

Development of Biochemistry Reagents

Technical Report



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Alkaline Phosphatase

CLINICAL EVIDENCE EVALUATION REPORT

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1.0 Details of Reagents

Type of Reagents developed	Liquid Clinical Chemistry Reagents
Instrument Model	Biochemistry Semi-automated analyzer (BTS-350)
Reference Reagents	Reference Diasys Reagents

2.0 Coefficient of Correlation Studies: Accuracy study

- I. The objective was to determine the correlation between the results obtained with the Clinical Chemistry reagents of Vanguard Diagnostics and the benchmarked Clinical Chemistry reagents from Diasys.
- II. The Coefficient of Correlation ("r") was calculated for Alkaline Phosphatase kit.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x ($\bar{x}$)
 - 3 Mean y ($\bar{y}$)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of "r"
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, x_i ($x_1, x_2, \dots, x_n$) are the x values and y_i are the y values.

2.1 Coefficient of Correlation (“r”): Alkaline Phosphatase

X AXIS = Reference Diasys Reagent.

Y AXIS = Alkaline Phosphatase kit from Vanguard Diagnostics (P) Ltd.

$$“r” = 0.996$$

Sample size: 20

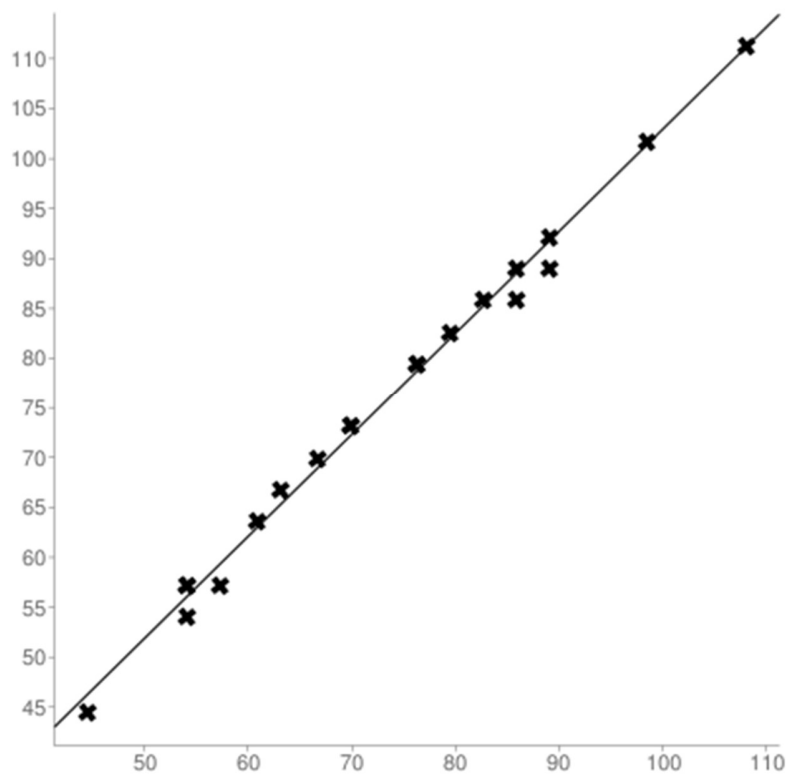
Mean x (x̄): 73.258

Mean y (ȳ): 75.636

Intercept (a): 0.7788001623156

Slope (b): 1.0218296955648

Regression line equation: $y = 0.7788001623156 + 1.0218296955648x$



3.0 Comparative evaluation report: Alkaline Phosphatase

Vanguard Alkaline Phosphatase Kit				Reference Kit		
S.no	Test	Δ Abs/min	Conc (IU/L)	Δ Abs/min	Conc (IU/L)	%
	Factor		2764		2764	
1	Sample 1	0.020	54.03	0.020	54.03	100
2	Sample 2	0.029	79.45	0.030	82.63	96.15
3	Sample 3	0.025	69.92	0.026	73.09	95.65
4	Sample 4	0.020	54.03	0.021	57.2	94.44
5	Sample 5	0.030	82.63	0.031	85.81	96.3
6	Sample 6	0.024	66.74	0.025	69.92	95.45
7	Sample 7	0.021	57.2	0.021	57.2	100
8	Sample 8	0.023	63.2	0.024	66.74	95.24
9	Sample 9	0.032	88.98	0.033	92.16	96.55
10	Sample 10	0.028	76.27	0.029	79.45	96
11	Sample 11	0.031	85.81	0.031	85.81	100
12	Sample 12	0.039	108.05	0.040	111.23	97.14
13	Sample 13	0.028	76.27	0.029	79.45	96
14	Sample 14	0.032	88.98	0.032	88.98	100
15	Sample 15	0.020	54.03	0.021	57.2	94.44
16	Sample 16	0.025	69.92	0.026	73.09	95.65
17	Sample 17	0.022	60.83	0.023	63.56	95
18	Sample 18	0.016	44.49	0.016	44.49	100
19	Sample 19	0.036	98.52	0.037	101.7	96.88
20	Sample 20	0.031	85.81	0.032	88.98	96.43

4.0 Coefficient of Variation: Repeatability/Reproducibility/Precision study

1. Biorad Controls Normal and Abnormal were used to calculate “Within Run” and “Between Run” Precision.
2. The Biorad Controls were tested in 25 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.
4. **Acceptance criteria = NMT 10%.**

4.1 Precision “Within Run” and “Between Run”

4.1.1 Bio-Rad Control (Level-1)

Within Run				Run to Run			
S.No.	Test	Δ Abs/min	Conc (IU/L)	S.No.	Test	Δ Abs/min	Conc (IU/L)
	Factor	2764			Factor	2764	
01	Bio-Rad 1	0.036	99.50	01	Bio-Rad 1	0.036	99.50
02	Bio-Rad 1	0.036	99.50	02	Bio-Rad 1	0.036	99.50
03	Bio-Rad 1	0.036	99.50	03	Bio-Rad 1	0.036	99.50
04	Bio-Rad 1	0.036	99.50	04	Bio-Rad 1	0.036	99.50
05	Bio-Rad 1	0.036	99.50	05	Bio-Rad 1	0.038	105.03
06	Bio-Rad 1	0.036	99.50	06	Bio-Rad 1	0.035	96.74
07	Bio-Rad 1	0.036	99.50	07	Bio-Rad 1	0.036	99.50
08	Bio-Rad 1	0.036	99.50	08	Bio-Rad 1	0.036	99.50
09	Bio-Rad 1	0.036	99.50	09	Bio-Rad 1	0.035	96.74
10	Bio-Rad 1	0.035	96.74	10	Bio-Rad 1	0.036	99.50
11	Bio-Rad 1	0.036	99.50	11	Bio-Rad 1	0.038	105.03
12	Bio-Rad 1	0.036	99.50	12	Bio-Rad 1	0.036	99.50
13	Bio-Rad 1	0.035	96.74	13	Bio-Rad 1	0.036	99.50
14	Bio-Rad 1	0.035	96.74	14	Bio-Rad 1	0.037	102.27
15	Bio-Rad 1	0.036	99.50	15	Bio-Rad 1	0.036	99.50
16	Bio-Rad 1	0.036	99.50	16	Bio-Rad 1	0.036	99.50
17	Bio-Rad 1	0.036	99.50	17	Bio-Rad 1	0.036	99.50
18	Bio-Rad 1	0.036	99.50	18	Bio-Rad 1	0.036	99.50
19	Bio-Rad 1	0.038	105.03	19	Bio-Rad 1	0.038	105.03
20	Bio-Rad 1	0.036	99.50	20	Bio-Rad 1	0.036	99.50
21	Bio-Rad 1	0.036	99.50	21	Bio-Rad 1	0.036	99.50
22	Bio-Rad 1	0.036	99.50	22	Bio-Rad 1	0.036	99.50
23	Bio-Rad 1	0.038	105.03	23	Bio-Rad 1	0.038	105.03
24	Bio-Rad 1	0.036	99.50	24	Bio-Rad 1	0.036	99.50
25	Bio-Rad 1	0.036	99.50	25	Bio-Rad 1	0.036	99.50
Mean			99.61	Mean			100.28
S.D.			1.87	S.D.			2.33
CV			0.02	CV			0.02
CV%			1.88	CV%			2.32

4.2 Precision “Within Run” and “Between Run”

4.2.1 Bio-Rad Control (Level-2)

Within Run				Run to Run			
s.no	Test	ΔAbs/min	Conc (IU/L)	S.No.	Test	ΔAbs/min	Conc (IU/L)
	Factor	2764			Factor	2764	
01	Bio-Rad 2	0.135	373.14	01	Bio-Rad 2	0.138	381.43
02	Bio-Rad 2	0.135	373.14	02	Bio-Rad 2	0.135	373.14
03	Bio-Rad 2	0.135	373.14	03	Bio-Rad 2	0.135	373.14
04	Bio-Rad 2	0.135	373.14	04	Bio-Rad 2	0.135	373.14
05	Bio-Rad 2	0.135	373.14	05	Bio-Rad 2	0.138	381.43
06	Bio-Rad 2	0.136	375.90	06	Bio-Rad 2	0.136	375.90
07	Bio-Rad 2	0.135	373.14	07	Bio-Rad 2	0.135	373.14
08	Bio-Rad 2	0.142	392.49	08	Bio-Rad 2	0.140	386.96
09	Bio-Rad 2	0.136	375.90	09	Bio-Rad 2	0.138	381.43
10	Bio-Rad 2	0.135	373.14	10	Bio-Rad 2	0.135	373.14
11	Bio-Rad 2	0.135	373.14	11	Bio-Rad 2	0.135	373.14
12	Bio-Rad 2	0.142	392.49	12	Bio-Rad 2	0.140	386.96
13	Bio-Rad 2	0.135	373.14	13	Bio-Rad 2	0.132	364.85
14	Bio-Rad 2	0.136	375.90	14	Bio-Rad 2	0.136	375.90
15	Bio-Rad 2	0.135	373.14	15	Bio-Rad 2	0.138	381.43
16	Bio-Rad 2	0.136	375.90	16	Bio-Rad 2	0.139	384.20
17	Bio-Rad 2	0.140	386.96	17	Bio-Rad 2	0.140	386.96
18	Bio-Rad 2	0.135	373.14	18	Bio-Rad 2	0.135	373.14
19	Bio-Rad 2	0.135	373.14	19	Bio-Rad 2	0.132	364.85
20	Bio-Rad 2	0.136	375.90	20	Bio-Rad 2	0.139	384.20
21	Bio-Rad 2	0.135	373.14	21	Bio-Rad 2	0.140	386.96
22	Bio-Rad 2	0.140	386.96	22	Bio-Rad 2	0.135	373.14
23	Bio-Rad 2	0.135	373.14	23	Bio-Rad 2	0.136	375.90
24	Bio-Rad 2	0.135	373.14	24	Bio-Rad 2	0.135	373.14
25	Bio-Rad 2	0.135	373.14	25	Bio-Rad 2	0.140	386.96
Mean			376.35	Mean			377.78
S.D.			6.16	S.D.			6.76
CV			0.02	CV			0.02
CV%			1.64	CV%			1.79

5.0 Performance Evaluation Report of Alkaline Phosphatase

Time interval= Day-0

Storage Temperature = 2°C – 8°C

Test	Vanguard Reagent		Reference Diasys Reagent		Specification (IU/L)
	ΔAbs./min.	Conc. (IU/L)	ΔAbs./min.	Conc. (IU/L)	
Factor 2764	0.169	-	0.150	-	-
Controls					
Biorad- 1	0.047	129.90	0.047	130.1	83.9-141 IU/L
Biorad- 2	0.137	378.60	0.137	379	309 - 441 IU/L
Known normal/ abnormal Serum samples					
Sample-1	0.051	140.9	0.050	139.5	25 - 140 IU/L
Sample-2	0.037	102.2	0.036	100.8	
Sample-3	0.011	30.4	0.010	29.0	
Sample-4	0.026	71.8	0.025	69.1	
Sample-5	0.044	121.6	0.045	122.9	
Linearity					
1600.0 IU/L	0.575	1591 (99.44%)	0.576	1594 (99.63%)	± 10%

6.0 Accelerated Stability Studies: Summary

1. Stability studies were conducted at 37°C till 21 days.
2. Stability studies were conducted using Bio-Rad Control (Level-1 & Level-2).
3. It was not possible to use the “same” samples in the study due to the very limited stability of samples.
4. The values obtained with Alkaline Phosphatase were found to be in the ranges specified for the Bio-Rad controls till 21 days at 37°C and found to be comparable with the reference reagent.
5. Alkaline Phosphatase reagent was therefore found to be stable at 37°C for 21 days.
6. This data has been extrapolated to conclude that Alkaline Phosphatase reagent will be stable for 18 months under the recommended temperature conditions of 2°C- 8°C.

6.1 Accelerated stability study: Alkaline Phosphatase

Time interval= Day-7

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Diasys Reagent		Specification (IU/L)
	ΔAbs./min.	Conc. (IU/L)	ΔAbs./min.	Conc. (IU/L)	
Factor 2764	0.205	-	0.191	-	-
Controls					
Biorad- 1	0.048	132	0.047	130	83.9-141 IU/L
Biorad- 2	0.138	381	0.137	379	309 - 441 IU/L
Known normal/ abnormal Serum samples					
Sample-1	0.050	138.20	0.049	135.43	25 - 140 IU/L
Sample-2	0.038	105	0.038	105.0	
Sample-3	0.010	27.64	0.010	27.64	
Sample-4	0.025	69.1	0.024	66.3	
Sample-5	0.045	124.38	0.044	121.61	
Linearity					
1600.0 IU/L	0.564	1558.8 (97.5%)	0.563	1557.5 (97.4%)	± 10%

6.2 Accelerated stability study: Alkaline Phosphatase

Time interval= Day-14

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Diasys Reagent		Specification (IU/L)
	ΔAbs./min.	Conc. (IU/L)	ΔAbs./min.	Conc. (IU/L)	
Factor 2764	0.246	-	0.230	-	-
Controls					
Biorad- 1	0.047	130.1	0.047	130.05	83.9-141 IU/L
Biorad- 2	0.137	379		378.6	309 - 441 IU/L
Known normal/ abnormal Serum samples					
Sample-1	0.052	143.7	0.052	141.2	25 - 140 IU/L
Sample-2	0.039	107.7	0.039	108.2	
Sample-3	0.010	27.84	0.011	30.40	
Sample-4	0.025	69.1	0.026	71.8	
Sample-5	0.045	124.38	0.044	122.9	
Linearity					
1600.0 IU/L	0.554	1531.2 (95.7%)	0.553	1529.8 (95.7%)	± 10%

6.3 Accelerated stability study: Alkaline Phosphatase

Time interval= Day-21

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Diasys Reagent		Specification (IU/L)
	ΔAbs./min.	Conc. (IU/L)	ΔAbs./min.	Conc. (IU/L)	
Factor 2764	0.264	-	0.250	-	-
Controls					
Biorad- 1	0.048	132	0.047	130.1	83.9-141 IU/L
Biorad- 2	0.138	381	0.137	379	309 - 441 IU/L
Known normal/ abnormal Serum samples					
Sample-1	0.049	135.43	0.050	138.2	25 - 140 IU/L
Sample-2	0.038	105	0.039	107.7	
Sample-3	0.010	27.64	0.011	29.35	
Sample-4	0.024	66.3	0.025	69.13	
Sample-5	0.044	121.616	0.043	120	
Linearity					
1600.0 IU/L	0.530	1464.9 (91.6%)	0.534	1475.9 (92.3%)	± 10%

7.0 Conclusions

1. The Alkaline Phosphatase reagent showed an excellent Coefficient of Correlation (“r”) using Diasys as Reference.
2. Alkaline Phosphatase showed values of “r” was 0.996 displaying the highest degree of correlation between the two sets of reagents.
3. The Alkaline Phosphatase reagent showed an excellent coefficient of Variation (CV %).
4. The CV % was found to be in the range of 1.64% and 2.32% displaying a very high level of precision and repeatability.
5. The Alkaline Phosphatase reagent showed an excellent performance even under stressful conditions. The reagents were found to be stable at 37°C for 21 days.

The Alkaline Phosphatase reagent was thus concluded to be Accurate, Precise and Stable, while using clinical normal and abnormal samples and 3rd Party controls (Level-1 and Level-2).

Calcium

CLINICAL EVIDENCE EVALUATION REPORT

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1. Details of Reagents

Type of Reagents developed	Liquid Clinical Chemistry Reagents
Instrument Model	Biochemistry Semi-automated analyzer (BTS-350)
Reference Reagents	Reference Reagents

1.0 Coefficient of Correlation Studies: Accuracy study

- I. The objective was to determine the correlation between the results obtained with the Clinical Chemistry reagents of Vanguard Diagnostics and the benchmarked Clinical Chemistry reagents from Diasys.
- II. The Coefficient of Correlation ("r") was calculated for Calcium kit.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x (x̄)
 - 3 Mean y (ȳ)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of "r"
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, xi (x1, x2,...,xn) are the x values and yi are the y values.

2.1 Coefficient of Correlation (“r”): Calcium

X AXIS = Reference Reagent.

Y AXIS = Calcium kit from Vanguard Diagnostics (P) Ltd.

$$“r” = 0.997$$

Sample size: 20

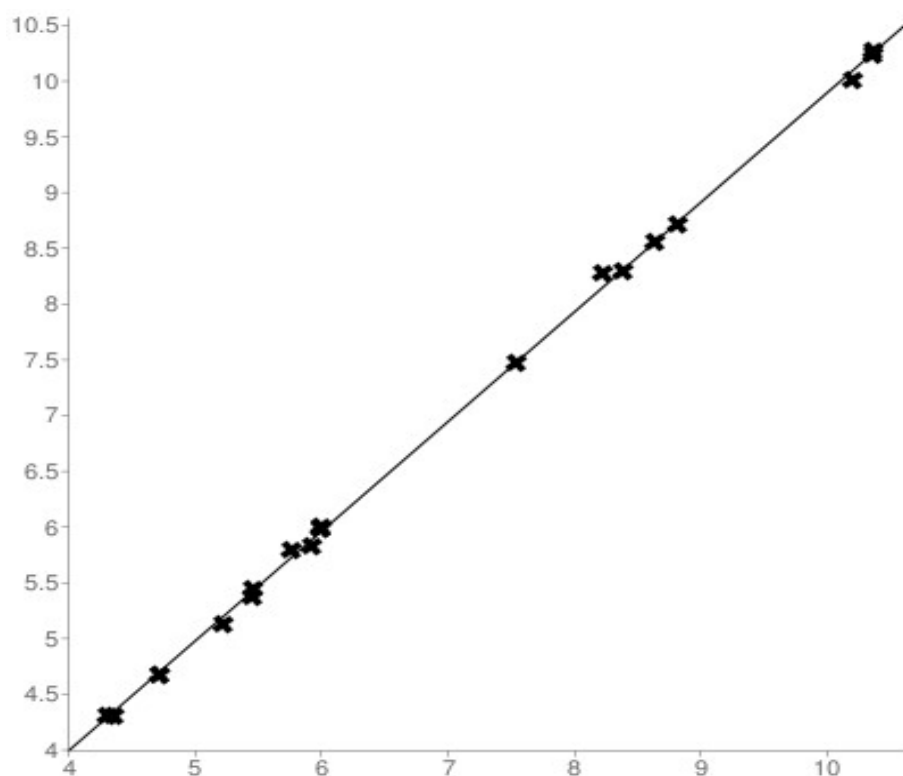
Mean x ($\bar{x}$): 6.8175

Mean y ($\bar{y}$): 6.7675

Intercept (a): 0.059327516681856

Slope (b): 0.98396369392272

Regression line equation: $y=0.059327516681856+0.98396369392272x$



3.0 Comparative evaluation report: Calcium

Vanguard Calcium Kit				Reference Kit		
S.No.	Test	Abs	Conc (mg/dl)	Abs	Conc (mg/dl)	%
	Standard	0.365	10 mg/dl	0.376	10 mg/dl	
01	Sample 1	0.306	8.38	0.312	8.30	101.03
02	Sample 2	0.19	5.21	0.193	5.13	101.41
03	Sample 3	0.378	10.36	0.385	10.24	101.14
04	Sample 4	0.199	5.45	0.202	5.37	101.48
05	Sample 5	0.219	6.00	0.225	5.98	100.27
06	Sample 6	0.275	7.53	0.281	7.47	100.81
07	Sample 7	0.210	5.75	0.218	5.80	99.23
08	Sample 8	0.315	8.63	0.322	8.56	100.77
09	Sample 9	0.216	5.92	0.219	5.82	101.60
10	Sample 10	0.372	10.19	0.376	10.00	101.92
11	Sample 11	0.172	4.71	0.176	4.68	100.67
12	Sample 12	0.300	8.22	0.311	8.27	99.37
13	Sample 13	0.157	4.30	0.162	4.31	99.83
14	Sample 14	0.322	8.82	0.328	8.72	101.13
15	Sample 15	0.378	10.36	0.386	10.27	100.88
16	Sample 16	0.219	6.00	0.225	5.98	100.27
17	Sample 17	0.172	4.71	0.176	4.68	100.67
18	Sample 18	0.159	4.36	0.162	4.31	101.11
19	Sample 19	0.199	5.45	0.205	5.45	100.00
20	Sample 20	0.219	6.00	0.226	6.01	99.82

4.0 Coefficient of Variation: Repeatability/Reproducibility/Precision study

5. Biorad Controls Normal and Abnormal were used to calculate “Within Run” and “Between Run” Precision.
6. The Biorad Controls were tested in 25 replicates to study Precision.
7. Coefficient of Variation (CV %) was calculated.
8. **Acceptance criteria = NMT 10%.**

4.1 Precision “Within Run” and “Between Run”

4.1.1 Bio-Rad Control (Level-1)

Within Run				Run to Run			
S.No.	Test	Abs.	Conc. (mg/dl)	S.No.	Test	Abs.	Conc. (mg/dl)
	Standard (10 mg/dl)	0.369			Standard (10 mg/dl)	0.374	
01	Bio-Rad 1	0.362	9.81	01	Bio-Rad 1	0.369	9.87
02	Bio-Rad 1	0.365	9.89	02	Bio-Rad 1	0.368	9.84
03	Bio-Rad 1	0.362	9.81	03	Bio-Rad 1	0.367	9.81
04	Bio-Rad 1	0.365	9.89	04	Bio-Rad 1	0.368	9.84
05	Bio-Rad 1	0.362	9.81	05	Bio-Rad 1	0.367	9.81
06	Bio-Rad 1	0.364	9.86	06	Bio-Rad 1	0.367	9.81
07	Bio-Rad 1	0.362	9.81	07	Bio-Rad 1	0.368	9.84
08	Bio-Rad 1	0.365	9.89	08	Bio-Rad 1	0.365	9.76
09	Bio-Rad 1	0.363	9.84	09	Bio-Rad 1	0.367	9.81
10	Bio-Rad 1	0.362	9.81	10	Bio-Rad 1	0.368	9.84
11	Bio-Rad 1	0.365	9.89	11	Bio-Rad 1	0.367	9.81
12	Bio-Rad 1	0.364	9.86	12	Bio-Rad 1	0.368	9.84
13	Bio-Rad 1	0.362	9.81	13	Bio-Rad 1	0.367	9.81
14	Bio-Rad 1	0.365	9.89	14	Bio-Rad 1	0.365	9.76
15	Bio-Rad 1	0.362	9.81	15	Bio-Rad 1	0.368	9.84
16	Bio-Rad 1	0.363	9.84	16	Bio-Rad 1	0.367	9.81
17	Bio-Rad 1	0.365	9.89	17	Bio-Rad 1	0.368	9.84
18	Bio-Rad 1	0.362	9.81	18	Bio-Rad 1	0.367	9.81
19	Bio-Rad 1	0.364	9.86	19	Bio-Rad 1	0.365	9.76
20	Bio-Rad 1	0.362	9.81	20	Bio-Rad 1	0.368	9.84
21	Bio-Rad 1	0.365	9.89	21	Bio-Rad 1	0.368	9.84
22	Bio-Rad 1	0.362	9.81	22	Bio-Rad 1	0.367	9.81
23	Bio-Rad 1	0.364	9.86	23	Bio-Rad 1	0.368	9.84
24	Bio-Rad 1	0.365	9.89	24	Bio-Rad 1	0.367	9.81
25	Bio-Rad 1	0.362	9.81	25	Bio-Rad 1	0.368	9.84
Mean			9.85	Mean			9.82
S.D.			0.04	S.D.			0.03
CV			0.00	CV			0.00
CV%			0.37	CV%			0.28

4.2 Precision “Within Run” and “Between Run”

4.2.1 Bio-Rad Control (Level-2)

Within Run				Run to Run			
S.No.	Test	Abs.	Conc. (mg/dl)	S.No.	Test	Abs.	Conc. (mg/dl)
	Standard (10 mg/dl)	0.369			Standard (10 mg/dl)	0.374	
01	Bio-Rad 2	0.436	11.82	01	Bio-Rad 2	0.436	11.66
02	Bio-Rad 2	0.432	11.71	02	Bio-Rad 2	0.438	11.71
03	Bio-Rad 2	0.431	11.68	03	Bio-Rad 2	0.439	11.74
04	Bio-Rad 2	0.432	11.71	04	Bio-Rad 2	0.438	11.71
05	Bio-Rad 2	0.431	11.68	05	Bio-Rad 2	0.437	11.68
06	Bio-Rad 2	0.432	11.71	06	Bio-Rad 2	0.438	11.71
07	Bio-Rad 2	0.431	11.68	07	Bio-Rad 2	0.436	11.66
08	Bio-Rad 2	0.431	11.68	08	Bio-Rad 2	0.438	11.71
09	Bio-Rad 2	0.432	11.71	09	Bio-Rad 2	0.438	11.71
10	Bio-Rad 2	0.431	11.68	10	Bio-Rad 2	0.437	11.68
11	Bio-Rad 2	0.432	11.71	11	Bio-Rad 2	0.437	11.68
12	Bio-Rad 2	0.431	11.68	12	Bio-Rad 2	0.438	11.71
13	Bio-Rad 2	0.431	11.68	13	Bio-Rad 2	0.437	11.68
14	Bio-Rad 2	0.429	11.63	14	Bio-Rad 2	0.438	11.71
15	Bio-Rad 2	0.429	11.63	15	Bio-Rad 2	0.436	11.66
16	Bio-Rad 2	0.428	11.60	16	Bio-Rad 2	0.438	11.71
17	Bio-Rad 2	0.429	11.63	17	Bio-Rad 2	0.437	11.68
18	Bio-Rad 2	0.428	11.60	18	Bio-Rad 2	0.438	11.71
19	Bio-Rad 2	0.429	11.63	19	Bio-Rad 2	0.437	11.68
20	Bio-Rad 2	0.429	11.63	20	Bio-Rad 2	0.436	11.66
21	Bio-Rad 2	0.431	11.68	21	Bio-Rad 2	0.437	11.68
22	Bio-Rad 2	0.429	11.63	22	Bio-Rad 2	0.438	11.71
23	Bio-Rad 2	0.428	11.60	23	Bio-Rad 2	0.437	11.68
24	Bio-Rad 2	0.429	11.63	24	Bio-Rad 2	0.438	11.71
25	Bio-Rad 2	0.431	11.68	25	Bio-Rad 2	0.436	11.66
Mean			11.67	Mean			11.69
S.D.			0.05	S.D.			0.02
CV			0.00	CV			0.00
CV%			0.42	CV%			0.19

5.0 Performance Evaluation Report of Calcium

Time interval= Day-0

Storage Temperature = 2°C – 8°C

Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
Reagent Blank	0.352		0.362		
Standard	0.347	10 mg/dl	0.352	10 mg/dl	-
Controls					
Biorad- 1	0.326	9.39	0.328	9.32	8.26 - 10.2 mg/dl
Biorad- 2	0.406	11.70	0.408	11.59	10.6 - 12.9 mg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.325	9.37	0.329	9.35	8.5 - 10.2 mg/dl
Sample-2	0.312	8.99	0.321	9.12	
Sample-3	0.322	9.28	0.328	9.32	
Sample-4	0.302	8.70	0.308	8.75	
Sample-5	0.343	9.88	0.345	9.80	
Linearity					
16.0 mg/dl	0.552	15.90 (99.37%)	0.558	15.85 (99.07%)	± 10%

6.0 Accelerated Stability Studies: Summary

1. Stability studies were conducted at 37°C till 21 days.
2. Stability studies were conducted using Bio-Rad Control (Level-1 & Level-2).
3. It was not possible to use the “same” samples in the study due to the very limited stability of samples.
4. The values obtained with Calcium were found to be in the ranges specified for the Bio-Rad controls till 21 days at 37°C and found to be comparable with the reference reagent.
5. Calcium reagent was therefore found to be stable at 37°C for 21 days.
6. This data has been extrapolated to conclude that Calcium reagent will be stable for 18 months under the recommended temperature conditions of 2°C- 8°C.

6.1 Accelerated stability study: Calcium

Time interval= Day-7

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
Reagent Blank	0.354		0.356		
Standard	0.362	10 mg/dl	0.368	10 mg/dl	-
Controls					
Biorad- 1	0.328	9.06	0.331	8.99	8.26 - 10.2 mg/dl
Biorad- 2	0.412	11.38	0.418	11.36	10.6 - 12.9 mg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.328	9.06	0.332	9.02	8.5 - 10.2 mg/dl
Sample-2	0.316	8.73	0.321	8.72	
Sample-3	0.326	9.01	0.331	8.99	
Sample-4	0.306	8.45	0.311	8.45	
Sample-5	0.346	9.56	0.352	9.57	
Linearity					
16.0 mg/dl	0.562	15.52 (97.03%)	0.572	15.54 (97.14%)	± 10%

6.2 Accelerated stability study: Calcium

Time interval= Day-14

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
Reagent Blank	0.356		0.358		
Standard	0.368	10 mg/dl	0.372	10 mg/dl	-
Controls					
Biorad- 1	0.329	8.94	0.332	8.92	8.26 - 10.2 mg/dl
Biorad- 2	0.415	11.28	0.421	11.32	10.6 - 12.9 mg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.329	8.94	0.336	9.03	8.5 - 10.2 mg/dl
Sample-2	0.314	8.53	0.319	8.58	
Sample-3	0.321	8.72	0.328	8.82	
Sample-4	0.325	8.83	0.329	8.84	
Sample-5	0.332	9.02	0.338	9.09	
Linearity					
16.0 mg/dl	0.582	15.81 (98.84%)	0.592	15.91 (99.46%)	± 10%

6.3 Accelerated stability study: Calcium

Time interval= Day-21

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
Reagent Blank	0.362		0.372		
Standard	0.378	10 mg/dl	0.382	10 mg/dl	-
Controls					
Biorad- 1	0.342	9.05	0.345	9.03	8.26 - 10.2 mg/dl
Biorad- 2	0.432	11.43	0.438	11.47	10.6 - 12.9 mg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.342	9.05	0.348	9.11	8.5 - 10.2 mg/dl
Sample-2	0.325	8.60	0.329	8.61	
Sample-3	0.352	9.31	0.362	9.48	
Sample-4	0.346	9.15	0.348	9.11	
Sample-5	0.362	9.58	0.368	9.63	
Linearity					
16.0 mg/dl	0.592	15.66 (97.88%)	0.598	15.65 (97.84%)	± 10%

7.0 Conclusions

1. The Calcium reagent showed an excellent Coefficient of Correlation (“r”) using as Reference.
2. Calcium showed values of “r” was 0.997 displaying the highest degree of correlation between the two sets of reagents.
3. The Calcium reagent showed an excellent coefficient of Variation (CV %).
4. The CV % was found to be in the range of 0.19% and 0.42% displaying a very high level of precision and repeatability.
5. The Calcium reagent showed an excellent performance even under stressful conditions. The reagents were found to be stable at 37°C for 21 days.

The Calcium reagent was thus concluded to be Accurate, Precise and Stable, while using clinical normal and abnormal samples and 3rd Party controls (Level-1 and Level-2).

Chloride

CLINICAL EVIDENCE EVALUATION REPORT

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1. Details of Reagents

Type of Reagents developed	Liquid Clinical Chemistry Reagents
Instrument Model	Biochemistry Semi-automated analyzer (BTS-350)
Reference Reagents	Reference Reagents

2.0 Coefficient of Correlation Studies: Accuracy study

- I. The objective was to determine the correlation between the results obtained with the Clinical Chemistry reagents of Vanguard Diagnostics and the benchmarked Clinical Chemistry reagents from Diasys.
- II. The Coefficient of Correlation ("r") was calculated for Chloride kit.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x (x̄)
 - 3 Mean y (ȳ)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of "r"
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, xi (x1, x2,...,xn) are the x values and yi are the y values.

2.1 Coefficient of Correlation (“r”): Chloride

X AXIS = Reference Diasys Reagent.

