

CALIBRATION CERTIFICATE

This is to certify that the system maintenance & calibration was performed on **06th APRIL 2021** for the VITROS V5600 Integrated system installed at **CIHSR** laboratory, 4th mile, Dimapur bearing Serial No.56001966

The system's calibration includes checking the reproducibility performance of the instrument as per the guidelines provided by the manufacture.

Validity: Six months for Optics Calibration.

For *Ortho Clinical Diagnostics*.



Monuj Saikia
Sr. Service Engineer



DIAGNOSTICS - Luminometer Performance Tests

IRS Aim: 1993276

LRS Aim: 2002676

Reference Photon Values

Reference Analog Values

	Reference Photon Values		IRS		LRS	Reference Analog Values		LRS	
	IRS	LRS	Dark	%Bias	%Bias	IRS	LRS	Dark	%Bias
1	1983039	2026856	8	0.51	1.21	1972198	2037000	42000	1.71
2	1981530	2004964	8	0.59	0.11	1970966	2021000	48000	0.91
3	1985317	1987810	4	0.40	0.74	1982699	2005000	48000	0.12
4	1983480	1975518	16	0.49	1.36	1965719	2005000	42000	0.12
5	1986359	1963784	12	0.35	1.94	1983536	1988000	44000	0.73
6	1985744	1957254	8	0.38	2.27	1970407	1986000	40000	0.83
7	1984815	1954766	8	0.42	2.39	1967364	1985000	50000	0.88
8	1989483	1949094	4	0.19	2.68	1984479	1981000	48000	1.08
9	1988522	1945738	12	0.24	2.84	1971242	1975000	52000	1.38
10	1987249	1944404	4	0.30	2.91	1976231	1969000	52000	1.68
11	1988252	1942134	4	0.25	3.02	1970244	1976000	44000	1.33

Touch 'Start' to begin test.



Return



Start



Stop



Print



Help



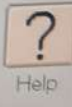
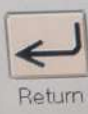
612001

DIAGNOSTICS - Reflectometer Performance Tests

Tests: **Static** Static Interleaved Reference Dynamic Slide Dynamic

Filter	Gain	Ref Mean	Ref SD	Ref SD Limit	Dark Mean	Dark SD	Dark SD Limit
340	64	24272.3	6.9	12.5	152.4	0.9	3.0
400	62	47080.0	10.8	23.7	152.6	1.3	3.0
460	35	60068.0	10.2	30.2	156.5	0.8	3.0
540	9	59200.6	12.9	29.8	159.8	0.4	3.0
600	10	57950.4	13.9	29.1	159.9	0.5	3.0
630	7	57542.5	12.0	28.9	160.1	0.4	3.0
670	11	59037.2	10.8	29.7	159.6	0.6	3.0
680	16	59001.6	10.4	29.7	158.9	0.5	3.0

Performance test completed successfully.



Precision appears to be adequate for a reliable determination of linearity.

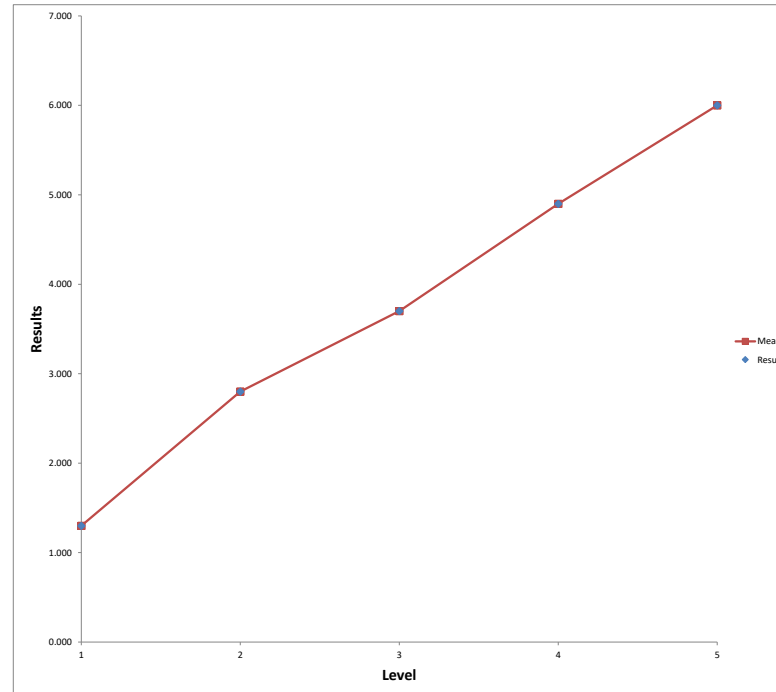
Statistically significant non-linearity detected

Non-linearity within Linearity/Accuracy Goal

Analyte: ALB
Units: g/dL
Analyser: 5600
Repeatability Goal: 15 %
Linearity/Accuracy Cut-off: 125 g/dL
Linearity/Accuracy Goal <= Cut-off: 15 g/dL
Linearity/Accuracy Goal > Cut-off: 12 %

Level		
1	Measuring Range Low	1.000
2	3:1	
3	3:3	
4	1:3	
5	Measuring Range High	6.000

Level	Result	Mean
1	1.300	1.300
1	1.300	1.300
2	2.800	2.800
2	2.800	2.800
3	3.700	3.700
3	3.700	3.700
4	4.900	4.900
4	4.900	4.900
5	6.000	6.000
5	6.000	6.000



