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VALIDATION REPORT: ACT5 AL: AX26057

Complied: MGW Ditshego

Approved: JG Kubheka

Date of approval: January 2021

Validation was done using EQA/ IQC/Analyser comparison using patient samples.

ACT5AL Precision

The ACT5AL SN: AX26057 was validated using Beckman IQC (level 1, 2, 3)

The IQC material was analysed on different days and SDI, CV% established.

Precision was acceptable based on the CV% which was within set target.

Hierarchy

- Manufacturers claims
- CLIA
- RIQAS EQA

ACT5AL Accuracy

The ACT5AL SN: AX26057 was validated using EQA & Patient samples.
Accuracy was acceptable based on:

- the correlation factor (r-value) of >/= 0.975
- slope of 1.0 (closeness to 1.0)
- y-intercept
- bias
- SD diff

Notes:

MCH, MCHC, RDW, MPV do not meet all requirements for accuracy. R-value between 0.8 – 1.0 which is still acceptable (calculated parameters). The WBC, RBC, HB, MCV, HCT, MCH, MCHC, PLT, RDW, MPV do not meet manufacturers' claim. However, are within the CLIA allowable error & RIQAS acceptance performance. Validations was done using - IQC, EQA & patient samples.

Proteus Laboratories ACT5AL AX26057 is deemed fit for purpose.

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Precision records for ACT5AL

Quality Control: HGB			
	Level 1: 360720	Level 2: 370720	Level 3: 380720
1	6,2	13,7	16,7
2	6,2	13,6	16,9
3	6,2	13,4	16,8
4	6,2	13,4	16,7
5	6,2	13,5	16,8
6	6,3	13,6	16,9
7	6,3	13,5	16,7
8	6,2	13,6	16,6
9	6,2	13,4	16,7
10	6,1	13,4	16,5
11	6,3	13,5	16,5
12	6,1	13,2	16,5
13	6,2	13,4	16,6
14	6,2	13,2	16,5
15	6,2	13,4	16,6
16	6,4	13,8	17,2
17	6,2	13,6	16,8
18	6,3	13,3	16,7
19	6,3	13,6	16,9
20	6,3	13,5	16,6
21	5,9	13,7	16,8
22	5,8	13,1	16,0
23	5,9	12,8	15,9
24	5,8	12,9	15,9
Total	148,00	322,10	398,80
Mean	6,17	13,42	16,62
SDI	0,16	0,24	0,31
CV%	2,60	1,81	1,87

CLIA allowable CV% for HB is +/-7%. Therefore CV% is within set Target.
Acceptable limit performance for RIQAS is 4%.

Quality Control: HCT			
	Level 1: 360720	Level 2: 370720	Level 3: 380720
1	18,9	40,6	47,9
2	19,1	40,5	49,4
3	18,5	39,2	48,7
4	18,6	38,9	48,4
5	18,8	39,7	48,6
6	18,9	39,3	48,6
7	19,4	39,8	49,0
8	18,7	39,7	48,2
9	19,0	39,2	49,2
10	18,7	39,6	47,5
11	19,0	39,2	47,7
12	18,8	38,8	48,7
13	19,0	38,6	48,1
14	18,8	37,8	48,1
15	19,3	39,2	47,9
16	19,1	39,7	48,9
17	19,3	39,7	48,9
18	19,5	39,1	48,8
19	19,5	39,9	48,6
20	19,0	39,5	48,1
21	18,4	39,2	47,7
22	18,1	37,9	46,7
23	17,8	37,5	46,2
24	17,7	37,3	46,6
Total	451,90	939,90	1156,50
Mean	18,83	39,16	48,19
SDI	0,48	0,85	0,82
CV%	2,52	2,16	1,70

CLIA allowable CV% for HCT is +/-6%. Therefore CV% is within set Target.
Acceptable limit performance for RIQAS is 7,2%.

