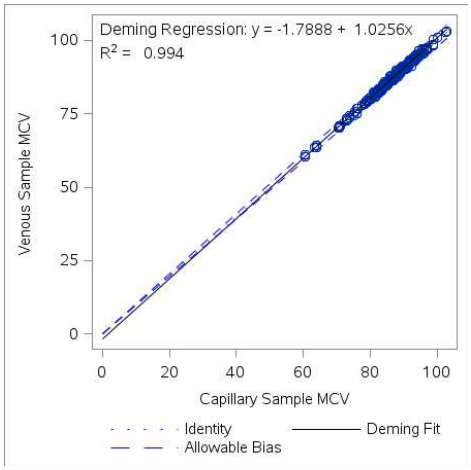
Bland-Altman Plot - PLT - 10^3/uL



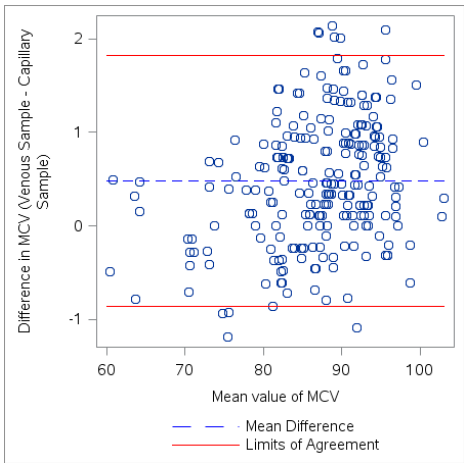
Mean Corpuscular Volume (MCV)

Normal range: 73.7 – 95.5 fL

Deming Regression - MCV - fL



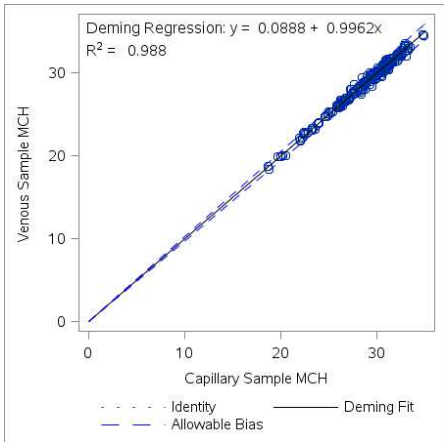
Bland-Altman Plot - MCV - fL



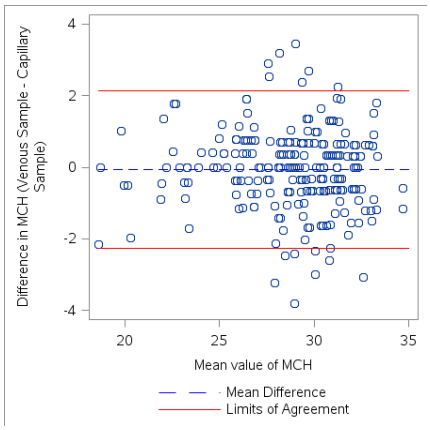
Mean Corpuscular Hemoglobin (MCH)