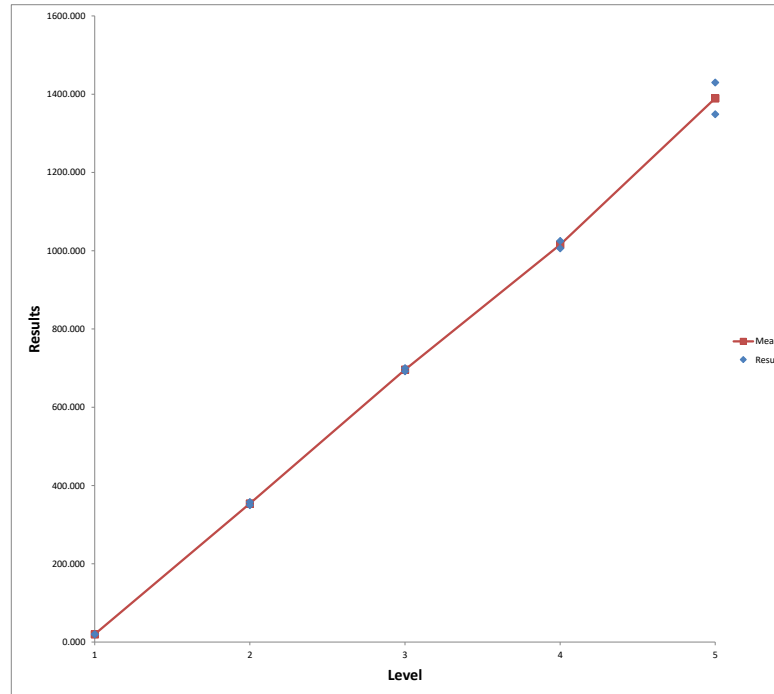
Precision appears to be adequate for a reliable determination of linearity.

Linearity Verified

Analyte: ALKP
Units: U/L
Analyser: 5600
Repeatability Goal: 15 %
Linearity/Accuracy Cut-off: 125 U/L
Linearity/Accuracy Goal <= Cut-off: 15 U/L
Linearity/Accuracy Goal > Cut-off: 12 %

Level		
1	Measuring Range Low	20.000
2	3:1	
3	3:3	
4	1:3	
5	Measuring Range High	1500.000

Level	Result	Mean
1	20.000	20.000
1	20.000	20.000
2	358.000	354.000
2	350.000	354.000
3	700.000	696.000
3	692.000	696.000
4	1025.000	1015.500
4	1006.000	1015.500
5	1349.000	1389.500
5	1430.000	1389.500



Precision appears to be adequate for a reliable determination of linearity.

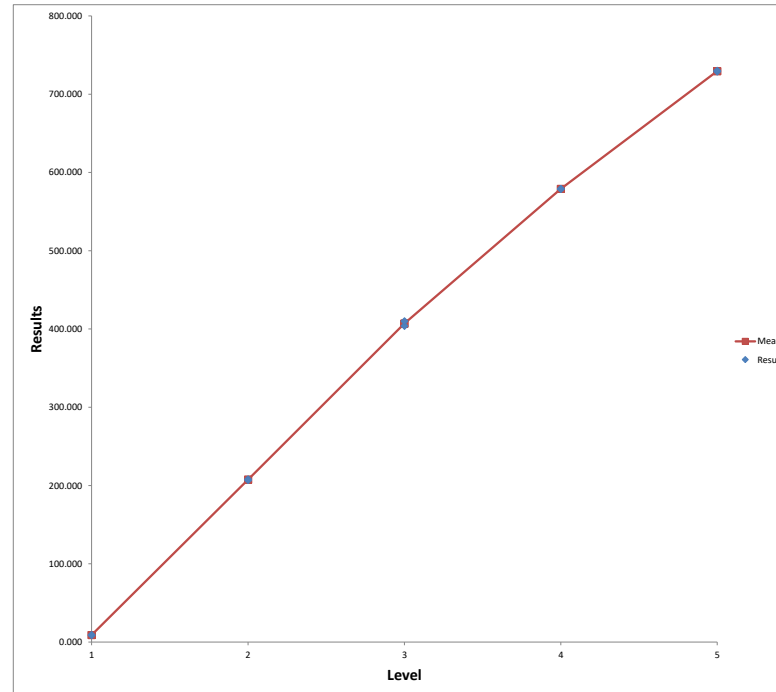
Statistically significant non-linearity detected

Non-linearity beyond Linearity/Accuracy Goal

Analyte: ALT
Units: U/L
Analyser: 5600
Repeatability Goal: 15 %
Linearity/Accuracy Cut-off: 125 U/L
Linearity/Accuracy Goal <= Cut-off: 15 U/L
Linearity/Accuracy Goal > Cut-off: 12 %

Level		
1	Measuring Range Low	4.000
2	3:1	
3	3:3	
4	1:3	
5	Measuring Range High	750.000

Level	Result	Mean
1	9.000	9.000
1	9.000	9.000
2	208.000	207.500
2	207.000	207.500
3	404.000	407.000
3	410.000	407.000
4	579.000	579.000
4	579.000	579.000
5	729.000	729.500
5	730.000	729.500



Precision appears to be adequate for a reliable determination of linearity.