Y AXIS = Chloride kit from Vanguard Diagnostics (P) Ltd.

$$“r” = 0.997$$

Sample size: 20

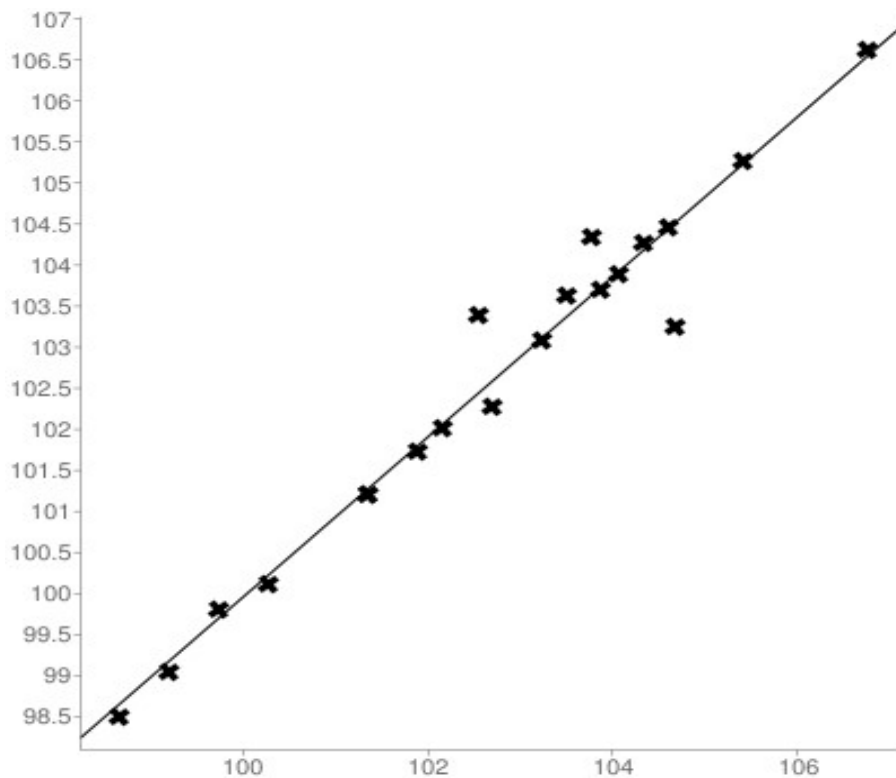
Mean x (x̄): 102.7015

Mean y (ȳ): 102.5905

Intercept (a): 2.376221523151

Slope (b): 0.97578203314313

Regression line equation: $y = 2.376221523151 + 0.97578203314313x$



3.0 Comparative evaluation report: Chloride

Vanguard chloride Kit				Reference Kit		
S.No.	Test	Abs.	Conc. (mmol/L)	Abs.	Conc. (mmol/L)	%
	Standard (100 mmol/L)	0.370	-	0.360	-	
01	Sample 1	0.369	99.73	0.359	99.80	99.93
02	Sample 2	0.383	103.51	0.373	103.64	99.88
03	Sample 3	0.391	105.68	0.372	103.26	102.34
04	Sample 4	0.367	99.19	0.357	99.04	100.15
05	Sample 5	0.375	101.35	0.368	102.20	99.17
06	Sample 6	0.365	98.65	0.355	98.50	100.15
07	Sample 7	0.380	102.70	0.368	102.27	100.42
08	Sample 8	0.388	104.86	0.373	103.71	101.11
09	Sample 9	0.390	105.41	0.379	105.26	100.14
10	Sample 10	0.375	101.35	0.364	101.20	100.15
11	Sample 11	0.372	100.54	0.372	103.39	97.24
12	Sample 12	0.371	100.27	0.360	100.12	100.15
13	Sample 13	0.378	102.16	0.360	100.01	102.15
14	Sample 14	0.377	101.89	0.366	101.74	100.15
15	Sample 15	0.384	103.78	0.376	104.34	99.47
16	Sample 16	0.385	104.05	0.374	103.90	100.14
17	Sample 17	0.386	104.32	0.375	104.27	100.05
18	Sample 18	0.387	104.59	0.376	104.45	100.14
19	Sample 19	0.382	103.24	0.371	103.09	100.15
20	Sample 20	0.395	106.76	0.384	106.62	100.13

4.0 Coefficient of Variation: Repeatability/Reproducibility/Precision study

1. Biorad Controls Normal and Abnormal were used to calculate “Within Run” and “Between Run” Precision.
2. The Biorad Controls were tested in 25 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.
4. **Acceptance criteria = NMT 10%.**

4.1 Precision “Within Run” and “Between Run”

4.1.1 Bio-Rad Control (Level-1)

Within Run				Run to Run			
S.No.	Test	Abs.	Conc. (mmol/L)	S.No.	Test	Abs.	Conc. (mmol/L)
	Standard (100 mmol/L)	0.370	-		Standard (100 mmol/L)	0.370	-
01	Biorad 1	0.391	105.68	01	Biorad 1	0.383	103.50
02	Biorad 1	0.390	105.41	02	Biorad 1	0.392	106.00
03	Biorad 1	0.388	104.86	03	Biorad 1	0.393	106.25
04	Biorad 1	0.385	104.05	04	Biorad 1	0.383	103.56
05	Biorad 1	0.386	104.32	05	Biorad 1	0.390	105.35
06	Biorad 1	0.387	104.59	06	Biorad 1	0.397	107.26
07	Biorad 1	0.388	104.86	07	Biorad 1	0.397	107.35
08	Biorad 1	0.395	106.76	08	Biorad 1	0.398	107.46
09	Biorad 1	0.391	105.68	09	Biorad 1	0.401	108.26
10	Biorad 1	0.392	105.95	10	Biorad 1	0.405	109.35
11	Biorad 1	0.392	105.81	11	Biorad 1	0.393	106.26
12	Biorad 1	0.395	106.76	12	Biorad 1	0.390	105.37
13	Biorad 1	0.396	106.92	13	Biorad 1	0.386	104.26
14	Biorad 1	0.394	106.49	14	Biorad 1	0.391	105.76
15	Biorad 1	0.394	106.54	15	Biorad 1	0.399	107.78
16	Biorad 1	0.393	106.08	16	Biorad 1	0.401	108.34
17	Biorad 1	0.391	105.68	17	Biorad 1	0.405	109.46
18	Biorad 1	0.392	105.95	18	Biorad 1	0.402	108.76
19	Biorad 1	0.390	105.41	19	Biorad 1	0.401	108.34
20	Biorad 1	0.391	105.54	20	Biorad 1	0.402	108.65
21	Biorad 1	0.392	105.81	21	Biorad 1	0.405	109.36
22	Biorad 1	0.391	105.78	22	Biorad 1	0.404	109.15
23	Biorad 1	0.392	105.84	23	Biorad 1	0.404	109.25
24	Biorad 1	0.392	105.89	24	Biorad 1	0.401	108.34
25	Biorad 1	0.392	105.95	25	Biorad 1	0.382	103.24
Mean			105.70	Mean			107.07
S.D.			0.73	S.D.			1.99
CV			0.01	CV			0.02
CV%			0.69	CV%			1.86

4.2 Precision “Within Run” and “Between Run”

4.2.1 Bio-Rad Control (Level-2)

Within Run				Run to Run			
S.No.	Test	Abs.	Conc. (mmol/L)	S.No.	Test	Abs.	Conc. (mmol/L)
	Standard (100 mmol/L)	0.370	-		Standard (100 mmol/L)	0.370	-
01	Biorad 2	0.322	87.03	01	Biorad 2	0.327	88.26
02	Biorad 2	0.322	86.89	02	Biorad 2	0.323	87.35
03	Biorad 2	0.322	87.03	03	Biorad 2	0.327	88.36
04	Biorad 2	0.323	87.19	04	Biorad 2	0.309	83.46
05	Biorad 2	0.322	87.03	05	Biorad 2	0.312	84.26
06	Biorad 2	0.323	87.19	06	Biorad 2	0.312	84.35
07	Biorad 2	0.322	87.14	07	Biorad 2	0.315	85.26
08	Biorad 2	0.322	87.05	08	Biorad 2	0.316	85.34
09	Biorad 2	0.321	86.73	09	Biorad 2	0.320	86.37
10	Biorad 2	0.322	87.03	10	Biorad 2	0.322	86.94
11	Biorad 2	0.322	87.14	11	Biorad 2	0.320	86.53
12	Biorad 2	0.322	87.08	12	Biorad 2	0.323	87.23
13	Biorad 2	0.323	87.19	13	Biorad 2	0.327	88.38
14	Biorad 2	0.322	87.14	14	Biorad 2	0.320	86.36
15	Biorad 2	0.323	87.16	15	Biorad 2	0.327	88.25
16	Biorad 2	0.322	87.05	16	Biorad 2	0.323	87.26
17	Biorad 2	0.322	87.11	17	Biorad 2	0.323	87.35
18	Biorad 2	0.322	87.14	18	Biorad 2	0.327	88.35
19	Biorad 2	0.323	87.19	19	Biorad 2	0.314	84.76
20	Biorad 2	0.323	87.16	20	Biorad 2	0.316	85.36
21	Biorad 2	0.322	87.11	21	Biorad 2	0.312	84.36
22	Biorad 2	0.321	86.76	22	Biorad 2	0.323	87.26
23	Biorad 2	0.322	86.92	23	Biorad 2	0.328	88.76
24	Biorad 2	0.322	86.97	24	Biorad 2	0.330	89.24
25	Biorad 2	0.323	87.27	25	Biorad 2	0.334	90.26
Mean		87.07		Mean		86.7864	
S.D.		0.13		S.D.		1.7714704	
CV		0.002		CV		0.020	
CV%		0.15		CV%		2.04	

5.0 Performance Evaluation Report of Chloride

Time interval= Day-0

Storage Temperature = 2°C – 8°C

Test	Vanguard Reagent		Reference Reagent		Specification (mmol/L)
	Abs	Conc. (mmol/L)	Abs	Conc. (mmol/L)	
Reagent Blank	0.037	-	0.040		
Standard (100 mmol/L)	0.370		0.360		
Controls					
Biorad 1	0.390	105.54	0.374	104.08	98.5 - 114 mmol/L
Biorad 2	0.319	86.34	0.317	87.94	81.6 - 92.6 mmol/L
Known normal/ abnormal Serum samples					
Sample-1	0.365	98.60	0.358	99.32	98 - 107 mmol/L
Sample-2	0.375	101.30	0.361	100.35	
Sample-3	0.382	103.20	0.369	102.75	
Sample-4	0.386	104.30	0.375	104.30	
Sample-5	0.395	106.75	0.397	105.89	
Linearity					
150 (mmol/L)	0.551	149.00 (99.40%)	0.538	148.00 (98.7%)	± 10%

6.0 Accelerated Stability Studies: Summary

- Stability studies were conducted at 37°C till 21 days.
- Stability studies were conducted using Bio-Rad Control (Level-1 & Level-2).
- It was not possible to use the “same” samples in the study due to the very limited stability of samples.
- The values obtained with Chloride were found to be in the ranges specified for the Bio-Rad controls till 21 days at 37°C and found to be comparable with the reference reagent.
- Chloride reagent was therefore found to be stable at 37°C for 21 days.
- This data has been extrapolated to conclude that Chloride reagent will be stable for 18 months under the recommended temperature conditions of 2°C- 8°C.

6.1 Accelerated stability study: Chloride

Time interval= Day-7

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (mmol/L)
	Abs	Conc. (mmol/L)	Abs	Conc. (mmol/L)	
Reagent Blank	0.039	-	0.041		
Standard (100 mmol/L)	0.371	-	0.362	-	
Controls					
Biorad 1	0.390	105.12	0.374	103.31	98.5 - 114 mmol/L
Biorad 2	0.319	85.98	0.317	87.57	81.6 - 92.6 mmol/L
Known normal/ abnormal Serum samples					
Sample-1	0.365	98.38	0.358	98.90	98 - 107 mmol/L
Sample-2	0.375	101.08	0.361	99.72	
Sample-3	0.382	102.96	0.369	101.93	
Sample-4	0.386	104.04	0.375	103.59	
Sample-5	0.395	106.47	0.389	107.46	
Linearity					
150 (mmol/L)	0.545	147.12 (98.12%)	0.528	1460.10 (97.41%)	± 10%

6.2 Accelerated stability study: Chloride

Time interval= Day-14

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (mmol/L)
	Abs	Conc. (mmol/L)	Abs	Conc. (mmol/L)	
Reagent Blank	0.041	-	0.042		
Standard (100 mmol/L)	0.375	-	0.366	-	
Controls					
Biorad 1	0.390	104.00	0.384	104.92	98.5 - 114 mmol/L
Biorad 2	0.319	85.07	0.32	87.43	81.6 - 92.6 mmol/L
Known normal/ abnormal Serum samples					
Sample-1	0.365	97.33	0.358	97.81	98 - 107 mmol/L
Sample-2	0.374	99.73	0.361	98.63	
Sample-3	0.382	97.95	0.36	98.36	
Sample-4	0.336	105.33	0.38	103.83	
Sample-5	0.365	97.33	0.36	98.36	
Linearity					
150 (mmol/L)	0.532	142.00 (94.72%)	0.523	143.00 (95.41%)	± 10%

6.3 Accelerated stability study: Chloride

Time interval= Day-21

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (mmol/L)
	Abs	Conc. (mmol/L)	Abs	Conc. (mmol/L)	
Reagent Blank	0.037	-	0.040		
Standard (100 mmol/L)	0.350		0.340		
Controls					
Biorad 1	0.390	111.43	0.374	110.00	98.5 - 114 mmol/L
Biorad 2	0.319	91.14	0.317	93.24	81.6 - 92.6 mmol/L
Known normal/ abnormal Serum samples					
Sample-1	0.365	104.29	0.358	105.29	98 - 107 mmol/L
Sample-2	0.375	107.14	0.361	106.18	
Sample-3	0.372	106.29	0.364	107.06	
Sample-4	0.374	106.86	0.355	104.41	
Sample-5	0.365	104.29	0.357	105.00	
Linearity					
150 (mmol/L)	0.479	137.00 (91.40%)	0.469	138.00 (92.12%)	± 10%

7.0 Conclusions

- The Chloride reagent showed an excellent Coefficient of Correlation (“r”) using Diasys as Reference.
- Chloride showed values of “r” was 0.980 displaying the highest degree of correlation between the two sets of reagents.
- The Chloride reagent showed an excellent coefficient of Variation (CV %).
- The CV % was found to be in the range of 0.15% and 2.04% displaying a very high level of precision and repeatability.
- The Chloride reagent showed an excellent performance even under stressful conditions. The reagents were found to be stable at 37°C for 21 days.
- **The Chloride reagent was thus concluded to be Accurate, Precise and Stable, while using clinical normal and abnormal samples and 3rd Party controls (Level-1 and Level-2).**

HDL-Cholesterol

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1.0 Details of Reagents

Type of Reagents developed	Liquid Clinical Chemistry Reagents
Instrument Model	Biochemistry Semi-automated analyzer (BTS-350)
Reference Reagents	Reference Diasys Reagents

2.0 Coefficient of Correlation Studies: Accuracy study

- I. The objective was to determine the correlation between the results obtained with the Clinical Chemistry reagents of Vanguard Diagnostics and the benchmarked Clinical Chemistry reagents from Diasys.
- II. The Coefficient of Correlation ("r") was calculated for HDL-Cholesterol kit.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x (x̄)
 - 3 Mean y (ȳ)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of "r"
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, xi (x1, x2,...,xn) are the x values and yi are the y values.

2.1 Coefficient of Correlation (“r”): HDL-Cholesterol

X AXIS = Reference Diasys Reagent.

Y AXIS = HDL-Cholesterol kit from Vanguard Diagnostics (P) Ltd.

$$“r” = 0.998$$

Sample size: 20

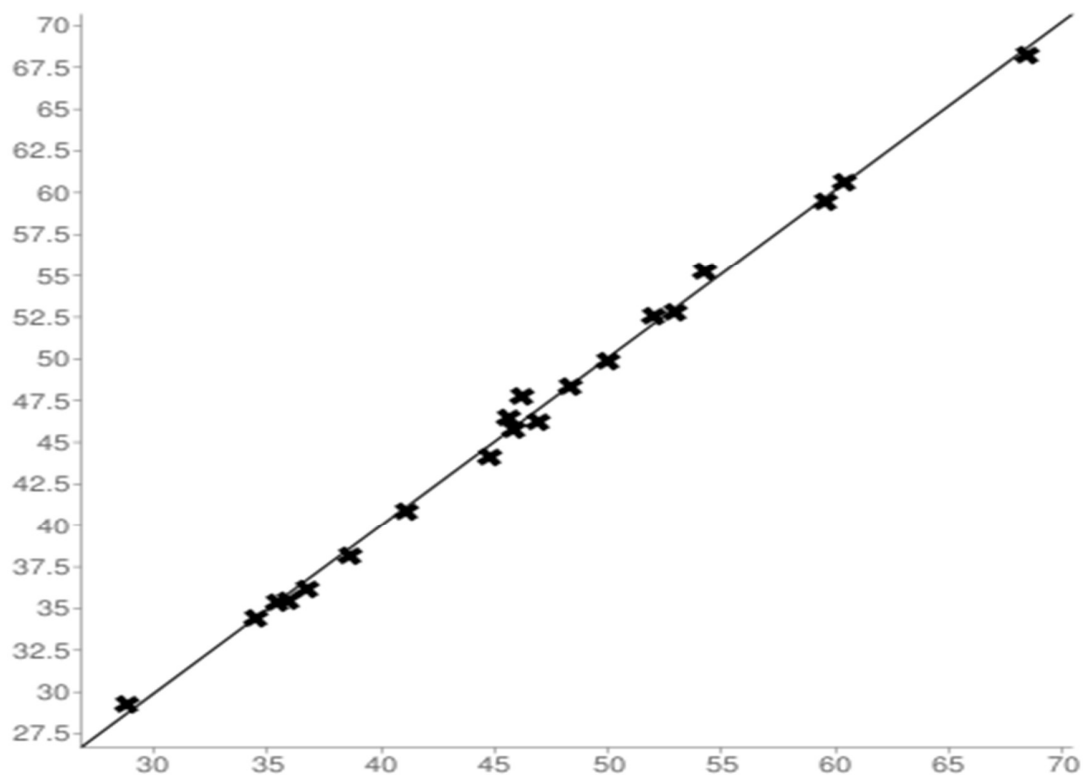
Mean x (x̄): 46.3145

Mean y (ȳ): 46.3585

Intercept (a): -0.35057893316986

Slope (b): 1.0085195550674

Regression line equation: $y = 1.0085195550674x - 0.35057893316986$



3.0 Comparative evaluation report: HDL-Cholesterol

Vanguard HDL-Cholesterol Kit				Reference Kit		
S.no	Test	Abs	Conc (mg/dl)	Abs	Conc (mg/dl)	%
	Standard	0.157	53	0.152	53	
1	Sample 1	0.161	54.24	0.158	55.23	98.2
2	Sample 2	0.133	44.81	0.126	44.09	101.6
3	Sample 3	0.122	41.12	0.117	40.84	100.7
4	Sample 4	0.179	60.42	0.174	60.65	99.6
5	Sample 5	0.176	59.54	0.171	59.5	100.1
6	Sample 6	0.203	68.46	0.196	68.22	100.4
7	Sample 7	0.154	52.01	0.151	52.57	98.9
8	Sample 8	0.137	46.25	0.137	47.8	96.8
9	Sample 9	0.139	46.92	0.133	46.26	101.4
10	Sample 10	0.148	49.96	0.143	49.91	100.1
11	Sample 11	0.114	38.6	0.109	38.11	101.3
12	Sample 12	0.085	28.79	0.084	29.21	98.6
13	Sample 13	0.102	34.5	0.099	34.42	100.2
14	Sample 14	0.143	48.33	0.138	48.29	100.1
15	Sample 15	0.105	35.43	0.102	35.4	100.1
16	Sample 16	0.136	45.79	0.131	45.71	100.2
17	Sample 17	0.135	45.61	0.133	46.49	98.1
18	Sample 18	0.106	35.87	0.102	35.51	101.0
19	Sample 19	0.109	36.72	0.104	36.14	101.6
20	Sample 20	0.157	52.92	0.151	52.82	100.2

4.0 Coefficient of Variation: Repeatability/Reproducibility/Precision study

- Biorad Controls Normal and Abnormal were used to calculate “Within Run” and “Between Run” Precision.
- The Biorad Controls were tested in 25 replicates to study Precision.
- Coefficient of Variation (CV %) was calculated.
- **Acceptance criteria = NMT 10%.**

4.1 Precision “Within Run” and “Between Run”

4.1.1 Bio-Rad Control (Level-1)

Within Run				Run to Run			
S.No .	Test	Abs.	Conc (mg/dl)	S.No .	Test	Abs.	Conc (mg/dl)
	Blank	0.006			Blank	0.006	
	Standard	0.175	53		Standard	0.173	53
01	Bio-Rad 1	0.239	72.38	01	Bio-Rad 1	0.242	74.14
02	Bio-Rad 1	0.239	72.38	02	Bio-Rad 1	0.237	72.61
03	Bio-Rad 1	0.239	72.38	03	Bio-Rad 1	0.237	72.61
04	Bio-Rad 1	0.239	72.38	04	Bio-Rad 1	0.242	74.14
05	Bio-Rad 1	0.237	71.78	05	Bio-Rad 1	0.237	72.61
06	Bio-Rad 1	0.239	72.38	06	Bio-Rad 1	0.238	72.91
07	Bio-Rad 1	0.239	72.38	07	Bio-Rad 1	0.237	72.61
08	Bio-Rad 1	0.240	72.69	08	Bio-Rad 1	0.245	75.06
09	Bio-Rad 1	0.239	72.38	09	Bio-Rad 1	0.242	74.14
10	Bio-Rad 1	0.240	72.69	10	Bio-Rad 1	0.237	72.61
11	Bio-Rad 1	0.245	74.20	11	Bio-Rad 1	0.237	72.61
12	Bio-Rad 1	0.239	72.38	12	Bio-Rad 1	0.243	74.45
13	Bio-Rad 1	0.237	71.78	13	Bio-Rad 1	0.238	72.91
14	Bio-Rad 1	0.246	74.50	14	Bio-Rad 1	0.237	72.61
15	Bio-Rad 1	0.239	72.38	15	Bio-Rad 1	0.245	75.06
16	Bio-Rad 1	0.240	72.69	16	Bio-Rad 1	0.237	72.61
17	Bio-Rad 1	0.239	72.38	17	Bio-Rad 1	0.237	72.61
18	Bio-Rad 1	0.240	72.69	18	Bio-Rad 1	0.242	74.14
19	Bio-Rad 1	0.239	72.38	19	Bio-Rad 1	0.236	72.30
20	Bio-Rad 1	0.239	72.38	20	Bio-Rad 1	0.237	72.61
21	Bio-Rad 1	0.248	75.11	21	Bio-Rad 1	0.243	74.45
22	Bio-Rad 1	0.237	71.78	22	Bio-Rad 1	0.237	72.61
23	Bio-Rad 1	0.239	72.38	23	Bio-Rad 1	0.236	72.30
24	Bio-Rad 1	0.239	72.38	24	Bio-Rad 1	0.245	75.06
25	Bio-Rad 1	0.239	72.38	25	Bio-Rad 1	0.237	72.61
Mean			72.63	Mean			73.29
S.D.			0.80	S.D.			0.97
CV			0.01	CV			0.01
CV%			1.10	CV%			1.33

4.2 Precision “Within Run” and “Between Run”

4.2.2 Bio-Rad Control (Level-2)

Within Run				Run to Run			
S.No.	Test	Abs.	Conc (mg/dl)	S.No.	Test	Abs.	Conc (mg/dl)
	Blank	0.006			Blank	0.006	
	Standard	0.175	53		Standard	0.173	53
01	Bio-Rad 2	0.096	29.07	01	Bio-Rad 2	0.091	27.88
02	Bio-Rad 2	0.094	28.47	02	Bio-Rad 2	0.090	27.57
03	Bio-Rad 2	0.092	27.86	03	Bio-Rad 2	0.090	27.57
04	Bio-Rad 2	0.092	27.86	04	Bio-Rad 2	0.093	28.49
05	Bio-Rad 2	0.092	27.86	05	Bio-Rad 2	0.090	27.57
06	Bio-Rad 2	0.092	27.86	06	Bio-Rad 2	0.090	27.57
07	Bio-Rad 2	0.092	27.86	07	Bio-Rad 2	0.088	26.96
08	Bio-Rad 2	0.092	27.86	08	Bio-Rad 2	0.090	27.57
09	Bio-Rad 2	0.091	27.56	09	Bio-Rad 2	0.090	27.57
10	Bio-Rad 2	0.091	27.56	10	Bio-Rad 2	0.092	28.19
11	Bio-Rad 2	0.092	27.86	11	Bio-Rad 2	0.092	28.19
12	Bio-Rad 2	0.092	27.86	12	Bio-Rad 2	0.090	27.57
13	Bio-Rad 2	0.091	27.56	13	Bio-Rad 2	0.090	27.57
14	Bio-Rad 2	0.092	27.86	14	Bio-Rad 2	0.091	27.88
15	Bio-Rad 2	0.092	27.86	15	Bio-Rad 2	0.090	27.57
16	Bio-Rad 2	0.091	27.56	16	Bio-Rad 2	0.090	27.57
17	Bio-Rad 2	0.092	27.86	17	Bio-Rad 2	0.089	27.27
18	Bio-Rad 2	0.092	27.86	18	Bio-Rad 2	0.090	27.57
19	Bio-Rad 2	0.091	27.56	19	Bio-Rad 2	0.090	27.57
20	Bio-Rad 2	0.092	27.86	20	Bio-Rad 2	0.088	26.96
21	Bio-Rad 2	0.092	27.86	21	Bio-Rad 2	0.090	27.57
22	Bio-Rad 2	0.091	27.56	22	Bio-Rad 2	0.093	28.49
23	Bio-Rad 2	0.092	27.86	23	Bio-Rad 2	0.091	27.88
24	Bio-Rad 2	0.091	27.56	24	Bio-Rad 2	0.092	28.19
25	Bio-Rad 2	0.092	27.86	25	Bio-Rad 2	0.090	27.57
Mean			27.85	Mean			27.69
S.D.			0.32	S.D.			0.39
CV			0.01	CV			0.01
CV%			1.15	CV%			1.39

5.0 Performance Evaluation Report of HDL-Cholesterol

Time interval= Day-0

Storage Temperature = 2°C – 8°C

Test	Vanguard Reagent		Reference Diasys Reagent		Specification (mg/dl)
	Abs	Conc. (mg/dl)	Abs	Conc. (mg/dl)	
Reagent Blank	0.002		0.003		
Standard	0.153	53 mg/dl	0.154	53 mg/dl	-
Controls					
Biorad- 1	0.214	74.13	0.204	70.41	56-88 mg/dl
Biorad- 2	0.088	30.48	0.086	29.81	18-35 mg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.213	73.7	0.210	72.5	35-80 mg/dl
Sample-2	0.154	53.30	0.154	53.0	
Sample-3	0.099	34.29	0.103	35.60	
Sample-4	0.179	62.0	0.186	64.30	
Sample-5	0.100	34.6	0.106	36.70	
Linearity					
150.0 mg/dl	0.440	152.4 (101.6%)	0.446	153.6 (103.6%)	± 10%

6.0 Accelerated Stability Studies: Summary

- Stability studies were conducted at 37°C till 21 days.
- Stability studies were conducted using Bio-Rad Control (Level-1 & Level-2).
- It was not possible to use the “same” samples in the study due to the very limited stability of samples.
- The values obtained with HDL-Cholesterol were found to be in the ranges specified for the Bio-Rad controls till 21 days at 37°C and found to be comparable with the reference reagent.
- HDL-Cholesterol reagent was therefore found to be stable at 37°C for 21 days.
- This data has been extrapolated to conclude that HDL-Cholesterol reagent will be stable for 18 months under the recommended temperature conditions of 2°C- 8°C.

6.1 Accelerated stability study: HDL-Cholesterol

Time interval= Day-7

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Diasys Reagent		Specification (mg/dl)
	Abs	Conc. (mg/dl)	Abs	Conc. (mg/dl)	
Reagent Blank	0.005		0.008		
Standard	0.158	53 mg/dl	0.156	53 mg/dl	-
Controls					
Biorad- 1	0.224	75.1	0.216	73.3	56-88 mg/dl
Biorad- 2	0.092	30.8	0.086	29.2	18-35 mg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.213	71.4	0.210	71.3	35-80 mg/dl
Sample-2	0.154	51.6	0.154	52.3	
Sample-3	0.099	33.2	0.103	34.9	
Sample-4	0.179	60.0	0.186	63.1	
Sample-5	0.100	33.5	0.106	36.0	
Linearity					
150.0 mg/dl	0.430	144.2 (96.2%)	0.426	144.7 (96.5%)	± 10%

6.2 Accelerated stability study: HDL-Cholesterol

Time interval= Day-14

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Diasys Reagent		Specification (mg/dl)
	Abs	Conc. (mg/dl)	Abs	Conc. (mg/dl)	
Reagent Blank	0.010		0.012		
Standard	0.164	53 mg/dl	0.160	53 mg/dl	-
Controls					
Biorad- 1	0.214	69.1	0.208	68.9	56-88 mg/dl
Biorad- 2	0.084	27.1	0.086	28.4	18-35 mg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.215	69.4	0.210	69.5	35-80 mg/dl
Sample-2	0.152	49.1	0.154	51.0	
Sample-3	0.099	31.9	0.103	34.1	
Sample-4	0.179	57.8	0.186	61.6	
Sample-5	0.102	32.9	0.106	35.1	
Linearity					
150.0 mg/dl	0.437	141.2 (94.1%)	0.425	140.7 (93.8%)	± 10%

6.3 Accelerated stability study: HDL-Cholesterol

Time interval= Day-21

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Diasys Reagent		Specification (mg/dl)
	Abs	Conc. (mg/dl)	Abs	Conc. (mg/dl)	
Reagent Blank	0.020		0.025		
Standard	0.175	53 mg/dl	0.168	53 mg/dl	-
Controls					
Biorad- 1	0.210	63.6	0.208	65.6	56-88 mg/dl
Biorad- 2	0.084	25.4	0.078	24.6	18-35 mg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.215	65.1	0.210	66.25	35-80 mg/dl
Sample-2	0.152	46	0.154	48.5	
Sample-3	0.099	29.9	0.103	32.4	
Sample-4	0.179	54.2	0.186	58.6	
Sample-5	0.102	30.8	0.106	33.4	
Linearity					
150.0 mg/dl	0.450	136.2 (90.7%)	0.430	135.6 (90.4%)	± 10%

7.0 Conclusions

- The HDL-Cholesterol reagent showed an excellent Coefficient of Correlation (“r”) using Diasys as Reference.
- HDL-Cholesterol showed values of “r” was 0.998 displaying the highest degree of correlation between the two sets of reagents.
- The HDL-Cholesterol reagent showed an excellent coefficient of Variation (CV %).
- The CV % was found to be in the range of 1.10% and 1.39% displaying a very high level of precision and repeatability.
- The HDL-Cholesterol reagent showed an excellent performance even under stressful conditions. The reagents were found to be stable at 37°C for 21 days.
- **The HDL-Cholesterol reagent was thus concluded to be Accurate, Precise and Stable, while using clinical normal and abnormal samples and 3rd Party controls (Level-1 and Level-2).**

LDL-Cholesterol

CLINICAL EVIDENCE EVALUATION REPORT

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1.Details of Reagents

Type of Reagents developed	Liquid Clinical Chemistry Reagents
Instrument Model	Biochemistry Semi-automated analyzer (BTS-350)
Reference Reagents	Reference Diasys Reagents

2.0 Coefficient of Correlation Studies: Accuracy study

- I. The objective was to determine the correlation between the results obtained with the Clinical Chemistry reagents of Vanguard Diagnostics and the benchmarked Clinical Chemistry reagents from Diasys.
- II. The Coefficient of Correlation ("r") was calculated for LDL-Cholesterol kit.
- III. The data has been presented in the form of:

- 1 Sample size
- 2 Mean x ($\bar{x}$)
- 3 Mean y ($\bar{y}$)
- 4 Intercept (a)
- 5 Slope (b)
- 6 Regression line equation
- 7 Value of "r"
- 8 Linear Regression Graph
- 9 Raw Data of values
- 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, x_i ($x_1, x_2, \dots, x_n$) are the x values and y_i are the y values.

2.1 Coefficient of Correlation (“r”): LDL-Cholesterol

X AXIS = Reference Diasys Reagent.

Y AXIS = LDL-Cholesterol kit from Vanguard Diagnostics (P) Ltd.

$$“r” = 0.998$$

Sample size: 20

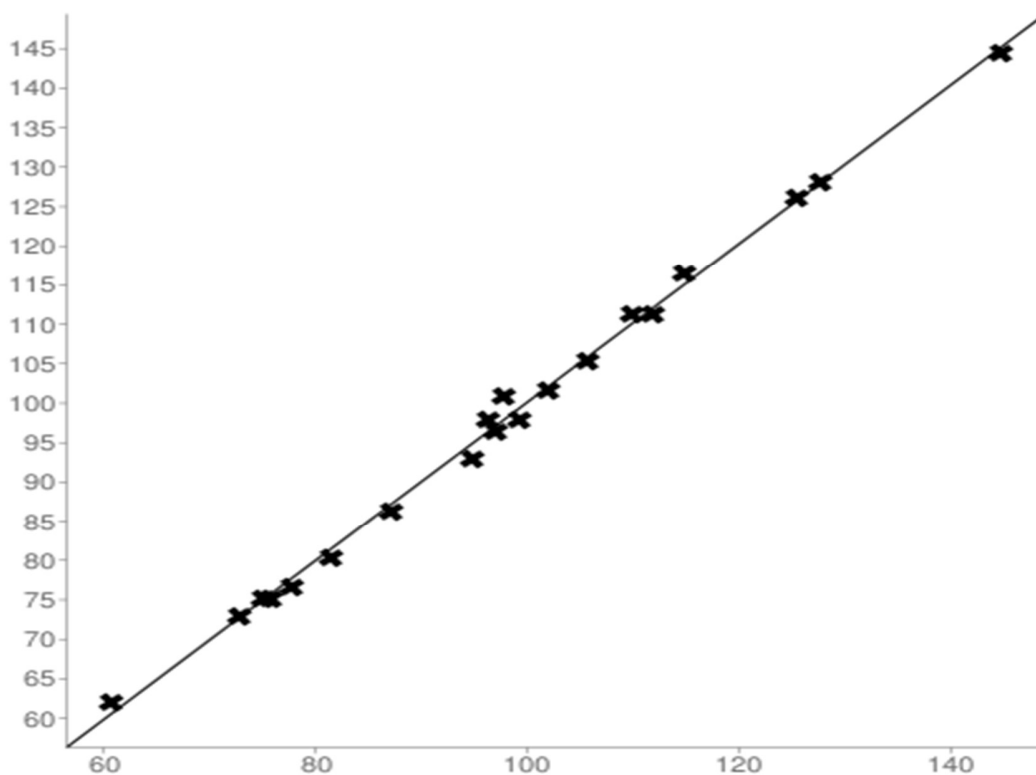
Mean x (x̄): 97.8745

Mean y (ȳ): 97.963

Intercept (a): -0.40253537942418

Slope (b): 1.0050169899149

Regression line equation: $y = 1.0050169899149x - 0.40253537942418$



3.0 Comparative evaluation report: LDL-Cholesterol

Vanguard HDL-Cholesterol Kit				Reference Kit		
S.no	Test	Abs	Conc (mg/dl)	Abs	Conc (mg/dl)	%
	Standard	0.314	112	0.304	112	
1	Sample 1	0.322	114.85	0.316	116.42	98.65
2	Sample 2	0.266	94.88	0.252	92.84	102.19
3	Sample 3	0.244	87.03	0.234	86.21	100.95
4	Sample 4	0.358	127.69	0.348	128.21	99.60
5	Sample 5	0.352	125.55	0.342	126.00	99.65
6	Sample 6	0.406	144.82	0.392	144.42	100.27
7	Sample 7	0.308	109.86	0.302	111.26	98.74
8	Sample 8	0.274	97.73	0.274	100.95	96.82
9	Sample 9	0.278	99.16	0.266	98.00	101.18
10	Sample 10	0.296	105.58	0.286	105.37	100.20
11	Sample 11	0.228	81.32	0.218	80.32	101.26
12	Sample 12	0.17	60.64	0.168	61.89	97.97
13	Sample 13	0.204	72.76	0.198	72.95	99.75
14	Sample 14	0.286	102.01	0.276	101.68	100.32
15	Sample 15	0.21	74.90	0.204	75.16	99.66
16	Sample 16	0.272	97.02	0.262	96.53	100.51
17	Sample 17	0.27	96.31	0.266	98.00	98.27
18	Sample 18	0.212	75.62	0.204	75.16	100.61
19	Sample 19	0.218	77.76	0.208	76.63	101.47
20	Sample 20	0.314	112.00	0.302	111.26	100.66

4.0 Coefficient of Variation: Repeatability/Reproducibility/Precision study

- 1.0 Biorad Controls Normal and Abnormal were used to calculate “Within Run” and “Between Run” Precision.
- 2.0 The Biorad Controls were tested in 25 replicates to study Precision.
- 3.0 Coefficient of Variation (CV %) was calculated.
- 4.0 **Acceptance criteria = NMT 10%.**

4.1 Precision “Within Run” and “Between Run”

4.1.1 Bio-Rad Control (Level-1)

Within Run				Run to Run			
S.No .	Test	Abs.	Conc (mg/dl)	S.No .	Test	Abs.	Conc (mg/dl)
	Blank	0.019			Blank	0.019	
	Standard	0.227	112		Standard	0.225	112
01	Bio-Rad 1	0.388	191.44	01	Bio-Rad 1	0.386	192.14
02	Bio-Rad 1	0.388	191.44	02	Bio-Rad 1	0.395	196.62
03	Bio-Rad 1	0.387	190.94	03	Bio-Rad 1	0.387	192.64
04	Bio-Rad 1	0.387	190.94	04	Bio-Rad 1	0.386	192.14
05	Bio-Rad 1	0.388	191.44	05	Bio-Rad 1	0.385	191.65
06	Bio-Rad 1	0.388	191.44	06	Bio-Rad 1	0.387	192.64
07	Bio-Rad 1	0.388	191.44	07	Bio-Rad 1	0.395	196.62
08	Bio-Rad 1	0.387	190.94	08	Bio-Rad 1	0.386	192.14
09	Bio-Rad 1	0.387	190.94	09	Bio-Rad 1	0.389	193.64
10	Bio-Rad 1	0.387	190.94	10	Bio-Rad 1	0.387	192.64
11	Bio-Rad 1	0.395	194.89	11	Bio-Rad 1	0.386	192.14
12	Bio-Rad 1	0.388	191.44	12	Bio-Rad 1	0.396	197.12
13	Bio-Rad 1	0.388	191.44	13	Bio-Rad 1	0.386	192.14
14	Bio-Rad 1	0.395	194.89	14	Bio-Rad 1	0.387	192.64
15	Bio-Rad 1	0.388	191.44	15	Bio-Rad 1	0.386	192.14
16	Bio-Rad 1	0.387	190.94	16	Bio-Rad 1	0.386	192.14
17	Bio-Rad 1	0.387	190.94	17	Bio-Rad 1	0.395	196.62
18	Bio-Rad 1	0.388	191.44	18	Bio-Rad 1	0.385	191.65
19	Bio-Rad 1	0.395	194.89	19	Bio-Rad 1	0.389	193.64
20	Bio-Rad 1	0.387	190.94	20	Bio-Rad 1	0.387	192.64
21	Bio-Rad 1	0.388	191.44	21	Bio-Rad 1	0.386	192.14
22	Bio-Rad 1	0.388	191.44	22	Bio-Rad 1	0.386	192.14
23	Bio-Rad 1	0.387	190.94	23	Bio-Rad 1	0.395	196.62
24	Bio-Rad 1	0.390	192.42	24	Bio-Rad 1	0.387	192.64
25	Bio-Rad 1	0.388	191.44	25	Bio-Rad 1	0.386	192.14
Mean			191.71	Mean			193.26
S.D.			1.24	S.D.			1.83
CV			0.01	CV			0.01
CV%			0.65	CV%			0.95

4.2 Precision “Within Run” and “Between Run”

4.2.1 Bio-Rad Control (Level-2)

Within Run				Run to Run			
S.No.	Test	Abs.	Conc (mg/dl)	S.No.	Test	Abs.	Conc (mg/dl)
	Blank	0.019			Blank	0.019	
	Standard	0.227	112		Standard	0.225	112
01	Bio-Rad 2	0.157	77.46	01	Bio-Rad 2	0.153	76.16
02	Bio-Rad 2	0.154	75.98	02	Bio-Rad 2	0.152	75.66
03	Bio-Rad 2	0.154	75.98	03	Bio-Rad 2	0.152	75.66
04	Bio-Rad 2	0.154	75.98	04	Bio-Rad 2	0.152	75.66
05	Bio-Rad 2	0.153	75.49	05	Bio-Rad 2	0.151	75.16
06	Bio-Rad 2	0.154	75.98	06	Bio-Rad 2	0.152	75.66
07	Bio-Rad 2	0.154	75.98	07	Bio-Rad 2	0.152	75.66
08	Bio-Rad 2	0.154	75.98	08	Bio-Rad 2	0.152	75.66
09	Bio-Rad 2	0.154	75.98	09	Bio-Rad 2	0.152	75.66
10	Bio-Rad 2	0.153	75.49	10	Bio-Rad 2	0.155	77.16
11	Bio-Rad 2	0.153	75.49	11	Bio-Rad 2	0.152	75.66
12	Bio-Rad 2	0.154	75.98	12	Bio-Rad 2	0.152	75.66
13	Bio-Rad 2	0.153	75.49	13	Bio-Rad 2	0.152	75.66
14	Bio-Rad 2	0.154	75.98	14	Bio-Rad 2	0.152	75.66
15	Bio-Rad 2	0.154	75.98	15	Bio-Rad 2	0.155	77.16
16	Bio-Rad 2	0.155	76.48	16	Bio-Rad 2	0.152	75.66
17	Bio-Rad 2	0.155	76.48	17	Bio-Rad 2	0.152	75.66
18	Bio-Rad 2	0.154	75.98	18	Bio-Rad 2	0.158	78.65
19	Bio-Rad 2	0.154	75.98	19	Bio-Rad 2	0.152	75.66
20	Bio-Rad 2	0.154	75.98	20	Bio-Rad 2	0.154	76.66
21	Bio-Rad 2	0.154	75.98	21	Bio-Rad 2	0.152	75.66
22	Bio-Rad 2	0.155	76.48	22	Bio-Rad 2	0.152	75.66
23	Bio-Rad 2	0.154	75.98	23	Bio-Rad 2	0.152	75.66
24	Bio-Rad 2	0.154	75.98	24	Bio-Rad 2	0.152	75.66
25	Bio-Rad 2	0.153	75.49	25	Bio-Rad 2	0.152	75.66
Mean			76.00	Mean			75.94
S.D.			0.41	S.D.			0.73
CV			0.01	CV			0.01
CV%			0.55	CV%			0.97

5.0 Performance Evaluation Report of LDL-Cholesterol

Time interval= Day-0

Storage Temperature = 2°C – 8°C

Test	Vanguard Reagent		Reference Diasys Reagent		Specification (mg/dl)
	Abs	Conc. (mg/dl)	Abs	Conc. (mg/dl)	
Reagent Blank	0.010		0.008		
Standard	0.334	112 mg/dl	0.332	112 mg/dl	-
Controls					
Biorad- 1	0.407	136.4	0.413	139.3	117-169 mg/dl
Biorad- 2	0.169	56.6	0.170	57.3	49.1-75.1 mg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.276	92.5	0.269	90.7	<130 mg/dl
Sample-2	0.317	106.2	0.314	105.9	
Sample-3	0.228	76.4	0.230	77.5	
Sample-4	0.237	79.4	0.237	79.9	
Sample-5	0.338	113.3	0.337	113.6	
Linearity					
300.0 mg/dl	0.890	298.4 (99.5%)	0.888	299.5 (99.9%)	± 10%

6.0 Accelerated Stability Studies: Summary

- Stability studies were conducted at 37°C till 21 days.
- Stability studies were conducted using Bio-Rad Control (Level-1 & Level-2).
- It was not possible to use the “same” samples in the study due to the very limited stability of samples.
- The values obtained with LDL-Cholesterol were found to be in the ranges specified for the Bio-Rad controls till 21 days at 37°C and found to be comparable with the reference reagent.
- LDL-Cholesterol reagent was therefore found to be stable at 37°C for 21 days.
- This data has been extrapolated to conclude that LDL-Cholesterol reagent will be stable for 18 months under the recommended temperature conditions of 2°C- 8°C.