Quality Control: MCH			
	Level 1: 360720	Level 2: 370720	Level 3: 380720
1	26,9	28,6	33,2
2	26,8	28,7	32,6
3	27,4	29,2	32,7
4	27,0	29,4	32,7
5	27,0	29,2	32,8
6	27,0	29,5	33,2
7	26,5	28,9	32,6
8	27,2	29,4	33,0
9	26,6	29,3	32,5
10	27,2	29,1	33,3
11	27,1	29,3	33,2
12	26,8	29,0	32,5
13	26,7	29,6	32,9
14	27,3	30,0	32,9
15	26,7	29,5	33,1
16	27,7	29,5	33,3
17	26,6	29,1	32,8
18	26,6	29,2	32,7
19	26,8	29,2	33,0
20	27,5	29,3	33,1
21	26,9	29,9	33,6
22	26,7	29,7	33,1
23	27,4	29,6	33,1
24	27,3	29,8	33,4
Total	647,70	704,00	791,30
Mean	26,99	29,33	32,97
SDI	0,33	0,35	0,30
CV%	1,21	1,18	0,90

CLIA allowable CV% for MCH is +/-15%. Therefore CV% is within set Target.
Acceptable limit performance for RIQAS is 7,2%.

Quality Control: MCHC			
	Level 1: 360720	Level 2: 370720	Level 3: 380720
1	32,8	33,7	34,9
2	32,7	33,7	34,3
3	33,6	34,3	34,5
4	33,0	34,4	34,4
5	33,0	34,1	34,5
6	33,0	34,6	34,8
7	32,4	33,8	34,2
8	33,0	34,3	34,4
9	32,5	34,2	34,0
10	32,8	33,9	34,7
11	33,0	34,3	34,7
12	32,4	34,1	34,0
13	32,3	34,7	34,4
14	32,9	34,9	34,4
15	32,2	34,3	34,8
16	33,5	34,6	35,1
17	32,4	34,2	34,4
18	32,2	34,1	34,2
19	32,5	34,1	34,8
20	33,4	34,2	34,6
21	32,3	34,9	35,1
22	32,2	34,5	34,2
23	33,2	34,3	34,6
24	32,9	34,7	34,5
Total	786,20	822,90	828,50
Mean	32,76	34,29	34,52
SDI	0,42	0,34	0,30
CV%	1,29	0,98	0,88

CLIA allowable CV% for MCHC is +/-15%. Therefore CV% is within set Target.
Acceptable limit performance for RIQAS is 7,2%.

Quality Control: MCV			
	Level 1: 360720	Level 2: 370720	Level 3: 380720
1	82	85	95
2	82	85	95
3	82	85	95
4	82	85	95
5	82	86	95
6	82	85	95
7	82	85	95
8	83	86	96
9	82	85	96
10	83	86	96
11	82	85	96
12	83	85	96
13	83	85	96
14	83	86	96
15	83	86	95
16	83	85	95
17	82	85	95
18	83	85	95
19	83	85	95
20	82	86	95
21	83	86	96
22	83	86	97
23	83	87	96
24	83	86	97
Total	1981,00	2051,00	2293,00
Mean	82,54	85,46	95,54
SDI	0,51	0,59	0,66
CV%	0,62	0,69	0,69

CLIA allowable CV% for MCV is +/-15%. Therefore CV% is within set Target.
Acceptable limit performance for RIQAS is 7,2%.

Quality Control: MPV			
	Level 1: 360720	Level 2: 370720	Level 3: 380720
1	9,7	8,8	8,6
2	9,3	9,0	8,4
3	9,9	9,0	8,7
4	10,0	9,0	8,6
5	9,9	8,8	8,4
6	10,0	9,0	8,3
7	9,7	9,0	8,4
8	10,0	9,0	8,3
9	10,4	9,0	8,4
10	9,9	8,8	8,3
11	9,9	9,0	8,6
12	9,9	9,2	8,6
13	10,1	9,0	8,4
14	9,6	9,2	8,7
15	9,9	9,0	8,3
16	10,0	9,1	8,7
17	10,2	9,1	8,7
18	9,7	9,0	8,6
19	10,1	9,1	8,6
20	9,5	8,8	8,4
21	9,9	9,2	8,6
22	9,9	9,1	8,4
23	9,6	9,1	8,4
24	9,7	9,0	8,4
Total	236,80	216,30	203,80
Mean	9,87	9,01	8,49
SDI	0,24	0,12	0,14
CV%	2,40	1,32	1,70

CLIA allowable CV% for MPV is +/-15%. Therefore CV% is within set Target.
Acceptable limit performance for RIQAS is 10,9%.