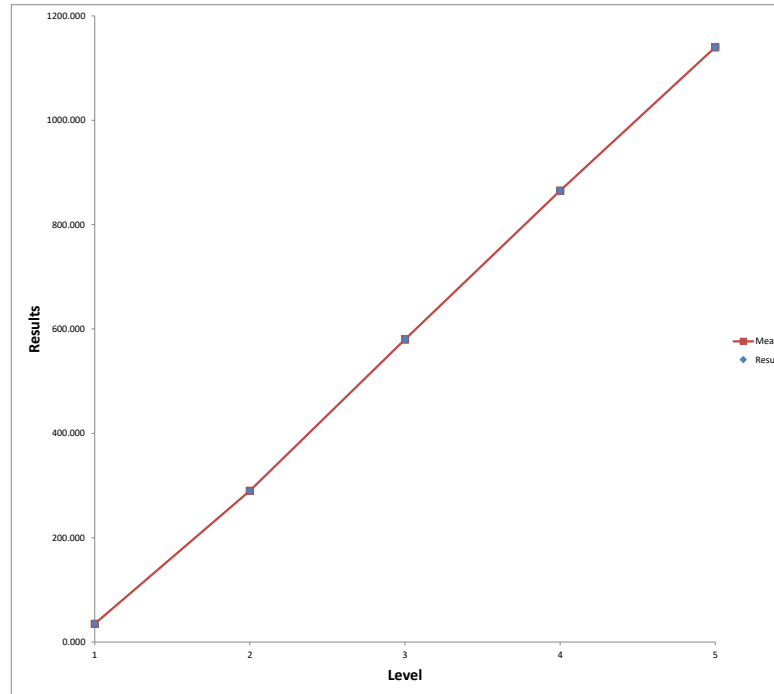
Statistically significant non-linearity detected

Non-linearity within Linearity/Accuracy Goal

Analyte: AMYL
Units: U/L
Analysers: 4600
Repeatability Goal: 15 %
Linearity/Accuracy Cut-off: 125 U/L
Linearity/Accuracy Goal <= Cut-off: 15 U/L
Linearity/Accuracy Goal > Cut-off: 12 %

Level		
1	Measuring Range Low	30.000
2	3:1	
3	3:3	
4	1:3	
5	Measuring Range High	1200.000

Level	Result	Mean
1	35.000	35.000
1	35.000	35.000
2	290.000	290.000
2	290.000	290.000
3	580.000	580.000
3	580.000	580.000
4	865.000	865.000
4	865.000	865.000
5	1140.000	1140.000
5	1140.000	1140.000



Precision appears to be adequate for a reliable determination of linearity.

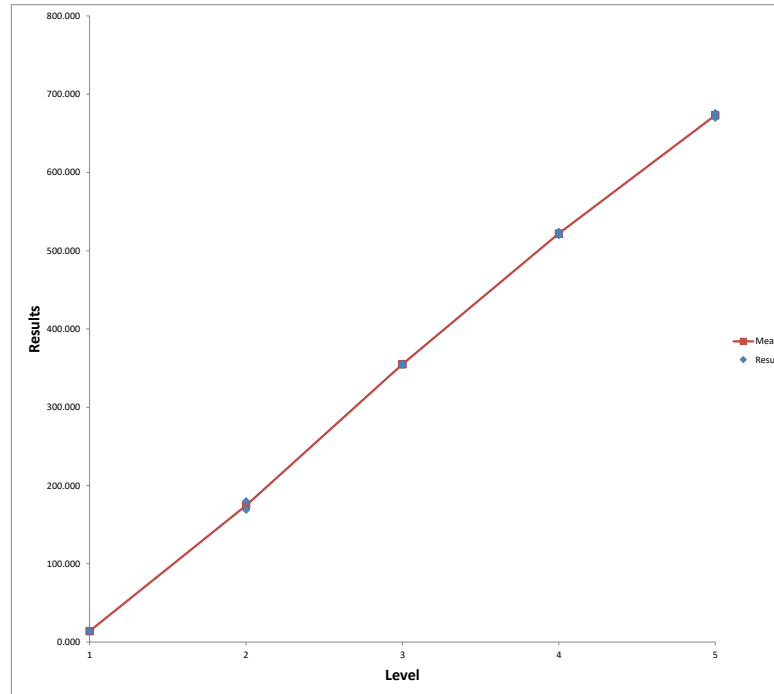
Statistically significant non-linearity detected

Non-linearity within Linearity/Accuracy Goal

Analyte: AST
Units: U/L
Analyser: 5600
Repeatability Goal: 15 %
Linearity/Accuracy Cut-off: 750 U/L
Linearity/Accuracy Goal <= Cut-off: 60 U/L
Linearity/Accuracy Goal > Cut-off: 12 %

Level		
1	Measuring Range Low	3.000
2	3:1	
3	3:3	
4	1:3	
5	Measuring Range High	750.000

Level	Result	Mean
1	14.000	14.000
1	14.000	14.000
2	169.000	174.500
2	180.000	174.500
3	356.000	355.000
3	354.000	355.000
4	524.000	522.000
4	520.000	522.000
5	670.000	673.000
5	676.000	673.000