6.1 Accelerated stability study: LDL-Cholesterol

Time interval= Day-7

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Diasys Reagent		Specification (mg/dl)
	Abs	Conc. (mg/dl)	Abs	Conc. (mg/dl)	
Reagent Blank	0.025		0.030		
Standard	0.332	112 mg/dl	0.332	112 mg/dl	-
Controls					
Biorad- 1	0.395	133.2	0.398	134	117-169 mg/dl
Biorad- 2	0.166	56	0.170	57.3	49.1-75.1 mg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.275	92.7	0.269	90.7	<130 mg/dl
Sample-2	0.33	111.3	0.325	109.6	
Sample-3	0.226	76.2	0.230	77.5	
Sample-4	0.240	80.96	0.237	79.9	
Sample-5	0.326	109.9	0.330	111.3	
Linearity					
300.0 mg/dl	0.885	298.5 (99.5%)	0.879	296.5 (98.9%)	± 10%

6.2 Accelerated stability study: LDL-Cholesterol

Time interval= Day-14

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Diasys Reagent		Specification (mg/dl)
	Abs	Conc. (mg/dl)	Abs	Conc. (mg/dl)	
Reagent Blank	0.040		0.045		
Standard	0.327	112 mg/dl	0.332	112 mg/dl	-
Controls					
Biorad- 1	0.407	139.4	0.416	140.3	117-169 mg/dl
Biorad- 2	0.160	54.8	0.158	53.3	49.1-75.1 mg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.280	95.9	0.280	94.4	<130 mg/dl
Sample-2	0.310	106.1	0.314	105.9	
Sample-3	0.229	78.4	0.230	77.5	
Sample-4	0.242	82.8	0.240	80.9	
Sample-5	0.330	113	0.337	113.6	
Linearity					
300.0 mg/dl	0.855	292.8 (97.6%)	0.860	290.1 (96.7%)	± 10%

6.3 Accelerated stability study: LDL-Cholesterol

Time interval= Day-21

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Diasys Reagent		Specification (mg/dl)
	Abs	Conc. (mg/dl)	Abs	Conc. (mg/dl)	
Reagent Blank	0.065		0.070		
Standard	0.322	112 mg/dl	0.327	112 mg/dl	-
Controls					
Biorad- 1	0.387	134.6	0.391	133.9	117-169 mg/dl
Biorad- 2	0.159	55.3	0.161	55.1	49.1-75.1 mg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.270	93.9	0.280	95.9	<130 mg/dl
Sample-2	0.325	113.0	0.332	113.7	
Sample-3	0.225	78.2	0.231	79.1	
Sample-4	0.234	81.39	0.232	79.46	
Sample-5	0.310	107.7	0.317	108.5	
Linearity					
300.0 mg/dl	0.811	282.08 (94.1%)	0.820	280.8 (93.6%)	± 10%

7.0 Conclusions

- The LDL-Cholesterol reagent showed an excellent Coefficient of Correlation (“r”) using Diasys as Reference.
- LDL-Cholesterol showed values of “r” was 0.998 displaying the highest degree of correlation between the two sets of reagents.
- The LDL-Cholesterol reagent showed an excellent coefficient of Variation (CV %).
- The CV % was found to be in the range of 0.55% and 0.97% displaying a very high level of precision and repeatability.
- The LDL-Cholesterol reagent showed an excellent performance even under stressful conditions. The reagents were found to be stable at 37°C for 21 days.
- **The LDL-Cholesterol reagent was thus concluded to be Accurate, Precise and Stable, while using clinical normal and abnormal samples and 3rd Party controls (Level-1 and Level-2).**

Creatine Kinase (CK-NAC)

CLINICAL EVIDENCE EVALUATION REPORT

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1 Details of Reagents

Type of Reagents developed	Liquid Clinical Chemistry Reagents
Instrument Model	Biochemistry Semi-automated analyzer (BTS-350)
Reference Reagents	Reference Reagents

2.0 Coefficient of Correlation Studies: Accuracy study

- I. The objective was to determine the correlation between the results obtained with the Clinical Chemistry reagents of Vanguard Diagnostics and the benchmarked Clinical Chemistry reagents from Diasys.
- II. The Coefficient of Correlation ("r") was calculated for Creatine Kinase (CK-NAC) kit.
- III. The data has been presented in the form of:

- 1 Sample size
- 2 Mean x ($\bar{x}$)
- 3 Mean y ($\bar{y}$)
- 4 Intercept (a)
- 5 Slope (b)
- 6 Regression line equation
- 7 Value of "r"
- 8 Linear Regression Graph
- 9 Raw Data of values
- 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, x_i ($x_1, x_2, \dots, x_n$) are the x values and y_i are the y values.

2.1 Coefficient of Correlation (“r”): Creatine Kinase (CK-NAC)

X AXIS = Reference Diasys Reagent.

Y AXIS = Creatine Kinase (CK-NAC) kit from Vanguard Diagnostics (P) Ltd.

$$“r” = 0.995$$

Sample size: 20

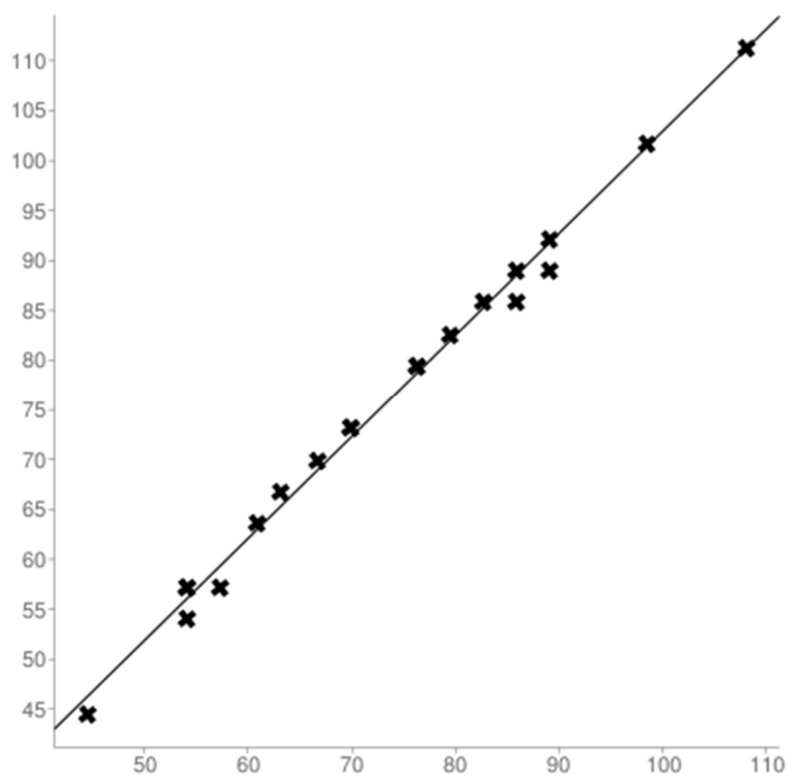
Mean x (x̄): 98.258

Mean y (ȳ): 98.636

Intercept (a): 0.7788001623156

Slope (b): 1.0218296955648

Regression line equation: $y = 0.7788001623156 + 1.0218296955648x$



3.0 Comparative evaluation report: Creatine Kinase (CK-NAC)

Vanguard Creatine Kinase (CK-NAC) Kit				Reference Kit		
S.NO.	Test	Δ Abs/min	Conc (IU/L)	Δ Abs/min	Conc (IU/L)	%
	Factor		3376		3376	
01	Sample 1	0.020	67.52	0.020	67.52	100.00
02	Sample 2	0.018	60.77	0.018	60.77	100.00
03	Sample 3	0.016	54.02	0.017	57.39	94.12
04	Sample 4	0.018	60.77	0.018	60.77	100.00
05	Sample 5	0.016	54.02	0.017	57.39	94.12
06	Sample 6	0.012	40.51	0.012	40.51	100.00
07	Sample 7	0.011	37.14	0.012	40.51	91.67
08	Sample 8	0.012	40.51	0.012	40.51	100.00
09	Sample 9	0.014	47.26	0.015	50.64	93.33
10	Sample 10	0.015	50.64	0.015	50.64	100.00
11	Sample 11	0.016	54.02	0.016	54.02	100.00
12	Sample 12	0.014	47.26	0.014	47.26	100.00
13	Sample 13	0.016	54.02	0.016	54.02	100.00
14	Sample 14	0.018	60.77	0.017	57.39	105.88
15	Sample 15	0.015	50.64	0.015	50.64	100.00
16	Sample 16	0.016	54.02	0.016	54.02	100.00
17	Sample 17	0.022	74.27	0.023	77.65	95.65
18	Sample 18	0.023	77.65	0.024	81.02	95.83
19	Sample 19	0.021	70.90	0.021	70.90	100.00
20	Sample 20	0.018	60.77	0.018	60.77	100.00

4.0 Coefficient of Variation: Repeatability/Reproducibility/Precision study

- Biorad Controls Normal and Abnormal were used to calculate “Within Run” and “Between Run” Precision.
- The Biorad Controls were tested in 25 replicates to study Precision.
- Coefficient of Variation (CV %) was calculated.
- **Acceptance criteria = NMT 10%.**

4.1 Precision “Within Run” and “Between Run”

4.1.1 Bio-Rad Control (Level-1)

Within Run				Run to Run			
S.No.	Test	ΔAbs/min	Conc (IU/L)	S.No.	Test	ΔAbs/min	Conc (IU/L)
	Factor	3376			Factor	3376	
01	Bio-Rad 1	0.037	124.912	01	Bio-Rad 1	0.037	124.912
02	Bio-Rad 1	0.037	124.912	02	Bio-Rad 1	0.037	124.912
03	Bio-Rad 1	0.037	124.912	03	Bio-Rad 1	0.037	124.912
04	Bio-Rad 1	0.037	124.912	04	Bio-Rad 1	0.037	124.912
05	Bio-Rad 1	0.038	128.288	05	Bio-Rad 1	0.037	124.912
06	Bio-Rad 1	0.038	128.288	06	Bio-Rad 1	0.037	124.912
07	Bio-Rad 1	0.037	124.912	07	Bio-Rad 1	0.037	124.912
08	Bio-Rad 1	0.037	124.912	08	Bio-Rad 1	0.038	128.288
09	Bio-Rad 1	0.037	124.912	09	Bio-Rad 1	0.037	124.912
10	Bio-Rad 1	0.038	128.288	10	Bio-Rad 1	0.038	128.288
11	Bio-Rad 1	0.038	128.288	11	Bio-Rad 1	0.037	124.912
12	Bio-Rad 1	0.037	124.912	12	Bio-Rad 1	0.037	124.912
13	Bio-Rad 1	0.037	124.912	13	Bio-Rad 1	0.037	124.912
14	Bio-Rad 1	0.037	124.912	14	Bio-Rad 1	0.037	124.912
15	Bio-Rad 1	0.038	128.288	15	Bio-Rad 1	0.038	128.288
16	Bio-Rad 1	0.038	128.288	16	Bio-Rad 1	0.038	128.288
17	Bio-Rad 1	0.038	128.288	17	Bio-Rad 1	0.038	128.288
18	Bio-Rad 1	0.038	128.288	18	Bio-Rad 1	0.038	128.288
19	Bio-Rad 1	0.037	124.912	19	Bio-Rad 1	0.037	124.912
20	Bio-Rad 1	0.037	124.912	20	Bio-Rad 1	0.037	124.912
21	Bio-Rad 1	0.037	124.912	21	Bio-Rad 1	0.037	124.912
22	Bio-Rad 1	0.037	124.912	22	Bio-Rad 1	0.037	124.912
23	Bio-Rad 1	0.037	124.912	23	Bio-Rad 1	0.037	124.912
24	Bio-Rad 1	0.037	124.912	24	Bio-Rad 1	0.037	124.912
25	Bio-Rad 1	0.037	124.912	25	Bio-Rad 1	0.038	128.288
Mean			125.99	Mean			125.86
S.D.			1.61	S.D.			1.55
CV			0.01	CV			0.01
CV%			1.28	CV%			1.23

4.2 Precision “Within Run” and “Between Run”

4.2.1 Bio-Rad Control (Level-2)

Within Run				Run to Run			
S.No.	Test	ΔAbs/min	Conc (IU/L)	S.No.	Test	ΔAbs/min	Conc (IU/L)
	Factor	3376			Factor	3376	
01	Bio-Rad 2	0.116	391.62	01	Bio-Rad 2	0.116	391.62
02	Bio-Rad 2	0.117	394.99	02	Bio-Rad 2	0.118	398.37
03	Bio-Rad 2	0.116	391.62	03	Bio-Rad 2	0.116	391.62
04	Bio-Rad 2	0.117	394.99	04	Bio-Rad 2	0.118	398.37
05	Bio-Rad 2	0.116	391.62	05	Bio-Rad 2	0.117	394.99
06	Bio-Rad 2	0.117	394.99	06	Bio-Rad 2	0.117	394.99
07	Bio-Rad 2	0.117	394.99	07	Bio-Rad 2	0.118	398.37
08	Bio-Rad 2	0.117	394.99	08	Bio-Rad 2	0.117	394.99
09	Bio-Rad 2	0.116	391.62	09	Bio-Rad 2	0.117	394.99
10	Bio-Rad 2	0.116	391.62	10	Bio-Rad 2	0.117	394.99
11	Bio-Rad 2	0.117	394.99	11	Bio-Rad 2	0.116	391.62
12	Bio-Rad 2	0.116	391.62	12	Bio-Rad 2	0.118	398.37
13	Bio-Rad 2	0.117	394.99	13	Bio-Rad 2	0.117	394.99
14	Bio-Rad 2	0.116	391.62	14	Bio-Rad 2	0.116	391.62
15	Bio-Rad 2	0.117	394.99	15	Bio-Rad 2	0.117	394.99
16	Bio-Rad 2	0.116	391.62	16	Bio-Rad 2	0.116	391.62
17	Bio-Rad 2	0.116	391.62	17	Bio-Rad 2	0.117	394.99
18	Bio-Rad 2	0.116	391.62	18	Bio-Rad 2	0.116	391.62
19	Bio-Rad 2	0.117	394.99	19	Bio-Rad 2	0.116	391.62
20	Bio-Rad 2	0.116	391.62	20	Bio-Rad 2	0.117	394.99
21	Bio-Rad 2	0.116	391.62	21	Bio-Rad 2	0.116	391.62
22	Bio-Rad 2	0.117	394.99	22	Bio-Rad 2	0.117	394.99
23	Bio-Rad 2	0.116	391.62	23	Bio-Rad 2	0.116	391.62
24	Bio-Rad 2	0.116	391.62	24	Bio-Rad 2	0.116	391.62
25	Bio-Rad 2	0.116	391.62	25	Bio-Rad 2	0.117	394.99
Mean			392.97	Mean			394.18
S.D.			1.69	S.D.			2.44
CV			0.00	CV			0.01
CV%			0.43	CV%			0.62

5.0 Performance Evaluation Report of Creatine Kinase (CK-NAC)

Time interval= Day-0

Storage Temperature = 2°C – 8°C

Test	Vanguard Reagent		Reference Reagent		Specification (IU/L)
	ΔAbs./min.	Conc. (IU/L)	ΔAbs./min.	Conc. (IU/L)	
Factor 3376	-	-	-	-	-
Controls					
Biorad- 1	0.037	124.91	0.036	121.54	86.8 - 161 IU/L
Biorad- 2	0.119	401.74	0.118	398.37	275 - 512 IU/L
Known normal/ abnormal Serum samples					
Sample-1	0.021	70.90	0.022	74.27	26 - 174 IU/L
Sample-2	0.024	81.02	0.024	81.02	
Sample-3	0.023	77.65	0.023	77.65	
Sample-4	0.024	81.02	0.023	77.65	
Sample-5	0.022	74.27	0.022	74.27	
Linearity					
1000.0 IU/L	0.285	962.16 (96.21%)	0.289	975.66 (97.56%)	± 10%

6.0 Accelerated Stability Studies: Summary

- Stability studies were conducted at 37°C till 21 days.
- Stability studies were conducted using Bio-Rad Control (Level-1 & Level-2).
- It was not possible to use the “same” samples in the study due to the very limited stability of samples.
- The values obtained with Creatine Kinase (CK-NAC) were found to be in the ranges specified for the Bio-Rad controls till 21 days at 37°C and found to be comparable with the reference reagent.
- Creatine Kinase (CK-NAC) reagent was therefore found to be stable at 37°C for 21 days.
- This data has been extrapolated to conclude that Creatine Kinase (CK-NAC) reagent will be stable for 18 months under the recommended temperature conditions of 2°C- 8°C.

6.1 Accelerated stability study: Creatine Kinase (CK-NAC)

Time interval= Day-7

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (IU/L)
	ΔAbs./min.	Conc. (IU/L)	ΔAbs./min.	Conc. (IU/L)	
Factor 3376	-	-	-	-	-
Controls					
Biorad- 1	0.037	124.91	0.036	121.54	86.8 - 161 IU/L
Biorad- 2	0.118	398.37	0.119	401.74	275 - 512 IU/L
Known normal/ abnormal Serum samples					
Sample-1	0.022	74.27	0.023	77.65	26 - 174 IU/L
Sample-2	0.023	77.65	0.022	74.27	
Sample-3	0.024	81.02	0.025	84.40	
Sample-4	0.023	77.65	0.022	74.27	
Sample-5	0.021	70.90	0.02	67.52	
Linearity					
1000.0 IU/L	0.283	955.41 (95.54%)	0.287	968.91 (96.89%)	± 10%

6.2 Accelerated stability study: Creatine Kinase (CK-NAC)

Time interval= Day-14

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (IU/L)
	ΔAbs./min.	Conc. (IU/L)	ΔAbs./min.	Conc. (IU/L)	
Factor 3376	-	-	-	-	-
Controls					
Biorad- 1	0.036	121.54	0.036	121.54	86.8 - 161 IU/L
Biorad- 2	0.117	394.99	0.118	398.37	275 - 512 IU/L
Known normal/ abnormal Serum samples					
Sample-1	0.022	74.27	0.023	77.65	26 - 174 IU/L
Sample-2	0.025	84.40	0.024	81.02	
Sample-3	0.026	87.78	0.025	84.40	
Sample-4	0.024	81.02	0.025	84.40	
Sample-5	0.026	87.78	0.025	84.40	
Linearity					
1000.0 IU/L	0.281	948.65 (94.86%)	0.282	952.03 (95.20%)	± 10%

6.3 Accelerated stability study: Creatine Kinase (CK-NAC)

Time interval= Day-21

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (IU/L)
	ΔAbs./min.	Conc. (IU/L)	ΔAbs./min.	Conc. (IU/L)	
Factor 3376	-	-	-	-	-
Controls					
Biorad- 1	0.037	124.91	0.036	121.54	86.8 - 161 IU/L
Biorad- 2	0.118	398.37	0.119	401.74	275 - 512 IU/L
Known normal/ abnormal Serum samples					
Sample-1	0.022	74.27	0.023	77.65	26 - 174 IU/L
Sample-2	0.023	77.65	0.022	74.27	
Sample-3	0.024	81.02	0.025	84.40	
Sample-4	0.023	77.65	0.022	74.27	
Sample-5	0.021	70.90	0.02	67.52	
Linearity					
1000.0 IU/L	0.283	955.41 (95.54%)	0.287	968.91 (96.89%)	± 10%

7.0 Conclusions

- The Creatine Kinase (CK-NAC) reagent showed an excellent Coefficient of Correlation (“r”) using Diasys as Reference.
- Creatine Kinase (CK-NAC) showed values of “r” was 0.995 displaying the highest degree of correlation between the two sets of reagents.
- The Creatine Kinase (CK-NAC) reagent showed an excellent coefficient of Variation (CV %).
- The CV % was found to be in the range of 0.43% and 1.28% displaying a very high level of precision and repeatability.
- The Creatine Kinase (CK-NAC) reagent showed an excellent performance even under stressful conditions. The reagents were found to be stable at 37°C for 21 days.

The Creatine Kinase (CK-NAC) reagent was thus concluded to be Accurate, Precise and Stable, while using clinical normal and abnormal samples and 3rd Party controls (Level-1 and Level-2).

Creatine Kinase-MB

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1. Details of Reagents

Type of Reagents developed	Liquid Clinical Chemistry Reagents
Instrument Model	Biochemistry Semi-automated analyzer (BTS-350)
Reference Reagents	Reference Reagents

2.0 Coefficient of Correlation Studies: Accuracy study

- I. The objective was to determine the correlation between the results obtained with the Clinical Chemistry reagents of Vanguard Diagnostics and the benchmarked Clinical Chemistry reagent from Diasys.
- II. The Coefficient of Correlation ("r") was calculated for Creatine Kinase-MB kit.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x (x̄)
 - 3 Mean y (ȳ)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of "r"
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, xi (x1, x2,...,xn) are the x values and yi are the y values.

2.1 Coefficient of Correlation (“r”): Creatine Kinase-MB

X AXIS = Reference Diasys Reagent.

Y AXIS = Creatine Kinase-MB kit from Vanguard Diagnostics (P) Ltd.

$$“r” = 0.935$$

Sample size: 20

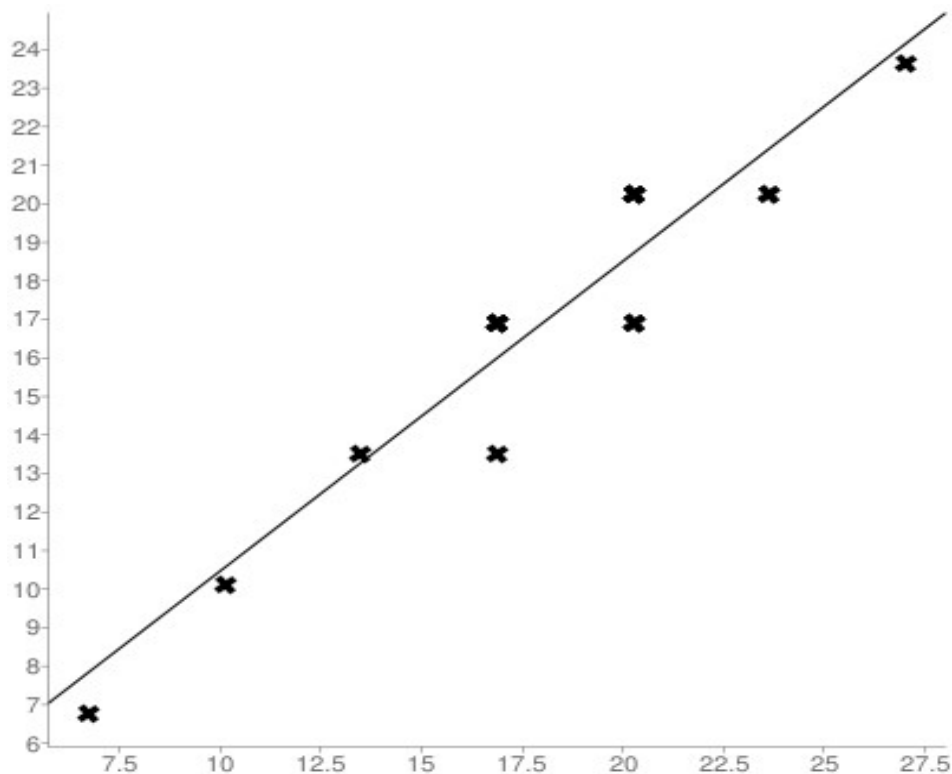
Mean x (x̄): 18.4005

Mean y (ȳ): 17.2185

Intercept (a): 2.4224890095104

Slope (b): 0.80410918129885

Regression line equation: $y = 2.4224890095104 + 0.80410918129885x$



3.0 Comparative evaluation report: Creatine Kinase-MB

Vanguard Creatine Kinase-MB Kit				Reference Kit		
S.NO.	Test	Δ Abs/min	Conc (IU/L)	Δ Abs/min	Conc (IU/L)	%
	Factor		3376		3376	
01	Sample 1	0.005	16.88	0.005	16.88	100.00
02	Sample 2	0.006	20.26	0.006	20.26	100.00
03	Sample 3	0.005	16.88	0.005	16.88	100.00
04	Sample 4	0.006	20.26	0.006	20.26	100.00
05	Sample 5	0.005	16.88	0.005	16.88	100.00
06	Sample 6	0.007	23.63	0.006	20.26	116.67
07	Sample 7	0.006	20.26	0.005	16.88	120.00
08	Sample 8	0.007	23.63	0.006	20.26	116.67
09	Sample 9	0.008	27.01	0.007	23.63	114.29
10	Sample 10	0.005	16.88	0.005	16.88	100.00
11	Sample 11	0.006	20.26	0.006	20.26	100.00
12	Sample 12	0.006	20.26	0.005	16.88	120.00
13	Sample 13	0.006	20.26	0.006	20.26	100.00
14	Sample 14	0.005	16.88	0.005	16.88	100.00
15	Sample 15	0.006	20.26	0.005	16.88	120.00
16	Sample 16	0.002	6.75	0.002	6.75	100.00
17	Sample 17	0.003	10.13	0.003	10.13	100.00
18	Sample 18	0.004	13.50	0.004	13.50	100.00
19	Sample 19	0.005	16.88	0.004	13.50	125.00
20	Sample 20	0.006	20.26	0.006	20.26	100.00

4.0 Coefficient of Variation: Repeatability/Reproducibility/Precision study

- Biorad Controls Normal and Abnormal were used to calculate “Within Run” and “Between Run” Precision.
- The Biorad Controls were tested in 25 replicates to study Precision.
- Coefficient of Variation (CV %) was calculated.
- **Acceptance criteria = NMT 10%.**

4.1 Precision “Within Run” and “Between Run”

4.1.1 Bio-Rad Control (Level-1)

Within Run				Run to Run			
S.No.	Test	ΔAbs/min	Conc (IU/L)	S.No.	Test	ΔAbs/min	Conc (IU/L)
	Factor	3376			Factor	3376	
01	Bio-Rad 1	0.028	94.528	01	Bio-Rad 1	0.028	94.528
02	Bio-Rad 1	0.028	94.528	02	Bio-Rad 1	0.029	97.904
03	Bio-Rad 1	0.028	94.528	03	Bio-Rad 1	0.028	94.528
04	Bio-Rad 1	0.028	94.528	04	Bio-Rad 1	0.028	94.528
05	Bio-Rad 1	0.028	94.528	05	Bio-Rad 1	0.029	97.904
06	Bio-Rad 1	0.029	97.904	06	Bio-Rad 1	0.028	94.528
07	Bio-Rad 1	0.028	94.528	07	Bio-Rad 1	0.028	94.528
08	Bio-Rad 1	0.028	94.528	08	Bio-Rad 1	0.029	97.904
09	Bio-Rad 1	0.029	97.904	09	Bio-Rad 1	0.028	94.528
10	Bio-Rad 1	0.028	94.528	10	Bio-Rad 1	0.028	94.528
11	Bio-Rad 1	0.029	97.904	11	Bio-Rad 1	0.028	94.528
12	Bio-Rad 1	0.028	94.528	12	Bio-Rad 1	0.029	97.904
13	Bio-Rad 1	0.029	97.904	13	Bio-Rad 1	0.028	94.528
14	Bio-Rad 1	0.028	94.528	14	Bio-Rad 1	0.029	97.904
15	Bio-Rad 1	0.028	94.528	15	Bio-Rad 1	0.028	94.528
16	Bio-Rad 1	0.029	97.904	16	Bio-Rad 1	0.029	97.904
17	Bio-Rad 1	0.028	94.528	17	Bio-Rad 1	0.028	94.528
18	Bio-Rad 1	0.029	97.904	18	Bio-Rad 1	0.029	97.904
19	Bio-Rad 1	0.028	94.528	19	Bio-Rad 1	0.028	94.528
20	Bio-Rad 1	0.029	97.904	20	Bio-Rad 1	0.029	97.904
21	Bio-Rad 1	0.028	94.528	21	Bio-Rad 1	0.028	94.528
22	Bio-Rad 1	0.029	97.904	22	Bio-Rad 1	0.028	94.528
23	Bio-Rad 1	0.028	94.528	23	Bio-Rad 1	0.028	94.528
24	Bio-Rad 1	0.028	94.528	24	Bio-Rad 1	0.028	94.528
25	Bio-Rad 1	0.028	94.528	25	Bio-Rad 1	0.029	97.904
Mean			95.61	Mean			95.74
S.D.			1.61	S.D.			1.65
CV			0.02	CV			0.02
CV%			1.68	CV%			1.73

4.2 Precision “Within Run” and “Between Run”

4.2.1 Bio-Rad Control (Level-2)

Within Run				Run to Run			
S.No.	Test	ΔAbs/min	Conc (IU/L)	S.No.	Test	ΔAbs/min	Conc (IU/L)
	Factor	3376			Factor	3376	
01	Bio-Rad 2	0.036	121.54	01	Bio-Rad 2	0.036	121.54
02	Bio-Rad 2	0.036	121.54	02	Bio-Rad 2	0.036	121.54
03	Bio-Rad 2	0.037	124.91	03	Bio-Rad 2	0.037	124.91
04	Bio-Rad 2	0.036	121.54	04	Bio-Rad 2	0.037	124.91
05	Bio-Rad 2	0.037	124.91	05	Bio-Rad 2	0.036	121.54
06	Bio-Rad 2	0.036	121.54	06	Bio-Rad 2	0.037	124.91
07	Bio-Rad 2	0.036	121.54	07	Bio-Rad 2	0.036	121.54
08	Bio-Rad 2	0.037	124.91	08	Bio-Rad 2	0.036	121.54
09	Bio-Rad 2	0.036	121.54	09	Bio-Rad 2	0.037	124.91
10	Bio-Rad 2	0.036	121.54	10	Bio-Rad 2	0.036	121.54
11	Bio-Rad 2	0.036	121.54	11	Bio-Rad 2	0.036	121.54
12	Bio-Rad 2	0.037	124.91	12	Bio-Rad 2	0.036	121.54
13	Bio-Rad 2	0.036	121.54	13	Bio-Rad 2	0.036	121.54
14	Bio-Rad 2	0.037	124.91	14	Bio-Rad 2	0.037	124.91
15	Bio-Rad 2	0.036	121.54	15	Bio-Rad 2	0.036	121.54
16	Bio-Rad 2	0.036	121.54	16	Bio-Rad 2	0.036	121.54
17	Bio-Rad 2	0.036	121.54	17	Bio-Rad 2	0.037	124.91
18	Bio-Rad 2	0.037	124.91	18	Bio-Rad 2	0.036	121.54
19	Bio-Rad 2	0.036	121.54	19	Bio-Rad 2	0.036	121.54
20	Bio-Rad 2	0.037	124.91	20	Bio-Rad 2	0.036	121.54
21	Bio-Rad 2	0.037	124.91	21	Bio-Rad 2	0.037	124.91
22	Bio-Rad 2	0.036	121.54	22	Bio-Rad 2	0.036	121.54
23	Bio-Rad 2	0.037	124.91	23	Bio-Rad 2	0.036	121.54
24	Bio-Rad 2	0.036	121.54	24	Bio-Rad 2	0.037	124.91
25	Bio-Rad 2	0.037	124.91	25	Bio-Rad 2	0.036	121.54
Mean			122.89	Mean			122.62
S.D.			1.69	S.D.			1.61
CV			0.01	CV			0.01
CV%			1.37	CV%			1.31

5.0 Performance Evaluation Report of Creatine Kinase-MB

Time interval= Day-0

Storage Temperature = 2°C – 8°C

Test	Vanguard Reagent		Reference Reagent		Specification (IU/L)
	ΔAbs./min.	Conc. (IU/L)	ΔAbs./min.	Conc. (IU/L)	
Factor 3376	-	-	-	-	-
Known normal/ abnormal Serum samples					
Sample-1	0.006	20.26	0.005	16.88	0 - 24 IU/L
Sample-2	0.005	16.88	0.005	16.88	
Sample-3	0.006	20.26	0.006	20.26	
Sample-4	0.005	16.88	0.006	20.26	
Sample-5	0.006	20.26	0.006	20.26	
Linearity					
175.0 IU/L	0.051	172.17 (98.38%)	0.052	175.55 (100.31%)	± 10%

6.0 Accelerated Stability Studies: Summary

- Stability studies were conducted at 37°C till 21 days.
- Stability studies were conducted using Bio-Rad Control (Level-1 & Level-2).
- It was not possible to use the “same” samples in the study due to the very limited stability of samples.
- The values obtained with Creatine Kinase-MB were found to be in the ranges specified for the Bio-Rad controls till 21 days at 37°C and found to be comparable with the reference reagent.
- Creatine Kinase-MB reagent was therefore found to be stable at 37°C for 21 days.
- This data has been extrapolated to conclude that Creatine Kinase-MB reagent will be stable for 18 months under the recommended temperature conditions of 2°C- 8°C.

6.1 Accelerated stability study: Creatine Kinase-MB

Time interval= Day-7

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (IU/L)
	ΔAbs./min.	Conc. (IU/L)	ΔAbs./min.	Conc. (IU/L)	
Factor 3376	-	-	-	-	-
Known normal/ abnormal Serum samples					
Sample-1	0.004	13.50	0.004	13.50	0 - 24 IU/L
Sample-2	0.003	10.13	0.004	13.50	
Sample-3	0.005	16.88	0.005	16.88	
Sample-4	0.006	20.26	0.005	16.88	
Sample-5	0.004	13.50	0.004	13.50	
Linearity					
175.0 IU/L	0.048	162.04 (92.59%)	0.049	165.42 (94.52%)	± 10%

6.2 Accelerated stability study: Creatine Kinase-MB

Time interval= Day-14

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (IU/L)
	ΔAbs./min.	Conc. (IU/L)	ΔAbs./min.	Conc. (IU/L)	
Factor 3376	-	-	-	-	-
Known normal/ abnormal Serum samples					
Sample-1	0.003	10.13	0.004	13.50	0 - 24 IU/L
Sample-2	0.004	13.50	0.004	13.50	
Sample-3	0.005	16.88	0.005	16.88	
Sample-4	0.004	13.50	0.003	10.13	
Sample-5	0.005	16.88	0.004	13.50	
Linearity					
175.0 IU/L	0.049	165.42 (94.52%)	0.050	168.80 (96.45%)	± 10%

6.3 Accelerated stability study: Creatine Kinase-MB

Time interval= Day-21

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (IU/L)
	ΔAbs./min.	Conc. (IU/L)	ΔAbs./min.	Conc. (IU/L)	
Factor 3376	-	-	-	-	-
Known normal/ abnormal Serum samples					
Sample-1	0.002	6.75	0.003	10.13	0 - 24 IU/L
Sample-2	0.003	10.13	0.003	10.13	
Sample-3	0.002	6.75	0.002	6.75	
Sample-4	0.001	3.38	0.001	3.38	
Sample-5	0.002	6.75	0.002	6.75	
Linearity					
175.0 IU/L	0.049	165.42 (94.52%)	0.050	168.80 (96.45%)	± 10%

7.0 Conclusions

1. The Creatine Kinase-MB reagent showed an excellent Coefficient of Correlation (“r”) using Diasys as Reference.
2. Creatine Kinase-MB showed values of “r” was 0.935 displaying the highest degree of correlation between the two sets of reagents.
3. The Creatine Kinase-MB reagent showed an excellent coefficient of Variation (CV %).
4. The CV % was found to be in the range of 1.31% and 1.73% displaying a very high level of precision and repeatability.
5. The Creatine Kinase-MB reagent showed an excellent performance even under stressful conditions. The reagents were found to be stable at 37°C for 21 days.

The Creatine Kinase-MB reagent was thus concluded to be Accurate, Precise and Stable, while using clinical normal and abnormal samples and 3rd Party controls (Level-1 and Level-2).

Gamma GT

CLINICAL EVIDENCE EVALUATION REPORT

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1 Details of Reagents

Type of Reagents developed	Liquid Clinical Chemistry Reagents
Instrument Model	Biochemistry Semi-automated analyzer (BTS-350)
Reference Reagents	Reference Diasys Reagents

2.0 Coefficient of Correlation Studies: Accuracy study

- I. The objective was to determine the correlation between the results obtained with the Clinical Chemistry reagents of Vanguard Diagnostics and the benchmarked Clinical Chemistry reagents from Diasys.
- II. The Coefficient of Correlation ("r") was calculated for Gamma GT kit.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x (x̄)
 - 3 Mean y (ȳ)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of "r"
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, xi (x1, x2,...,xn) are the x values and yi are the y values.

2.1 Coefficient of Correlation (“r”): Gamma GT

X AXIS = Reference Diasys Reagent.