Quality Control: Platlets			
	Level 1: 360720	Level 2: 370720	Level 3: 380720
1	68	240	485
2	67	256	503
3	68	242	497
4	72	242	487
5	73	252	495
6	79	253	525
7	73	243	502
8	68	244	519
9	73	244	518
10	75	244	494
11	79	244	485
12	72	246	500
13	81	261	499
14	78	256	509
15	66	241	512
16	72	262	494
17	69	260	509
18	69	259	506
19	70	264	512
20	84	258	504
21	71	261	502
22	83	259	474
23	102	245	483
24	91	254	462
Total	1803,00	6030,00	11976,00
Mean	75,13	251,25	499,00
SDI	8,47	8,11	14,66
CV%	11,28	3,23	2,94

CLIA allowable CV% for Platelets is +/- 25%. Therefore CV% is within set Target.
Acceptable limit performance for RIQAS is 27%.

Quality Control: RBC			
	Level 1: 360720	Level 2: 370720	Level 3: 380720
1	2,31	4,78	5,4
2	2,33	4,76	5,19
3	2,27	4,61	5,15
4	2,28	4,56	5,09
5	2,30	4,63	5,11
6	2,31	4,62	5,10
7	2,37	4,66	5,13
8	2,26	4,63	5,04
9	2,31	4,59	5,14
10	2,25	4,63	4,94
11	2,31	4,59	4,97
12	2,28	4,55	5,09
13	2,30	4,53	5,04
14	2,26	4,39	5,03
15	2,33	4,56	5,02
16	2,31	4,66	5,16
17	2,34	4,67	5,12
18	2,36	4,58	5,11
19	2,37	4,67	5,13
20	2,31	4,60	5,04
21	2,21	4,58	4,99
22	2,18	4,41	4,83
23	2,15	4,33	4,82
24	2,14	4,34	4,81
Total	54,84	109,93	121,45
Mean	2,29	4,58	5,06
SDI	0,06	0,11	0,13
CV%	2,74	2,50	2,55

CLIA allowable CV% for RBC is +/-6%. Therefore CV% is within set Target.
Acceptable limit performance for RIQAS is 5,5%.

Quality Control: RDW			
	Level 1: 360720	Level 2: 370720	Level 3: 380720
1	12,9	11,9	11,3
2	12,4	12,4	11,1
3	13,1	12,4	11,4
4	13,0	12,6	11,0
5	13,1	12,1	11,5
6	13,3	12,1	11,3
7	12,8	12,6	11,2
8	12,8	12,4	11,1
9	12,7	12,0	11,4
10	13,2	12,1	11,0
11	12,9	12,0	11,5
12	12,7	12,0	11,2
13	13,2	12,4	10,9
14	13,3	12,4	11,4
15	12,4	12,5	11,5
16	13,0	12,5	11,4
17	13,6	11,9	11,5
18	12,6	12,4	11,2
19	13,3	12,0	11,2
20	13,3	11,9	11,5
21	13,0	12,1	11,1
22	12,9	12,3	11,9
23	13,0	12,5	12,0
24	13,0	12,4	11,4
Total	311,50	293,90	272,00
Mean	12,98	12,25	11,33
SDI	0,29	0,24	0,26
CV%	2,26	1,94	2,31

CLIA allowable CV% for RDW is +/-15%. Therefore CV% is within set Target.
Acceptable limit performance for RIQAS is 8,7%.

Quality Control: WBC			
	Level 1: 360720	Level 2: 370720	Level 3: 380720
1	2,3	6,8	16,9
2	2,3	7,3	17,9
3	2,3	7,5	17,7
4	2,4	7,5	15,7
5	2,4	7,5	15,0
6	2,4	7,0	18,1
7	2,4		18,3
8	2,4	7,3	15,6
9	2,3	7,5	17,9
10	2,4	7,5	17,7
11	2,2	6,9	17,1
12	2,4	7,3	17,8
13	2,2	6,5	17,5
14	2,4	7,5	
15	2,3	6,5	18,1
16	2,4	7,1	17,5
17	2,4	7,6	17,7
18	2,4	7,6	18,3
19	2,5	7,3	17,9
20	2,4	7,6	17,1
21	2,5	7,3	17,5
22	2,5	7,6	18,6
23	2,4	7,6	16,1
24	2,5	7,6	17,7
Total	57,10	167,90	399,70
Mean	2,38	7,00	16,65
SDI	0,08	0,34	0,94
CV%	3,50	4,91	5,63

CLIA allowable CV% for WBC is +/-15%. Therefore CV% is within set Target.
Acceptable limit performance for RIQAS is 7,1%.