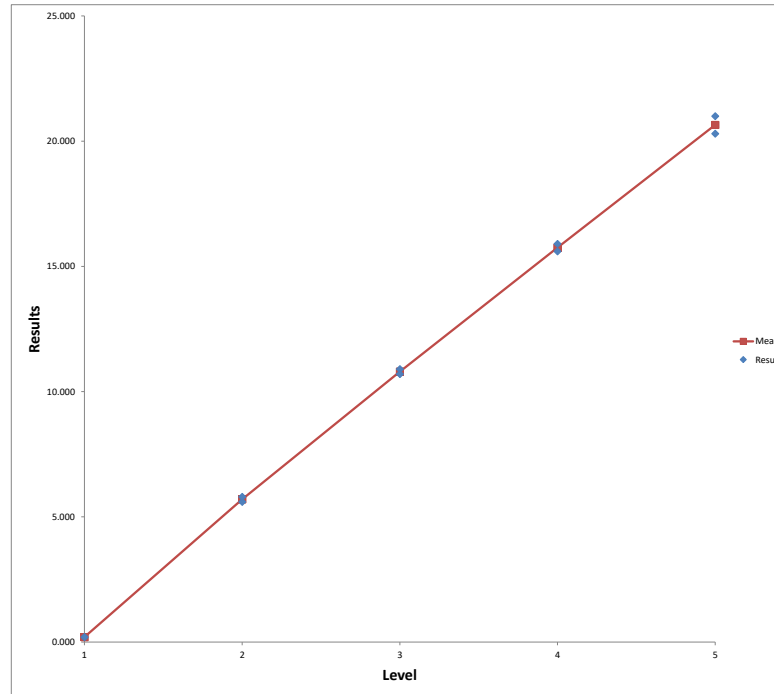
Precision appears to be adequate for a reliable determination of linearity.

Statistically significant non-linearity detected
Non-linearity within Linearity/Accuracy Goal

Analyte: Bc
Units: mg/dL
Analyser: 5600
Repeatability Goal: 15 %
Linearity/Accuracy Cut-off: 125 mg/dL
Linearity/Accuracy Goal <= Cut-off: 15 mg/dL
Linearity/Accuracy Goal > Cut-off: 12 %

Level		
1	Measuring Range Low	0.000
2	3:1	
3	3:3	
4	1:3	
5	Measuring Range High	27.018

Level	Result	Mean
1	0.200	0.200
1	0.200	0.200
2	5.600	5.700
2	5.800	5.700
3	10.900	10.800
3	10.700	10.800
4	15.600	15.750
4	15.900	15.750
5	21.000	20.650
5	20.300	20.650



Precision appears to be adequate for a reliable determination of linearity.

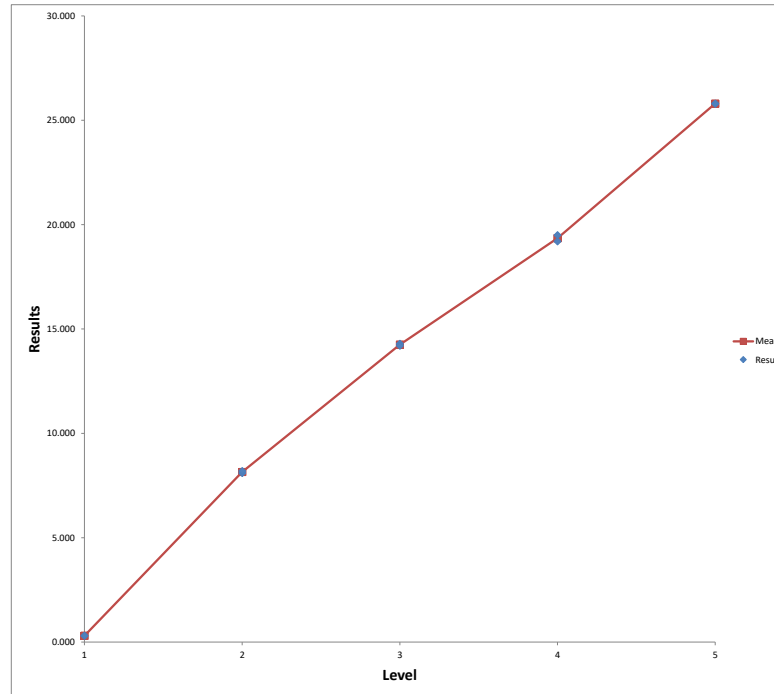
Statistically significant non-linearity detected

Non-linearity within Linearity/Accuracy Goal

Analyte: Bu
Units: mg/dL
Analyser: 5600
Repeatability Goal: 15 %
Linearity/Accuracy Cut-off: 125 mg/dL
Linearity/Accuracy Goal <= Cut-off: 15 mg/dL
Linearity/Accuracy Goal > Cut-off: 12 %

Level		
1	Measuring Range Low	0.000
2	3:1	
3	3:3	
4	1:3	
5	Measuring Range High	27.018

Level	Result	Mean
1	0.300	0.300
1	0.300	0.300
2	8.100	8.150
2	8.200	8.150
3	14.300	14.250
3	14.200	14.250
4	19.200	19.350
4	19.500	19.350
5	25.800	25.800
5	25.800	25.800



Precision appears to be adequate for a reliable determination of linearity.