Y AXIS = Gamma GT kit from Vanguard Diagnostics (P) Ltd.

$$“r” = 0.992$$

Sample size: 20

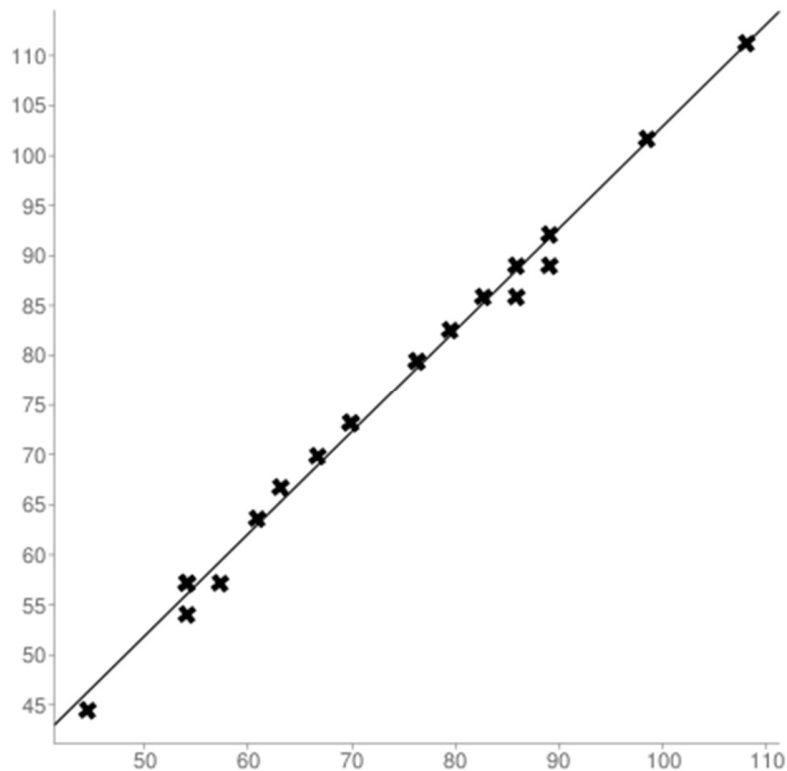
Mean x (x̄): 73.258

Mean y (ȳ): 75.636

Intercept (a): 0.7788001623156

Slope (b): 1.0218296955648

Regression line equation: $y = 0.7788001623156 + 1.0218296955648x$



3.0 Comparative evaluation report: Gamma GT

Vanguard Gamma GT Kit				Reference Kit		
S.NO.	Test	Δ Abs/min	Conc (IU/L)	Δ Abs/min	Conc (IU/L)	%
	Factor		1158		1158	
01	Sample 1	0.020	23.16	0.020	23.16	100.00
02	Sample 2	0.018	20.84	0.018	20.84	100.00
03	Sample 3	0.016	18.53	0.017	19.69	94.12
04	Sample 4	0.018	20.84	0.018	20.84	100.00
05	Sample 5	0.016	18.53	0.017	19.69	94.12
06	Sample 6	0.012	13.90	0.012	13.90	100.00
07	Sample 7	0.011	12.74	0.012	13.90	91.67
08	Sample 8	0.012	13.90	0.012	13.90	100.00
09	Sample 9	0.014	16.21	0.015	17.37	93.33
10	Sample 10	0.015	17.37	0.015	17.37	100.00
11	Sample 11	0.016	18.53	0.016	18.53	100.00
12	Sample 12	0.014	16.21	0.014	16.21	100.00
13	Sample 13	0.016	18.53	0.016	18.53	100.00
14	Sample 14	0.018	20.84	0.017	19.69	105.88
15	Sample 15	0.015	17.37	0.015	17.37	100.00
16	Sample 16	0.016	18.53	0.016	18.53	100.00
17	Sample 17	0.022	25.48	0.023	26.63	95.65
18	Sample 18	0.023	26.63	0.024	27.79	95.83
19	Sample 19	0.021	24.32	0.021	24.32	100.00
20	Sample 20	0.018	20.84	0.018	20.84	100.00

4.0 Coefficient of Variation: Repeatability/Reproducibility/Precision study

- Biorad Controls Normal and Abnormal were used to calculate “Within Run” and “Between Run” Precision.
- The Biorad Controls were tested in 25 replicates to study Precision.
- Coefficient of Variation (CV %) was calculated.
- **Acceptance criteria = NMT 10%.**

4.1 Precision “Within Run” and “Between Run”

4.1.1 Bio-Rad Control (Level-1)

Within Run				Run to Run			
S.No.	Test	Δ Abs/min	Conc (IU/L)	S.No.	Test	Δ Abs/min	Conc (IU/L)
	Factor	1158			Factor	1158	
01	Bio-Rad 1	0.037	42.846	01	Bio-Rad 1	0.036	41.688
02	Bio-Rad 1	0.037	42.846	02	Bio-Rad 1	0.036	41.688
03	Bio-Rad 1	0.036	41.688	03	Bio-Rad 1	0.036	41.688
04	Bio-Rad 1	0.036	41.688	04	Bio-Rad 1	0.036	41.688
05	Bio-Rad 1	0.036	41.688	05	Bio-Rad 1	0.037	42.846
06	Bio-Rad 1	0.036	41.688	06	Bio-Rad 1	0.037	42.846
07	Bio-Rad 1	0.036	41.688	07	Bio-Rad 1	0.036	41.688
08	Bio-Rad 1	0.036	41.688	08	Bio-Rad 1	0.036	41.688
09	Bio-Rad 1	0.036	41.688	09	Bio-Rad 1	0.037	42.846
10	Bio-Rad 1	0.037	42.846	10	Bio-Rad 1	0.036	41.688
11	Bio-Rad 1	0.036	41.688	11	Bio-Rad 1	0.037	42.846
12	Bio-Rad 1	0.036	41.688	12	Bio-Rad 1	0.036	41.688
13	Bio-Rad 1	0.037	42.846	13	Bio-Rad 1	0.036	41.688
14	Bio-Rad 1	0.037	42.846	14	Bio-Rad 1	0.037	42.846
15	Bio-Rad 1	0.036	41.688	15	Bio-Rad 1	0.036	41.688
16	Bio-Rad 1	0.036	41.688	16	Bio-Rad 1	0.036	41.688
17	Bio-Rad 1	0.036	41.688	17	Bio-Rad 1	0.036	41.688
18	Bio-Rad 1	0.036	41.688	18	Bio-Rad 1	0.036	41.688
19	Bio-Rad 1	0.037	42.846	19	Bio-Rad 1	0.037	42.846
20	Bio-Rad 1	0.036	41.688	20	Bio-Rad 1	0.036	41.688
21	Bio-Rad 1	0.036	41.688	21	Bio-Rad 1	0.036	41.688
22	Bio-Rad 1	0.036	41.688	22	Bio-Rad 1	0.036	41.688
23	Bio-Rad 1	0.037	42.846	23	Bio-Rad 1	0.037	42.846
24	Bio-Rad 1	0.036	41.688	24	Bio-Rad 1	0.036	41.688
25	Bio-Rad 1	0.036	41.688	25	Bio-Rad 1	0.036	41.688
Mean			42.01	Mean			42.01
S.D.			0.53	S.D.			0.53
CV			0.01	CV			0.01
CV%			1.26	CV%			1.26

4.2 Precision “Within Run” and “Between Run”

4.2.1 Bio-Rad Control (Level-2)

Within Run				Run to Run			
S.No.	Test	ΔAbs/min	Conc (IU/L)	S.No.	Test	ΔAbs/min	Conc (IU/L)
	Factor	1158			Factor	1158	
01	Bio-Rad 2	0.105	121.59	01	Bio-Rad 2	0.105	121.59
02	Bio-Rad 2	0.106	122.748	02	Bio-Rad 2	0.106	122.748
03	Bio-Rad 2	0.104	120.432	03	Bio-Rad 2	0.104	120.432
04	Bio-Rad 2	0.105	121.59	04	Bio-Rad 2	0.105	121.59
05	Bio-Rad 2	0.105	121.59	05	Bio-Rad 2	0.104	120.432
06	Bio-Rad 2	0.104	120.432	06	Bio-Rad 2	0.105	121.59
07	Bio-Rad 2	0.106	122.748	07	Bio-Rad 2	0.106	122.748
08	Bio-Rad 2	0.105	121.59	08	Bio-Rad 2	0.104	120.432
09	Bio-Rad 2	0.105	121.59	09	Bio-Rad 2	0.105	121.59
10	Bio-Rad 2	0.105	121.59	10	Bio-Rad 2	0.106	122.748
11	Bio-Rad 2	0.104	120.432	11	Bio-Rad 2	0.104	120.432
12	Bio-Rad 2	0.104	120.432	12	Bio-Rad 2	0.105	121.59
13	Bio-Rad 2	0.106	122.748	13	Bio-Rad 2	0.106	122.748
14	Bio-Rad 2	0.105	121.59	14	Bio-Rad 2	0.104	120.432
15	Bio-Rad 2	0.104	120.432	15	Bio-Rad 2	0.105	121.59
16	Bio-Rad 2	0.106	122.748	16	Bio-Rad 2	0.105	121.59
17	Bio-Rad 2	0.105	121.59	17	Bio-Rad 2	0.105	121.59
18	Bio-Rad 2	0.104	120.432	18	Bio-Rad 2	0.104	120.432
19	Bio-Rad 2	0.105	121.59	19	Bio-Rad 2	0.106	122.748
20	Bio-Rad 2	0.105	121.59	20	Bio-Rad 2	0.105	121.59
21	Bio-Rad 2	0.104	120.432	21	Bio-Rad 2	0.104	120.432
22	Bio-Rad 2	0.106	122.748	22	Bio-Rad 2	0.106	122.748
23	Bio-Rad 2	0.105	121.59	23	Bio-Rad 2	0.105	121.59
24	Bio-Rad 2	0.104	120.432	24	Bio-Rad 2	0.105	121.59
25	Bio-Rad 2	0.105	121.59	25	Bio-Rad 2	0.104	120.432
Mean			121.45	Mean			121.50
S.D.			0.84	S.D.			0.88
CV			0.01	CV			0.01
CV%			0.69	CV%			0.72

5.0 Performance Evaluation Report of Gamma GT

Time interval= Day-0

Storage Temperature = 2°C – 8°C

Test	Vanguard Reagent		Reference Reagent		Specification (IU/L)
	ΔAbs./min.	Conc. (IU/L)	ΔAbs./min.	Conc. (IU/L)	
Factor 1158	-	-	-	-	-
Controls					
Biorad- 1	0.037	42.85	0.036	41.69	34.5 - 51.7 IU/L
Biorad- 2	0.106	122.75	0.107	123.91	96.8 - 145 IU/L
Known normal/ abnormal Serum samples					
Sample-1	0.021	24.32	0.022	25.48	6 - 54 IU/L
Sample-2	0.024	27.79	0.024	27.79	
Sample-3	0.023	26.63	0.023	26.63	
Sample-4	0.024	27.79	0.023	26.63	
Sample-5	0.022	25.48	0.022	25.48	
Linearity					
800.0 IU/L	0.685	793.23 (99.15%)	0.682	789.75 98.71%)	± 10%

6.0 Accelerated Stability Studies: Summary

- Stability studies were conducted at 37°C till 21 days.
- Stability studies were conducted using Bio-Rad Control (Level-1 & Level-2).
- It was not possible to use the “same” samples in the study due to the very limited stability of samples.
- The values obtained with Gamma GT were found to be in the ranges specified for the Bio-Rad controls till 21 days at 37°C and found to be comparable with the reference reagent.
- Gamma GT reagent was therefore found to be stable at 37°C for 21 days.
- This data has been extrapolated to conclude that Gamma GT reagent will be stable for 18 months under the recommended temperature conditions of 2°C- 8°C.

6.1 Accelerated stability study: Gamma GT

Time interval= Day-7

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (IU/L)
	ΔAbs./min.	Conc. (IU/L)	ΔAbs./min.	Conc. (IU/L)	
Factor 1158	-	-	-	-	-
Controls					
Biorad- 1	0.036	41.69	0.036	41.69	34.5 - 51.7 IU/L
Biorad- 2	0.105	121.59	0.106	122.75	96.8 - 145 IU/L
Known normal/ abnormal Serum samples					
Sample-1	0.022	25.48	0.023	26.63	6 - 54 IU/L
Sample-2	0.023	26.63	0.022	25.48	
Sample-3	0.024	27.79	0.025	28.95	
Sample-4	0.023	26.63	0.022	25.48	
Sample-5	0.021	24.32	0.02	23.16	
Linearity					
800.0 IU/L	0.682	789.75 98.71%)	0.684	792.07 (99.00%)	± 10%

6.2 Accelerated stability study: Gamma GT

Time interval= Day-14

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (IU/L)
	ΔAbs./min.	Conc. (IU/L)	ΔAbs./min.	Conc. (IU/L)	
Factor 1158	-	-	-	-	-
Controls					
Biorad- 1	0.037	42.85	0.036	41.69	34.5 - 51.7 IU/L
Biorad- 2	0.108	125.06	0.107	123.91	96.8 - 145 IU/L
Known normal/ abnormal Serum samples					
Sample-1	0.022	25.48	0.023	26.63	6 - 54 IU/L
Sample-2	0.025	28.95	0.024	27.79	
Sample-3	0.026	30.11	0.025	28.95	
Sample-4	0.024	27.79	0.025	28.95	
Sample-5	0.026	30.11	0.025	28.95	
Linearity					
800.0 IU/L	0.682	789.75 98.71%)	0.68	787.44 (98.43%)	± 10%

6.3 Accelerated stability study: Gamma GT

Time interval= Day-21

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (IU/L)
	ΔAbs./min.	Conc. (IU/L)	ΔAbs./min.	Conc. (IU/L)	
Factor 1158	-	-	-	-	-
Controls					
Biorad- 1	0.036	41.69	0.036	41.69	34.5 - 51.7 IU/L
Biorad- 2	0.106	122.75	0.107	123.91	96.8 - 145 IU/L
Known normal/ abnormal Serum samples					
Sample-1	0.023	26.63	0.023	26.63	6 - 54 IU/L
Sample-2	0.024	27.79	0.025	28.95	
Sample-3	0.027	31.27	0.026	30.11	
Sample-4	0.025	28.95	0.026	30.11	
Sample-5	0.024	27.79	0.024	27.79	
Linearity					
800.0 IU/L	0.682	789.75 98.71%)	0.680	787.44 (98.43%)	± 10%

7.0 Conclusions

- The Gamma GT reagent showed an excellent Coefficient of Correlation (“r”) using Diasys as Reference.
- Gamma GT showed values of “r” was 0.996 displaying the highest degree of correlation between the two sets of reagents.
- The Gamma GT reagent showed an excellent coefficient of Variation (CV %).
- The CV % was found to be in the range of 0.69% and 1.26% displaying a very high level of precision and repeatability.
- The Gamma GT reagent showed an excellent performance even under stressful conditions. The reagents were found to be stable at 37°C for 21 days.

The Gamma GT reagent was thus concluded to be Accurate, Precise and Stable, while using clinical normal and abnormal samples and 3rd Party controls (Level-1 and Level-2).

Lipase

CLINICAL EVIDENCE EVALUATION REPORT

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1. Details of Reagents

Type of Reagents developed	Liquid Clinical Chemistry Reagents
Instrument Model	Biochemistry Semi-automated analyzer (BTS-350)
Reference Reagents	Reference Reagents

2.0 Coefficient of Correlation Studies: Accuracy study

- I. The objective was to determine the correlation between the results obtained with the Clinical Chemistry reagents of Vanguard Diagnostics and the benchmarked Clinical Chemistry reagents from Diasys.
- II. The Coefficient of Correlation ("r") was calculated for Lipase kit.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x (x̄)
 - 3 Mean y (ȳ)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of "r"
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, xi (x1, x2,...,xn) are the x values and yi are the y values.

2.1 Coefficient of Correlation (“r”): Lipase

X AXIS = Reference Diasys Reagent.

Y AXIS = Lipase kit from Vanguard Diagnostics (P) Ltd.

$$“r” = 0.998$$

Sample size: 20

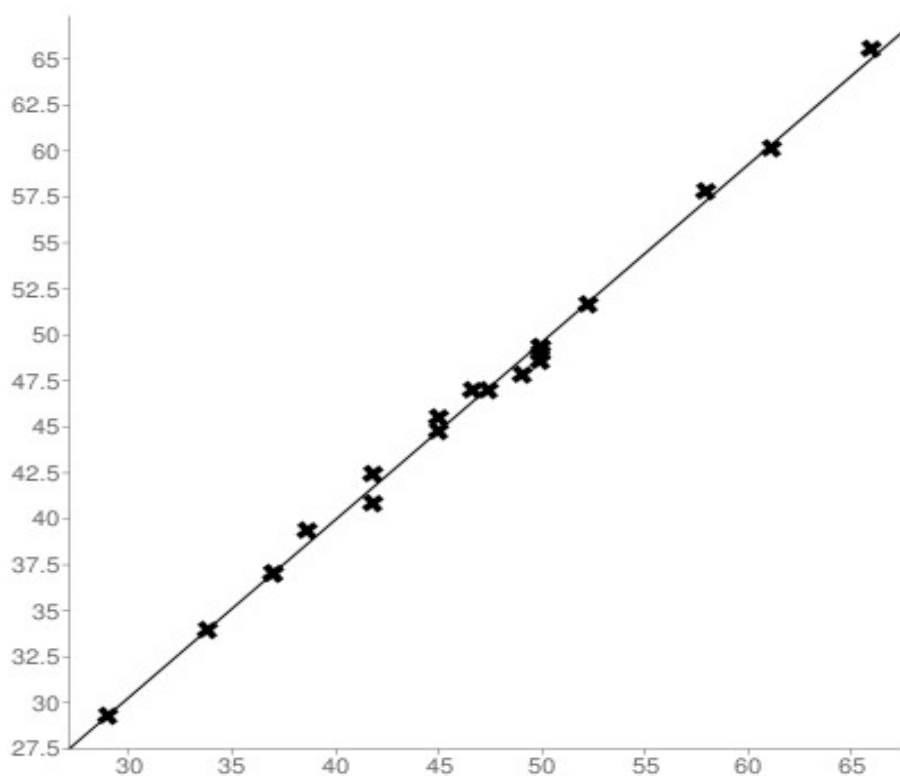
Mean x (x̄): 46.449

Mean y (ȳ): 46.1735

Intercept (a): 1.3106269226086

Slope (b): 0.96585229127412

Regression line equation: $y = 1.3106269226086 + 0.96585229127412x$



3.0 Comparative evaluation report: Lipase

Vanguard Lipase Kit				Reference Kit		
S.NO.	Test	Δ Abs/min	Conc (IU/L)	Δ Abs/min	Conc (IU/L)	%
	Calibrator (93.3 IU/L)	0.116		0.121		
01	Sample 1	0.062	49.87	0.064	49.35	101.05
02	Sample 2	0.065	52.28	0.067	51.66	101.20
03	Sample 3	0.072	57.91	0.075	57.83	100.14
04	Sample 4	0.082	65.95	0.085	65.54	100.63
05	Sample 5	0.062	49.87	0.063	48.58	102.65
06	Sample 6	0.052	41.82	0.055	42.41	98.62
07	Sample 7	0.042	33.78	0.044	33.93	99.57
08	Sample 8	0.036	28.96	0.038	29.30	98.82
09	Sample 9	0.059	47.45	0.061	47.04	100.89
10	Sample 10	0.076	61.13	0.078	60.14	101.64
11	Sample 11	0.046	37.00	0.048	37.01	99.96
12	Sample 12	0.052	41.82	0.053	40.87	102.34
13	Sample 13	0.048	38.61	0.051	39.32	98.17
14	Sample 14	0.061	49.06	0.062	47.81	102.63
15	Sample 15	0.062	49.87	0.064	49.35	101.05
16	Sample 16	0.056	45.04	0.059	45.49	99.01
17	Sample 17	0.046	37.00	0.048	37.01	99.96
18	Sample 18	0.062	49.87	0.064	49.35	101.05
19	Sample 19	0.056	45.04	0.058	44.72	100.71
20	Sample 20	0.058	46.65	0.061	47.04	99.18

4.0 Coefficient of Variation: Repeatability/Reproducibility/Precision study

- Biorad Controls Normal and Abnormal were used to calculate “Within Run” and “Between Run” Precision.
- The Biorad Controls were tested in 25 replicates to study Precision.
- Coefficient of Variation (CV %) was calculated.
- **Acceptance criteria = NMT 10%.**

4.1 Precision “Within Run” and “Between Run”

4.1.1 Bio-Rad Control (Level-1)

Within Run				Run to Run			
S.No.	Test	ΔAbs/min	Conc (IU/L)	S.No.	Test	ΔAbs/min	Conc (IU/L)
	Calibrator (93.3 IU/L)	0.119			Calibrator (93.3 IU/L)	0.124	
01	Bio-Rad 1	0.052	40.77	01	Bio-Rad 1	0.053	39.88
02	Bio-Rad 1	0.053	41.55	02	Bio-Rad 1	0.056	42.14
03	Bio-Rad 1	0.054	42.34	03	Bio-Rad 1	0.054	40.63
04	Bio-Rad 1	0.055	43.12	04	Bio-Rad 1	0.052	39.13
05	Bio-Rad 1	0.052	40.77	05	Bio-Rad 1	0.053	39.88
06	Bio-Rad 1	0.056	43.91	06	Bio-Rad 1	0.052	39.13
07	Bio-Rad 1	0.053	41.55	07	Bio-Rad 1	0.054	40.63
08	Bio-Rad 1	0.054	42.34	08	Bio-Rad 1	0.054	40.63
09	Bio-Rad 1	0.056	43.91	09	Bio-Rad 1	0.053	39.88
10	Bio-Rad 1	0.052	40.77	10	Bio-Rad 1	0.056	42.14
11	Bio-Rad 1	0.056	43.91	11	Bio-Rad 1	0.054	40.63
12	Bio-Rad 1	0.053	41.55	12	Bio-Rad 1	0.056	42.14
13	Bio-Rad 1	0.053	41.55	13	Bio-Rad 1	0.053	39.88
14	Bio-Rad 1	0.054	42.34	14	Bio-Rad 1	0.054	40.63
15	Bio-Rad 1	0.056	43.91	15	Bio-Rad 1	0.056	42.14
16	Bio-Rad 1	0.052	40.77	16	Bio-Rad 1	0.052	39.13
17	Bio-Rad 1	0.053	41.55	17	Bio-Rad 1	0.053	39.88
18	Bio-Rad 1	0.056	43.91	18	Bio-Rad 1	0.054	40.63
19	Bio-Rad 1	0.054	42.34	19	Bio-Rad 1	0.052	39.13
20	Bio-Rad 1	0.053	41.55	20	Bio-Rad 1	0.053	39.88
21	Bio-Rad 1	0.056	43.91	21	Bio-Rad 1	0.054	40.63
22	Bio-Rad 1	0.054	42.34	22	Bio-Rad 1	0.052	39.13
23	Bio-Rad 1	0.054	42.34	23	Bio-Rad 1	0.053	39.88
24	Bio-Rad 1	0.052	40.77	24	Bio-Rad 1	0.054	40.63
25	Bio-Rad 1	0.053	41.55	25	Bio-Rad 1	0.053	39.88
Mean			42.21	Mean			40.33
S.D.			1.15	S.D.			0.97
CV			0.03	CV			0.02
CV%			2.72	CV%			2.41

4.2 Precision “Within Run” and “Between Run”

4.2.1 Bio-Rad Control (Level-2)

Within Run				Run to Run			
S.No.	Test	ΔAbs/min	Conc (IU/L)	S.No.	Test	ΔAbs/min	Conc (IU/L)
	Calibrator (93.3 IU/L)	0.119			Calibrator (93.3 IU/L)	0.124	
01	Bio-Rad 2	0.099	77.62	01	Bio-Rad 2	0.098	73.74
02	Bio-Rad 2	0.098	76.84	02	Bio-Rad 2	0.096	72.23
03	Bio-Rad 2	0.097	76.05	03	Bio-Rad 2	0.095	71.48
04	Bio-Rad 2	0.096	75.27	04	Bio-Rad 2	0.098	73.74
05	Bio-Rad 2	0.098	76.84	05	Bio-Rad 2	0.096	72.23
06	Bio-Rad 2	0.095	74.48	06	Bio-Rad 2	0.095	71.48
07	Bio-Rad 2	0.096	75.27	07	Bio-Rad 2	0.098	73.74
08	Bio-Rad 2	0.095	74.48	08	Bio-Rad 2	0.094	70.73
09	Bio-Rad 2	0.098	76.84	09	Bio-Rad 2	0.096	72.23
10	Bio-Rad 2	0.096	75.27	10	Bio-Rad 2	0.095	71.48
11	Bio-Rad 2	0.095	74.48	11	Bio-Rad 2	0.096	72.23
12	Bio-Rad 2	0.096	75.27	12	Bio-Rad 2	0.098	73.74
13	Bio-Rad 2	0.095	74.48	13	Bio-Rad 2	0.095	71.48
14	Bio-Rad 2	0.096	75.27	14	Bio-Rad 2	0.096	72.23
15	Bio-Rad 2	0.098	76.84	15	Bio-Rad 2	0.095	71.48
16	Bio-Rad 2	0.096	75.27	16	Bio-Rad 2	0.096	72.23
17	Bio-Rad 2	0.095	74.48	17	Bio-Rad 2	0.098	73.74
18	Bio-Rad 2	0.096	75.27	18	Bio-Rad 2	0.095	71.48
19	Bio-Rad 2	0.095	74.48	19	Bio-Rad 2	0.096	72.23
20	Bio-Rad 2	0.096	75.27	20	Bio-Rad 2	0.094	70.73
21	Bio-Rad 2	0.095	74.48	21	Bio-Rad 2	0.095	71.48
22	Bio-Rad 2	0.094	73.70	22	Bio-Rad 2	0.096	72.23
23	Bio-Rad 2	0.096	75.27	23	Bio-Rad 2	0.095	71.48
24	Bio-Rad 2	0.098	76.84	24	Bio-Rad 2	0.098	73.74
25	Bio-Rad 2	0.096	75.27	25	Bio-Rad 2	0.096	72.23
Mean			75.42	Mean			72.23
S.D.			1.01	S.D.			0.97
CV			0.01	CV			0.01
CV%			1.34	CV%			1.34

5.0 Performance Evaluation Report of Lipase

Time interval= Day-0

Storage Temperature = 2°C – 8°C

Test	Vanguard Reagent		Reference Reagent		Specification (IU/L)
	ΔAbs./min.	Conc. (IU/L)	ΔAbs./min.	Conc. (IU/L)	
Calibrator (93.3 IU/L	0.118	-	0.122	-	-
Controls					
Biorad- 1	0.052	41.12	0.054	41.30	34.5 - 51.7 IU/L
Biorad- 2	0.098	77.49	0.099	75.71	57.1 - 85.6 IU/L
Known normal/ abnormal Serum samples					
Sample-1	0.045	35.58	0.046	35.18	0 - 60 IU/L
Sample-2	0.056	44.28	0.058	44.36	
Sample-3	0.058	45.86	0.061	46.65	
Sample-4	0.042	33.21	0.043	32.88	
Sample-5	0.053	41.91	0.055	42.06	
Linearity					
400.0 IU/L	0.502	396.92 (99.23%)	0.512	391.55 (97.88%)	± 10%

6.0 Accelerated Stability Studies: Summary

- Stability studies were conducted at 37°C till 21 days.
- Stability studies were conducted using Bio-Rad Control (Level-1 & Level-2).
- It was not possible to use the “same” samples in the study due to the very limited stability of samples.
- The values obtained with Lipase were found to be in the ranges specified for the Bio-Rad controls till 21 days at 37°C and found to be comparable with the reference reagent.
- Lipase reagent was therefore found to be stable at 37°C for 21 days.
- This data has been extrapolated to conclude that Lipase reagent will be stable for 18 months under the recommended temperature conditions of 2°C- 8°C.

6.1 Accelerated stability study: Lipase

Time interval= Day-7

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (IU/L)
	ΔAbs./min.	Conc. (IU/L)	ΔAbs./min.	Conc. (IU/L)	
Calibrator (93.3 IU/L)	0.116	-	0.121	-	-
Controls					
Biorad- 1	0.051	40.32	0.053	40.53	34.5 - 51.7 IU/L
Biorad- 2	0.097	76.70	0.098	74.95	57.1 - 85.6 IU/L
Known normal/ abnormal Serum samples					
Sample-1	0.056	44.28	0.055	42.06	0 - 60 IU/L
Sample-2	0.042	33.21	0.043	32.88	
Sample-3	0.056	44.28	0.055	42.06	
Sample-4	0.055	43.49	0.056	42.83	
Sample-5	0.062	49.02	0.063	48.18	
Linearity					
400.0 IU/L	0.501	402.95 (100.73%)	0.510	393.24 (98.31%)	± 10%

6.2 Accelerated stability study: Lipase

Time interval= Day-14

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (IU/L)
	ΔAbs./min.	Conc. (IU/L)	ΔAbs./min.	Conc. (IU/L)	
Calibrator (93.3 IU/L	0.114	-	0.118	-	-
Controls					
Biorad- 1	0.052	41.12	0.053	40.53	34.5 - 51.7 IU/L
Biorad- 2	0.096	75.91	0.098	74.95	57.1 - 85.6 IU/L
Known normal/ abnormal Serum samples					
Sample-1	0.042	33.21	0.044	33.65	0 - 60 IU/L
Sample-2	0.056	44.28	0.056	42.83	
Sample-3	0.023	18.19	0.025	19.12	
Sample-4	0.042	33.21	0.044	33.65	
Sample-5	0.036	28.46	0.038	29.06	
Linearity					
400.0 IU/L	0.499	401.49 (100.37%)	0.510	404.74 (101.18%)	± 10%

6.3 Accelerated stability study: Lipase

Time interval= Day-21

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (IU/L)
	ΔAbs./min.	Conc. (IU/L)	ΔAbs./min.	Conc. (IU/L)	
Calibrator (93.3 IU/L	0.115	-	0.116	-	-
Controls					
Biorad- 1	0.051	40.32	0.052	39.77	34.5 - 51.7 IU/L
Biorad- 2	0.095	75.11	0.097	74.18	57.1 - 85.6 IU/L
Known normal/ abnormal Serum samples					
Sample-1	0.038	30.05	0.040	30.59	0 - 60 IU/L
Sample-2	0.042	33.21	0.043	32.88	
Sample-3	0.052	41.12	0.051	39.00	
Sample-4	0.035	27.67	0.036	27.53	
Sample-5	0.012	9.49	0.012	9.18	
Linearity					
400.0 IU/L	0.495	406.36 101.59%)	0.506	406.98 (101.74%)	± 10%

7.0 Conclusions

- The Lipase reagent showed an excellent Coefficient of Correlation (“r”) using Diasys as Reference.
- Lipase showed values of “r” was 0.998 displaying the highest degree of correlation between the two sets of reagents.
- The Lipase reagent showed an excellent coefficient of Variation (CV %).
- The CV % was found to be in the range of 1.34% and 2.72% displaying a very high level of precision and repeatability.
- The Lipase reagent showed an excellent performance even under stressful conditions. The reagents were found to be stable at 37°C for 21 days.

The Lipase reagent was thus concluded to be Accurate, Precise and Stable, while using clinical normal and abnormal samples and 3rd Party controls (Level-1 and Level-2).

Sodium

CLINICAL EVIDENCE EVALUATION REPORT

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1.0 Details of Reagents

Type of Reagents developed	Liquid Clinical Chemistry Reagents
Instrument Model	Biochemistry Semi-automated analyzer (BTS-350)
Reference Reagents	Reference Reagents

2.0 Coefficient of Correlation Studies: Accuracy study

- I. The objective was to determine the correlation between the results obtained with the Clinical Chemistry reagents of Vanguard Diagnostics and the benchmarked Clinical Chemistry reagents from Diasys.
- II. The Coefficient of Correlation ("r") was calculated for Sodium kit.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x (x̄)
 - 3 Mean y (ȳ)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of "r"
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, xi (x1, x2,...,xn) are the x values and yi are the y values.

2.1 Coefficient of Correlation (“r”): Sodium

X AXIS = Reference Reagent.

Y AXIS = Sodium kit from Vanguard Diagnostics (P) Ltd.

$$“r” = 0.997$$

Sample size: 20

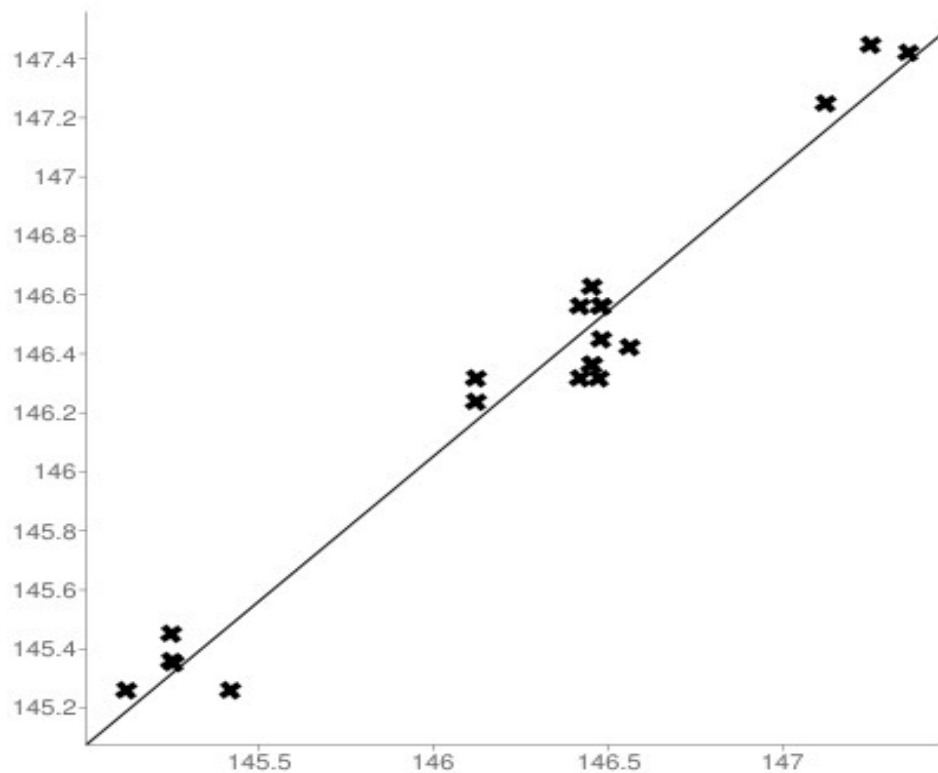
Mean x (x̄): 146.2465

Mean y (ȳ): 146.295

Intercept (a): 2.1723265443214

Slope (b): 0.98547776155791

Regression line equation: $y = 2.1723265443214 + 0.98547776155791x$



3.0 Comparative evaluation report: Sodium

Vanguard Sodium Kit				Reference Kit		
S.No.	Test	Abs.	Conc (mEq/L)	Abs.	Conc (mEq/L)	%
	Standard (150 mEq/L)	0.426	-	0.424	-	
01	Sample 1	0.412	145.07	0.411	145.40	99.77
02	Sample 2	0.413	145.42	0.412	145.75	99.77
03	Sample 3	0.415	146.13	0.415	146.82	99.53
04	Sample 4	0.413	145.42	0.413	146.11	99.53
05	Sample 5	0.412	145.07	0.415	146.82	98.81
06	Sample 6	0.413	145.42	0.416	147.17	98.81
07	Sample 7	0.415	146.13	0.412	145.75	100.26
08	Sample 8	0.416	146.48	0.412	145.75	100.50
09	Sample 9	0.413	145.42	0.412	145.75	99.77
10	Sample 10	0.415	146.13	0.415	146.82	99.53
11	Sample 11	0.416	146.48	0.412	145.75	100.50
12	Sample 12	0.412	145.07	0.409	144.69	100.26
13	Sample 13	0.413	145.42	0.411	145.40	100.01
14	Sample 14	0.415	146.13	0.412	145.75	100.26
15	Sample 15	0.412	145.07	0.408	144.34	100.51
16	Sample 16	0.416	146.48	0.412	145.75	100.50
17	Sample 17	0.413	145.42	0.411	145.40	100.01
18	Sample 18	0.415	146.13	0.412	145.75	100.26
19	Sample 19	0.416	146.48	0.412	145.75	100.50
20	Sample 20	0.415	146.13	0.413	146.11	100.01

4.0 Coefficient of Variation: Repeatability/Reproducibility/Precision study

- Biorad Controls Normal and Abnormal were used to calculate “Within Run” and “Between Run” Precision.
- The Biorad Controls were tested in 25 replicates to study Precision.
- Coefficient of Variation (CV %) was calculated.
- **Acceptance criteria = NMT 10%.**

4.1 Precision “Within Run” and “Between Run”

4.1.1 Bio-Rad Control (Level-1)

Within Run				Run to Run			
S.No.	Test	Abs.	Conc. (mEq/L)	S.No.	Test	Abs.	Conc. (mEq/L)
	Standard (150 mEq/L)	0.426			Standard (150 mEq/L)	0.424	
01	Bio-Rad 1	0.392	138.03	01	Bio-Rad 1	0.394	139.39
02	Bio-Rad 1	0.392	138.03	02	Bio-Rad 1	0.393	139.03
03	Bio-Rad 1	0.393	138.38	03	Bio-Rad 1	0.392	138.68
04	Bio-Rad 1	0.392	138.03	04	Bio-Rad 1	0.394	139.39
05	Bio-Rad 1	0.394	138.73	05	Bio-Rad 1	0.395	139.74
06	Bio-Rad 1	0.392	138.03	06	Bio-Rad 1	0.393	139.03
07	Bio-Rad 1	0.393	138.38	07	Bio-Rad 1	0.394	139.39
08	Bio-Rad 1	0.394	138.73	08	Bio-Rad 1	0.393	139.03
09	Bio-Rad 1	0.392	138.03	09	Bio-Rad 1	0.392	138.68
10	Bio-Rad 1	0.393	138.38	10	Bio-Rad 1	0.394	139.39
11	Bio-Rad 1	0.394	138.73	11	Bio-Rad 1	0.393	139.03
12	Bio-Rad 1	0.392	138.03	12	Bio-Rad 1	0.394	139.39
13	Bio-Rad 1	0.393	138.38	13	Bio-Rad 1	0.392	138.68
14	Bio-Rad 1	0.394	138.73	14	Bio-Rad 1	0.393	139.03
15	Bio-Rad 1	0.393	138.38	15	Bio-Rad 1	0.394	139.39
16	Bio-Rad 1	0.392	138.03	16	Bio-Rad 1	0.392	138.68
17	Bio-Rad 1	0.394	138.73	17	Bio-Rad 1	0.393	139.03
18	Bio-Rad 1	0.392	138.03	18	Bio-Rad 1	0.394	139.39
19	Bio-Rad 1	0.393	138.38	19	Bio-Rad 1	0.393	139.03
20	Bio-Rad 1	0.394	138.73	20	Bio-Rad 1	0.394	139.39
21	Bio-Rad 1	0.392	138.03	21	Bio-Rad 1	0.392	138.68
22	Bio-Rad 1	0.392	138.03	22	Bio-Rad 1	0.393	139.03
23	Bio-Rad 1	0.393	138.38	23	Bio-Rad 1	0.394	139.39
24	Bio-Rad 1	0.394	138.73	24	Bio-Rad 1	0.393	139.03
25	Bio-Rad 1	0.392	138.03	25	Bio-Rad 1	0.394	139.39
Mean			138.32	Mean			139.13
S.D.			0.30	S.D.			0.30
CV			0.00	CV			0.00
CV%			0.22	CV%			0.21

4.2 Precision “Within Run” and “Between Run”

4.2.1 Bio-Rad Control (Level-2)

Within Run				Run to Run			
S.No.	Test	Abs.	Conc. (mEq/L)	S.No.	Test	Abs.	Conc. (mEq/L)
	Standard (150 mEq/L)	0.426			Standard (150 mEq/L)	0.424	
01	Bio-Rad 2	0.362	127.46	01	Bio-Rad 2	0.363	128.42
02	Bio-Rad 2	0.363	127.82	02	Bio-Rad 2	0.365	129.13
03	Bio-Rad 2	0.362	127.46	03	Bio-Rad 2	0.366	129.48
04	Bio-Rad 2	0.364	128.17	04	Bio-Rad 2	0.362	128.07
05	Bio-Rad 2	0.363	127.82	05	Bio-Rad 2	0.363	128.42
06	Bio-Rad 2	0.362	127.46	06	Bio-Rad 2	0.364	128.77
07	Bio-Rad 2	0.364	128.17	07	Bio-Rad 2	0.365	129.13
08	Bio-Rad 2	0.363	127.82	08	Bio-Rad 2	0.363	128.42
09	Bio-Rad 2	0.362	127.46	09	Bio-Rad 2	0.364	128.77
10	Bio-Rad 2	0.364	128.17	10	Bio-Rad 2	0.363	128.42
11	Bio-Rad 2	0.363	127.82	11	Bio-Rad 2	0.365	129.13
12	Bio-Rad 2	0.364	128.17	12	Bio-Rad 2	0.364	128.77
13	Bio-Rad 2	0.363	127.82	13	Bio-Rad 2	0.363	128.42
14	Bio-Rad 2	0.364	128.17	14	Bio-Rad 2	0.364	128.77
15	Bio-Rad 2	0.363	127.82	15	Bio-Rad 2	0.365	129.13
16	Bio-Rad 2	0.362	127.46	16	Bio-Rad 2	0.363	128.42
17	Bio-Rad 2	0.364	128.17	17	Bio-Rad 2	0.364	128.77
18	Bio-Rad 2	0.363	127.82	18	Bio-Rad 2	0.365	129.13
19	Bio-Rad 2	0.362	127.46	19	Bio-Rad 2	0.363	128.42
20	Bio-Rad 2	0.364	128.17	20	Bio-Rad 2	0.364	128.77
21	Bio-Rad 2	0.363	127.82	21	Bio-Rad 2	0.362	128.07
22	Bio-Rad 2	0.364	128.17	22	Bio-Rad 2	0.363	128.42
23	Bio-Rad 2	0.362	127.46	23	Bio-Rad 2	0.364	128.77
24	Bio-Rad 2	0.363	127.82	24	Bio-Rad 2	0.363	128.42
25	Bio-Rad 2	0.364	128.17	25	Bio-Rad 2	0.365	129.13
Mean			127.85	Mean			128.70
S.D.			0.29	S.D.			0.37
CV			0.00	CV			0.00
CV%			0.22	CV%			0.29

5.0 Performance Evaluation Report of Sodium

Time interval= Day-0

Storage Temperature = 2°C – 8°C

Test	Vanguard Reagent		Reference Reagent		Specification (mEq/L)
	Abs.	Conc. (mEq/L)	Abs.	Conc. (mEq/L)	
Reagent Blank	0.352		0.362		
Standard	0.426	150 mEq/L	0.428	150 mEq/L	-
Controls					
Biorad- 1	0.396	139.44	0.395	138.43	124 - 153 mEq/L
Biorad- 2	0.362	127.46	0.359	125.82	114 - 140 mEq/L
Known normal/abnormal Serum samples					
Sample-1	0.412	145.07	0.409	143.34	135 - 155 mEq/L
Sample-2	0.408	143.66	0.406	142.29	
Sample-3	0.421	148.24	0.419	146.85	
Sample-4	0.402	141.55	0.399	139.84	
Sample-5	0.436	153.52	0.432	151.40	
Linearity					
180 mEq/L	0.512	179.44 (99.68%)	0.515	180.49 (100.27%)	± 10%

6.0 Accelerated Stability Studies: Summary

- Stability studies were conducted at 37°C till 21 days.
- Stability studies were conducted using Bio-Rad Control (Level-1 & Level-2).
- It was not possible to use the “same” samples in the study due to the very limited stability of samples.
- The values obtained with Sodium were found to be in the ranges specified for the Bio-Rad controls till 21 days at 37°C and found to be comparable with the reference reagent.
- Sodium reagent was therefore found to be stable at 37°C for 21 days.
- This data has been extrapolated to conclude that Sodium reagent will be stable for 18 months under the recommended temperature conditions of 2°C- 8°C.

