

CVA (Calibration Verification Assessment)

LAB ACCT#: 00100

SAMPLE LAB REPORT
1234 MAIN STREET
ANYTOWN, NE, USA 12345

TEST DATE: 10/01/2008
REPORT DATE: 10/03/2008
LOT #: 8217
LOT EXP. DATE: 12/01/2008

Attention: LAB MANAGER
Phone #: 000.000.0000
Fax #: 000.000.0000
INSTRUMENT #: 132 ADVIA® 2120

Thank you for purchasing Streck's CVA product for your hematology analyzer. The data that you have collected has been used to prepare the enclosed instrument performance analysis.

- Reportable Range - Establishes the minimum and maximum values for your analyzer within the performance limit criteria. This data will only be provided for analyzers that are included on the CVA assay.
- Calibration Verification - Verifies that your instrument's established reportable range is accurate.
- Linearity - r values are provided. The r value is the correlation factor in the linearity of the parameter.

Each laboratory must evaluate the data provided and use it as a guide in determining its level of instrument or testing accuracy, as well as evaluating acceptable reportable ranges. Performance goals for linearity should also be established by a laboratory based on clinical need and what is technically achievable with your instrumentation. Limits should not exceed the instrument manufacturer's linearity specification.

If you have any questions about the information contained in this report please contact our Technical Services department at 800-843-0912 ext. 7510.

Reportable Range

Parameter	Minimum	Maximum	r Value
WBC	0.70	391.03	0.99979
RBC	0.37	7.06	0.99986
HGB	1.10	21.60	0.99990
PLT	16.00	3623.00	0.99998

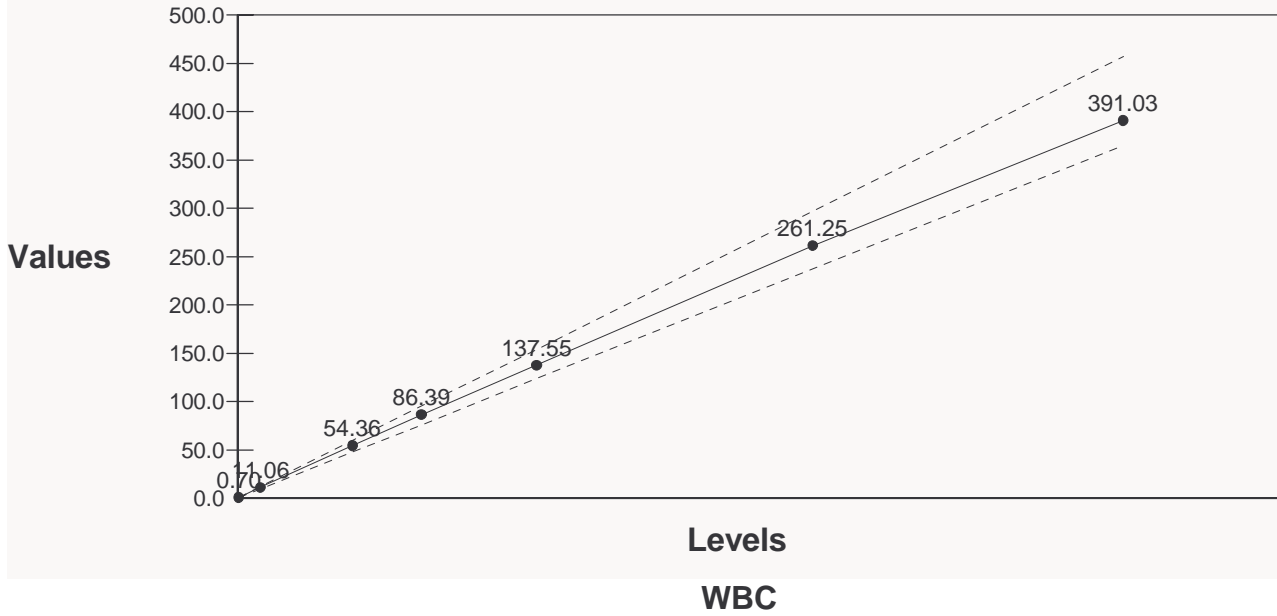
Summary Report

Parameter Within Limits?	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6	Level 7
WBC	Yes	Yes	Yes	Yes	Yes	Yes	Yes
RBC	Yes	Yes	Yes	Yes	Yes		
HGB	Yes	Yes	Yes	Yes	Yes		
PLT	Yes	Yes	Yes	Yes	Yes	Yes	