Normal range: 24.3 – 33.2 pg

Deming Regression - MCH - pg



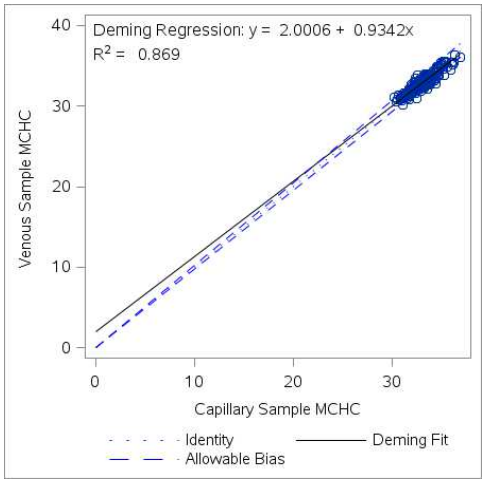
Bland-Altman Plot - MCH – pg



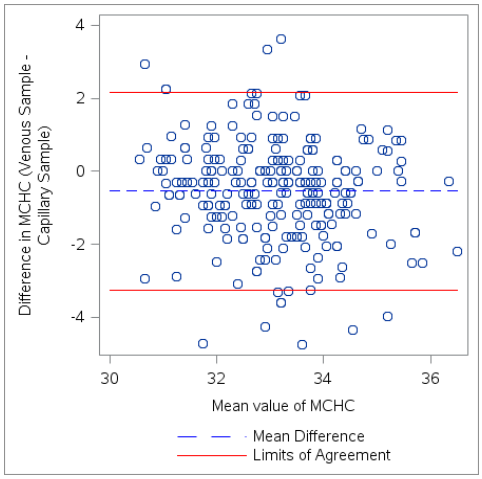
Mean Corpuscular Hemoglobin Concentration (MCHC)

Normal range: 32.5-35.8 g/dl

Deming Regression - MCHC - g/dL



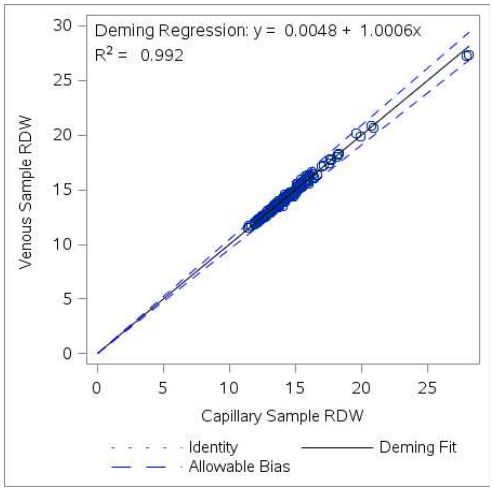
Bland-Altman Plot - MCHC - g/dL



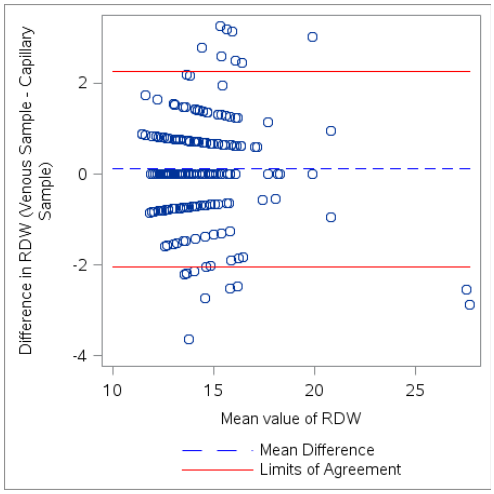
Red Cell Distribution Width (RDW)