6.1 Accelerated stability study: Sodium

Time interval= Day-7

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (mEq/L)
	Abs.	Conc. (mEq/L)	Abs.	Conc. (mEq/L)	
Reagent Blank	0.345		0.348		
Standard	0.422	150 mEq/L	0.425	150 mEq/L	-
Controls					
Biorad- 1	0.396	140.76	0.395	139.41	124 - 153 mEq/L
Biorad- 2	0.362	128.67	0.359	126.71	114 - 140 mEq/L
Known normal/abnormal Serum samples					
Sample-1	0.412	146.45	0.409	144.35	135 - 155 mEq/L
Sample-2	0.408	145.02	0.411	145.06	
Sample-3	0.421	149.64	0.425	150.00	
Sample-4	0.402	142.89	0.399	140.82	
Sample-5	0.436	154.98	0.438	154.59	
Linearity					
180 mEq/L	0.509	180.92 (100.51%)	0.512	180.71 (100.39%)	± 10%

6.2 Accelerated stability study: Sodium

Time interval= Day-14

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (mEq/L)
	Abs.	Conc. (mEq/L)	Abs.	Conc. (mEq/L)	
Reagent Blank	0.341		0.346		
Standard	0.418	150 mEq/L	0.421	150 mEq/L	-
Controls					
Biorad- 1	0.402	144.26	0.405	144.30	124 - 153 mEq/L
Biorad- 2	0.376	134.93	0.378	134.68	114 - 140 mEq/L
Known normal/abnormal Serum samples					
Sample-1	0.415	148.92	0.419	149.29	135 - 155 mEq/L
Sample-2	0.382	137.08	0.385	137.17	
Sample-3	0.425	152.51	0.429	152.85	
Sample-4	0.403	144.62	0.406	144.66	
Sample-5	0.395	141.75	0.402	143.23	
Linearity					
180 mEq/L	0.499	179.07 (99.48%)	0.502	178.86 (99.36%)	± 10%

6.3 Accelerated stability study: Sodium

Time interval= Day-21

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (mEq/L)
	Abs.	Conc. (mEq/L)	Abs.	Conc. (mEq/L)	
Reagent Blank	0.338		0.342		
Standard	0.421	150 mEq/L	0.424	150 mEq/L	-
Controls					
Biorad- 1	0.402	143.23	0.405	143.28	124 - 153 mEq/L
Biorad- 2	0.376	133.97	0.378	133.73	114 - 140 mEq/L
Known normal/abnormal Serum samples					
Sample-1	0.415	147.86	0.419	148.23	135 - 155 mEq/L
Sample-2	0.382	136.10	0.385	136.20	
Sample-3	0.425	151.43	0.429	151.77	
Sample-4	0.403	143.59	0.406	143.63	
Sample-5	0.395	140.74	0.402	142.22	
Linearity					
180 mEq/L	0.499	177.79 (98.77%)	0.502	177.59 (98.66%)	± 10%

7.0 Conclusions

- The Sodium reagent showed an excellent Coefficient of Correlation (“r”) using as Reference.
- Sodium showed values of “r” was 0.981 displaying the highest degree of correlation between the two sets of reagents.
- The Sodium reagent showed an excellent coefficient of Variation (CV %).
- The CV % was found to be in the range of 0.21% and 0.29% displaying a very high level of precision and repeatability.
- The Sodium reagent showed an excellent performance even under stressful conditions. The reagents were found to be stable at 37°C for 21 days.

The Sodium reagent was thus concluded to be Accurate, Precise and Stable, while using clinical normal and abnormal samples and 3rd Party controls (Level-1 and Level-2).

Potassium

CLINICAL EVIDENCE EVALUATION REPORT

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1.0 Details of Reagents

Type of Reagents developed	Liquid Clinical Chemistry Reagents
Instrument Model	Biochemistry Semi-automated analyzer (BTS-350)
Reference Reagents	Reference Reagents

2.0 Coefficient of Correlation Studies: Accuracy study

- I. The objective was to determine the correlation between the results obtained with the Clinical Chemistry reagents of Vanguard Diagnostics and the benchmarked Clinical Chemistry reagents from Diasys.
- II. The Coefficient of Correlation ("r") was calculated for Potassium kit.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x (x̄)
 - 3 Mean y (ȳ)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of "r"
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, xi (x1, x2,...,xn) are the x values and yi are the y values.

2.1 Coefficient of Correlation (“r”): Potassium

X AXIS = Reference Reagent.

Y AXIS = Potassium kit from Vanguard Diagnostics (P) Ltd.

$$“r” = 0.997$$

Sample size: 20

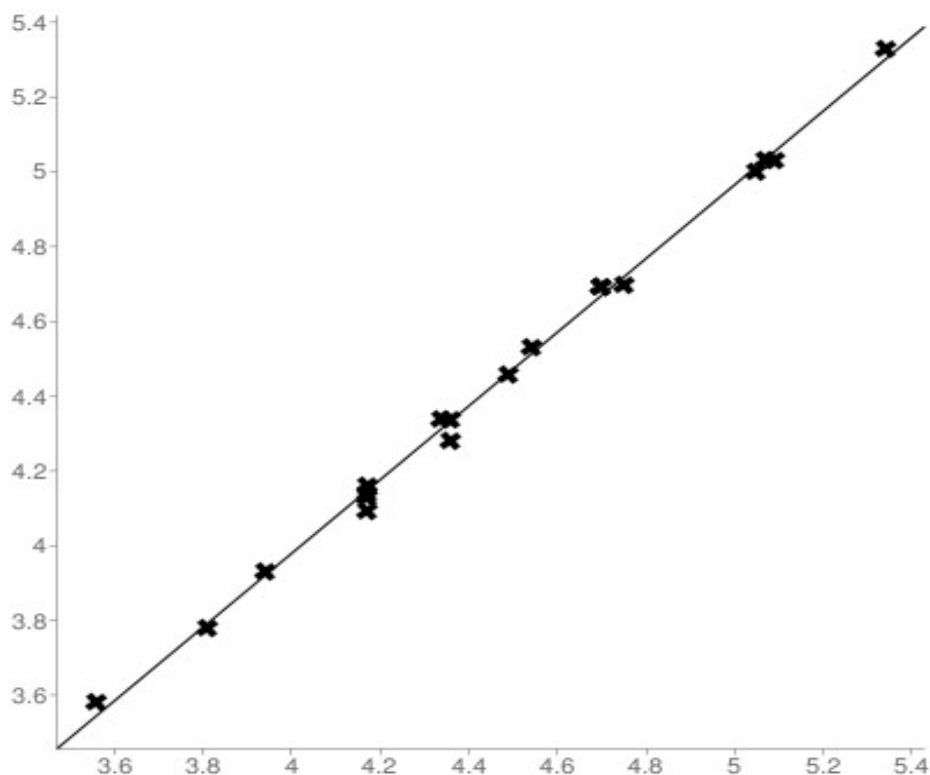
Mean x (x̄): 4.474

Mean y (ȳ): 4.446

Intercept (a): 0.030860816598253

Slope (b): 0.98684380496239

Regression line equation: $y = 0.030860816598253 + 0.98684380496239x$



3.0 Comparative evaluation report: Potassium

Vanguard Potassium Kit				Reference Kit		
S.No.	Test	Abs.	Conc (mEq/L)	Abs.	Conc (mEq/L)	%
	Standard (5 mEq/L)	0.282	-	0.286	-	
01	Sample 1	0.201	3.56	0.205	3.58	99.44
02	Sample 2	0.301	5.34	0.305	5.33	100.09
03	Sample 3	0.222	3.94	0.225	3.93	100.07
04	Sample 4	0.286	5.07	0.288	5.03	100.71
05	Sample 5	0.256	4.54	0.259	4.53	100.24
06	Sample 6	0.265	4.70	0.268	4.69	100.28
07	Sample 7	0.235	4.17	0.238	4.16	100.14
08	Sample 8	0.246	4.36	0.245	4.28	101.83
09	Sample 9	0.265	4.70	0.268	4.69	100.28
10	Sample 10	0.287	5.09	0.288	5.03	101.07
11	Sample 11	0.235	4.17	0.2368	4.14	100.65
12	Sample 12	0.253	4.49	0.255	4.46	100.62
13	Sample 13	0.265	4.70	0.268	4.69	100.28
14	Sample 14	0.235	4.17	0.234	4.09	101.85
15	Sample 15	0.215	3.81	0.216	3.78	100.95
16	Sample 16	0.245	4.34	0.248	4.34	100.19
17	Sample 17	0.235	4.17	0.236	4.13	100.99
18	Sample 18	0.246	4.36	0.248	4.34	100.60
19	Sample 19	0.268	4.75	0.269	4.70	101.04
20	Sample 20	0.285	5.05	0.286	5.00	101.06

4.0 Coefficient of Variation: Repeatability/Reproducibility/Precision study

- Biorad Controls Normal and Abnormal were used to calculate “Within Run” and “Between Run” Precision.
- The Biorad Controls were tested in 25 replicates to study Precision.
- Coefficient of Variation (CV %) was calculated.
- **Acceptance criteria = NMT 10%.**

4.1 Precision “Within Run” and “Between Run”

4.1.1 Bio-Rad Control (Level-1)

Within Run				Run to Run			
S.No.	Test	Abs.	Conc. (mEq/L)	S.No.	Test	Abs.	Conc. (mEq/L)
	Standard (5 mEq/L)	0.278			Standard (5 mEq/L)	0.277	
01	Bio-Rad 1	0.235	4.23	01	Bio-Rad 1	0.231	4.17
02	Bio-Rad 1	0.236	4.24	02	Bio-Rad 1	0.231	4.17
03	Bio-Rad 1	0.234	4.21	03	Bio-Rad 1	0.233	4.21
04	Bio-Rad 1	0.235	4.23	04	Bio-Rad 1	0.232	4.19
05	Bio-Rad 1	0.236	4.24	05	Bio-Rad 1	0.232	4.19
06	Bio-Rad 1	0.235	4.23	06	Bio-Rad 1	0.231	4.17
07	Bio-Rad 1	0.234	4.21	07	Bio-Rad 1	0.234	4.22
08	Bio-Rad 1	0.235	4.23	08	Bio-Rad 1	0.235	4.24
09	Bio-Rad 1	0.236	4.24	09	Bio-Rad 1	0.231	4.17
10	Bio-Rad 1	0.235	4.23	10	Bio-Rad 1	0.235	4.24
11	Bio-Rad 1	0.234	4.21	11	Bio-Rad 1	0.236	4.26
12	Bio-Rad 1	0.231	4.15	12	Bio-Rad 1	0.234	4.22
13	Bio-Rad 1	0.235	4.23	13	Bio-Rad 1	0.235	4.24
14	Bio-Rad 1	0.236	4.24	14	Bio-Rad 1	0.231	4.17
15	Bio-Rad 1	0.235	4.23	15	Bio-Rad 1	0.235	4.24
16	Bio-Rad 1	0.234	4.21	16	Bio-Rad 1	0.234	4.22
17	Bio-Rad 1	0.235	4.23	17	Bio-Rad 1	0.235	4.24
18	Bio-Rad 1	0.231	4.15	18	Bio-Rad 1	0.231	4.17
19	Bio-Rad 1	0.235	4.23	19	Bio-Rad 1	0.235	4.24
20	Bio-Rad 1	0.234	4.21	20	Bio-Rad 1	0.235	4.24
21	Bio-Rad 1	0.234	4.21	21	Bio-Rad 1	0.234	4.22
22	Bio-Rad 1	0.231	4.15	22	Bio-Rad 1	0.231	4.17
23	Bio-Rad 1	0.235	4.23	23	Bio-Rad 1	0.235	4.24
24	Bio-Rad 1	0.234	4.21	24	Bio-Rad 1	0.231	4.17
25	Bio-Rad 1	0.235	4.23	25	Bio-Rad 1	0.235	4.24
Mean			4.22	Mean			4.21
S.D.			0.03	S.D.			0.03
CV			0.01	CV			0.01
CV%			0.62	CV%			0.79

4.2 Precision “Within Run” and “Between Run”

4.2.1 Bio-Rad Control (Level-2)

Within Run				Run to Run			
S.No.	Test	Abs.	Conc. (mEq/L)	S.No.	Test	Abs.	Conc. (mEq/L)
	Standard (5 mEq/L)	0.278			Standard (5 mEq/L)	0.277	
01	Bio-Rad 2	0.362	6.51	01	Bio-Rad 2	0.363	6.55
02	Bio-Rad 2	0.363	6.53	02	Bio-Rad 2	0.365	6.59
03	Bio-Rad 2	0.362	6.51	03	Bio-Rad 2	0.366	6.61
04	Bio-Rad 2	0.364	6.55	04	Bio-Rad 2	0.362	6.53
05	Bio-Rad 2	0.363	6.53	05	Bio-Rad 2	0.363	6.55
06	Bio-Rad 2	0.362	6.51	06	Bio-Rad 2	0.364	6.57
07	Bio-Rad 2	0.364	6.55	07	Bio-Rad 2	0.365	6.59
08	Bio-Rad 2	0.363	6.53	08	Bio-Rad 2	0.363	6.55
09	Bio-Rad 2	0.362	6.51	09	Bio-Rad 2	0.364	6.57
10	Bio-Rad 2	0.364	6.55	10	Bio-Rad 2	0.363	6.55
11	Bio-Rad 2	0.363	6.53	11	Bio-Rad 2	0.365	6.59
12	Bio-Rad 2	0.364	6.55	12	Bio-Rad 2	0.364	6.57
13	Bio-Rad 2	0.363	6.53	13	Bio-Rad 2	0.363	6.55
14	Bio-Rad 2	0.364	6.55	14	Bio-Rad 2	0.364	6.57
15	Bio-Rad 2	0.363	6.53	15	Bio-Rad 2	0.365	6.59
16	Bio-Rad 2	0.362	6.51	16	Bio-Rad 2	0.363	6.55
17	Bio-Rad 2	0.364	6.55	17	Bio-Rad 2	0.364	6.57
18	Bio-Rad 2	0.363	6.53	18	Bio-Rad 2	0.365	6.59
19	Bio-Rad 2	0.362	6.51	19	Bio-Rad 2	0.363	6.55
20	Bio-Rad 2	0.364	6.55	20	Bio-Rad 2	0.364	6.57
21	Bio-Rad 2	0.363	6.53	21	Bio-Rad 2	0.362	6.53
22	Bio-Rad 2	0.364	6.55	22	Bio-Rad 2	0.363	6.55
23	Bio-Rad 2	0.362	6.51	23	Bio-Rad 2	0.364	6.57
24	Bio-Rad 2	0.363	6.53	24	Bio-Rad 2	0.363	6.55
25	Bio-Rad 2	0.364	6.55	25	Bio-Rad 2	0.365	6.59
Mean			6.53	Mean			6.57
S.D.			0.01	S.D.			0.02
CV			0.00	CV			0.00
CV%			0.22	CV%			0.29

5.0 Performance Evaluation Report of Potassium

Time interval= Day-0

Storage Temperature = 2°C – 8°C

Test	Vanguard Reagent		Reference Reagent		Specification (mEq/L)
	Abs.	Conc. (mEq/L)	Abs.	Conc. (mEq/L)	
Reagent Blank	0.012		0.008		
Standard	0.278	5 mEq/L	0.276	5 mEq/L	-
Controls					
Biorad- 1	0.221	3.97	0.224	4.06	3.70 - 4.50 mEq/L
Biorad- 2	0.342	6.15	0.341	6.18	5.50 - 6.70 mEq/L
Known normal/abnormal Serum samples					
Sample-1	0.301	5.41	0.302	5.47	3.5 - 5.5 mEq/L
Sample-2	0.208	3.74	0.211	3.82	
Sample-3	0.221	3.97	0.225	4.08	
Sample-4	0.246	4.42	0.241	4.37	
Sample-5	0.236	4.24	0.231	4.18	
Linearity					
7 mEq/L	0.386	6.94 (99.14%)	0.385	6.97 (99.57%)	± 10%

6.0 Accelerated Stability Studies: Summary

- Stability studies were conducted at 37°C till 21 days.
- Stability studies were conducted using Bio-Rad Control (Level-1 & Level-2).
- It was not possible to use the “same” samples in the study due to the very limited stability of samples.
- The values obtained with Potassium were found to be in the ranges specified for the Bio-Rad controls till 21 days at 37°C and found to be comparable with the reference reagent.
- Potassium reagent was therefore found to be stable at 37°C for 21 days.
- This data has been extrapolated to conclude that Potassium reagent will be stable for 18 months under the recommended temperature conditions of 2°C- 8°C.

6.1 Accelerated stability study: Potassium

Time interval= Day-7

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (mEq/L)
	Abs.	Conc. (mEq/L)	Abs.	Conc. (mEq/L)	
Reagent Blank	0.016		0.012		
Standard	0.281	5 mEq/L	0.284	5 mEq/L	-
Controls					
Biorad- 1	0.221	3.89	0.224	3.94	3.70 - 4.50 mEq/L
Biorad- 2	0.342	6.02	0.341	6.00	5.50 - 6.70 mEq/L
Known normal/abnormal Serum samples					
Sample-1	0.301	5.30	0.302	5.32	3.5 - 5.5 mEq/L
Sample-2	0.208	3.66	0.211	3.71	
Sample-3	0.221	3.89	0.225	3.96	
Sample-4	0.246	4.33	0.241	4.24	
Sample-5	0.236	4.15	0.231	4.07	
Linearity					
7 mEq/L	0.388	6.83 (97.57%)	0.392	6.90 (98.57%)	± 10%

6.2 Accelerated stability study: Potassium

Time interval= Day-14

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (mEq/L)
	Abs.	Conc. (mEq/L)	Abs.	Conc. (mEq/L)	
Reagent Blank	0.018		0.016		
Standard	0.284	5 mEq/L	0.285	5 mEq/L	-
Controls					
Biorad- 1	0.224	3.94	0.226	3.96	3.70 - 4.50 mEq/L
Biorad- 2	0.345	6.07	0.347	6.09	5.50 - 6.70 mEq/L
Known normal/abnormal Serum samples					
Sample-1	0.306	5.39	0.308	5.40	3.5 - 5.5 mEq/L
Sample-2	0.218	3.84	0.221	3.88	
Sample-3	0.232	4.08	0.235	4.12	
Sample-4	0.256	4.51	0.258	4.53	
Sample-5	0.238	4.19	0.239	4.19	
Linearity					
7 mEq/L	0.392	6.90 (98.57%)	0.396	6.95 (99.28%)	± 10%

6.3 Accelerated stability study: Potassium

Time interval= Day-21

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (mEq/L)
	Abs.	Conc. (mEq/L)	Abs.	Conc. (mEq/L)	
Reagent Blank	0.018		0.016		
Standard	0.279	5 mEq/L	0.281	5 mEq/L	-
Controls					
Biorad- 1	0.224	4.01	0.226	4.02	3.70 - 4.50 mEq/L
Biorad- 2	0.345	6.18	0.347	6.17	5.50 - 6.70 mEq/L
Known normal/abnormal Serum samples					
Sample-1	0.306	5.48	0.308	5.48	3.5 - 5.5 mEq/L
Sample-2	0.218	3.91	0.221	3.93	
Sample-3	0.232	4.16	0.235	4.18	
Sample-4	0.256	4.59	0.258	4.59	
Sample-5	0.238	4.27	0.239	4.25	
Linearity					
7 mEq/L	0.386	6.92 (98.85%)	0.388	6.90 (98.57%)	± 10%

7.0 Conclusions

- The Potassium reagent showed an excellent Coefficient of Correlation (“r”) using as Reference.
- Potassium showed values of “r” was 0.981 displaying the highest degree of correlation between the two sets of reagents.
- The Potassium reagent showed an excellent coefficient of Variation (CV %).
- The CV % was found to be in the range of 0.21% and 0.29% displaying a very high level of precision and repeatability.
- The Potassium reagent showed an excellent performance even under stressful conditions. The reagents were found to be stable at 37°C for 21 days.

The Potassium reagent was thus concluded to be Accurate, Precise and Stable, while using clinical normal and abnormal samples and 3rd Party controls (Level-1 and Level-2).

Microprotein

CLINICAL EVIDENCE EVALUATION REPORT

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1.0 Details of Reagents

Type of Reagents developed	Liquid Clinical Chemistry Reagents
Instrument Model	Biochemistry Semi-automated analyzer (BTS-350)
Reference Reagents	Reference Reagents

2.0 Coefficient of Correlation Studies: Accuracy study

- I. The objective was to determine the correlation between the results obtained with the Clinical Chemistry reagents of Vanguard Diagnostics and the benchmarked Clinical Chemistry reagents.
- II. The Coefficient of Correlation ("r") was calculated for Microprotein kit.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x (x̄)
 - 3 Mean y (ȳ)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of "r"
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, xi (x1, x2,...,xn) are the x values and yi are the y values.

2.1 Coefficient of Correlation (“r”): Microprotein

X AXIS = Reference Reagent.

Y AXIS = Microprotein kit from Vanguard Diagnostics (P) Ltd.

$$“r” = 0.999$$

Sample size: 20

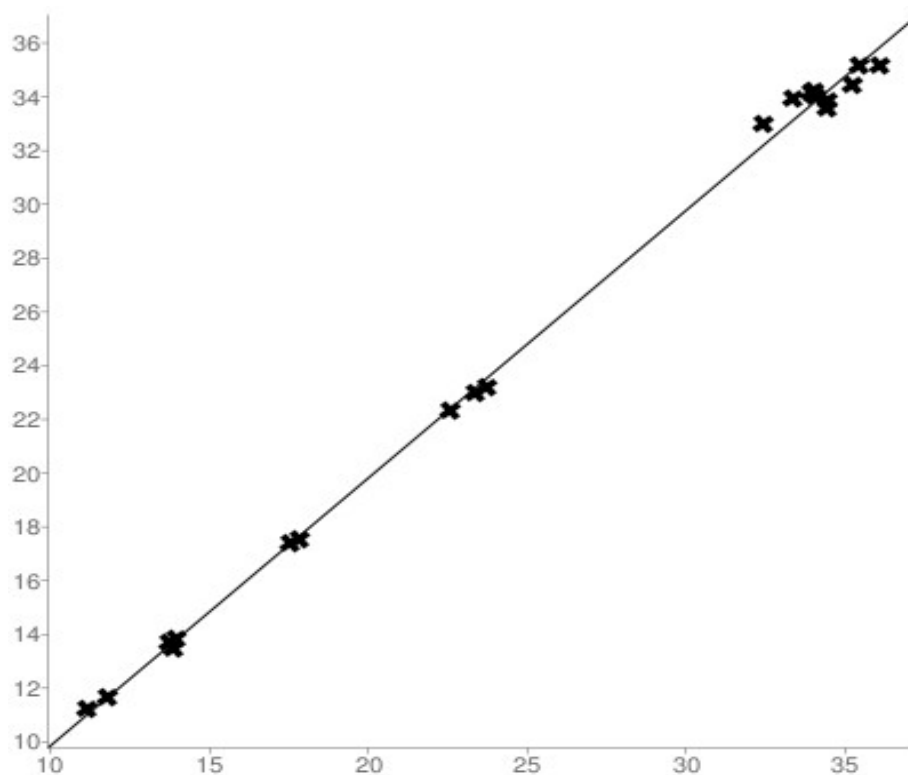
Mean x (x̄): 25.652

Mean y (ȳ): 25.4385

Intercept (a): -0.10502758320149

Slope (b): 0.99577138559182

Regression line equation: $y = 0.99577138559182x - 0.10502758320149$



3.0 Comparative evaluation report: Microprotein

Vanguard Microprotein Kit				Reference Kit		
S.No.	Test	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	%
	Standard (100 mg/dl)	0.219	-	0.218	-	
01	Sample 1	0.071	32.42	0.072	32.96	98.36
02	Sample 2	0.075	34.02	0.075	34.23	99.39
03	Sample 3	0.039	17.85	0.038	17.51	101.96
04	Sample 4	0.024	11.17	0.024	11.21	99.67
05	Sample 5	0.030	13.70	0.030	13.69	100.10
06	Sample 6	0.073	33.33	0.074	33.91	98.31
07	Sample 7	0.030	13.88	0.029	13.51	102.74
08	Sample 8	0.078	35.43	0.077	35.17	100.74
09	Sample 9	0.052	23.74	0.051	23.18	102.45
10	Sample 10	0.075	34.25	0.074	33.88	101.07
11	Sample 11	0.074	33.97	0.074	34.15	99.49
12	Sample 12	0.049	22.59	0.049	22.35	101.06
13	Sample 13	0.075	34.06	0.074	33.99	100.23
14	Sample 14	0.075	34.43	0.073	33.60	102.46
15	Sample 15	0.051	23.38	0.050	22.97	101.77
16	Sample 16	0.039	17.58	0.038	17.39	101.10
17	Sample 17	0.077	35.25	0.075	34.44	102.36
18	Sample 18	0.026	11.77	0.025	11.65	100.98
19	Sample 19	0.031	13.95	0.030	13.82	100.96
20	Sample 20	0.079	36.07	0.077	35.16	102.61

4.0 Coefficient of Variation: Repeatability/Reproducibility/Precision study

- Controls Normal and Abnormal were used to calculate “Within Run” and “Between Run” Precision.
- The Controls were tested in 20 replicates to study Precision.
- Coefficient of Variation (CV %) was calculated.
- **Acceptance criteria = NMT 10%.**

4.1 Precision “Within Run” and “Between Run”

4.1.1 Control (Level-1)

Within Run				Run to Run			
S.No.	Test	Abs.	Conc. (mg/dl)	S.No.	Test	Abs.	Conc. (mg/dl)
	Standard 100 mg/dl	0.219	-		Standard 100 mg/dl	0.219	-
01	Control 1	0.060	27.47	01	Control 1	0.059	26.90
02	Control 1	0.060	27.40	02	Control 1	0.060	27.55
03	Control 1	0.060	27.26	03	Control 1	0.060	27.62
04	Control 1	0.059	27.05	04	Control 1	0.059	26.92
05	Control 1	0.059	27.12	05	Control 1	0.060	27.38
06	Control 1	0.060	27.19	06	Control 1	0.061	27.88
07	Control 1	0.060	27.26	07	Control 1	0.061	27.90
08	Control 1	0.061	27.75	08	Control 1	0.061	27.93
09	Control 1	0.060	27.47	09	Control 1	0.062	28.14
10	Control 1	0.060	27.54	10	Control 1	0.062	28.42
11	Control 1	0.060	27.50	11	Control 1	0.060	27.62
12	Control 1	0.061	27.75	12	Control 1	0.060	27.39
13	Control 1	0.061	27.79	13	Control 1	0.059	27.10
14	Control 1	0.061	27.68	14	Control 1	0.060	27.49
15	Control 1	0.061	27.69	15	Control 1	0.061	28.01
16	Control 1	0.060	27.57	16	Control 1	0.062	28.16
17	Control 1	0.060	27.47	17	Control 1	0.062	28.45
18	Control 1	0.060	27.54	18	Control 1	0.062	28.27
19	Control 1	0.060	27.40	19	Control 1	0.062	28.16
20	Control 1	0.060	27.43	20	Control 1	0.062	28.24
Mean		27.47		Mean		27.78	
S.D.		0.21		S.D.		0.48	
CV		0.01		CV		0.02	
CV%		0.77		CV%		1.72	

4.2 Precision “Within Run” and “Between Run”

4.2.1 Control (Level-2)

Within Run				Run to Run			
S.No.	Test	Abs.	Conc. (mg/dl)	S.No.	Test	Abs.	Conc. (mg/dl)
	Standard 100 mg/dl	0.219	-		Standard 100 mg/dl	0.219	-
01	Control 2	0.159	72.61	01	Control 2	0.159	72.74
02	Control 2	0.163	74.32	02	Control 2	0.158	71.99
03	Control 2	0.159	72.61	03	Control 2	0.159	72.82
04	Control 2	0.159	72.74	04	Control 2	0.151	68.78
05	Control 2	0.159	72.61	05	Control 2	0.152	69.44
06	Control 2	0.157	71.83	06	Control 2	0.152	69.52
07	Control 2	0.159	72.70	07	Control 2	0.154	70.27
08	Control 2	0.159	72.63	08	Control 2	0.154	70.33
09	Control 2	0.158	72.36	09	Control 2	0.156	71.18
10	Control 2	0.159	72.61	10	Control 2	0.157	71.65
11	Control 2	0.159	72.70	11	Control 2	0.156	71.31
12	Control 2	0.159	72.65	12	Control 2	0.157	71.89
13	Control 2	0.159	72.74	13	Control 2	0.160	72.84
14	Control 2	0.163	74.53	14	Control 2	0.156	71.17
15	Control 2	0.159	72.72	15	Control 2	0.159	72.73
16	Control 2	0.159	72.63	16	Control 2	0.157	71.91
17	Control 2	0.159	72.68	17	Control 2	0.158	71.99
18	Control 2	0.159	72.70	18	Control 2	0.159	72.81
19	Control 2	0.159	72.74	19	Control 2	0.153	69.85
20	Control 2	0.159	72.72	20	Control 2	0.154	70.35
Mean			72.79	Mean			71.28
S.D.			0.59	S.D.			1.27
CV			0.008	CV			0.018
CV%			0.82	CV%			1.79

5.0 Performance Evaluation Report of Microprotein

Time interval= Day-0

Storage Temperature = Room Temperature.

Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
Reagent Blank	0.113	-	0.11		
Standard 100 mg/dl	0.219	-	0.218	-	
Controls					
CSF 1	0.060	27.50	0.060	27.47	22.0 - 33.0 mg/dl
CSF 2	0.150	68.60	0.152	69.73	54.9 - 82.3 mg/dl
Known normal/ abnormal Urine samples					
Sample-1	0.039	17.58	0.038	17.43	10 - 50 mg/dl
Sample-2	0.077	35.25	0.075	34.44	
Sample-3	0.026	11.77	0.025	11.65	
Sample-4	0.031	13.95	0.030	13.82	
Sample-5	0.079	36.07	0.077	35.16	
Linearity					
250 (mg/dl)	0.545	249 (99.6%)	0.541	248 (99.2%)	± 10%

6.0 Accelerated Stability Studies: Summary

- Stability studies were conducted at 37°C till 21 days.
- Stability studies were conducted using Control (Level-1 & Level-2).
- It was not possible to use the “same” samples in the study due to the very limited stability of samples.
- The values obtained with Microprotein were found to be in the ranges specified for the controls till 21 days at 37°C and found to be comparable with the reference reagent.
- Microprotein reagent was therefore found to be stable at 37°C for 21 days.
- This data has been extrapolated to conclude that Microprotein reagent will be stable for 18 months under the recommended temperature conditions of 2°C- 8°C.

6.1 Accelerated stability study: Microprotein

Time interval= Day-7

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
Reagent Blank	0.128	-	0.124		
Standard 100 mg/dl	0.224	-	0.225	-	
Controls					
CSF 1	0.062	27.68	0.062	27.56	22.0 - 33.0 mg/dl
CSF 2	0.151	67.41	0.152	67.56	54.9 - 82.3 mg/dl
Known normal/ abnormal Urine samples					
Sample-1	0.074	33.21	0.074	33.08	10 - 50 mg/dl
Sample-2	0.049	22.08	0.049	21.66	
Sample-3	0.075	33.30	0.074	32.93	
Sample-4	0.075	33.66	0.073	32.56	
Sample-5	0.051	22.86	0.050	22.26	
Linearity					
250 (mg/dl)	0.542	242 (96.8%)	0.542	241 (96.4%)	± 10%

6.2 Accelerated stability study: Microprotein

Time interval= Day-14

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
Reagent Blank	0.143	-	0.140		
Standard 100 mg/dl	0.232	-	0.233	-	
Controls					
CSF 1	0.061	26.38	0.061	26.18	22.0 - 33.0 mg/dl
CSF 2	0.151	65.09	0.153	65.67	54.9 - 82.3 mg/dl
Known normal/ abnormal Urine samples					
Sample-1	0.073	31.47	0.074	31.72	10 - 50 mg/dl
Sample-2	0.030	13.10	0.029	12.64	
Sample-3	0.078	33.45	0.077	32.91	
Sample-4	0.052	22.41	0.051	21.68	
Sample-5	0.075	32.33	0.074	31.70	
Linearity					
250 (mg/dl)	0.552	238 (95.2%)	0.552	237 (94.8%)	± 10%

6.3 Accelerated stability study: Microprotein

Time interval= Day-21

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
Reagent Blank	0.155	-	0.160		
Standard 100 mg/dl	0.237	-	0.238	-	
Controls					
CSF 1	0.060	25.32	0.060	25.21	22.0 - 33.0 mg/dl
CSF 2	0.150	63.29	0.152	63.87	54.9 - 82.3 mg/dl
Known normal/ abnormal Urine samples					
Sample-1	0.071	29.96	0.072	30.19	10 - 50 mg/dl
Sample-2	0.075	31.43	0.075	31.35	
Sample-3	0.039	16.50	0.038	16.04	
Sample-4	0.024	10.32	0.024	10.27	
Sample-5	0.030	12.66	0.030	12.54	
Linearity					
250 (mg/dl)	0.545	230 (92%)	0.549	231 (92.4%)	± 10%

7.0 Conclusions

- The Microprotein reagent showed an excellent Coefficient of Correlation (“r”) using as Reference.
- Microprotein showed values of “r” was 0.999 displaying the highest degree of correlation between the two sets of reagents.
- The Microprotein reagent showed an excellent coefficient of Variation (CV %).
- The CV % was found to be in the range of 0.77% and 1.79% displaying a very high level of precision and repeatability.
- The Microprotein reagent showed an excellent performance even under stressful conditions.