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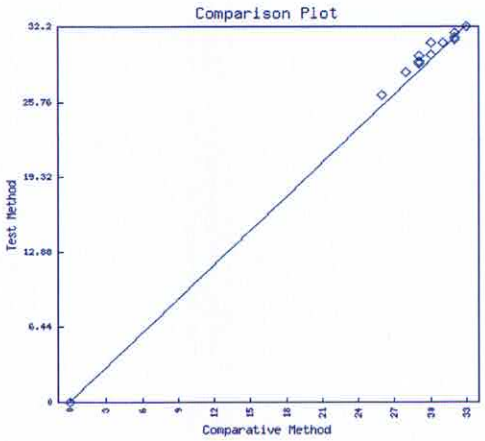
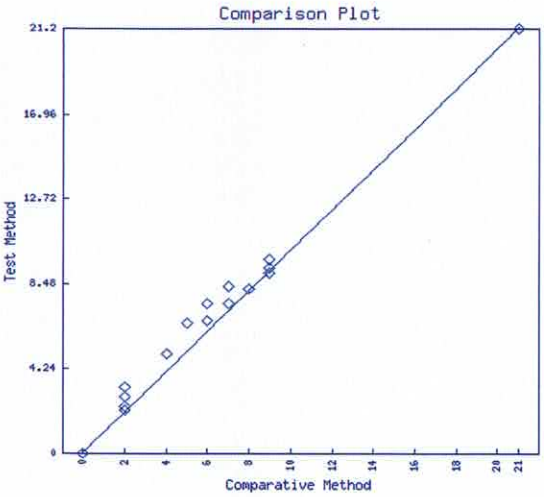
Accuracy records for ACT5AL

X: ACT5 AL SERIAL NO:		AX26057
Y: EQA		mch
Cycle	X	Y
13;09	29.8	29.7
13;10	30.5	30.77
13;11	31.5	30.77
13;12	32	31.65
44;02	30.3	29.76
44;04	30.5	29.75
44;08	29.4	29.02
44;12	29.7	29.2
139537	26.8	26.4
139447	29.1	29.1
139662	32.3	31.1
139257	32.3	31.6
139258	32	31.3
139661	33.9	32.2
139663	28.7	28.3



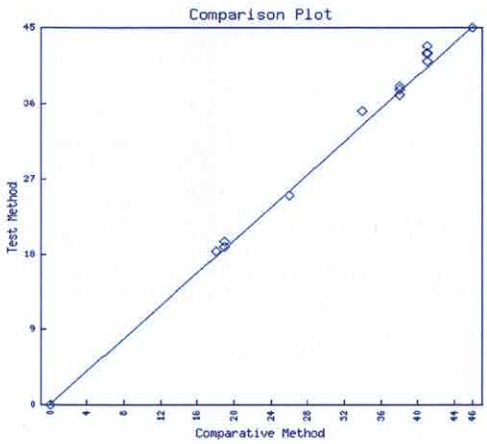
slope :	1.136	
y-intercept:	-3.5403	
r:	0.971	
bias:	0.2186	
SDdiff:	0.5873	

AL SERIAL NO:		AX26057
Y: SAMPLES		wbc
Cycle	X	Y
13;09	4.85	4.968
13;10	9.1	9
13;11	21.5	21.2
13;12	2.4	2.36
44;02	8.1	8.25
44;04	7.9	8.33
44;08	2.8	2.89
44;12	9	9.23
137537	6.5	7.5
139447	6.37	6.65
139662	7.61	7.52
139257	5.77	6.49
139258	2.78	3.38
139661	2.07	2.22
139663	9.26	9.69



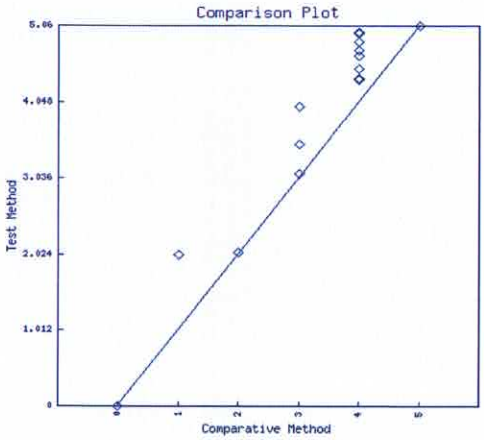
slope :	1.0217	
y-intercept:	-0.4031	
r:	0.9975	
bias:	-0.2444	
SDdiff:	0.3442	