Reviewed By: _____ Title: _____ Date: _____

Linearity Graph

Your Mean
 - - - Assay/Low
 - - - Assay/High



Data Section for Calibration Verification

	Your Values	Your Mean	Group Mean	Group % Difference	Assay % Difference	Assay	Limits	
Level 1 Run #	1	0.71	0.70	0.68	2.94%	9.38%	0.64	0.34-0.94
	2	0.72						
	3	0.69						
	4	0.67						
Level 2 Run #	1	11.01	11.06	10.93	1.19%	3.56%	10.68	9.48-11.88
	2	11.25						
	3	11.08						
	4	10.89						
Level 3 Run #	1	54.78	54.36	54.26	0.18%	1.84%	53.38	47.38-59.38
	2	53.59						
	3	54.43						
	4	54.63						
Level 4 Run #	1	85.39	86.39	86.39	0.00%	1.16%	85.40	75.40-95.40
	2	86.19						
	3	86.63						
	4	87.33						
Level 5 Run #	1	135.39	137.55	139.31	-1.26%	-0.89%	138.78	123.78-153.78
	2	139.88						
	3	138.13						
	4	136.78						
Level 6 Run #	1	261.59	261.25	267.36	-2.29%	-2.11%	266.88	236.88-296.88
	2	257.14						
	3	263.69						
	4	262.57						

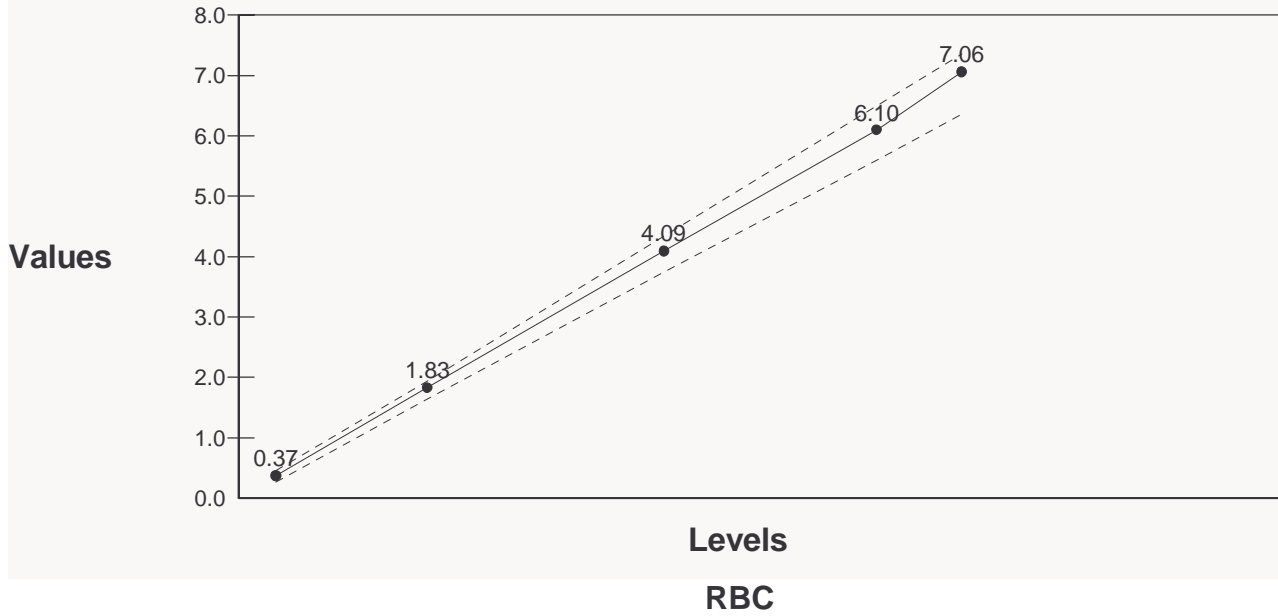
WBC

Data Section for Calibration Verification

	Your Values	Your Mean	Group Mean	Group % Difference	Assay % Difference	Assay	Limits
Level 7 Run # 1	387.49	391.03	404.07	-3.23%	-4.86%	410.99	364.99-456.99
2	387.34						
3	392.56						
4	396.71						