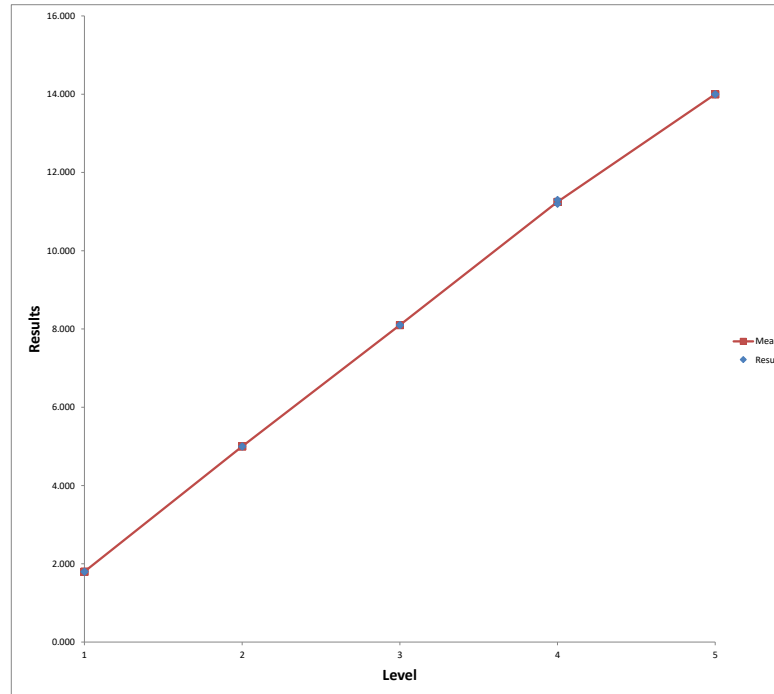
Statistically significant non-linearity detected

Non-linearity within Linearity/Accuracy Goal

Analyte: Ca
Units: mg/dL
Analyser: 5600
Repeatability Goal: 15 %
Linearity/Accuracy Cut-off: 15 mg/dL
Linearity/Accuracy Goal <= Cut-off: 11 mg/dL
Linearity/Accuracy Goal > Cut-off: 12 %

Level		
1	Measuring Range Low	1.002
2	3:1	
3	3:3	
4	1:3	
5	Measuring Range High	13.988

Level	Result	Mean
1	1.800	1.800
1	1.800	1.800
2	5.000	5.000
2	5.000	5.000
3	8.100	8.100
3	8.100	8.100
4	11.200	11.250
4	11.300	11.250
5	14.000	14.000
5	14.000	14.000



Precision appears to be adequate for a reliable determination of linearity.

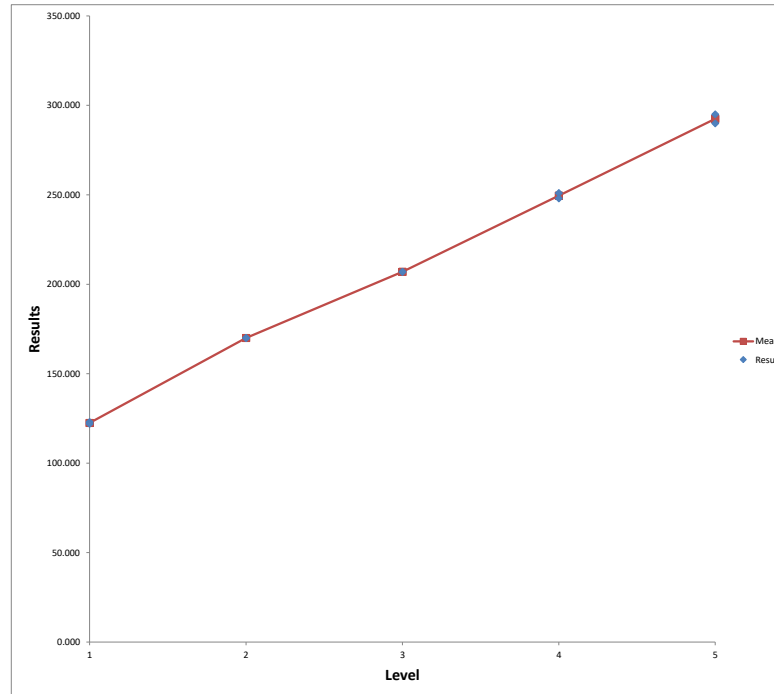
Statistically significant non-linearity detected

Non-linearity within Linearity/Accuracy Goal

Analyte: CHOL
Units: mg/dL
Analyser: 5600
Repeatability Goal: 15 %
Linearity/Accuracy Cut-off: 350 mg/dL
Linearity/Accuracy Goal <= Cut-off: 230 mg/dL
Linearity/Accuracy Goal > Cut-off: 12 %

Level		
1	Measuring Range Low	49.884
2	3:1	
3	3:3	
4	1:3	
5	Measuring Range High	324.826

Level	Result	Mean
1	123.000	122.500
1	122.000	122.500
2	170.000	170.000
2	170.000	170.000
3	207.000	207.000
3	207.000	207.000
4	251.000	249.500
4	248.000	249.500
5	295.000	292.500
5	290.000	292.500



Precision appears to be adequate for a reliable determination of linearity.