X: ACT5 AL SERIAL NO		AX26057
Y: EQA		hct
Cycle	X	Y
13;09	41.8	41.86
13;10	38.4	37.96
13;11	41.7	42.81
13;12	19.1	19.48
44;02	18	18.33
44;04	19	18.9
44;08	26	25.08
44;12	38.1	37.64
139537	38	37
139447	46	45
139662	41	41
139257	38	38
139258	46	45
139661	34	35
139663	41	42



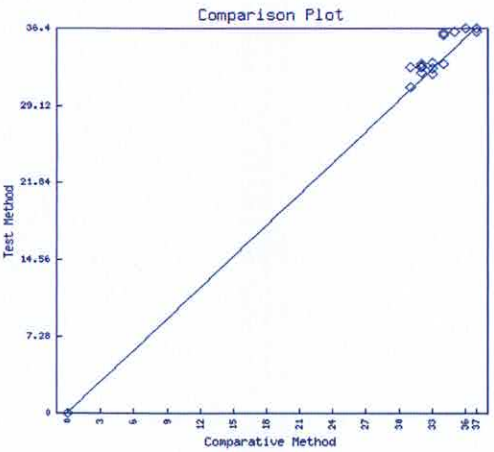
slope :	1.007	
y-intercept	-0.1757	
r:	0.9971	
bias:	0.0693	
SDdiff:	0.7405	

X: ACT5 AL SN:		AX26057
Y: EQA		hgb
Cycle	X	Y
13;09	14.5	14.99
13;10	13.9	13.81
13;11	15.5	15.4
13;12	6.3	6.45
44;02	6.1	6.12
44;04	6.1	6.11
44;08	9.1	9.03
44;12	13.5	13.61
139537	11.8	11.5
139447	14.9	14.7
139662	13.4	13.5
139257	12.5	12.6
139258	14.6	14.8
139661	11.3	11.2
139663	13.5	13.7



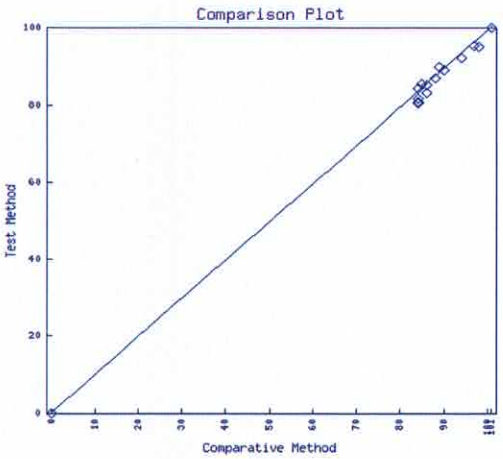
slope :	0.9921	
y-intercept	0.0588	
r:	0.9983	
bias:	-0.0345	
SDdiff:	0.1927	

X: ACT5 AL SERIAL NO:		AX26057
Y: RIQAS EQA		mchc
Cycle	X	Y
13;09	34.5	35.75
13;10	36.1	36.4
13;11	37.2	36.04
13;12	33	33.18
44;02	34	33.04
44;04	32.3	32.2
44;08	34.9	35.97
44;12	35.5	36.06
139537	31.1	30.9
139447	32.5	32.8
139662	33	32.6
139257	32.4	33.1
139258	31.8	32.7
139661	33.5	32.1
139663	32.8	32.7



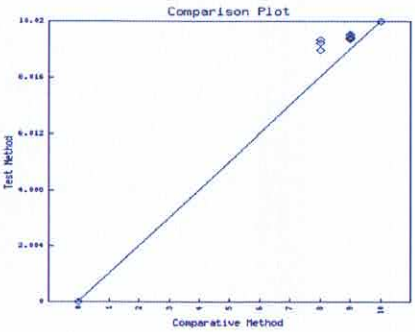
slope :	0.8492	
y-intercept	5.0197	
r:	0.8977	
bias:	-0.0625	
SDdiff:	0.7982	

X: ACT5 AL SN:		AX26057
Y:EQA		mcv
Cycle	X	Y
13;09	86	83.16
13;10	84	84.24
13;11	85	85.3
13;12	97	95.4
44;02	89	89.88
44;04	94	92.26
44;08	84	80.52
44;12	84	80.75
139537	86	85
139447	90	89
139662	98	95
139661	101	100
139663	88	87
14;01	84	81.65