Normal range: 12.3-17.0 %

Deming Regression - RDW - %



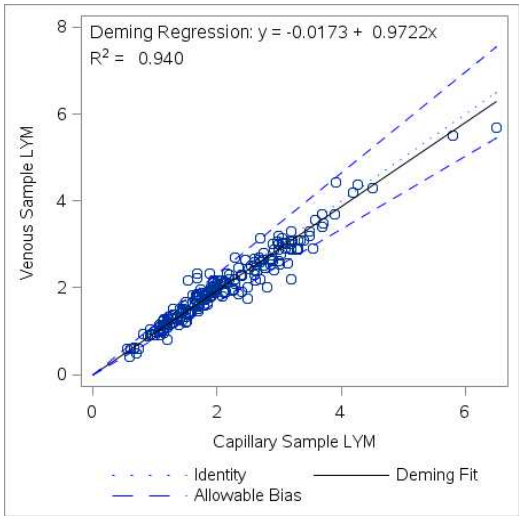
Bland-Altman Plot - RDW - %



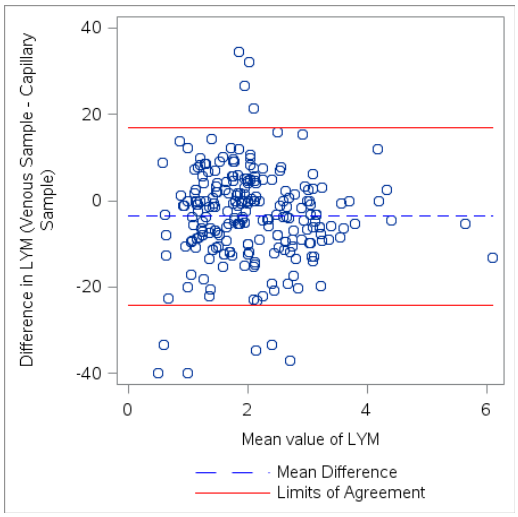
Lymphocytes (LYM)

Normal range: 1.0-3.0 x 10^3/µL

Deming Regression - LYM - 10^3/uL



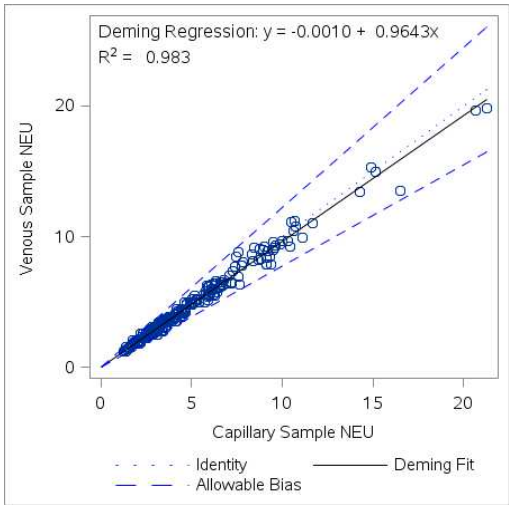
Bland-Altman Plot - LYM - 10^3/uL



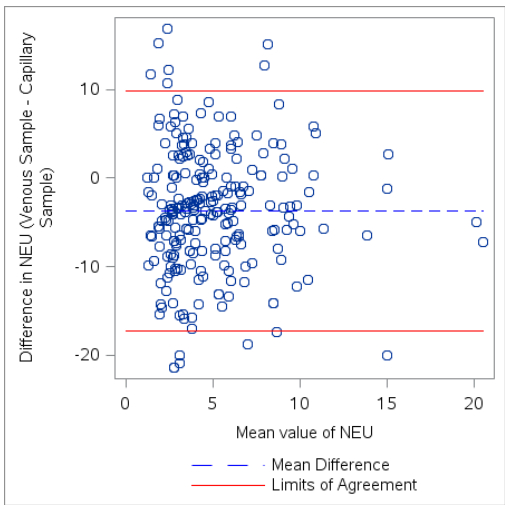
Neutrophils (NEU)