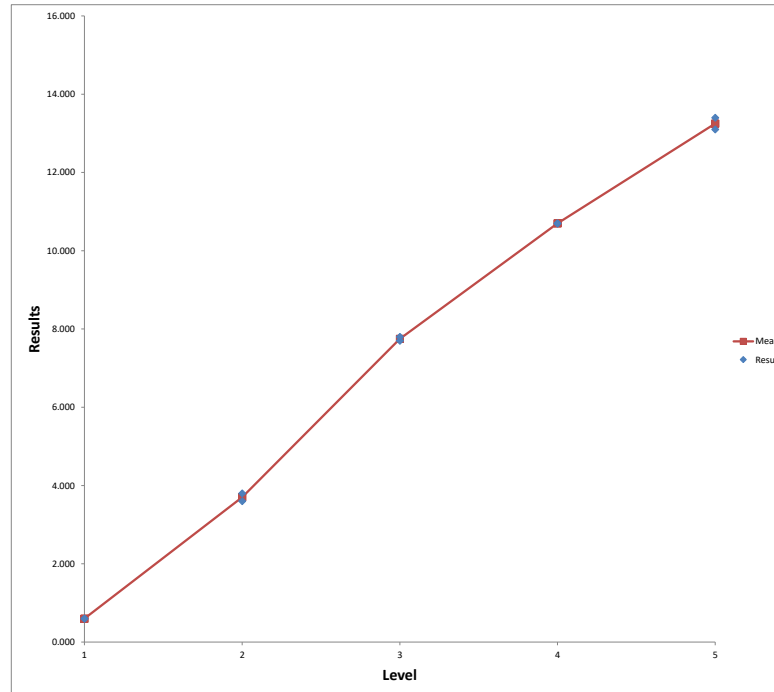
Statistically significant non-linearity detected

Non-linearity within Linearity/Accuracy Goal

Analyte: CREA
Units: mg/dL
Analyser: 5600
Repeatability Goal: 15 %
Linearity/Accuracy Cut-off: 14.5 mg/dL
Linearity/Accuracy Goal <= Cut-off: 2 mg/dL
Linearity/Accuracy Goal > Cut-off: 12 %

Level		
1	Measuring Range Low	0.045
2	3:1	
3	3:3	
4	1:3	
5	Measuring Range High	14.005

Level	Result	Mean
1	0.600	0.600
1	0.600	0.600
2	3.600	3.700
2	3.800	3.700
3	7.700	7.750
3	7.800	7.750
4	10.700	10.700
4	10.700	10.700
5	13.100	13.250
5	13.400	13.250



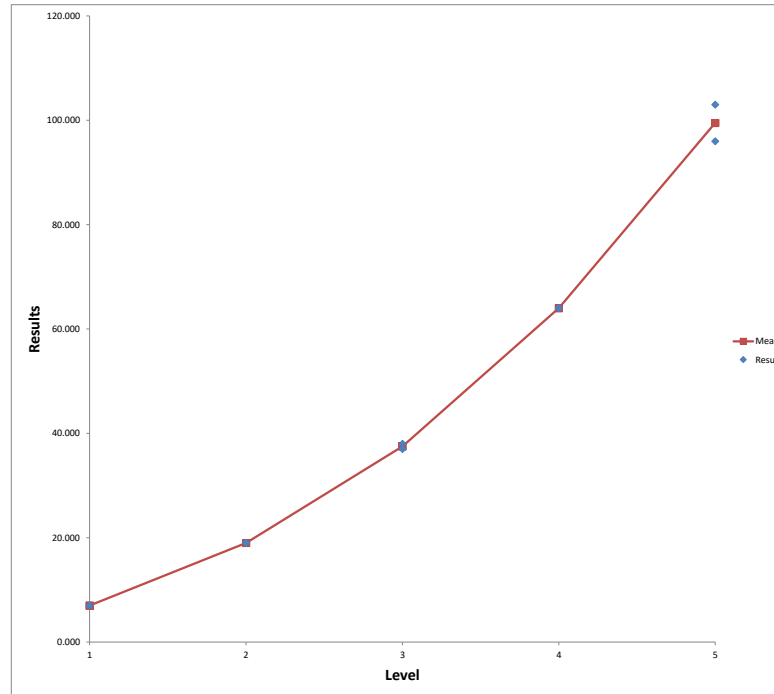
Precision appears to be adequate for a reliable determination of linearity.

Statistically significant non-linearity detected
Non-linearity within Linearity/Accuracy Goal

Analyte: dHDL
Units: mg/dL
Analyser: 5600
Repeatability Goal: 15 %
Linearity/Accuracy Cut-off: 125 mg/dL
Linearity/Accuracy Goal <= Cut-off: 15 mg/dL
Linearity/Accuracy Goal > Cut-off: 12 %

Level		
1	Measuring Range Low	5.027
2	3:1	
3	3:3	
4	1:3	
5	Measuring Range High	109.822

Level	Result	Mean
1	7.000	7.000
1	7.000	7.000
2	19.000	19.000
2	19.000	19.000
3	38.000	37.500
3	37.000	37.500
4	64.000	64.000
4	64.000	64.000
5	103.000	99.500
5	96.000	99.500



Precision appears to be adequate for a reliable determination of linearity.