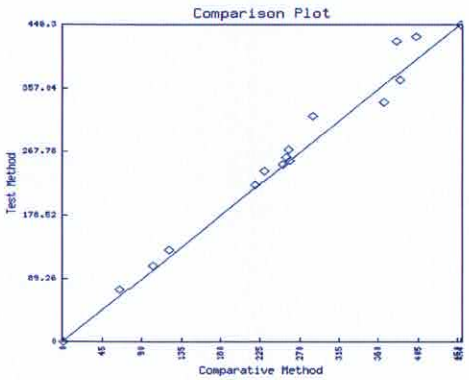
slope :	0.956	
y-intercept:	5.306	
r:	0.972	
bias:	1.899	
SDdiff:	1.815	

X: ACT5 AL SERIAL NO		AX26057
Y: RIQAS EQA		mpv
Cycle	X	Y
13;09	8.6	9.36
13;10	9.5	9.56
13;11	9.5	9.46
13;12	8.8	8.97
44;02	9.3	9.41
44;04	9.1	9.39
44;08	10	10.02
44;12	9.7	9.49
14:01	8.8	9.25



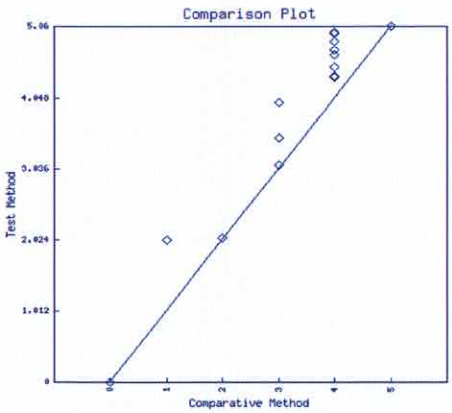
slope :	1.2943	
y-intercept	-2.9283	
r:	0.8038	
bias:	-0.145	
SDdiff:	0.2888	

X: ACT5 AL SERIAL NO:		AX26057
Y: EQA		plt
Cycle	X	Y
13;09	219	220.67
13;10	251	249.2
13;11	380	422.6
13;12	121	129.66
44;02	454	446.3
44;04	403	429.9
44;08	64	73.7
44;12	229	241
139537	384	368
139447	259	255
139662	285	318
139257	254	260
139258	257	270
139661	103	108
139663	366	337



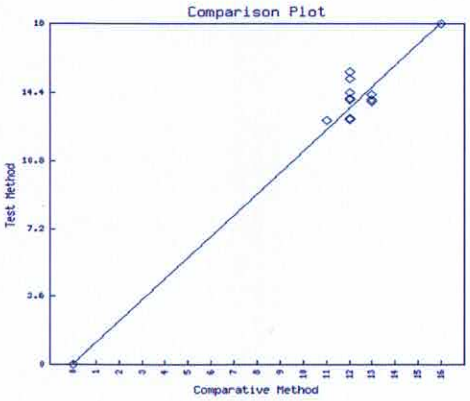
slope :	0.9855	
y-intercept:	-2.6772	
r:	0.9872	
bias:	-6.6685	
SDdiff:	18.2868	

X: ACT5 AL S/N:		AX26057
Y: RIQAS EQA		rbc
Cycle	X	Y
13;09	4.85	4.96
13;10	4.55	4.49
13;11	4.92	4.97
13;12	1.97	2.02
44;02	2.02	2.05
44;04	2.01	2.05
44;08	3.09	3.1
44;12	4.56	4.66
139537	4.38	4.36
139447	5.11	5.06
139662	4.14	4.35
139257	3.85	3.98
139258	4.57	4.73
139661	3.33	3.48
139663	4.7	4.84



slope :	0.99	
y-intercept	-0.0305	
r:	0.9974	
bias:	-0.0699	
SDdiff:	0.0807	

X: ACT5 AL SERIAL NO		AX26057
Y: EQA		rdw
Cycle	X	Y
13;09	13.7	14.25
13;10	12.4	13.03
13;11	13.5	13.9
13;12	11.9	12.94
44;02	12.7	15.09
44;04	12.9	15.46
44;08	12.9	14.06
44;12	12.9	14.4
139537	16	18
139447	13	14
139662	12	14
139257	12	14
139258	13	14
139661	12	14
139663	12	13



slope :	0.6908	
y-intercept	3.0407	
r:	0.8487	
bias:	-1.3513	
SDdiff:	0.6809	