Normal range: 2.0-7.0 x 10^3/µl

Deming Regression - NEU - 10^3/uL



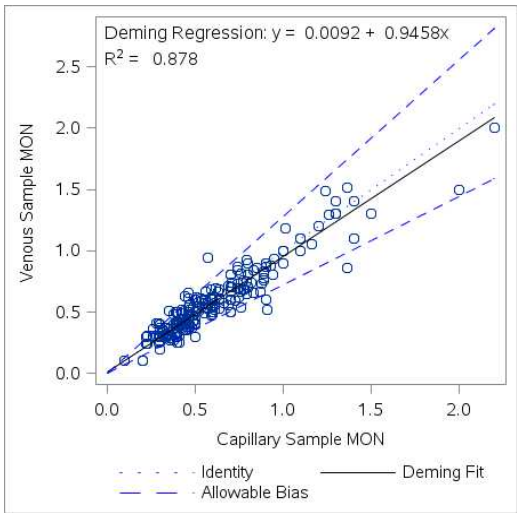
Bland-Altman Plot - NEU - 10^3/uL



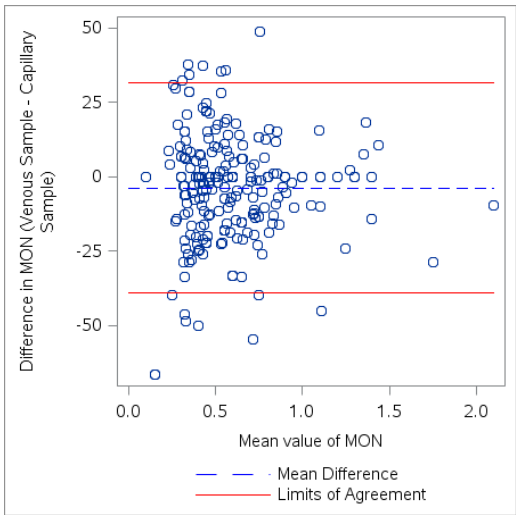
Monocytes (MON)

Normal range: 0.2-1.0 x 10^3/µL

Deming Regression - MON - 10^3/uL



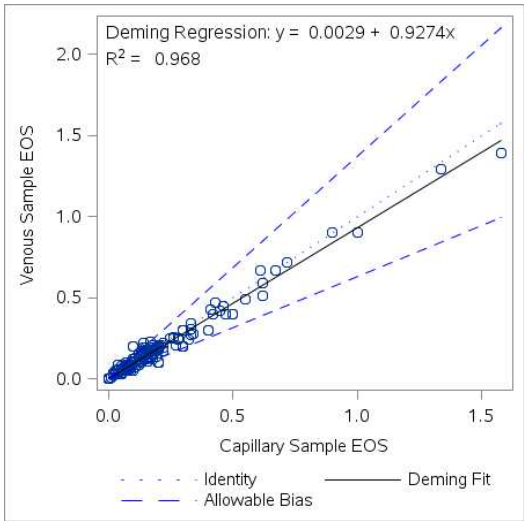
Bland-Altman Plot - MON - 10^3/uL



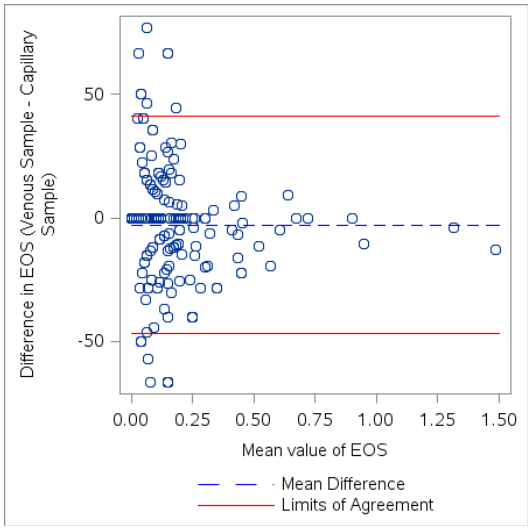
Eosinophils (EOS)

Normal range: 0.02-0.5 x 10^3/µL

Deming Regression - EOS - 10^3/uL



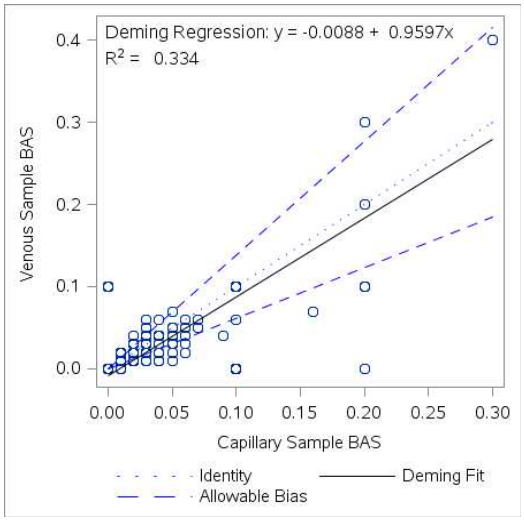
Bland-Altman Plot - EOS - 10^3/uL



Basophils (BAS)

Normal range: 0.02-0.1 x 10^3/µL

Deming Regression - BAS - 10^3/uL



Bland-Altman Plot - BAS - 10^3/uL