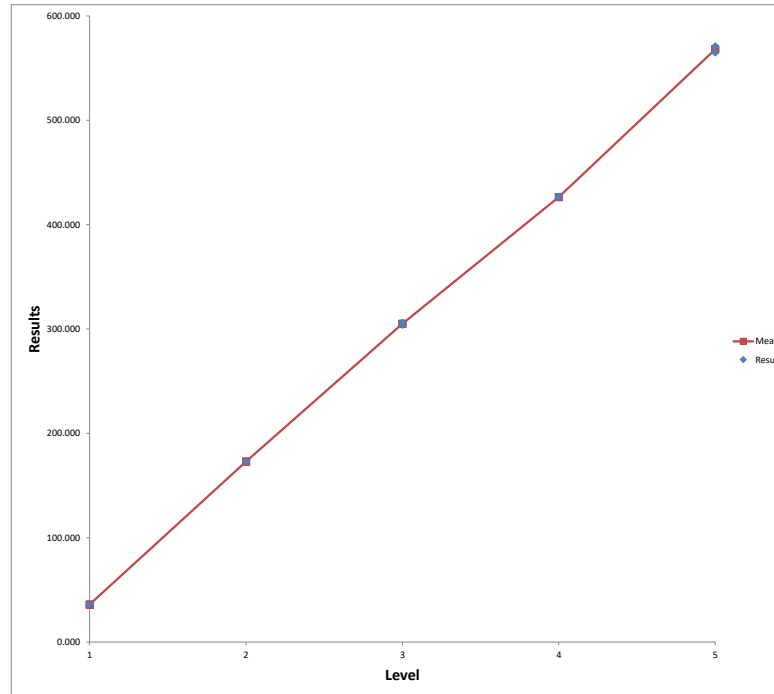
Statistically significant non-linearity detected

Non-linearity within Linearity/Accuracy Goal

Analyte: GLU
Units: mg/dL
Analyser: 5600
Repeatability Goal: 15 %
Linearity/Accuracy Cut-off: 125 mg/dL
Linearity/Accuracy Goal <= Cut-off: 15 mg/dL
Linearity/Accuracy Goal > Cut-off: 12 %

Level		
1	Measuring Range Low	19.996
2	3:1	
3	3:3	
4	1:3	
5	Measuring Range High	624.932

Level	Result	Mean
1	36.000	36.000
1	36.000	36.000
2	173.000	173.000
2	173.000	173.000
3	304.000	305.000
3	306.000	305.000
4	426.000	426.500
4	427.000	426.500
5	571.000	568.000
5	565.000	568.000



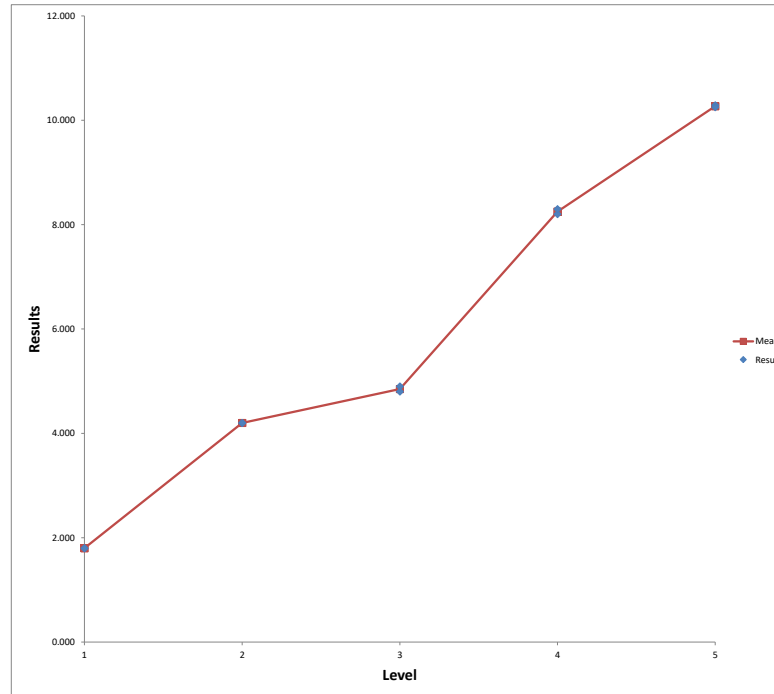
Precision appears to be adequate for a reliable determination of linearity.

Linearity Verified

Analyte: K+
Units: mmol/L
Analyser: 5600
Repeatability Goal: 15 %
Linearity/Accuracy Cut-off: 15 mmol/L
Linearity/Accuracy Goal <= Cut-off: 5.3 mmol/L
Linearity/Accuracy Goal > Cut-off: 12 %

Level		
1	Measuring Range Low	1.000
2	3:1	
3	3:3	
4	1:3	
5	Measuring Range High	14.000

Level	Result	Mean
1	1.800	1.800
1	1.800	1.800
2	4.200	4.200
2	4.200	4.200
3	4.800	4.850
3	4.900	4.850
4	8.200	8.250
4	8.300	8.250
5	10.290	10.270
5	10.250	10.270



Precision appears to be adequate for a reliable determination of linearity.