Linearity Graph

● Your Mean
 --- Assay/Low
 --- Assay/High

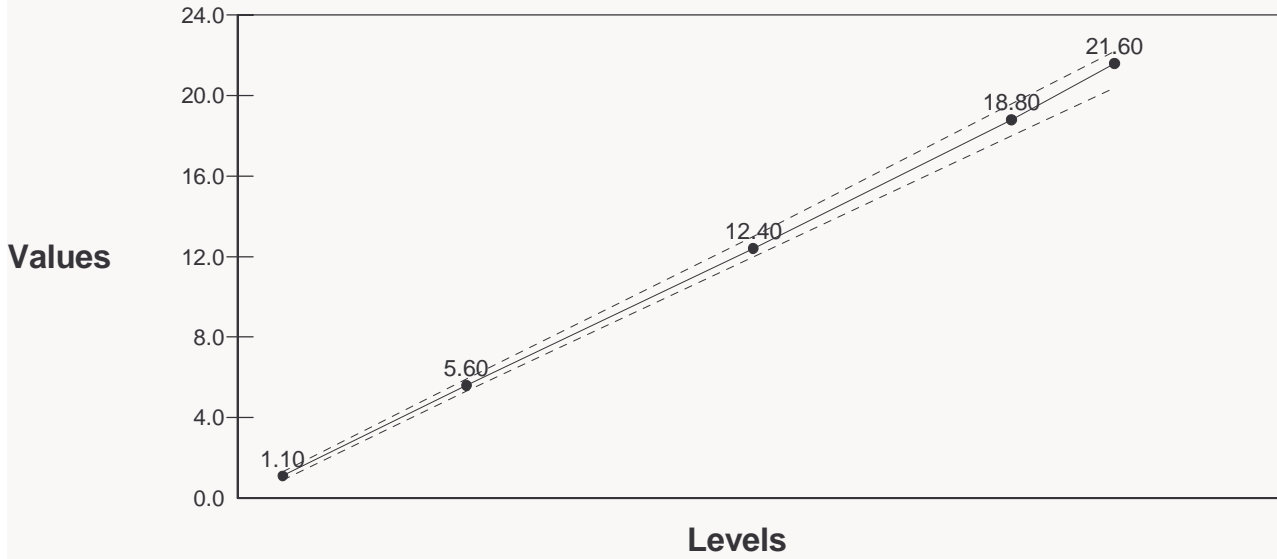


Data Section for Calibration Verification

	Your Values	Your Mean	Group Mean	Group % Difference	Assay % Difference	Assay	Limits
Level 1 Run # 1	0.37	0.37	0.37	0.00%	2.78%	0.36	0.26-0.46
2	0.35						
3	0.39						
4	0.37						
Level 2 Run # 1	1.84	1.83	1.82	0.55%	2.23%	1.79	1.64-1.94
2	1.84						
3	1.82						
4	1.82						
Level 3 Run # 1	4.11	4.09	4.07	0.49%	1.24%	4.04	3.74-4.34
2	4.04						
3	4.12						
4	4.09						
Level 4 Run # 1	6.13	6.10	6.15	-0.81%	0.83%	6.05	5.60-6.50
2	6.16						
3	6.03						
4	6.08						
Level 5 Run # 1	7.02	7.06	7.09	-0.42%	2.92%	6.86	6.36-7.36
2	7.12						
3	7.08						
4	7.00						