The reagents were found to be stable at 37°C for 21 days.

The Microprotein reagent was thus concluded to be Accurate, Precise and Stable, while using clinical normal and abnormal samples and 3rd Party controls (Level-1 and Level-2).

Ammonia

CLINICAL EVIDENCE EVALUATION REPORT

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1.0 Details of Reagents

Type of Reagents developed	Liquid Clinical Chemistry Reagents
Instrument Model	Biochemistry Semi-automated analyzer (BTS-350)
Reference Reagents	Reference Reagents

2.0 Coefficient of Correlation Studies: Accuracy study

- I. The objective was to determine the correlation between the results obtained with the Clinical Chemistry reagents of Vanguard Diagnostics and the benchmarked Clinical Chemistry reagents from Diasys.
- II. The Coefficient of Correlation ("r") was calculated for Ammonia kit.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x (x̄)
 - 3 Mean y (ȳ)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of "r"
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, xi (x1, x2,...,xn) are the x values and yi are the y values.

2.1 Coefficient of Correlation (“r”): Ammonia

X AXIS = Reference Diasys Reagent.

Y AXIS = Ammonia kit from Vanguard Diagnostics (P) Ltd.

$$“r” = 0.997$$

Sample size: 20

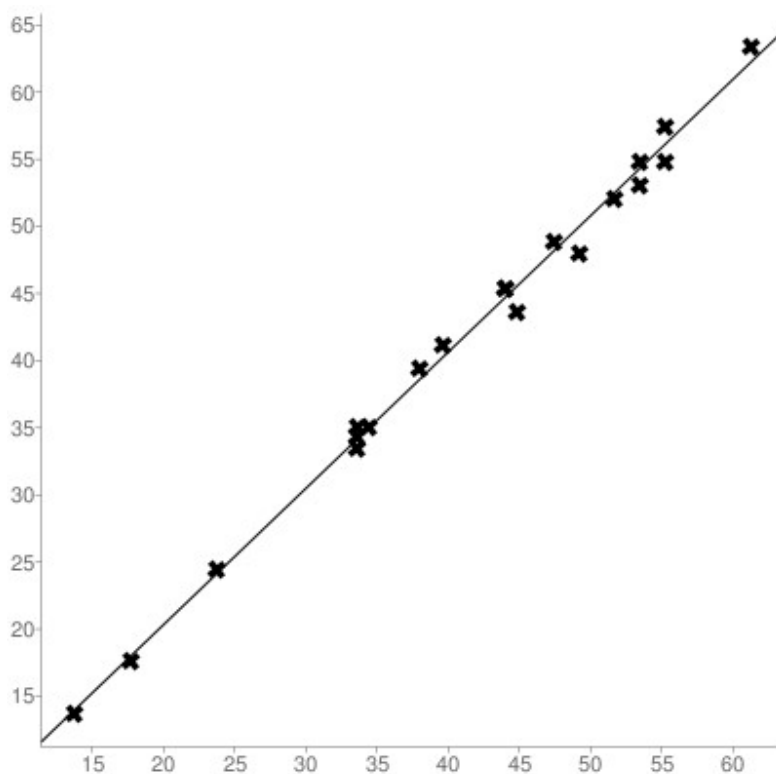
Mean x (x̄): 41.3795

Mean y (ȳ): 42.0285

Intercept (a): -0.02828127985088

Slope (b): 1.0163675559118

Regression line equation: $y = 1.0163675559118x - 0.02828127985088$



3.0 Comparative evaluation report: Ammonia

Vanguard Ammonia Kit				Reference kit		
S.No.	Test	Abs.	Conc. (µg/dl)	Abs.	Conc. (µg/dl)	%
	Standard (500 µg/dl)	0.145	-	0.146	-	
1	Sample 1	0.010	33.62	0.010	33.39	100.69
2	Sample 2	0.014	49.14	0.014	47.95	102.49
3	Sample 3	0.013	43.97	0.013	45.38	96.89
4	Sample 4	0.010	33.62	0.010	35.10	95.78
5	Sample 5	0.015	51.72	0.015	52.05	99.36
6	Sample 6	0.013	44.83	0.013	43.66	102.66
7	Sample 7	0.005	17.67	0.005	17.55	100.69
8	Sample 8	0.012	39.66	0.012	41.10	96.49
9	Sample 9	0.016	55.17	0.017	57.36	96.18
10	Sample 10	0.007	23.71	0.007	24.40	97.16
11	Sample 11	0.016	53.45	0.016	53.08	100.69
12	Sample 12	0.010	33.62	0.010	34.25	98.17
13	Sample 13	0.014	47.41	0.014	48.80	97.16
14	Sample 14	0.016	55.17	0.016	54.79	100.69
15	Sample 15	0.010	34.48	0.010	35.10	98.23
16	Sample 16	0.013	43.97	0.013	45.38	96.89
17	Sample 17	0.011	37.93	0.012	39.38	96.31
18	Sample 18	0.004	13.79	0.004	13.70	100.69
19	Sample 19	0.018	61.21	0.019	63.36	96.61
20	Sample 20	0.016	53.45	0.016	54.79	97.54

4.0 Coefficient of Variation: Repeatability/Reproducibility/Precision study

- Biorad Controls Normal and Abnormal were used to calculate “Within Run” and “Between Run” Precision.
- The Biorad Controls were tested in 25 replicates to study Precision.
- Coefficient of Variation (CV %) was calculated.
- **Acceptance criteria = NMT 10%.**

4.1 Precision “Within Run” and “Between Run”

4.1.1 Bio-Rad Control (Level-1)

Within Run				Run to Run			
S.No.	Test	Abs.	Conc. (µg/dl)	S.No.	Test	Abs.	Conc. (µg/dl)
	Standard (500 µg/dl)	-	-		Standard (500 µg/dl)	0.145	-
01	Level -1	0.018	62.07	01	Level -1	0.017	59.32
02	Level -1	0.018	62.07	02	Level -1	0.018	61.35
03	Level -1	0.018	60.34	03	Level -1	0.018	60.35
04	Level -1	0.018	62.07	04	Level -1	0.018	61.26
05	Level -1	0.018	60.34	05	Level -1	0.018	61.56
06	Level -1	0.018	61.38	06	Level -1	0.017	59.25
07	Level -1	0.017	60.00	07	Level -1	0.018	62.86
08	Level -1	0.018	60.34	08	Level -1	0.018	62.54
09	Level -1	0.018	61.38	09	Level -1	0.018	63.56
10	Level -1	0.018	60.69	10	Level -1	0.018	62.89
11	Level -1	0.018	62.76	11	Level -1	0.018	61.56
12	Level -1	0.018	62.07	12	Level -1	0.019	64.35
13	Level -1	0.018	62.76	13	Level -1	0.019	64.25
14	Level -1	0.019	63.79	14	Level -1	0.019	64.34
15	Level -1	0.018	62.76	15	Level -1	0.019	64.26
16	Level -1	0.018	62.07	16	Level -1	0.019	64.27
17	Level -1	0.018	63.45	17	Level -1	0.019	64.26
18	Level -1	0.018	62.76	18	Level -1	0.019	64.45
19	Level -1	0.018	60.34	19	Level -1	0.018	61.75
20	Level -1	0.018	60.69	20	Level -1	0.018	62.35
21	Level -1	0.018	61.38	21	Level -1	0.018	63.26
22	Level -1	0.017	60.00	22	Level -1	0.018	62.34
23	Level -1	0.018	60.34	23	Level -1	0.018	62.35
24	Level -1	0.018	62.41	24	Level -1	0.019	64.26
25	Level -1	0.018	62.07	25	Level -1	0.018	63.75
Mean			61.61	Mean			62.67
S.D.			1.12	S.D.			1.57
CV			0.02	CV			0.03
CV%			1.83	CV%			2.51

4.2 Precision “Within Run” and “Between Run”

4.2.1 Bio-Rad Control (Level-2)

Within Run				Run to Run			
S.No.	Test	Abs.	Conc. (µg/dl)	S.No.	Test	Abs.	Conc. (µg/dl)
	Standard (500 µg/dl)	0.145	-		Standard (500 µg/dl)	0.145	-
01	Level-3	0.145	500.20	01	Level-3	0.145	500.00
02	Level-3	0.144	498.20	02	Level-3	0.146	503.45
03	Level-3	0.145	499.60	03	Level-3	0.145	500.00
04	Level-3	0.145	500.00	04	Level-3	0.143	493.10
05	Level-3	0.145	499.50	05	Level-3	0.146	503.45
06	Level-3	0.145	500.20	06	Level-3	0.145	500.00
07	Level-3	0.145	501.00	07	Level-3	0.145	500.00
08	Level-3	0.146	502.00	08	Level-3	0.145	500.00
09	Level-3	0.145	500.00	09	Level-3	0.146	503.45
10	Level-3	0.145	500.00	10	Level-3	0.144	496.55
11	Level-3	0.145	501.00	11	Level-3	0.145	500.00
12	Level-3	0.146	502.00	12	Level-3	0.145	500.00
13	Level-3	0.145	500.00	13	Level-3	0.145	500.00
14	Level-3	0.145	500.00	14	Level-3	0.146	503.45
15	Level-3	0.145	499.00	15	Level-3	0.145	500.00
16	Level-3	0.145	501.00	16	Level-3	0.144	496.55
17	Level-3	0.145	501.00	17	Level-3	0.145	500.00
18	Level-3	0.145	500.00	18	Level-3	0.146	503.45
19	Level-3	0.145	499.00	19	Level-3	0.145	500.00
20	Level-3	0.145	500.60	20	Level-3	0.145	500.00
21	Level-3	0.145	500.20	21	Level-3	0.145	500.00
22	Level-3	0.145	500.00	22	Level-3	0.144	496.55
23	Level-3	0.145	499.00	23	Level-3	0.145	500.00
24	Level-3	0.145	501.00	24	Level-3	0.145	500.00
25	Level-3	0.145	500.10	25	Level-3	0.145	500.00
Mean			500.18	Mean			500.00
S.D.			0.90	S.D.			2.44
CV			0.002	CV			0.005
CV%			0.18	CV%			0.49

5.0 Performance Evaluation Report of Ammonia

Time interval= Day-0

Storage Temperature = 2°C – 8°C

Test	Vanguard Reagent		Reference Reagent		Specification (µg/dl)
	Abs	Conc. (µg/dl)	Abs	Conc. (µg/dl)	
Standard (500 µg/dl)	0.145	-	0.142	-	-
Controls					
Level -1	0.017	58.60	0.017	61.20	36.4 - 95.9 µg/dl
Level-2	0.055	189.20	0.055	192.00	153 - 229 µg/dl
Level-3	0.145	500.20	0.143	502.60	444 - 560 µg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.007	23.80	0.007	24.50	20 - 122 µg/dl
Sample-2	0.010	34.32	0.010	34.65	
Sample-3	0.013	45.86	0.013	45.73	
Sample-4	0.019	65.32	0.018	64.26	
Sample-5	0.021	75.63	0.022	78.56	
Linearity					
1500 µg/dl	0.434	1495.00 (99.70%)	0.423	1489.00 (99.30%)	± 10%

6.0 Accelerated Stability Studies: Summary

- Stability studies were conducted at 37°C till 21 days.
- Stability studies were conducted using Bio-Rad Control (Level-1 & Level-2).
- It was not possible to use the “same” samples in the study due to the very limited stability of samples.
- The values obtained with Ammonia were found to be in the ranges specified for the Bio-Rad controls till 21 days at 37°C and found to be comparable with the reference reagent.
- Ammonia reagent was therefore found to be stable at 37°C for 21 days.
- This data has been extrapolated to conclude that Ammonia reagent will be stable for 18 months under the recommended temperature conditions of 2°C- 8°C.

6.1 Accelerated stability study: Ammonia

Time interval= Day-7

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (µg/dl)
	Abs	Conc. (µg/dl)	Abs	Conc. (µg/dl)	
Standard (500 µg/dl)	0.148	-	0.145	-	-
Controls					
Level -1	0.019	64.18	0.019	65.51	36.4 - 95.9 µg/dl
Level-2	0.056	189.17	0.055	189.64	153 - 229 µg/dl
Level-3	0.147	496.57	0.145	499.96	444 - 560 µg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.008	27.02	0.009	31.03	20 - 122 µg/dl
Sample-2	0.011	37.16	0.012	41.38	
Sample-3	0.014	47.29	0.015	51.72	
Sample-4	0.020	67.56	0.019	65.51	
Sample-5	0.022	74.32	0.021	72.41	
Linearity					
1500 µg/dl	0.434	1466.00 (97.74%)	0.427	1472.00 (98.2%)	± 10%

6.2 Accelerated stability study: Ammonia

Time interval= Day-14

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (µg/dl)
	Abs	Conc. (µg/dl)	Abs	Conc. (µg/dl)	
Standard (500 µg/dl)	0.150		0.148		-
Controls					
Level -1	0.017	56.66	0.017	57.43	36.4 - 95.9 µg/dl
Level-2	0.055	183.32	0.055	185.79	153 - 229 µg/dl
Level-3	0.145	483.29	0.143	483.05	444 - 560 µg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.007	23.33	0.007	23.65	20 - 122 µg/dl
Sample-2	0.010	33.33	0.010	33.78	
Sample-3	0.013	43.33	0.013	43.91	
Sample-4	0.019	63.33	0.018	60.80	
Sample-5	0.021	69.99	0.022	74.32	
Linearity					
1500 µg/dl	0.424	1413.00 (94.2%)	0.423	1429.00 (95.3%)	± 10%

6.3 Accelerated stability study: Ammonia

Time interval= Day-21

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (µg/dl)
	Abs	Conc. (µg/dl)	Abs	Conc. (µg/dl)	
Standard (500 µg/dl)	0.151	-	0.149	-	-
Controls					
Level -1	0.019	62.91	0.019	63.75	36.4 - 95.9 µg/dl
Level-2	0.056	185.42	0.055	184.53	153 - 229 µg/dl
Level-3	0.147	486.72	0.145	486.48	444 - 560 µg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.008	26.49	0.008	26.84	20 - 122 µg/dl
Sample-2	0.011	36.42	0.011	36.91	
Sample-3	0.014	46.35	0.015	50.33	
Sample-4	0.020	66.22	0.019	63.75	
Sample-5	0.022	72.84	0.021	70.46	
Linearity					
1500 µg/dl	0.414	1370.00 (91.41%)	0.407	1368.00 (91.01%)	± 10%

7.0 Conclusions

- The Ammonia reagent showed an excellent Coefficient of Correlation (“r”) using Diasys as Reference.
- Ammonia showed values of “r” was 0.997 displaying the highest degree of correlation between the two sets of reagents.
- The Ammonia reagent showed an excellent coefficient of Variation (CV %).
- The CV % was found to be in the range of 0.18% and 2.51% displaying a very high level of precision and repeatability.
- The Ammonia reagent showed an excellent performance even under stressful conditions. The reagents were found to be stable at 37°C for 21 days.

The Ammonia reagent was thus concluded to be Accurate, Precise and Stable, while using clinical normal and abnormal samples and 3rd Party controls (Level-1 and Level-2).

Bilirubin T & D

CLINICAL EVIDENCE EVALUATION REPORT

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1.0 Details of Reagents

Type of Reagents developed	Liquid Clinical Chemistry Reagents
Instrument Model	Biochemistry Semi-automated analyzer (BTS-350)
Reference Reagents	Reference Reagents

2.0 Coefficient of Correlation Studies: Accuracy study

- I. The objective was to determine the correlation between the results obtained with the Clinical Chemistry reagents of Vanguard Diagnostics and the benchmarked Clinical Chemistry reagents.
- II. The Coefficient of Correlation ("r") was calculated for Bilirubin T & D kit.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x (x̄)
 - 3 Mean y (ȳ)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of "r"
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, x_i ($x_1, x_2, \dots, x_n$) are the x values and y_i are the y values.

2.1 Coefficient of Correlation (“r”): Bilirubin Total

X AXIS = Reference Reagent.

Y AXIS = Bilirubin Total kit from Vanguard Diagnostics (P) Ltd.

$$“r” = 0.998$$

Sample size: 20

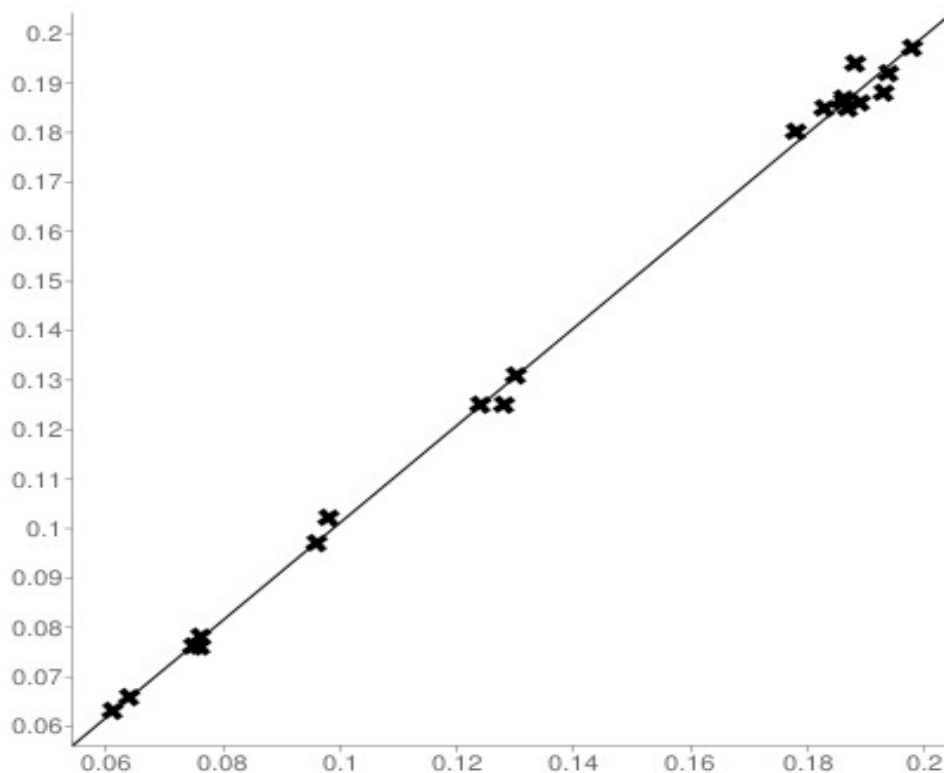
Mean x (x): 0.1405

Mean y (y): 0.14095

Intercept (a): 0.002835350959603

Slope (b): 0.98302241309891

Regression line equation: $y=0.002835350959603+0.98302241309891x$



2.2 Coefficient of Correlation (“r”): Bilirubin Direct

X AXIS = Reference Reagent.

Y AXIS = Bilirubin Direct kit from Vanguard Diagnostics (P) Ltd.

$$“r” = 0.999$$

Sample size: 20

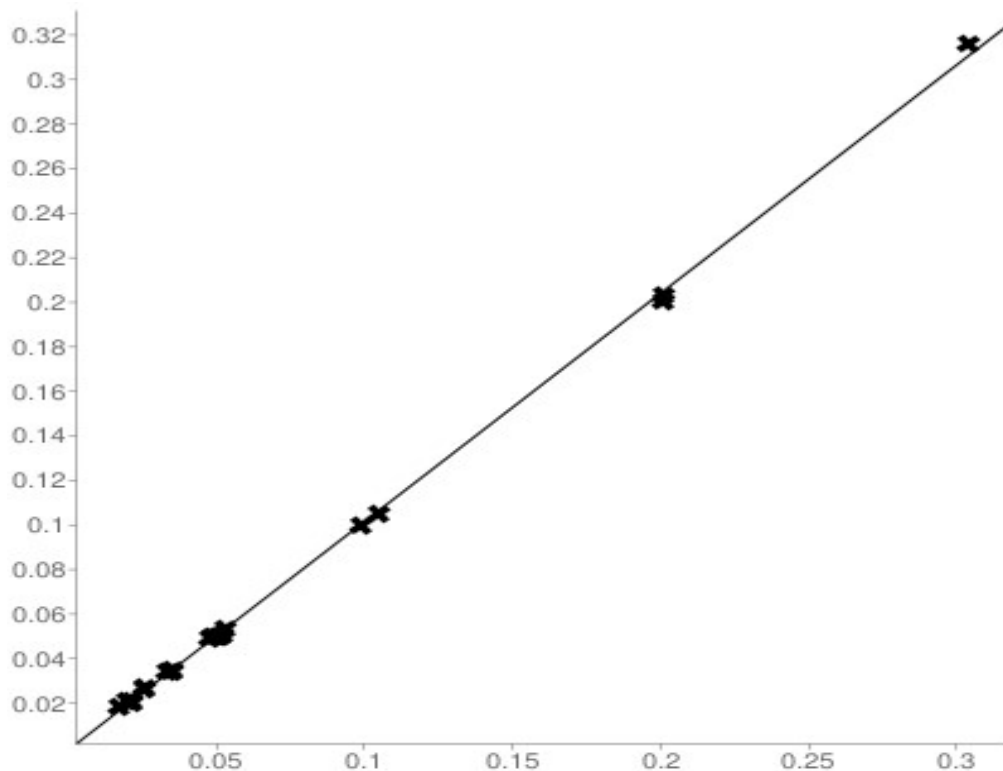
Mean x (x̄): 0.07235

Mean y (ȳ): 0.07315

Intercept (a): -0.0010387201819775

Slope (b): 1.0254142388663

Regression line equation: $y = 1.0254142388663x - 0.0010387201819775$



3.0 Comparative evaluation report: Bilirubin T & D.

3.1 Total Bilirubin Comparison.

S. No.	Test	Vanguard Total Bilirubin Kit		Reference Kit		%
		Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
	Factor		25.00		25.00	
01	Sample 1	0.007	0.178	0.007	0.180	98.811
02	Sample 2	0.007	0.186	0.007	0.187	99.843
03	Sample 3	0.004	0.098	0.004	0.102	96.190
04	Sample 4	0.002	0.061	0.003	0.063	97.546
05	Sample 5	0.003	0.075	0.003	0.076	98.369
06	Sample 6	0.007	0.183	0.007	0.185	98.757
07	Sample 7	0.003	0.076	0.003	0.076	100.178
08	Sample 8	0.008	0.194	0.008	0.192	101.207
09	Sample 9	0.005	0.130	0.005	0.131	99.257
10	Sample 10	0.008	0.188	0.008	0.194	96.588
11	Sample 11	0.007	0.186	0.007	0.186	99.945
12	Sample 12	0.005	0.124	0.005	0.125	98.762
13	Sample 13	0.007	0.187	0.007	0.185	100.692
14	Sample 14	0.008	0.189	0.007	0.186	101.543
15	Sample 15	0.005	0.128	0.005	0.125	102.148
16	Sample 16	0.004	0.096	0.004	0.097	99.199
17	Sample 17	0.008	0.193	0.008	0.188	102.827
18	Sample 18	0.003	0.064	0.003	0.066	98.342
19	Sample 19	0.003	0.076	0.003	0.078	97.551
20	Sample 20	0.008	0.198	0.008	0.197	100.457

3.2 Direct Bilirubin Comparison.

S. No.	Test	Vanguard Direct Bilirubin Kit		Reference Kit		%
		Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
	Factor		13.5		13.5	
01	Sample 1	0.004	0.048	0.004	0.049	98.81
02	Sample 2	0.015	0.201	0.015	0.203	99.01
03	Sample 3	0.002	0.026	0.002	0.027	96.19
04	Sample 4	0.007	0.099	0.007	0.100	99.19
05	Sample 5	0.002	0.020	0.002	0.021	98.37
06	Sample 6	0.004	0.049	0.004	0.050	98.76
07	Sample 7	0.002	0.021	0.002	0.020	100.18
08	Sample 8	0.008	0.105	0.008	0.105	99.49
09	Sample 9	0.003	0.035	0.003	0.035	99.26
10	Sample 10	0.023	0.304	0.023	0.316	96.05
11	Sample 11	0.004	0.050	0.004	0.050	99.94
12	Sample 12	0.002	0.033	0.003	0.034	98.76
13	Sample 13	0.015	0.201	0.015	0.200	100.69
14	Sample 14	0.004	0.051	0.004	0.050	101.54
15	Sample 15	0.003	0.035	0.003	0.034	102.15
16	Sample 16	0.002	0.026	0.002	0.026	99.20
17	Sample 17	0.004	0.052	0.004	0.051	102.83
18	Sample 18	0.001	0.017	0.001	0.018	98.34
19	Sample 19	0.002	0.021	0.002	0.021	97.55
20	Sample 20	0.004	0.053	0.004	0.053	100.46

4.0 Coefficient of Variation: Repeatability/Reproducibility/Precision study

- Biorad Controls Normal and Abnormal were used to calculate “Within Run” and “Between Run” Precision.
- The Biorad Controls were tested in 25 replicates to study Precision.
- Coefficient of Variation (CV %) was calculated.
- **Acceptance criteria = NMT 10%.**

4.1 Precision “Within Run” and “Between Run”

4.1.1 Bio-Rad Control (Level-1)

4.1.2 Total Bilirubin

Within Run				Run to Run			
S.No.	Test	Abs.	Conc. (mg/dl)	S.No.	Test	Abs.	Conc. (mg/dl)
	Factor	-	25		Factor	-	25
01	Biorad 1	0.041	1.02	1	Biorad 1	0.039	0.98
02	Biorad 1	0.040	1.00	2	Biorad 1	0.040	1.01
03	Biorad 1	0.040	0.99	3	Biorad 1	0.040	1.01
04	Biorad 1	0.039	0.99	4	Biorad 1	0.039	0.98
05	Biorad 1	0.040	0.99	5	Biorad 1	0.040	1.00
06	Biorad 1	0.040	0.99	6	Biorad 1	0.041	1.02
07	Biorad 1	0.040	0.99	7	Biorad 1	0.041	1.02
08	Biorad 1	0.041	1.01	8	Biorad 1	0.041	1.02
09	Biorad 1	0.040	1.00	9	Biorad 1	0.041	1.03
10	Biorad 1	0.040	1.01	10	Biorad 1	0.041	1.04
11	Biorad 1	0.040	1.00	11	Biorad 1	0.040	1.01
12	Biorad 1	0.041	1.01	12	Biorad 1	0.040	1.00
13	Biorad 1	0.041	1.01	13	Biorad 1	0.040	0.99
14	Biorad 1	0.040	1.01	14	Biorad 1	0.040	1.00
15	Biorad 1	0.040	1.01	15	Biorad 1	0.041	1.02
16	Biorad 1	0.040	1.01	16	Biorad 1	0.041	1.03
17	Biorad 1	0.040	1.00	17	Biorad 1	0.042	1.04
18	Biorad 1	0.040	1.01	18	Biorad 1	0.041	1.03
19	Biorad 1	0.040	1.00	19	Biorad 1	0.041	1.03
20	Biorad 1	0.040	1.00	20	Biorad 1	0.041	1.03
Mean			1.00	Mean			1.01
S.D.			0.01	S.D.			0.02
CV			0.01	CV			0.02
CV%			0.85	CV%			1.72

4.2 Precision “Within Run” and “Between Run”

4.2.1 Bio-Rad Control (Level-2)

4.2.2 Total Bilirubin

Within Run				Run to Run			
S.No.	Test	Abs.	Conc. (mg/dl)	S.No.	Test	Abs.	Conc. (mg/dl)
	Factor	-	25		Factor	-	25
01	Biorad 2	0.199	4.96	1	Biorad 2	0.199	4.98
02	Biorad 2	0.183	4.58	2	Biorad 2	0.197	4.93
03	Biorad 2	0.199	4.96	3	Biorad 2	0.199	4.98
04	Biorad 2	0.199	4.97	4	Biorad 2	0.188	4.71
05	Biorad 2	0.199	4.96	5	Biorad 2	0.190	4.75
06	Biorad 2	0.196	4.91	6	Biorad 2	0.190	4.76
07	Biorad 2	0.199	4.97	7	Biorad 2	0.192	4.81
08	Biorad 2	0.199	4.96	8	Biorad 2	0.193	4.81
09	Biorad 2	0.198	4.95	9	Biorad 2	0.195	4.87
10	Biorad 2	0.199	4.96	10	Biorad 2	0.196	4.90
11	Biorad 2	0.199	4.97	11	Biorad 2	0.195	4.88
12	Biorad 2	0.199	4.97	12	Biorad 2	0.197	4.92
13	Biorad 2	0.199	4.97	13	Biorad 2	0.199	4.98
14	Biorad 2	0.204	5.09	14	Biorad 2	0.195	4.87
15	Biorad 2	0.199	4.97	15	Biorad 2	0.199	4.98
16	Biorad 2	0.199	4.96	16	Biorad 2	0.197	4.92
17	Biorad 2	0.199	4.97	17	Biorad 2	0.197	4.93
18	Biorad 2	0.199	4.97	18	Biorad 2	0.199	4.98
19	Biorad 2	0.199	4.97	19	Biorad 2	0.191	4.78
20	Biorad 2	0.199	4.97	20	Biorad 2	0.193	4.81
Mean			4.95	Mean			4.88
S.D.			0.09	S.D.			0.09
CV			0.019	CV			0.018
CV%			1.88	CV%			1.79

4.3 Precision “Within Run” and “Between Run”

4.3.1 Bio-Rad Control (Level-1)

4.3.2 Direct Bilirubin

Within Run				Run to Run			
S.No.	Test	Abs.	Conc. (mg/dl)	S.No.	Test	Abs.	Conc. (mg/dl)
	Factor	-	13.5		Factor	-	13.5
01	Biorad 1	0.023	0.305	1	Biorad 1	0.022	0.292
02	Biorad 1	0.022	0.300	2	Biorad 1	0.021	0.285
03	Biorad 1	0.022	0.298	3	Biorad 1	0.022	0.299
04	Biorad 1	0.022	0.296	4	Biorad 1	0.022	0.303
05	Biorad 1	0.022	0.297	5	Biorad 1	0.022	0.297
06	Biorad 1	0.022	0.298	6	Biorad 1	0.021	0.288
07	Biorad 1	0.022	0.298	7	Biorad 1	0.021	0.288
08	Biorad 1	0.023	0.304	8	Biorad 1	0.021	0.289
09	Biorad 1	0.022	0.301	9	Biorad 1	0.021	0.281
10	Biorad 1	0.022	0.302	10	Biorad 1	0.022	0.294
11	Biorad 1	0.022	0.301	11	Biorad 1	0.022	0.299
12	Biorad 1	0.023	0.304	12	Biorad 1	0.022	0.297
13	Biorad 1	0.023	0.304	13	Biorad 1	0.022	0.299
14	Biorad 1	0.022	0.303	14	Biorad 1	0.022	0.298
15	Biorad 1	0.022	0.303	15	Biorad 1	0.021	0.290
16	Biorad 1	0.022	0.302	16	Biorad 1	0.022	0.296
17	Biorad 1	0.022	0.301	17	Biorad 1	0.022	0.294
18	Biorad 1	0.022	0.302	18	Biorad 1	0.022	0.292
19	Biorad 1	0.022	0.300	19	Biorad 1	0.022	0.291
20	Biorad 1	0.022	0.300	20	Biorad 1	0.022	0.292
Mean			0.301	Mean			0.293
S.D.			0.003	S.D.			0.005
CV			0.008	CV			0.019
CV%			0.850	CV%			1.858

4.4 Precision “Within Run” and “Between Run”

4.4.1 Bio-Rad Control (Level-2)

4.4.2 Direct Bilirubin

Within Run				Run to Run			
S.No.	Test	Abs.	Conc. (mg/dl)	S.No.	Test	Abs.	Conc. (mg/dl)
	Factor	-	13.5		Factor	-	13.5
01	Biorad 2	0.090	1.218	1	Biorad 2	0.091	1.222
02	Biorad 2	0.093	1.252	2	Biorad 2	0.090	1.209
03	Biorad 2	0.090	1.218	3	Biorad 2	0.091	1.223
04	Biorad 2	0.090	1.220	4	Biorad 2	0.086	1.155
05	Biorad 2	0.090	1.218	5	Biorad 2	0.086	1.167
06	Biorad 2	0.093	1.252	6	Biorad 2	0.087	1.168
07	Biorad 2	0.090	1.220	7	Biorad 2	0.087	1.180
08	Biorad 2	0.090	1.219	8	Biorad 2	0.088	1.181
09	Biorad 2	0.090	1.214	9	Biorad 2	0.089	1.196
10	Biorad 2	0.090	1.218	10	Biorad 2	0.089	1.204
11	Biorad 2	0.090	1.220	11	Biorad 2	0.089	1.198
12	Biorad 2	0.090	1.219	12	Biorad 2	0.089	1.208
13	Biorad 2	0.090	1.220	13	Biorad 2	0.091	1.224
14	Biorad 2	0.093	1.250	14	Biorad 2	0.089	1.196
15	Biorad 2	0.090	1.220	15	Biorad 2	0.091	1.222
16	Biorad 2	0.090	1.219	16	Biorad 2	0.089	1.208
17	Biorad 2	0.090	1.219	17	Biorad 2	0.090	1.209
18	Biorad 2	0.090	1.220	18	Biorad 2	0.091	1.223
19	Biorad 2	0.090	1.220	19	Biorad 2	0.087	1.173
20	Biorad 2	0.090	1.220	20	Biorad 2	0.088	1.182
Mean			1.224	Mean			1.197
S.D.			0.012	S.D.			0.021
CV			0.010	CV			0.018
CV%			0.978	CV%			1.788

5.0 Performance Evaluation Report of Bilirubin T & D

Time interval= Day-0

Storage Temperature = 2°C – 8°C

Total Bilirubin					
Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
FACTOR	-	25	-	25	-
Controls					
Biorad 1	0.040	1.00	0.040	1.01	0.712 - 1.36 mg/dl
Biorad 2	0.199	4.96	0.199	4.98	3.66 - 5.21 mg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.007	0.183	0.007	0.185	0 - 1.1 mg/dl
Sample-2	0.003	0.076	0.003	0.076	
Sample-3	0.008	0.194	0.008	0.192	
Sample-4	0.005	0.130	0.005	0.131	
Sample-5	0.008	0.188	0.008	0.194	
Linearity					
20 (mg/dl)	0.792	19.8 (99%)	0.796	19.9 (99.5%)	± 10%
Direct Bilirubin					
Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
FACTOR	-	13.5	-	13.5	-
Controls					
Biorad 1	0.023	0.305	0.022	0.303	0.220 - 0.392 mg/dl
Biorad 2	0.090	1.218	0.091	1.222	0.945 - 1.48 mg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.007	0.099	0.007	0.100	0 - 0.32 mg/dl
Sample-2	0.002	0.020	0.002	0.021	
Sample-3	0.004	0.049	0.004	0.050	
Sample-4	0.002	0.021	0.002	0.020	
Sample-5	0.008	0.105	0.008	0.105	
Linearity					
20 (mg/dl)	1.466	19.8 (99%)	1.474	19.9 (99.5%)	± 10%

6.0 Accelerated Stability Studies: Summary

- Stability studies were conducted at 37°C till 21 days.
- Stability studies were conducted using Bio-Rad Control (Level-1 & Level-2).
- It was not possible to use the “same” samples in the study due to the very limited stability of samples.
- The values obtained with Bilirubin T & D were found to be in the ranges specified for the Bio-Rad controls till 21 days at 37°C and found to be comparable with the reference reagent.
- Bilirubin T & D reagent was therefore found to be stable at 37°C for 21 days.
- This data has been extrapolated to conclude that Bilirubin T & D reagent will be stable for 18 months under the recommended temperature conditions of 2°C- 8°C.