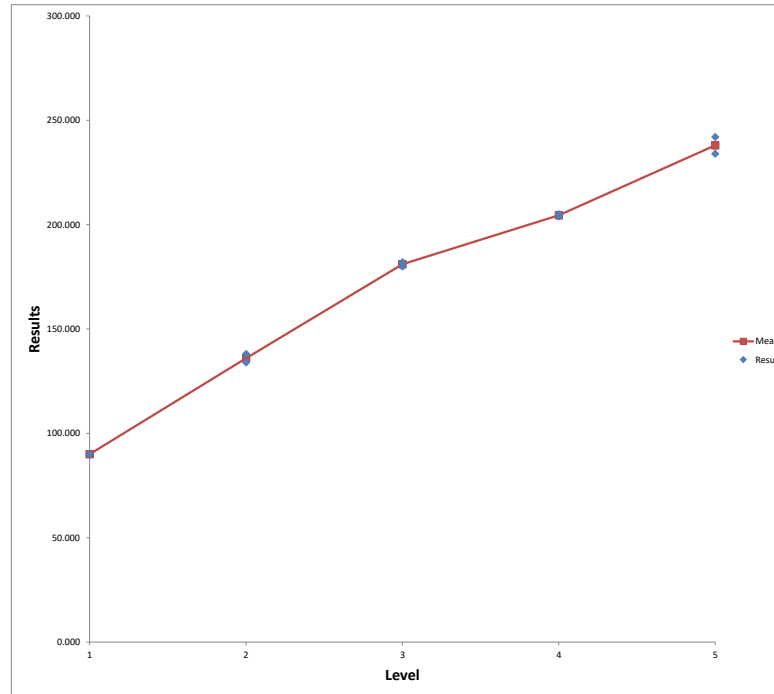
Statistically significant non-linearity detected

Non-linearity within Linearity/Accuracy Goal

Analyte: Na+
Units: mmol/L
Analyser: 5600
Repeatability Goal: 15 %
Linearity/Accuracy Cut-off: 250 mmol/L
Linearity/Accuracy Goal <= Cut-off: 150 mmol/L
Linearity/Accuracy Goal > Cut-off: 12 %

Level		
1	Measuring Range Low	75.000
2	3:1	
3	3:3	
4	1:3	
5	Measuring Range High	250.000

Level	Result	Mean
1	90.000	90.000
1	90.000	90.000
2	138.000	136.000
2	134.000	136.000
3	180.000	181.000
3	182.000	181.000
4	204.000	204.500
4	205.000	204.500
5	242.000	238.000
5	234.000	238.000



Precision appears to be adequate for a reliable determination of linearity.

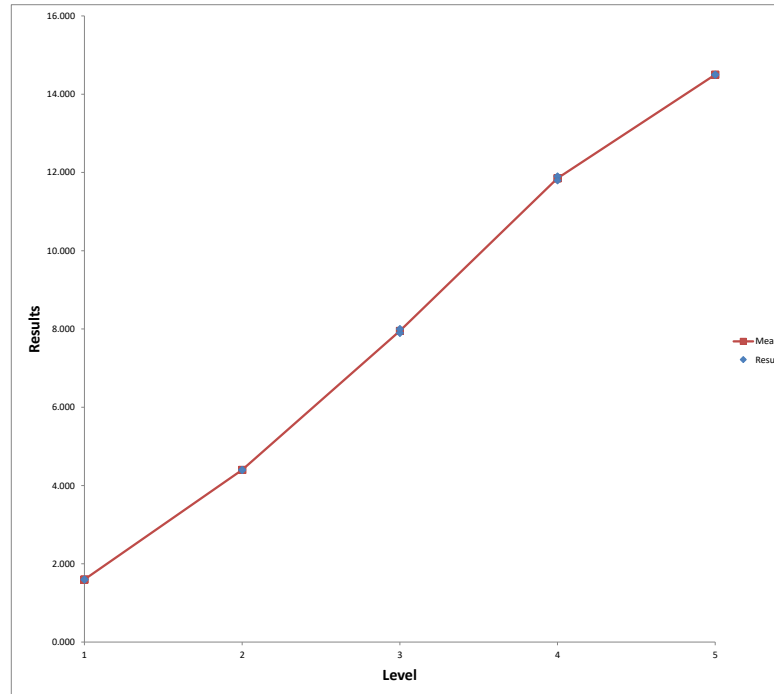
Statistically significant non-linearity detected

Non-linearity within Linearity/Accuracy Goal

Analyte: PHOS
Units: mg/dL
Analyser: 5600
Repeatability Goal: 15 %
Linearity/Accuracy Cut-off: 14 mg/dL
Linearity/Accuracy Goal <= Cut-off: 5 mg/dL
Linearity/Accuracy Goal > Cut-off: 15 %

Level		
1	Measuring Range Low	0.496
2	3:1	
3	3:3	
4	1:3	
5	Measuring Range High	13.007

Level	Result	Mean
1	1.600	1.600
1	1.600	1.600
2	4.400	4.400
2	4.400	4.400
3	7.900	7.950
3	8.000	7.950
4	11.900	11.850
4	11.800	11.850
5	14.500	14.500
5	14.500	14.500



Precision appears to be adequate for a reliable determination of linearity.

Statistically significant non-linearity detected

Non-linearity within Linearity/Accuracy Goal

Analyte: TP
Units: g/dL
Analyser: 5600
Repeatability Goal: 15 %
Linearity/Accuracy Cut-off: 125 g/dL
Linearity/Accuracy Goal <= Cut-off: 15 g/dL
Linearity/Accuracy Goal > Cut-off: 12 %

Level		
1	Measuring Range Low	2.000
2	3:1	
3	3:3	
4	1:3	
5	Measuring Range High	11.000

Level	Result	Mean
1	2.200	2.200
1	2.200	2.200
2	5.000	5.000
2	5.000	5.000
3	6.600	6.600
3	6.600	6.600
4	8.600	8.600
4	8.600	8.600
5	10.900	10.900
5	10.900	10.900