Linearity Graph

Your Mean
 - - - Assay/Low
 - - - Assay/High



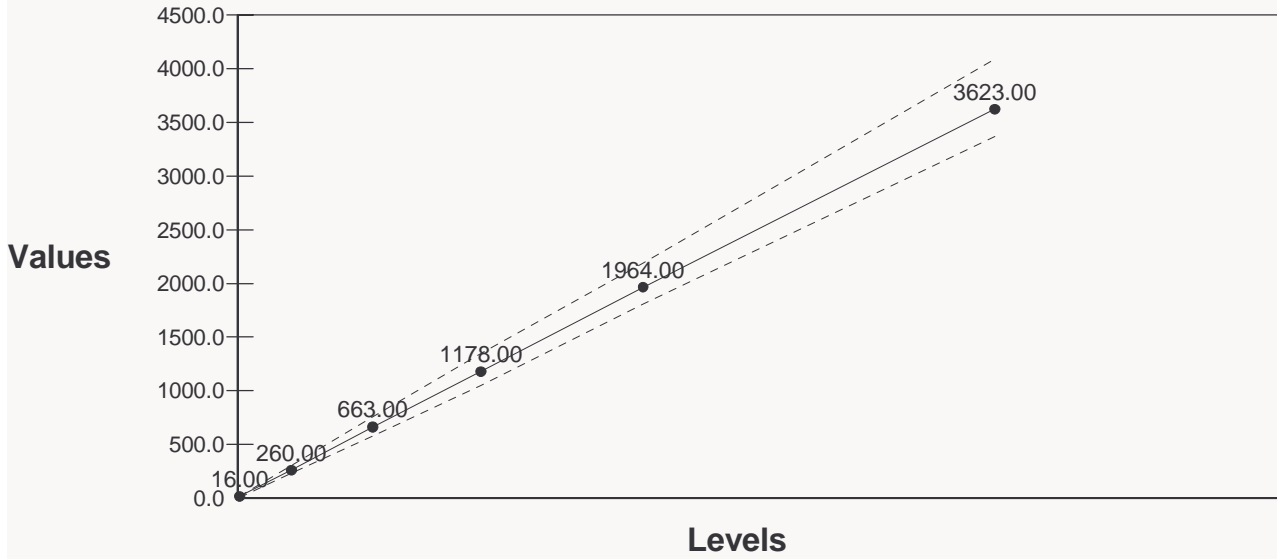
HGB

Data Section for Calibration Verification

	Your Values	Your Mean	Group Mean	Group % Difference	Assay % Difference	Assay	Limits
Level 1 Run # 1	1.1	1.1	1.0	9.64%	0.00%	1.1	0.9-1.3
2	1.0						
3	1.1						
4	1.0						
Level 2 Run # 1	5.6	5.6	5.6	0.00%	0.00%	5.6	5.3-5.9
2	5.6						
3	5.7						
4	5.6						
Level 3 Run # 1	12.4	12.4	12.5	-0.80%	-0.80%	12.5	12.0-13.0
2	12.3						
3	12.4						
4	12.5						
Level 4 Run # 1	19.1	18.8	19.1	-1.57%	0.00%	18.8	18.0-19.6
2	19.1						
3	19.0						
4	18.0						
Level 5 Run # 1	21.2	21.6	21.7	-0.46%	1.41%	21.3	20.4-22.2
2	21.9						
3	21.6						
4	21.6						

Linearity Graph

Your Mean
 - - - Assay/Low
 - - - Assay/High



PLT

Data Section for Calibration Verification

	Your Values	Your Mean	Group Mean	Group % Difference	Assay % Difference	Assay	Limits
Level 1 Run #	17	16	13	23.97%	45.45%	11	3-19
	2	15					
	3	15					
	4	15					
Level 2 Run #	259	260	266	-2.25%	-2.26%	266	231-301
	2	265					
	3	261					
	4	255					
Level 3 Run #	647	663	671	-1.19%	-0.45%	666	576-756
	2	661					
	3	674					
	4	668					
Level 4 Run #	1163	1178	1196	-1.51%	-1.75%	1199	1049-1349
	2	1196					
	3	1164					
	4	1188					
Level 5 Run #	1946	1964	1984	-1.01%	-1.70%	1998	1808-2188
	2	1967					
	3	1984					
	4	1957					
Level 6 Run #	3662	3623	3649	-0.71%	-2.84%	3729	3369-4089
	2	3593					
	3	3656					
	4	3581					