6.1 Accelerated stability study: Bilirubin T & D

Time interval= Day-7

Storage Temperature= 37°C

Total Bilirubin					
Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
FACTOR	-	25	-	25	-
Controls					
Biorad 1	0.039	0.98	0.040	1.00	0.712 - 1.36 mg/dl
Biorad 2	0.198	4.94	0.198	4.96	3.66 - 5.21 mg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.008	0.193	0.008	0.193	0 - 1.1 mg/dl
Sample-2	0.004	0.100	0.004	0.101	
Sample-3	0.007	0.180	0.007	0.179	
Sample-4	0.007	0.186	0.007	0.186	
Sample-5	0.005	0.124	0.005	0.125	
Linearity					
20 (mg/dl)	0.776	19.4 (97%)	0.778	19.45 (97.2%)	± 10%
Direct Bilirubin					
Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
FACTOR	-	13.5	-	13.5	-
Controls					
Biorad 1	0.022	0.300	0.022	0.301	0.220 - 0.392 mg/dl
Biorad 2	0.090	1.220	0.090	1.218	0.945 - 1.48 mg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.023	0.304	0.023	0.316	0 - 0.32 mg/dl
Sample-2	0.004	0.050	0.004	0.050	
Sample-3	0.002	0.033	0.003	0.034	
Sample-4	0.015	0.201	0.015	0.200	
Sample-5	0.004	0.051	0.004	0.050	
Linearity					
20 (mg/dl)	1.437	19.4 (97%)	1.44	19.45 (97.2%)	± 10%

6.2 Accelerated stability study: Bilirubin T & D

Time interval= Day-14

Storage Temperature= 37°C

Total Bilirubin					
Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
FACTOR	-	25	-	25	-
Controls					
Biorad 1	0.038	0.95	0.038	0.94	0.712 - 1.36 mg/dl
Biorad 2	0.197	4.91	0.196	4.91	3.66 - 5.21 mg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.004	0.096	0.004	0.097	0 - 1.1 mg/dl
Sample-2	0.008	0.193	0.008	0.195	
Sample-3	0.003	0.064	0.003	0.063	
Sample-4	0.003	0.076	0.003	0.078	
Sample-5	0.008	0.198	0.008	0.197	
Linearity					
20 (mg/dl)	0.764	19.1 (95.5%)	0.76	19.0 (95%)	± 10%
Direct Bilirubin					
Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
FACTOR	-	13.5	-	13.5	-
Controls					
Biorad 1	0.022	0.298	0.022	0.298	0.220 - 0.392 mg/dl
Biorad 2	0.093	1.252	0.093	1.250	0.945 - 1.48 mg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.002	0.026	0.002	0.026	0 - 0.32 mg/dl
Sample-2	0.004	0.052	0.004	0.051	
Sample-3	0.001	0.017	0.001	0.018	
Sample-4	0.002	0.021	0.002	0.021	
Sample-5	0.004	0.053	0.004	0.053	
Linearity					
20 (mg/dl)	1.414	19.1 (95.5%)	1.407	19.0 (95%)	± 10%

6.3 Accelerated stability study: Bilirubin T & D

Time interval= Day-21

Storage Temperature= 37°C

Total Bilirubin					
Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
FACTOR	-	25	-	25	-
Controls					
Biorad 1	0.037	0.93	0.036	0.91	0.712 - 1.36 mg/dl
Biorad 2	0.195	4.86	0.195	4.88	3.66 - 5.21 mg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.004	0.098	0.004	0.100	0 - 1.1 mg/dl
Sample-2	0.002	0.061	0.003	0.063	
Sample-3	0.003	0.075	0.003	0.076	
Sample-4	0.007	0.183	0.007	0.185	
Sample-5	0.003	0.076	0.003	0.076	
Linearity					
20 (mg/dl)	0.748	18.7 (93.5%)	0.756	18.9 (94.5%)	± 10%
Direct Bilirubin					
Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
FACTOR	-	13.5	-	13.5	-
Controls					
Biorad 1	0.022	0.297	0.022	0.297	0.220 - 0.392 mg/dl
Biorad 2	0.086	1.155	0.086	1.167	0.945 - 1.48 mg/dl
Known normal/ abnormal Serum samples					
Sample-1	0.004	0.048	0.004	0.049	0 - 0.32 mg/dl
Sample-2	0.015	0.201	0.015	0.203	
Sample-3	0.002	0.026	0.002	0.027	
Sample-4	0.007	0.099	0.007	0.100	
Sample-5	0.002	0.020	0.002	0.021	
Linearity					
20 (mg/dl)	1.385	18.7 (93.5%)	1.4	18.9 (94.5%)	± 10%

7.0 Conclusions

- The Bilirubin T & D reagent showed an excellent Coefficient of Correlation (“r”) using as Reference.
- Bilirubin T & D showed values of “r” was 0.998 displaying the highest degree of correlation between the two sets of reagents.
- The Bilirubin T & D reagent showed an excellent coefficient of Variation (CV %).
- The CV % was found to be in the range of 0.85% and 1.88% displaying a very high level of precision and repeatability.
- The Bilirubin T & D reagent showed an excellent performance even under stressful conditions. The reagents were found to be stable at 37°C for 21 days.

The Bilirubin T & D reagent was thus concluded to be Accurate, Precise and Stable, while using clinical normal and abnormal samples and 3rd Party controls (Level-1 and Level-2).

Phosphorus

CLINICAL EVIDENCE EVALUATION REPORT

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1.0 Details of Reagents

Type of Reagents developed	Liquid Clinical Chemistry Reagents
Instrument Model	Biochemistry Semi-automated analyzer (BTS-350)
Reference Reagents	Reference Reagents

2.0 Coefficient of Correlation Studies: Accuracy study

- I. The objective was to determine the correlation between the results obtained with the Clinical Chemistry reagents of Vanguard Diagnostics and the benchmarked Clinical Chemistry reagents.
- II. The Coefficient of Correlation ("r") was calculated for Phosphorus kit.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x (x̄)
 - 3 Mean y (ȳ)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of "r"
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, xi (x1, x2,...,xn) are the x values and yi are the y values.

2.1 Coefficient of Correlation (“r”): Phosphorus

X AXIS = Reference Reagent.

Y AXIS = Phosphorus kit from Vanguard Diagnostics (P) Ltd.

$$“r” = 0.999$$

Sample size: 20

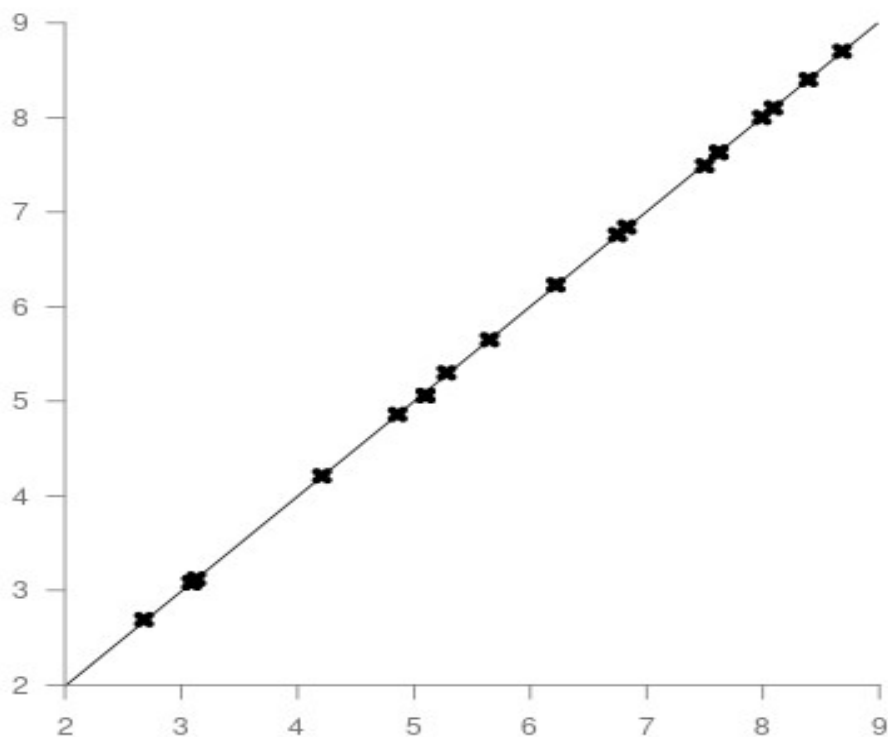
Mean x (x̄): 5.894

Mean y (ȳ): 5.8945

Intercept (a): -0.021053452411503

Slope (b): 1.0036568463542

Regression line equation: $y = 1.0036568463542x - 0.021053452411503$



3.0 Comparative evaluation report: Phosphorus

Vanguard Phosphorus Kit				Reference Kit		
S.No.	Test	Abs.	Conc (mg/dl)	Abs.	Conc (mg/dl)	%
	Standard (5 mg/dl)	0.253	-	0.254	-	
01	Sample 1	0.410	8.10	0.411	8.09	100.15
02	Sample 2	0.213	4.21	0.214	4.21	99.93
03	Sample 3	0.315	6.23	0.316	6.22	100.08
04	Sample 4	0.440	8.70	0.441	8.68	100.17
05	Sample 5	0.156	3.08	0.157	3.09	99.76
06	Sample 6	0.256	5.06	0.259	5.10	99.23
07	Sample 7	0.342	6.76	0.343	6.75	100.10
08	Sample 8	0.156	3.08	0.157	3.09	99.76
09	Sample 9	0.425	8.40	0.426	8.39	100.16
10	Sample 10	0.405	8.00	0.406	7.99	100.15
11	Sample 11	0.386	7.63	0.387	7.62	100.14
12	Sample 12	0.256	5.06	0.259	5.10	99.23
13	Sample 13	0.286	5.65	0.287	5.65	100.05
14	Sample 14	0.246	4.86	0.247	4.86	99.99
15	Sample 15	0.379	7.49	0.381	7.50	99.87
16	Sample 16	0.268	5.30	0.268	5.28	100.40
17	Sample 17	0.158	3.12	0.159	3.13	99.76
18	Sample 18	0.136	2.69	0.136	2.68	100.40
19	Sample 19	0.346	6.84	0.347	6.83	100.11
20	Sample 20	0.386	7.63	0.387	7.62	100.14

4.0 Coefficient of Variation: Repeatability/Reproducibility/Precision study

- Biorad Controls Normal and Abnormal were used to calculate “Within Run” and “Between Run” Precision.
- The Biorad Controls were tested in 25 replicates to study Precision.
- Coefficient of Variation (CV %) was calculated.
- **Acceptance criteria = NMT 10%.**

4.1 Precision “Within Run” and “Between Run”

4.1.1 Bio-Rad Control (Level-1)

Within Run				Run to Run			
S.No.	Test	Abs.	Conc. (mg/dl)	S.No.	Test	Abs.	Conc. (mg/dl)
	Standard (5 mg/dl)	0.253			Standard (5 mg/dl)	0.258	
01	Bio-Rad 1	0.192	3.79	01	Bio-Rad 1	0.194	3.76
02	Bio-Rad 1	0.192	3.79	02	Bio-Rad 1	0.193	3.74
03	Bio-Rad 1	0.193	3.81	03	Bio-Rad 1	0.192	3.72
04	Bio-Rad 1	0.192	3.79	04	Bio-Rad 1	0.194	3.76
05	Bio-Rad 1	0.194	3.83	05	Bio-Rad 1	0.192	3.72
06	Bio-Rad 1	0.192	3.79	06	Bio-Rad 1	0.193	3.74
07	Bio-Rad 1	0.193	3.81	07	Bio-Rad 1	0.193	3.74
08	Bio-Rad 1	0.194	3.83	08	Bio-Rad 1	0.193	3.74
09	Bio-Rad 1	0.192	3.79	09	Bio-Rad 1	0.191	3.70
10	Bio-Rad 1	0.193	3.81	10	Bio-Rad 1	0.192	3.72
11	Bio-Rad 1	0.194	3.83	11	Bio-Rad 1	0.193	3.74
12	Bio-Rad 1	0.192	3.79	12	Bio-Rad 1	0.194	3.76
13	Bio-Rad 1	0.193	3.81	13	Bio-Rad 1	0.192	3.72
14	Bio-Rad 1	0.194	3.83	14	Bio-Rad 1	0.193	3.74
15	Bio-Rad 1	0.193	3.81	15	Bio-Rad 1	0.194	3.76
16	Bio-Rad 1	0.192	3.79	16	Bio-Rad 1	0.192	3.72
17	Bio-Rad 1	0.192	3.79	17	Bio-Rad 1	0.194	3.76
18	Bio-Rad 1	0.192	3.79	18	Bio-Rad 1	0.194	3.76
19	Bio-Rad 1	0.193	3.81	19	Bio-Rad 1	0.193	3.74
20	Bio-Rad 1	0.194	3.83	20	Bio-Rad 1	0.194	3.76
21	Bio-Rad 1	0.192	3.79	21	Bio-Rad 1	0.192	3.72
22	Bio-Rad 1	0.192	3.79	22	Bio-Rad 1	0.193	3.74
23	Bio-Rad 1	0.193	3.81	23	Bio-Rad 1	0.192	3.72
24	Bio-Rad 1	0.194	3.83	24	Bio-Rad 1	0.193	3.74
25	Bio-Rad 1	0.192	3.79	25	Bio-Rad 1	0.194	3.76
Mean			3.81	Mean			3.74
S.D.			0.02	S.D.			0.02
CV			0.00	CV			0.00
CV%			0.43	CV%			0.46

4.2 Precision “Within Run” and “Between Run”

4.2.1 Bio-Rad Control (Level-2)

Within Run				Run to Run			
S.No.	Test	Abs.	Conc. (mg/dl)	S.No.	Test	Abs.	Conc. (mg/dl)
	Standard (5 mg/dl)	0.253			Standard (5 mg/dl)	0.258	
01	Bio-Rad 2	0.362	7.15	01	Bio-Rad 2	0.363	7.03
02	Bio-Rad 2	0.363	7.17	02	Bio-Rad 2	0.365	7.07
03	Bio-Rad 2	0.362	7.15	03	Bio-Rad 2	0.366	7.09
04	Bio-Rad 2	0.364	7.19	04	Bio-Rad 2	0.362	7.02
05	Bio-Rad 2	0.363	7.17	05	Bio-Rad 2	0.363	7.03
06	Bio-Rad 2	0.362	7.15	06	Bio-Rad 2	0.364	7.05
07	Bio-Rad 2	0.364	7.19	07	Bio-Rad 2	0.365	7.07
08	Bio-Rad 2	0.363	7.17	08	Bio-Rad 2	0.363	7.03
09	Bio-Rad 2	0.362	7.15	09	Bio-Rad 2	0.364	7.05
10	Bio-Rad 2	0.364	7.19	10	Bio-Rad 2	0.363	7.03
11	Bio-Rad 2	0.363	7.17	11	Bio-Rad 2	0.365	7.07
12	Bio-Rad 2	0.364	7.19	12	Bio-Rad 2	0.364	7.05
13	Bio-Rad 2	0.363	7.17	13	Bio-Rad 2	0.363	7.03
14	Bio-Rad 2	0.364	7.19	14	Bio-Rad 2	0.364	7.05
15	Bio-Rad 2	0.363	7.17	15	Bio-Rad 2	0.365	7.07
16	Bio-Rad 2	0.362	7.15	16	Bio-Rad 2	0.363	7.03
17	Bio-Rad 2	0.364	7.19	17	Bio-Rad 2	0.364	7.05
18	Bio-Rad 2	0.363	7.17	18	Bio-Rad 2	0.365	7.07
19	Bio-Rad 2	0.362	7.15	19	Bio-Rad 2	0.363	7.03
20	Bio-Rad 2	0.364	7.19	20	Bio-Rad 2	0.364	7.05
21	Bio-Rad 2	0.363	7.17	21	Bio-Rad 2	0.362	7.02
22	Bio-Rad 2	0.364	7.19	22	Bio-Rad 2	0.363	7.03
23	Bio-Rad 2	0.362	7.15	23	Bio-Rad 2	0.364	7.05
24	Bio-Rad 2	0.363	7.17	24	Bio-Rad 2	0.363	7.03
25	Bio-Rad 2	0.364	7.19	25	Bio-Rad 2	0.365	7.07
Mean			7.18	Mean			7.05
S.D.			0.02	S.D.			0.02
CV			0.00	CV			0.00
CV%			0.22	CV%			0.29

5.0 Performance Evaluation Report of Phosphorus

Time interval= Day-0

Storage Temperature = 2°C – 8°C

Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
Reagent Blank	0.072		0.082		
Standard	0.253	5 mg/dl	0.256	5 mg/dl	-
Controls					
Biorad- 1	0.192	3.79	0.196	3.83	2.97 - 3.92 mg/dl
Biorad- 2	0.362	7.15	0.359	7.01	6.45 - 8.23 mg/dl
Known normal/abnormal Serum samples					
Sample-1	0.412	8.14	0.409	7.99	2.3 - 9.0 mg/dl
Sample-2	0.408	8.06	0.406	7.93	
Sample-3	0.421	8.32	0.419	8.18	
Sample-4	0.402	7.94	0.399	7.79	
Sample-5	0.436	8.62	0.432	8.44	
Linearity					
15 mg/dl	0.725	14.33 (95.53%)	0.735	14.53 (96.86%)	± 10%

6.0 Accelerated Stability Studies: Summary

- Stability studies were conducted at 37°C till 14 days.
- Stability studies were conducted using Bio-Rad Control (Level-1 & Level-2).
- It was not possible to use the “same” samples in the study due to the very limited stability of samples.
- The values obtained with Phosphorus were found to be in the ranges specified for the Bio-Rad controls till 14 days at 37°C and found to be comparable with the reference reagent.
- Phosphorus reagent was therefore found to be stable at 37°C for 14 days.
- This data has been extrapolated to conclude that Phosphorus reagent will be stable for 15 months under the recommended temperature conditions of 2°C- 8°C.

6.1 Accelerated stability study: Phosphorus

Time interval= Day-7

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
Reagent Blank	0.086		0.088		
Standard	0.262	5 mg/dl	0.268	5 mg/dl	-
Controls					
Biorad- 1	0.189	3.61	0.196	3.66	2.97 - 3.92 mg/dl
Biorad- 2	0.372	7.10	0.376	7.01	6.45 - 8.23 mg/dl
Known normal/abnormal Serum samples					
Sample-1	0.412	7.86	0.409	7.63	2.3 - 9.0 mg/dl
Sample-2	0.408	7.79	0.411	7.67	
Sample-3	0.421	8.03	0.425	7.93	
Sample-4	0.402	7.67	0.399	7.44	
Sample-5	0.436	8.32	0.438	8.17	
Linearity					
15 mg/dl	0.756	14.43 (96.20%)	0.762	14.22 (94.80%)	± 10%

6.2 Accelerated stability study: Phosphorus

Time interval= Day-14

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
Reagent Blank	0.092		0.099		
Standard	0.259	5 mg/dl	0.256	5 mg/dl	-
Controls					
Biorad- 1	0.198	3.82	0.192	3.75	2.97 - 3.92 mg/dl
Biorad- 2	0.376	7.26	0.378	7.38	6.45 - 8.23 mg/dl
Known normal/abnormal Serum samples					
Sample-1	0.415	8.01	0.419	8.18	2.3 - 9.0 mg/dl
Sample-2	0.382	7.37	0.385	7.52	
Sample-3	0.425	8.20	0.429	8.38	
Sample-4	0.403	7.78	0.406	7.93	
Sample-5	0.395	7.63	0.402	7.85	
Linearity					
15 mg/dl	0.752	14.52 (96.80%)	0.742	14.49 (96.60%)	± 10%

7.0 Conclusions

- The Phosphorus reagent showed an excellent Coefficient of Correlation (“r”) using as Reference.
- Phosphorus showed values of “r” was 0.999 displaying the highest degree of correlation between the two sets of reagents.
- The Phosphorus reagent showed an excellent coefficient of Variation (CV %).
- The CV % was found to be in the range of 0.22% and 0.46% displaying a very high level of precision and repeatability.
- The Phosphorus reagent showed an excellent performance even under stressful conditions. The reagents were found to be stable at 37°C for 14 days.

The Phosphorus reagent was thus concluded to be Accurate, Precise and Stable, while using clinical normal and abnormal samples and 3rd Party controls (Level-1 and Level-2).

Magnesium

CLINICAL EVIDENCE EVALUATION REPORT

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1.0 Details of Reagents

Type of Reagents developed	Liquid Clinical Chemistry Reagents
Instrument Model	Biochemistry Semi-automated analyzer (BTS-350)
Reference Reagents	Reference Reagents

2.0 Coefficient of Correlation Studies: Accuracy study

- I. The objective was to determine the correlation between the results obtained with the Clinical Chemistry reagents of Vanguard Diagnostics and the benchmarked Clinical Chemistry reagent.
- II. The Coefficient of Correlation ("r") was calculated for Magnesium kit.
- III. The data has been presented in the form of:

- 1 Sample size
- 2 Mean x ($\bar{x}$)
- 3 Mean y ($\bar{y}$)
- 4 Intercept (a)
- 5 Slope (b)
- 6 Regression line equation
- 7 Value of "r"
- 8 Linear Regression Graph
- 9 Raw Data of values
- 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, x_i ($x_1, x_2, \dots, x_n$) are the x values and y_i are the y values.

2.1 Coefficient of Correlation (“r”): Magnesium

X AXIS = Reference Reagent.

Y AXIS = Magnesium kit from Vanguard Diagnostics (P) Ltd.

$$“r” = 0.991$$

Sample size: 20

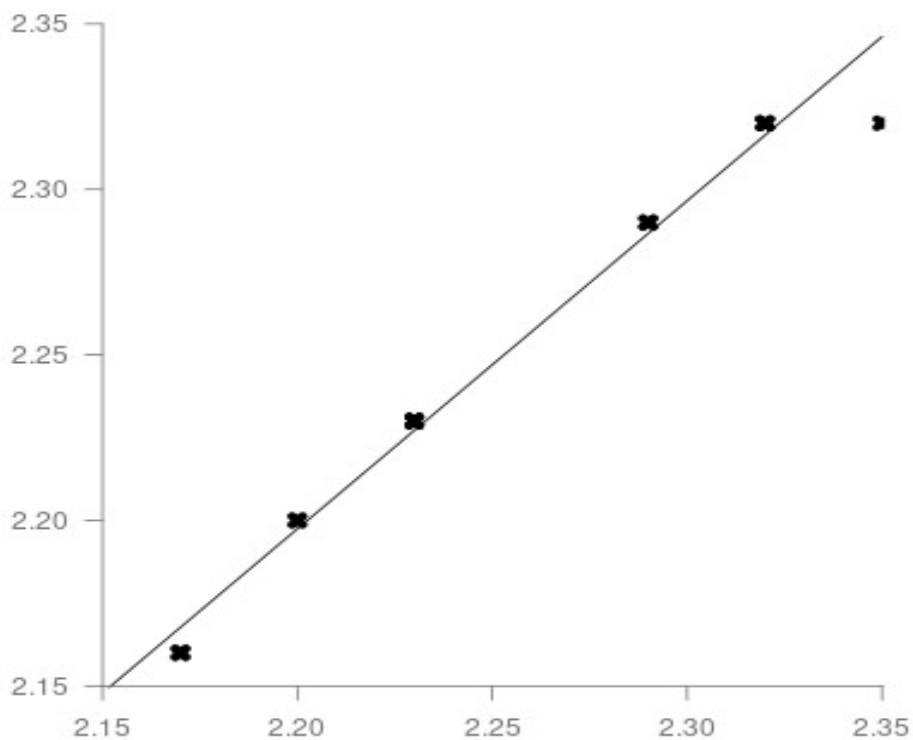
Mean x (x̄): 2.251

Mean y (ȳ): 2.248

Intercept (a): 0.016803519061606

Slope (b): 0.99120234604105

Regression line equation: $y = 0.016803519061606 + 0.99120234604105x$



3.0 Comparative evaluation report: Magnesium

Vanguard Phosphorus Kit				Reference Kit		
S.No.	Test	Abs.	Conc (mg/dl)	Abs.	Conc (mg/dl)	%
	Standard (2.5 mg/dl)	0.082	-	0.084	-	
01	Sample 1	0.071	2.16	0.073	2.17	99.63
02	Sample 2	0.072	2.20	0.074	2.20	99.67
03	Sample 3	0.073	2.23	0.075	2.23	99.71
04	Sample 4	0.071	2.16	0.073	2.17	99.63
05	Sample 5	0.073	2.23	0.075	2.23	99.71
06	Sample 6	0.073	2.23	0.075	2.23	99.71
07	Sample 7	0.076	2.32	0.078	2.32	99.81
08	Sample 8	0.075	2.29	0.077	2.29	99.78
09	Sample 9	0.076	2.32	0.079	2.35	98.55
10	Sample 10	0.073	2.23	0.075	2.23	99.71
11	Sample 11	0.071	2.16	0.073	2.17	99.63
12	Sample 12	0.072	2.20	0.074	2.20	99.67
13	Sample 13	0.073	2.23	0.075	2.23	99.71
14	Sample 14	0.076	2.32	0.078	2.32	99.81
15	Sample 15	0.075	2.29	0.077	2.29	99.78
16	Sample 16	0.076	2.32	0.078	2.32	99.81
17	Sample 17	0.073	2.23	0.075	2.23	99.71
18	Sample 18	0.075	2.29	0.077	2.29	99.78
19	Sample 19	0.076	2.32	0.078	2.32	99.81
20	Sample 20	0.073	2.23	0.075	2.23	99.71

4.0 Coefficient of Variation: Repeatability/Reproducibility/Precision study

- Biorad Controls Normal and Abnormal were used to calculate “Within Run” and “Between Run” Precision.
- The Biorad Controls were tested in 25 replicates to study Precision.
- Coefficient of Variation (CV %) was calculated.
- **Acceptance criteria = NMT 10%.**

4.1 Precision “Within Run” and “Between Run”

4.1.1 Bio-Rad Control (Level-1)

Within Run				Run to Run			
S.No.	Test	Abs.	Conc. (mg/dl)	S.No.	Test	Abs.	Conc. (mg/dl)
	Standard (2.5 mg/dl)	0.082			Standard (2.5 mg/dl)	0.084	
01	Bio-Rad 1	0.068	2.07	01	Bio-Rad 1	0.068	2.02
02	Bio-Rad 1	0.066	2.01	02	Bio-Rad 1	0.069	2.05
03	Bio-Rad 1	0.065	1.98	03	Bio-Rad 1	0.066	1.96
04	Bio-Rad 1	0.066	2.01	04	Bio-Rad 1	0.069	2.05
05	Bio-Rad 1	0.065	1.98	05	Bio-Rad 1	0.068	2.02
06	Bio-Rad 1	0.067	2.04	06	Bio-Rad 1	0.067	1.99
07	Bio-Rad 1	0.066	2.01	07	Bio-Rad 1	0.065	1.93
08	Bio-Rad 1	0.065	1.98	08	Bio-Rad 1	0.069	2.05
09	Bio-Rad 1	0.066	2.01	09	Bio-Rad 1	0.068	2.02
10	Bio-Rad 1	0.067	2.04	10	Bio-Rad 1	0.068	2.02
11	Bio-Rad 1	0.065	1.98	11	Bio-Rad 1	0.067	1.99
12	Bio-Rad 1	0.066	2.01	12	Bio-Rad 1	0.068	2.02
13	Bio-Rad 1	0.066	2.01	13	Bio-Rad 1	0.069	2.05
14	Bio-Rad 1	0.067	2.04	14	Bio-Rad 1	0.068	2.02
15	Bio-Rad 1	0.068	2.07	15	Bio-Rad 1	0.067	1.99
16	Bio-Rad 1	0.065	1.98	16	Bio-Rad 1	0.069	2.05
17	Bio-Rad 1	0.067	2.04	17	Bio-Rad 1	0.068	2.02
18	Bio-Rad 1	0.066	2.01	18	Bio-Rad 1	0.067	1.99
19	Bio-Rad 1	0.067	2.04	19	Bio-Rad 1	0.068	2.02
20	Bio-Rad 1	0.065	1.98	20	Bio-Rad 1	0.069	2.05
21	Bio-Rad 1	0.068	2.07	21	Bio-Rad 1	0.068	2.02
22	Bio-Rad 1	0.069	2.10	22	Bio-Rad 1	0.069	2.05
23	Bio-Rad 1	0.067	2.04	23	Bio-Rad 1	0.068	2.02
24	Bio-Rad 1	0.068	2.07	24	Bio-Rad 1	0.069	2.05
25	Bio-Rad 1	0.068	2.07	25	Bio-Rad 1	0.068	2.02
Mean			2.03	Mean			2.02
S.D.			0.04	S.D.			0.03
CV			0.02	CV			0.02
CV%			1.80	CV%			1.50

4.2 Precision “Within Run” and “Between Run”

4.2.1 Bio-Rad Control (Level-2)

Within Run				Run to Run			
S.No.	Test	Abs.	Conc. (mg/dl)	S.No.	Test	Abs.	Conc. (mg/dl)
	Standard (2.5 mg/dl)	0.082			Standard (2.5 mg/dl)	0.084	
01	Bio-Rad 2	0.162	4.94	01	Bio-Rad 2	0.165	4.91
02	Bio-Rad 2	0.163	4.97	02	Bio-Rad 2	0.164	4.88
03	Bio-Rad 2	0.162	4.94	03	Bio-Rad 2	0.163	4.85
04	Bio-Rad 2	0.164	5.00	04	Bio-Rad 2	0.165	4.91
05	Bio-Rad 2	0.162	4.94	05	Bio-Rad 2	0.164	4.88
06	Bio-Rad 2	0.162	4.94	06	Bio-Rad 2	0.165	4.91
07	Bio-Rad 2	0.164	5.00	07	Bio-Rad 2	0.166	4.94
08	Bio-Rad 2	0.163	4.97	08	Bio-Rad 2	0.163	4.85
09	Bio-Rad 2	0.162	4.94	09	Bio-Rad 2	0.165	4.91
10	Bio-Rad 2	0.163	4.97	10	Bio-Rad 2	0.164	4.88
11	Bio-Rad 2	0.164	5.00	11	Bio-Rad 2	0.163	4.85
12	Bio-Rad 2	0.163	4.97	12	Bio-Rad 2	0.165	4.91
13	Bio-Rad 2	0.162	4.94	13	Bio-Rad 2	0.163	4.85
14	Bio-Rad 2	0.163	4.97	14	Bio-Rad 2	0.164	4.88
15	Bio-Rad 2	0.164	5.00	15	Bio-Rad 2	0.165	4.91
16	Bio-Rad 2	0.163	4.97	16	Bio-Rad 2	0.163	4.85
17	Bio-Rad 2	0.163	4.97	17	Bio-Rad 2	0.164	4.88
18	Bio-Rad 2	0.164	5.00	18	Bio-Rad 2	0.164	4.88
19	Bio-Rad 2	0.162	4.94	19	Bio-Rad 2	0.166	4.94
20	Bio-Rad 2	0.163	4.97	20	Bio-Rad 2	0.165	4.91
21	Bio-Rad 2	0.164	5.00	21	Bio-Rad 2	0.166	4.94
22	Bio-Rad 2	0.162	4.94	22	Bio-Rad 2	0.164	4.88
23	Bio-Rad 2	0.163	4.97	23	Bio-Rad 2	0.163	4.85
24	Bio-Rad 2	0.164	5.00	24	Bio-Rad 2	0.164	4.88
25	Bio-Rad 2	0.163	4.97	25	Bio-Rad 2	0.165	4.91
Mean			4.97	Mean			4.89
S.D.			0.02	S.D.			0.03
CV			0.00	CV			0.01
CV%			0.48	CV%			0.60

5.0 Performance Evaluation Report of Magnesium

Time interval= Day-0

Storage Temperature = 2°C – 8°C

Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
Reagent Blank	0.697		0.656		
Standard	0.082	2.5 mg/dl	0.084	2.5 mg/dl	-
Controls					
Biorad- 1	0.069	2.10	0.072	2.14	1.70 - 2.30 mg/dl
Biorad- 2	0.159	4.85	0.165	4.91	4.20 - 5.20 mg/dl
Known normal/abnormal Serum samples					
Sample-1	0.078	2.38	0.082	2.44	1.9 - 2.5 mg/dl
Sample-2	0.072	2.20	0.075	2.23	
Sample-3	0.079	2.41	0.082	2.44	
Sample-4	0.068	2.07	0.072	2.14	
Sample-5	0.065	1.98	0.068	2.02	
Linearity					
5 mg/dl	0.162	4.94 (98.78%)	0.165	4.91 (98.20%)	± 10%

6.0 Accelerated Stability Studies: Summary

- Stability studies were conducted at 37°C till 14 days.
- Stability studies were conducted using Bio-Rad Control (Level-1 & Level-2).
- It was not possible to use the “same” samples in the study due to the very limited stability of samples.
- The values obtained with Magnesium were found to be in the ranges specified for the Bio-Rad controls till 14 days at 37°C and found to be comparable with the reference reagent.
- Magnesium reagent was therefore found to be stable at 37°C for 14 days.
- This data has been extrapolated to conclude that Magnesium reagent will be stable for 18 months under the recommended temperature conditions of 2°C- 8°C.

6.1 Accelerated stability study: Magnesium

Time interval= Day-7

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
Reagent Blank	0.682		0.662		
Standard	0.079	2.5 mg/dl	0.082	2.5 mg/dl	-
Controls					
Biorad- 1	0.068	2.15	0.071	2.16	1.70 - 2.30 mg/dl
Biorad- 2	0.159	5.03	0.162	4.94	4.20 - 5.20 mg/dl
Known normal/abnormal Serum samples					
Sample-1	0.062	1.96	0.063	1.92	1.9 - 2.5 mg/dl
Sample-2	0.072	2.28	0.073	2.23	
Sample-3	0.076	2.41	0.079	2.41	
Sample-4	0.068	2.15	0.071	2.16	
Sample-5	0.066	2.09	0.068	2.07	
Linearity					
5 mg/dl	0.152	4.81 (96.20%)	0.156	4.76 (95.20%)	± 10%

6.2 Accelerated stability study: Magnesium

Time interval= Day-14

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (mg/dl)
	Abs.	Conc. (mg/dl)	Abs.	Conc. (mg/dl)	
Reagent Blank	0.691		0.672		
Standard	0.081	2.5 mg/dl	0.083	2.5 mg/dl	-
Controls					
Biorad- 1	0.062	1.91	0.063	1.90	1.70 - 2.30 mg/dl
Biorad- 2	0.156	4.81	0.161	4.85	4.20 - 5.20 mg/dl
Known normal/abnormal Serum samples					
Sample-1	0.072	2.22	0.074	2.23	1.9 - 2.5 mg/dl
Sample-2	0.062	1.91	0.065	1.96	
Sample-3	0.078	2.41	0.081	2.44	
Sample-4	0.065	2.01	0.068	2.05	
Sample-5	0.076	2.35	0.079	2.38	
Linearity					
5 mg/dl	0.156	4.81 (96.20%)	0.162	4.88 (97.60%)	± 10%

7.0 Conclusions

- The Magnesium reagent showed an excellent Coefficient of Correlation (“r”) using as Reference.
- Magnesium showed values of “r” was 0.991 displaying the highest degree of correlation between the two sets of reagents.
- The Magnesium reagent showed an excellent coefficient of Variation (CV %).
- The CV % was found to be in the range of 0.48% and 1.8% displaying a very high level of precision and repeatability.
- The Magnesium reagent showed an excellent performance even under stressful conditions. The reagents were found to be stable at 37°C for 14 days.

The Magnesium reagent was thus concluded to be Accurate, Precise and Stable, while using clinical normal and abnormal samples and 3rd Party controls (Level-1 and Level-2).

Adenosine deaminase (ADA)

CLINICAL EVIDENCE EVALUATION REPORT

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1.0 Details of Reagents

Type of Reagents developed	Liquid Clinical Chemistry Reagents
Instrument Model	Biochemistry Semi-automated analyzer (BTS-350)
Reference Reagents	Reference Reagents

2.0 Coefficient of Correlation Studies: Accuracy study

- I. The objective was to determine the correlation between the results obtained with the Clinical Chemistry reagents of Vanguard Diagnostics and the benchmarked Clinical Chemistry reagents.
- II. The Coefficient of Correlation ("r") was calculated for Adenosine deaminase (ADA). kit.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x (x̄)
 - 3 Mean y (ȳ)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of "r"
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, xi (x1, x2,...,xn) are the x values and yi are the y values.

2.1 Coefficient of Correlation (“r”): Adenosine deaminase (ADA).

X AXIS = Reference Reagent.

Y AXIS = Adenosine deaminase (ADA). kit from Vanguard Diagnostics (P) Ltd.

$$“r” = 0.994$$

Sample size: 20

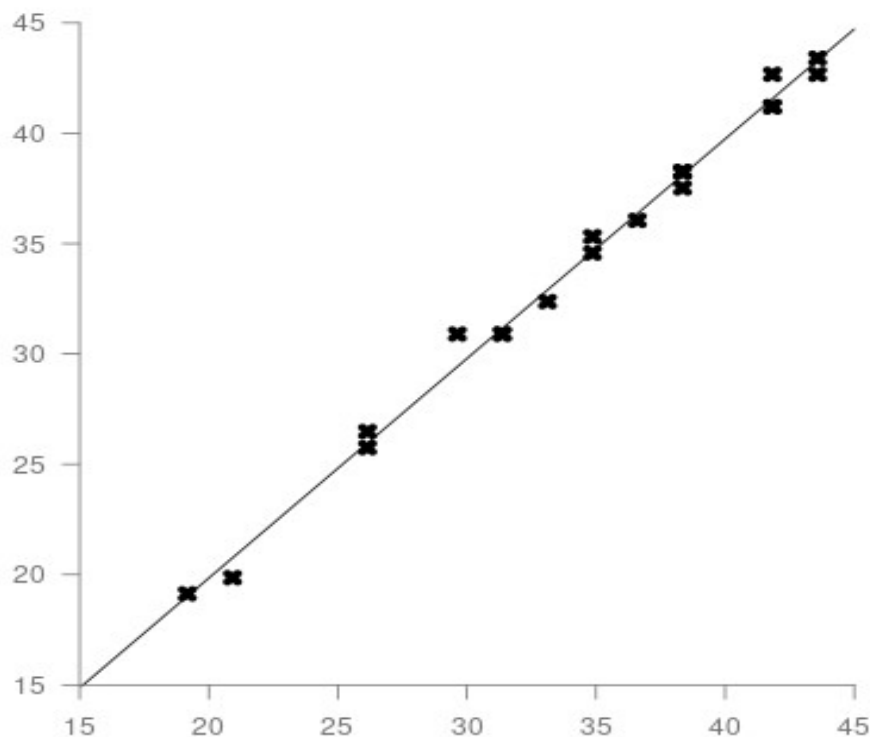
Mean x (x̄): 34.5125

Mean y (ȳ): 34.2815

Intercept (a): -0.058071409115733

Slope (b): 0.99498939251331

Regression line equation: $y = 0.99498939251331x - 0.058071409115733$



3.0 Comparative evaluation report: Adenosine deaminase (ADA).

Vanguard ADA Kit				Reference Kit		
S.No.	Test	Δ Abs./min	Conc (U/L)	Δ Abs./min	Conc (U/L)	%
	Calibrator (64 U/L)	0.087	-	Factor	1743	
01	Sample 1	0.027	19.86	0.012	20.92	94.96
02	Sample 2	0.042	30.90	0.017	29.63	104.27
03	Sample 3	0.052	38.25	0.022	38.35	99.76
04	Sample 4	0.059	43.40	0.025	43.58	99.60
05	Sample 5	0.035	25.75	0.015	26.15	98.48
06	Sample 6	0.026	19.13	0.011	19.17	99.76
07	Sample 7	0.058	42.67	0.024	41.83	102.00
08	Sample 8	0.052	38.25	0.022	38.35	99.76
09	Sample 9	0.048	35.31	0.020	34.86	101.29
10	Sample 10	0.036	26.48	0.015	26.15	101.29
11	Sample 11	0.049	36.05	0.021	36.60	98.48
12	Sample 12	0.044	32.37	0.019	33.12	97.74
13	Sample 13	0.056	41.20	0.024	41.83	98.48
14	Sample 14	0.052	38.25	0.022	38.35	99.76
15	Sample 15	0.058	42.67	0.025	43.58	97.92
16	Sample 16	0.042	30.90	0.018	31.37	98.48
17	Sample 17	0.047	34.57	0.020	34.86	99.18
18	Sample 18	0.051	37.52	0.022	38.35	97.84
19	Sample 19	0.042	30.90	0.018	31.37	98.48
20	Sample 20	0.056	41.20	0.024	41.83	98.48

4.0 Coefficient of Variation: Repeatability/Reproducibility/Precision study

- Biorad Controls Normal and Abnormal were used to calculate “Within Run” and “Between Run” Precision.
- The Biorad Controls were tested in 25 replicates to study Precision.
- Coefficient of Variation (CV %) was calculated.
- **Acceptance criteria = NMT 10%.**

4.1 Precision “Within Run” and “Between Run”

4.1.1 Bio-Rad Control (Level-1)

Within Run				Run to Run			
S.No.	Test	ΔAbs./min	Conc (U/L)	S.No.	Test	ΔAbs./min	Conc (U/L)
	Calibrator (64 U/L)	0.087			Calibrator (64 U/L)	0.087	
01	Bio-Rad 1	0.026	19.13	01	Bio-Rad 1	0.025	18.39
02	Bio-Rad 1	0.027	19.86	02	Bio-Rad 1	0.026	19.13
03	Bio-Rad 1	0.025	18.39	03	Bio-Rad 1	0.026	19.13
04	Bio-Rad 1	0.026	19.13	04	Bio-Rad 1	0.025	18.39
05	Bio-Rad 1	0.025	18.39	05	Bio-Rad 1	0.026	19.13
06	Bio-Rad 1	0.026	19.13	06	Bio-Rad 1	0.025	18.39
07	Bio-Rad 1	0.026	19.13	07	Bio-Rad 1	0.025	18.39
08	Bio-Rad 1	0.025	18.39	08	Bio-Rad 1	0.026	19.13
09	Bio-Rad 1	0.026	19.13	09	Bio-Rad 1	0.026	19.13
10	Bio-Rad 1	0.026	19.13	10	Bio-Rad 1	0.025	18.39
11	Bio-Rad 1	0.026	19.13	11	Bio-Rad 1	0.026	19.13
12	Bio-Rad 1	0.025	18.39	12	Bio-Rad 1	0.025	18.39
13	Bio-Rad 1	0.026	19.13	13	Bio-Rad 1	0.026	19.13
14	Bio-Rad 1	0.025	18.39	14	Bio-Rad 1	0.025	18.39
15	Bio-Rad 1	0.026	19.13	15	Bio-Rad 1	0.026	19.13
16	Bio-Rad 1	0.025	18.39	16	Bio-Rad 1	0.025	18.39
17	Bio-Rad 1	0.026	19.13	17	Bio-Rad 1	0.025	18.39
18	Bio-Rad 1	0.025	18.39	18	Bio-Rad 1	0.026	19.13
19	Bio-Rad 1	0.026	19.13	19	Bio-Rad 1	0.026	19.13
20	Bio-Rad 1	0.025	18.39	20	Bio-Rad 1	0.025	18.39
21	Bio-Rad 1	0.026	19.13	21	Bio-Rad 1	0.026	19.13
22	Bio-Rad 1	0.025	18.39	22	Bio-Rad 1	0.025	18.39
23	Bio-Rad 1	0.026	19.13	23	Bio-Rad 1	0.026	19.13
24	Bio-Rad 1	0.025	18.39	24	Bio-Rad 1	0.025	18.39
25	Bio-Rad 1	0.026	19.13	25	Bio-Rad 1	0.025	18.39
Mean			18.86	Mean			18.74
S.D.			0.42	S.D.			0.38
CV			0.02	CV			0.02
CV%			2.22	CV%			2.00

4.2 Precision “Within Run” and “Between Run”

4.2.1 Bio-Rad Control (Level-2)

Within Run				Run to Run			
S.No.	Test	ΔAbs./min	Conc (U/L)	S.No.	Test	ΔAbs./min	Conc (U/L)
	Calibrator (64 U/L)	0.087			Calibrator (64 U/L)	0.087	
01	Bio-Rad 2	0.045	33.10	01	Bio-Rad 2	0.045	33.10
02	Bio-Rad 2	0.046	33.84	02	Bio-Rad 2	0.046	33.84
03	Bio-Rad 2	0.045	33.10	03	Bio-Rad 2	0.045	33.10
04	Bio-Rad 2	0.046	33.84	04	Bio-Rad 2	0.046	33.84
05	Bio-Rad 2	0.045	33.10	05	Bio-Rad 2	0.045	33.10
06	Bio-Rad 2	0.045	33.10	06	Bio-Rad 2	0.045	33.10
07	Bio-Rad 2	0.046	33.84	07	Bio-Rad 2	0.046	33.84
08	Bio-Rad 2	0.045	33.10	08	Bio-Rad 2	0.046	33.84
09	Bio-Rad 2	0.046	33.84	09	Bio-Rad 2	0.046	33.84
10	Bio-Rad 2	0.045	33.10	10	Bio-Rad 2	0.046	33.84
11	Bio-Rad 2	0.046	33.84	11	Bio-Rad 2	0.045	33.10
12	Bio-Rad 2	0.045	33.10	12	Bio-Rad 2	0.046	33.84
13	Bio-Rad 2	0.046	33.84	13	Bio-Rad 2	0.045	33.10
14	Bio-Rad 2	0.046	33.84	14	Bio-Rad 2	0.046	33.84
15	Bio-Rad 2	0.045	33.10	15	Bio-Rad 2	0.046	33.84
16	Bio-Rad 2	0.046	33.84	16	Bio-Rad 2	0.046	33.84
17	Bio-Rad 2	0.046	33.84	17	Bio-Rad 2	0.045	33.10
18	Bio-Rad 2	0.045	33.10	18	Bio-Rad 2	0.046	33.84
19	Bio-Rad 2	0.045	33.10	19	Bio-Rad 2	0.045	33.10
20	Bio-Rad 2	0.045	33.10	20	Bio-Rad 2	0.046	33.84
21	Bio-Rad 2	0.046	33.84	21	Bio-Rad 2	0.045	33.10
22	Bio-Rad 2	0.045	33.10	22	Bio-Rad 2	0.046	33.84
23	Bio-Rad 2	0.046	33.84	23	Bio-Rad 2	0.045	33.10
24	Bio-Rad 2	0.045	33.10	24	Bio-Rad 2	0.046	33.84
25	Bio-Rad 2	0.045	33.10	25	Bio-Rad 2	0.045	33.10
Mean			33.43	Mean			33.52
S.D.			0.37	S.D.			0.37
CV			0.01	CV			0.01
CV%			1.11	CV%			1.11

5.0 Performance Evaluation Report of Adenosine deaminase (ADA).

Time interval= Day-0

Storage Temperature = 2°C – 8°C

Test	Vanguard Reagent		Reference Reagent		Specification (U/L)
	ΔAbs./min	Conc (U/L)	ΔAbs./min	Conc (U/L)	
Calibrator (64 U/L)	0.087	-	Factor	1743	-
Controls					
Biorad- 1	0.026	19.13	0.011	19.17	NA
Biorad- 2	0.046	33.84	0.019	33.12	NA
Known normal/abnormal Serum samples					
Sample-1	0.052	38.25	0.022	38.35	Upto 43 U/L
Sample-2	0.058	42.67	0.025	43.58	
Sample-3	0.036	26.48	0.015	26.15	
Sample-4	0.042	30.90	0.018	31.37	
Sample-5	0.048	35.31	0.021	36.60	
Linearity					
200 U/L	0.263	193.47 (96.73%)	0.109	189.99 (94.99)	± 10%

6.0 Accelerated Stability Studies: Summary

- Stability studies were conducted at 37°C till 14 days.
- Stability studies were conducted using Bio-Rad Control (Level-1 & Level-2).
- It was not possible to use the “same” samples in the study due to the very limited stability of samples.
- The values obtained with Adenosine deaminase (ADA). were found to be comparable with the reference reagent till day 14 at 37°C.
- Adenosine deaminase (ADA) reagent was therefore found to be stable at 37°C for 14 days.
- This data has been extrapolated to conclude that Adenosine deaminase (ADA). reagent will be stable for 18 months under the recommended temperature conditions of 2°C- 8°C.

6.1 Accelerated stability study: Adenosine deaminase (ADA).

Time interval= Day-7

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (U/L)
	ΔAbs./min	Conc (U/L)	ΔAbs./min	Conc (U/L)	
Calibrator (64 U/L)	0.089	-	Factor	1743	-
Controls					
Biorad- 1	0.028	20.13	0.012	20.92	NA
Biorad- 2	0.048	34.52	0.021	36.60	NA
Known normal/abnormal Serum samples					
Sample-1	0.053	38.11	0.022	38.35	Upto 43 U/L
Sample-2	0.059	42.43	0.024	41.83	
Sample-3	0.049	35.24	0.021	36.60	
Sample-4	0.035	25.17	0.015	26.15	
Sample-5	0.042	30.20	0.018	31.37	
Linearity					
200 U/L	0.265	190.56 (95.28%)	0.11	191.73 (95.86%)	± 10%

6.2 Accelerated stability study: Adenosine deaminase (ADA).

Time interval= Day-14

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (U/L)
	ΔAbs./min	Conc (U/L)	ΔAbs./min	Conc (U/L)	
Calibrator (64 U/L)	0.086	-	Factor	1743	-
Controls					
Biorad- 1	0.027	20.09	0.011	19.17	NA
Biorad- 2	0.047	34.98	0.020	34.86	NA
Known normal/abnormal Serum samples					
Sample-1	0.052	38.70	0.021	36.60	Upto 43 U/L
Sample-2	0.058	43.16	0.023	40.09	
Sample-3	0.048	35.72	0.02	34.86	
Sample-4	0.034	25.30	0.015	26.15	
Sample-5	0.041	30.51	0.018	31.37	
Linearity					
200 U/L	0.261	194.23 (97.11%)	0.111	193.47 (96.73%)	± 10%

7.0 Conclusions

- The Adenosine deaminase (ADA). reagent showed an excellent Coefficient of Correlation (“r”) using as Reference.
- Adenosine deaminase (ADA). showed values of “r” was 0.994 displaying the highest degree of correlation between the two sets of reagents.
- The Adenosine deaminase (ADA) reagent showed an excellent coefficient of Variation (CV %).
- The CV % was found to be in the range of 1.11% and 1.22% displaying a very high level of precision and repeatability.
- The Adenosine deaminase (ADA) reagent showed an excellent performance even under stressful conditions. The reagents were found to be stable at 37°C for 14 days.

The Adenosine deaminase (ADA) reagent was thus concluded to be Accurate, Precise and Stable, while using clinical normal and abnormal samples and 3rd Party controls (Level-1 and Level-2).

Lactate Dehydrogenase (LDH)

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1.0 Details of Reagents

Type of Reagents developed	Liquid Clinical Chemistry Reagents
Instrument Model	Biochemistry Semi-automated analyzer (BTS-350)
Reference Reagents	Reference Reagents

2.0 Coefficient of Correlation Studies: Accuracy study

- I. The objective was to determine the correlation between the results obtained with the Clinical Chemistry reagents of Vanguard Diagnostics and the benchmarked Clinical Chemistry reagents.
- II. The Coefficient of Correlation ("r") was calculated for Lactate Dehydrogenase (LDH) kit.
- III. The data has been presented in the form of:

- 1 Sample size
- 2 Mean x ($\bar{x}$)
- 3 Mean y ($\bar{y}$)
- 4 Intercept (a)
- 5 Slope (b)
- 6 Regression line equation
- 7 Value of "r"
- 8 Linear Regression Graph
- 9 Raw Data of values
- 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, x_i ($x_1, x_2, \dots, x_n$) are the x values and y_i are the y values.

2.1 Coefficient of Correlation (“r”): Lactate Dehydrogenase (LDH).

X AXIS = Reference Reagent.

Y AXIS = Lactate Dehydrogenase (LDH). kit from Vanguard Diagnostics (P) Ltd.

$$“r” = 1.020$$

Sample size: 20

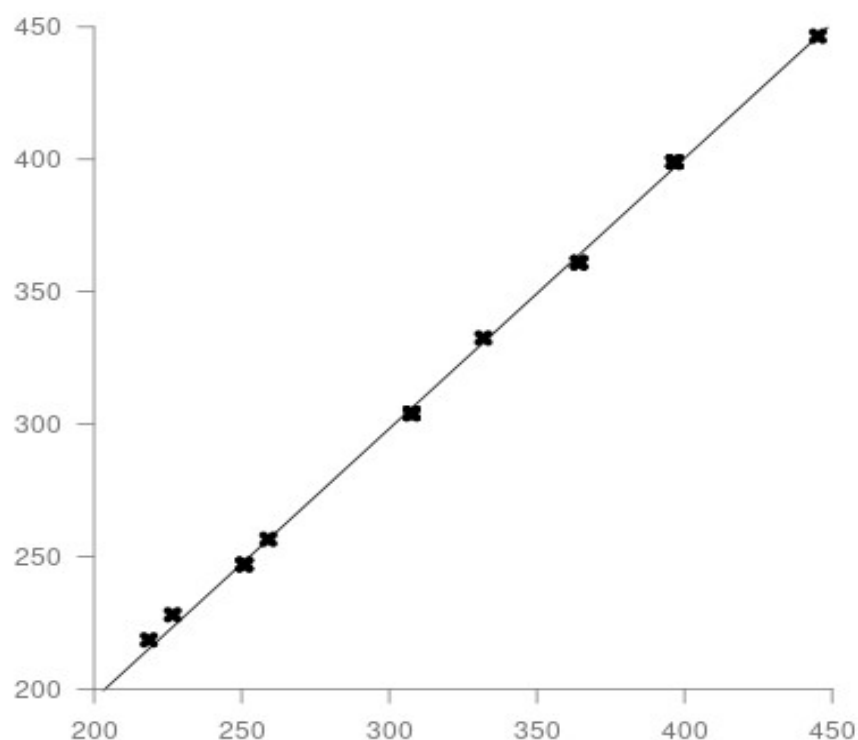
Mean x (x̄): 327.0415

Mean y (ȳ): 325.85

Intercept (a): -8.0102319242835

Slope (b): 1.0208497451372

Regression line equation: $y = 1.0208497451372x - 8.0102319242835$



3.0 Comparative evaluation report: Lactate Dehydrogenase (LDH).

Vanguard LDH Kit				Reference Kit		
S.No.	Test	Δ Abs./min	Conc (U/L)	Δ Abs./min	Conc (U/L)	%
	Factor	9500	-	Factor	8095	
01	Sample 1	0.027	256.50	0.032	259.04	99.02
02	Sample 2	0.047	446.50	0.055	445.23	100.29
03	Sample 3	0.023	218.50	0.027	218.57	99.97
04	Sample 4	0.042	399.00	0.049	396.66	100.59
05	Sample 5	0.038	361.00	0.045	364.28	99.10
06	Sample 6	0.042	399.00	0.049	396.66	100.59
07	Sample 7	0.026	247.00	0.031	250.95	98.43
08	Sample 8	0.032	304.00	0.038	307.61	98.83
09	Sample 9	0.042	399.00	0.049	396.66	100.59
10	Sample 10	0.038	361.00	0.045	364.28	99.10
11	Sample 11	0.042	399.00	0.049	396.66	100.59
12	Sample 12	0.038	361.00	0.045	364.28	99.10
13	Sample 13	0.032	304.00	0.038	307.61	98.83
14	Sample 14	0.026	247.00	0.031	250.95	98.43
15	Sample 15	0.024	228.00	0.028	226.66	100.59
16	Sample 16	0.026	247.00	0.031	250.95	98.43
17	Sample 17	0.032	304.00	0.038	307.61	98.83
18	Sample 18	0.042	399.00	0.049	396.66	100.59
19	Sample 19	0.032	304.00	0.038	307.61	98.83
20	Sample 20	0.035	332.50	0.041	331.90	100.18

4.0 Coefficient of Variation: Repeatability/Reproducibility/Precision study

- Biorad Controls Normal and Abnormal were used to calculate “Within Run” and “Between Run” Precision.
- The Biorad Controls were tested in 25 replicates to study Precision.
- Coefficient of Variation (CV %) was calculated.
- **Acceptance criteria = NMT 10%.**

4.1 Precision “Within Run” and “Between Run”

4.1.1 Bio-Rad Control (Level-1)

Within Run				Run to Run			
S.No.	Test	ΔAbs./min	Conc (U/L)	S.No.	Test	ΔAbs./min	Conc (U/L)
	Factor	9500			Factor	9500	
01	Bio-Rad 1	0.034	323.00	01	Bio-Rad 1	0.034	323.00
02	Bio-Rad 1	0.033	313.50	02	Bio-Rad 1	0.033	313.50
03	Bio-Rad 1	0.033	313.50	03	Bio-Rad 1	0.034	323.00
04	Bio-Rad 1	0.033	313.50	04	Bio-Rad 1	0.033	313.50
05	Bio-Rad 1	0.034	323.00	05	Bio-Rad 1	0.034	323.00
06	Bio-Rad 1	0.033	313.50	06	Bio-Rad 1	0.033	313.50
07	Bio-Rad 1	0.034	323.00	07	Bio-Rad 1	0.034	323.00
08	Bio-Rad 1	0.033	313.50	08	Bio-Rad 1	0.033	313.50
09	Bio-Rad 1	0.033	313.50	09	Bio-Rad 1	0.034	323.00
10	Bio-Rad 1	0.034	323.00	10	Bio-Rad 1	0.034	323.00
11	Bio-Rad 1	0.034	323.00	11	Bio-Rad 1	0.034	323.00
12	Bio-Rad 1	0.033	313.50	12	Bio-Rad 1	0.033	313.50
13	Bio-Rad 1	0.034	323.00	13	Bio-Rad 1	0.033	313.50
14	Bio-Rad 1	0.033	313.50	14	Bio-Rad 1	0.034	323.00
15	Bio-Rad 1	0.034	323.00	15	Bio-Rad 1	0.034	323.00
16	Bio-Rad 1	0.033	313.50	16	Bio-Rad 1	0.033	313.50
17	Bio-Rad 1	0.034	323.00	17	Bio-Rad 1	0.034	323.00
18	Bio-Rad 1	0.034	323.00	18	Bio-Rad 1	0.033	313.50
19	Bio-Rad 1	0.034	323.00	19	Bio-Rad 1	0.034	323.00
20	Bio-Rad 1	0.034	323.00	20	Bio-Rad 1	0.033	313.50
21	Bio-Rad 1	0.034	323.00	21	Bio-Rad 1	0.034	323.00
22	Bio-Rad 1	0.034	323.00	22	Bio-Rad 1	0.033	313.50
23	Bio-Rad 1	0.033	313.50	23	Bio-Rad 1	0.033	313.50
24	Bio-Rad 1	0.033	313.50	24	Bio-Rad 1	0.034	323.00
25	Bio-Rad 1	0.034	323.00	25	Bio-Rad 1	0.033	313.50
Mean			318.82	Mean			318.44
S.D.			4.81	S.D.			4.84
CV			0.02	CV			0.02
CV%			1.51	CV%			1.52

4.2 Precision “Within Run” and “Between Run”

4.2.1 Bio-Rad Control (Level-2)

Within Run				Run to Run			
S.No.	Test	ΔAbs./min	Conc (U/L)	S.No.	Test	ΔAbs./min	Conc (U/L)
	Factor	9500			Factor	9500	
01	Bio-Rad 2	0.082	779.00	01	Bio-Rad 2	0.082	663.79
02	Bio-Rad 2	0.081	769.50	02	Bio-Rad 2	0.081	655.70
03	Bio-Rad 2	0.082	779.00	03	Bio-Rad 2	0.082	663.79
04	Bio-Rad 2	0.081	769.50	04	Bio-Rad 2	0.081	655.70
05	Bio-Rad 2	0.082	779.00	05	Bio-Rad 2	0.082	663.79
06	Bio-Rad 2	0.081	769.50	06	Bio-Rad 2	0.081	655.70
07	Bio-Rad 2	0.082	779.00	07	Bio-Rad 2	0.082	663.79
08	Bio-Rad 2	0.081	769.50	08	Bio-Rad 2	0.081	655.70
09	Bio-Rad 2	0.082	779.00	09	Bio-Rad 2	0.081	655.70
10	Bio-Rad 2	0.081	769.50	10	Bio-Rad 2	0.082	663.79
11	Bio-Rad 2	0.082	779.00	11	Bio-Rad 2	0.081	655.70
12	Bio-Rad 2	0.081	769.50	12	Bio-Rad 2	0.082	663.79
13	Bio-Rad 2	0.082	779.00	13	Bio-Rad 2	0.081	655.70
14	Bio-Rad 2	0.081	769.50	14	Bio-Rad 2	0.082	663.79
15	Bio-Rad 2	0.082	779.00	15	Bio-Rad 2	0.081	655.70
16	Bio-Rad 2	0.082	779.00	16	Bio-Rad 2	0.082	663.79
17	Bio-Rad 2	0.082	779.00	17	Bio-Rad 2	0.082	663.79
18	Bio-Rad 2	0.081	769.50	18	Bio-Rad 2	0.081	655.70
19	Bio-Rad 2	0.081	769.50	19	Bio-Rad 2	0.081	655.70
20	Bio-Rad 2	0.082	779.00	20	Bio-Rad 2	0.082	663.79
21	Bio-Rad 2	0.082	779.00	21	Bio-Rad 2	0.082	663.79
22	Bio-Rad 2	0.081	769.50	22	Bio-Rad 2	0.081	655.70
23	Bio-Rad 2	0.082	779.00	23	Bio-Rad 2	0.082	663.79
24	Bio-Rad 2	0.081	769.50	24	Bio-Rad 2	0.081	655.70
25	Bio-Rad 2	0.081	769.50	25	Bio-Rad 2	0.082	663.79
Mean			774.44	Mean			659.90
S.D.			4.84	S.D.			4.13
CV			0.01	CV			0.01
CV%			0.63	CV%			0.63

5.0 Performance Evaluation Report of Lactate Dehydrogenase (LDH).

Time interval= Day-0

Storage Temperature = 2°C – 8°C

Test	Vanguard Reagent		Reference Reagent		Specification (U/L)
	ΔAbs./min	Conc (U/L)	ΔAbs./min	Conc (U/L)	
	Factor	9500	Factor	8095	-
Controls					
Biorad- 1	0.034	323.00	0.041	331.90	NA
Biorad- 2	0.082	779.00	0.096	777.12	NA
Known normal/abnormal Serum samples					
Sample-1	0.047	446.50	0.055	445.23	Upto 43 U/L
Sample-2	0.023	218.50	0.027	218.57	
Sample-3	0.042	399.00	0.049	396.66	
Sample-4	0.038	361.00	0.045	364.28	
Sample-5	0.042	399.00	0.049	396.66	
Linearity					
2000 U/L	0.206	1957.00 (97.85%)	0.241	1950.90 (97.54%)	± 10%

6.0 Accelerated Stability Studies: Summary

- Stability studies were conducted at 37°C till 14 days.
- Stability studies were conducted using Bio-Rad Control (Level-1 & Level-2).
- It was not possible to use the “same” samples in the study due to the very limited stability of samples.
- The values obtained with Lactate Dehydrogenase (LDH) were found to be comparable with the reference reagent till day 14 at 37°C.
- Lactate Dehydrogenase (LDH) reagent was therefore found to be stable at 37°C for 14 days.
- This data has been extrapolated to conclude that Lactate Dehydrogenase (LDH) reagent will be stable for 18 months under the recommended temperature conditions of 2°C- 8°C.

6.1 Accelerated stability study: Lactate Dehydrogenase (LDH).

Time interval= Day-7

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (U/L)
	ΔAbs./min	Conc (U/L)	ΔAbs./min	Conc (U/L)	
	Factor	9500	Factor	8095	-
Controls					
Biorad- 1	0.033	313.50	0.039	315.71	NA
Biorad- 2	0.081	769.50	0.095	769.03	NA
Known normal/abnormal Serum samples					
Sample-1	0.032	304.00	0.038	307.61	Upto 43 U/L
Sample-2	0.042	399.00	0.049	396.66	
Sample-3	0.038	361.00	0.045	364.28	
Sample-4	0.042	399.00	0.049	396.66	
Sample-5	0.038	361.00	0.045	364.28	
Linearity					
2000 U/L	0.202	1919.00 (95.95%)	0.238	1926.61 (96.33%)	± 10%

6.2 Accelerated stability study: Lactate Dehydrogenase (LDH).

Time interval= Day-14

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (U/L)
	ΔAbs./min	Conc (U/L)	ΔAbs./min	Conc (U/L)	
	Factor	9500	Factor	8095	-
Controls					
Biorad- 1	0.031	294.50	0.041	331.90	NA
Biorad- 2	0.081	769.50	0.095	769.03	NA
Known normal/abnormal Serum samples					
Sample-1	0.047	446.50	0.055	445.23	Upto 43 U/L
Sample-2	0.023	218.50	0.027	218.57	
Sample-3	0.042	399.00	0.049	396.66	
Sample-4	0.038	361.00	0.045	364.28	
Sample-5	0.042	399.00	0.049	396.66	
Linearity					
2000 U/L	0.201	1909.50 (95.47%)	0.236	1910.42 (95.52%)	± 10%

7.0 Conclusions

- The Lactate Dehydrogenase (LDH). reagent showed an excellent Coefficient of Correlation (“r”) using as Reference.
- Lactate Dehydrogenase (LDH). showed values of “r” was 1.020 displaying the highest degree of correlation between the two sets of reagents.
- The Lactate Dehydrogenase (LDH) reagent showed an excellent coefficient of Variation (CV %).
- The CV % was found to be in the range of 0.63% and 1.52% displaying a very high level of precision and repeatability.
- The Lactate Dehydrogenase (LDH) reagent showed an excellent performance even under stressful conditions. The reagents were found to be stable at 37°C for 14 days.

The Lactate Dehydrogenase (LDH) reagent was thus concluded to be Accurate, Precise and Stable, while using clinical normal and abnormal samples and 3rd Party controls (Level-1 and Level-2).

D-Dimer

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1.0 Details of Reagents

Type of Reagents developed	Liquid Clinical Chemistry Reagents
Instrument Model	Biochemistry Semi-automated analyzer (BTS-350)
Reference Reagents	Reference Reagents

2.0 Coefficient of Correlation Studies: Accuracy study

- I. The objective was to determine the correlation between the results obtained with the Clinical Chemistry reagents of Vanguard Diagnostics and the benchmarked Clinical Chemistry reagents.
- II. The Coefficient of Correlation ("r") was calculated for D-Dimer kit.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x (x̄)
 - 3 Mean y (ȳ)
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of "r"
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When "r" is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, xi (x1, x2,...,xn) are the x values and yi are the y values.

2.1 Coefficient of Correlation (“r”): D-Dimer.

X AXIS = Reference Reagent.

Y AXIS = D-Dimer kit from Vanguard Diagnostics (P) Ltd.

$$“r” = 0.939$$

Sample size: 20

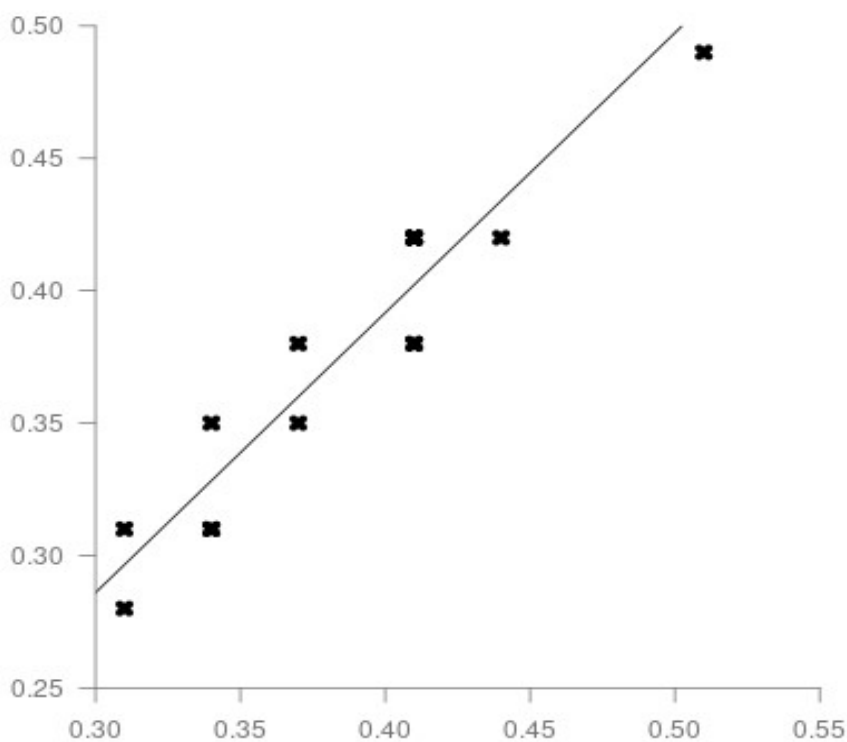
Mean x (x̄): 0.3885

Mean y (ȳ): 0.3795

Intercept (a): -0.031110111348564

Slope (b): 1.0569114835227

Regression line equation: $y = 1.0569114835227x - 0.031110111348564$



3.0 Comparative evaluation report: D-Dimer.

Vanguard D Dimer Kit				Reference Kit		
S.No.	Test	Δ Abs./min	Conc (mg/L)	Δ Abs./min	Conc (mg/L)	%
	Calibrator (11.6 mg/L)	0.334	-	Calibrator (12.0 mg/L)	0.342	
01	Sample 1	0.012	0.42	0.012	0.41	102.40
02	Sample 2	0.011	0.38	0.012	0.41	93.86
03	Sample 3	0.009	0.31	0.010	0.34	92.16
04	Sample 4	0.012	0.42	0.012	0.41	102.40
05	Sample 5	0.011	0.38	0.011	0.37	102.40
06	Sample 6	0.009	0.31	0.009	0.31	102.40
07	Sample 7	0.009	0.31	0.010	0.34	92.16
08	Sample 8	0.012	0.42	0.012	0.41	102.40
09	Sample 9	0.009	0.31	0.010	0.34	92.16
10	Sample 10	0.008	0.28	0.009	0.31	91.02
11	Sample 11	0.010	0.35	0.010	0.34	102.40
12	Sample 12	0.012	0.42	0.012	0.41	102.40
13	Sample 13	0.011	0.38	0.012	0.41	93.86
14	Sample 14	0.011	0.38	0.012	0.41	93.86
15	Sample 15	0.012	0.42	0.012	0.41	102.40
16	Sample 16	0.010	0.35	0.011	0.37	93.09
17	Sample 17	0.012	0.42	0.012	0.41	102.40
18	Sample 18	0.012	0.42	0.012	0.41	102.40
19	Sample 19	0.012	0.42	0.013	0.44	94.52
20	Sample 20	0.014	0.49	0.015	0.51	95.57

4.0 Coefficient of Variation: Repeatability/Reproducibility/Precision study

- Controls were used to calculate “Within Run” and “Between Run” Precision.
- The Controls were tested in 25 replicates to study Precision.
- Coefficient of Variation (CV %) was calculated.
- **Acceptance criteria = NMT 10%.**

4.1 Precision “Within Run” and “Between Run”

4.1.1 Control (Level-1)

Within Run				Run to Run			
S.No.	Test	ΔAbs./min	Conc (mg/L)	S.No.	Test	ΔAbs./min	Conc (mg/L)
	Calibrator (11.6 mg/L)	0.342			Calibrator (11.6 mg/L)	0.342	
01	Internal C1	0.062	2.10	01	Bio-Rad 1	0.063	2.14
02	Internal C1	0.061	2.07	02	Bio-Rad 1	0.062	2.10
03	Internal C1	0.062	2.10	03	Bio-Rad 1	0.061	2.07
04	Internal C1	0.061	2.07	04	Bio-Rad 1	0.063	2.14
05	Internal C1	0.063	2.14	05	Bio-Rad 1	0.064	2.17
06	Internal C1	0.064	2.17	06	Bio-Rad 1	0.063	2.14
07	Internal C1	0.063	2.14	07	Bio-Rad 1	0.064	2.17
08	Internal C1	0.062	2.10	08	Bio-Rad 1	0.062	2.10
09	Internal C1	0.064	2.17	09	Bio-Rad 1	0.063	2.14
10	Internal C1	0.063	2.14	10	Bio-Rad 1	0.062	2.10
11	Internal C1	0.062	2.10	11	Bio-Rad 1	0.064	2.17
12	Internal C1	0.063	2.14	12	Bio-Rad 1	0.063	2.14
13	Internal C1	0.062	2.10	13	Bio-Rad 1	0.062	2.10
14	Internal C1	0.063	2.14	14	Bio-Rad 1	0.063	2.14
15	Internal C1	0.064	2.17	15	Bio-Rad 1	0.064	2.17
16	Internal C1	0.063	2.14	16	Bio-Rad 1	0.062	2.10
17	Internal C1	0.064	2.17	17	Bio-Rad 1	0.063	2.14
18	Internal C1	0.063	2.14	18	Bio-Rad 1	0.064	2.17
19	Internal C1	0.062	2.10	19	Bio-Rad 1	0.062	2.10
20	Internal C1	0.063	2.14	20	Bio-Rad 1	0.063	2.14
21	Internal C1	0.062	2.10	21	Bio-Rad 1	0.063	2.14
22	Internal C1	0.063	2.14	22	Bio-Rad 1	0.062	2.10
23	Internal C1	0.064	2.17	23	Bio-Rad 1	0.063	2.14
24	Internal C1	0.063	2.14	24	Bio-Rad 1	0.064	2.17
25	Internal C1	0.064	2.17	25	Bio-Rad 1	0.063	2.14
Mean			2.13	Mean			2.13
S.D.			0.03	S.D.			0.03
CV			0.01	CV			0.01
CV%			1.45	CV%			1.32

4.2 Precision “Within Run” and “Between Run”

4.2.1 Control (Level-2)

Within Run				Run to Run			
S.No.	Test	ΔAbs./min	Conc (mg/L)	S.No.	Test	ΔAbs./min	Conc (mg/L)
	Calibrator (11.6 mg/L)	0.342			Calibrator (11.6 mg/L)	0.342	
01	Internal C2	0.158	5.36	01	Internal C2	0.158	5.36
02	Internal C2	0.157	5.33	02	Internal C2	0.156	5.29
03	Internal C2	0.156	5.29	03	Internal C2	0.157	5.33
04	Internal C2	0.158	5.36	04	Internal C2	0.157	5.33
05	Internal C2	0.156	5.29	05	Internal C2	0.156	5.29
06	Internal C2	0.156	5.29	06	Internal C2	0.158	5.36
07	Internal C2	0.158	5.36	07	Internal C2	0.157	5.33
08	Internal C2	0.157	5.33	08	Internal C2	0.157	5.33
09	Internal C2	0.158	5.36	09	Internal C2	0.156	5.29
10	Internal C2	0.156	5.29	10	Internal C2	0.158	5.36
11	Internal C2	0.156	5.29	11	Internal C2	0.158	5.36
12	Internal C2	0.156	5.29	12	Internal C2	0.157	5.33
13	Internal C2	0.158	5.36	13	Internal C2	0.156	5.29
14	Internal C2	0.157	5.33	14	Internal C2	0.157	5.33
15	Internal C2	0.156	5.29	15	Internal C2	0.156	5.29
16	Internal C2	0.157	5.33	16	Internal C2	0.158	5.36
17	Internal C2	0.157	5.33	17	Internal C2	0.157	5.33
18	Internal C2	0.157	5.33	18	Internal C2	0.156	5.29
19	Internal C2	0.156	5.29	19	Internal C2	0.157	5.33
20	Internal C2	0.158	5.36	20	Internal C2	0.156	5.29
21	Internal C2	0.157	5.33	21	Internal C2	0.158	5.36
22	Internal C2	0.156	5.29	22	Internal C2	0.156	5.29
23	Internal C2	0.157	5.33	23	Internal C2	0.157	5.33
24	Internal C2	0.157	5.33	24	Internal C2	0.156	5.29
25	Internal C2	0.158	5.36	25	Internal C2	0.158	5.36
Mean			5.32	Mean			5.32
S.D.			0.03	S.D.			0.03
CV			0.01	CV			0.01
CV%			0.52	CV%			0.52

5.0 Performance Evaluation Report of D-Dimer.

Time interval= Day-0

Storage Temperature = 2°C – 8°C

Test	Vanguard Reagent		Reference Reagent		Specification (mg/L)
	ΔAbs./min	Conc (mg/L)	ΔAbs./min	Conc (mg/L)	
Calibrator (11.6 mg/L)	0.343	-	Calibrator (12.0 mg/L)	0.352	-
Controls					
Internal C1	0.062	2.10	0.063	2.15	1.42 - 2.37 mg/L
Internal C2	0.152	5.14	0.155	5.28	3.75 - 6.25 mg/L
Known normal/abnormal Serum samples					
Sample-1	0.012	0.41	0.013	0.44	Upto 0.5 mg/L
Sample-2	0.009	0.30	0.010	0.34	
Sample-3	0.014	0.47	0.013	0.44	
Sample-4	0.008	0.27	0.009	0.31	
Sample-5	0.011	0.37	0.012	0.41	
Linearity					
20 mg/L	0.582	19.68 (98.40%)	0.584	19.91 (99.55%)	± 10%

6.0 Accelerated Stability Studies: Summary

- Stability studies were conducted at 37°C till 14 days.
- Stability studies were conducted using Control (Level-1 & Level-2).
- It was not possible to use the “same” samples in the study due to the very limited stability of samples.
- The values obtained with D-Dimer were found to be comparable with the reference reagent till day 14 at 37°C.
- D-Dimer reagent was therefore found to be stable at 37°C for 14 days.
- This data has been extrapolated to conclude that D-Dimer reagent will be stable for 18 months under the recommended temperature conditions of 2°C- 8°C.

6.1 Accelerated stability study: D-Dimer.

Time interval= Day-7

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (mg/L)
	ΔAbs./min	Conc (mg/L)	ΔAbs./min	Conc (mg/L)	
Calibrator (11.6 mg/L)	0.342	-	Calibrator (12.0 mg/L)	0.346	-
Controls					
Internal C1	0.062	2.10	0.063	2.18	1.42 - 2.37 mg/L
Internal C2	0.152	5.16	0.155	5.38	3.75 - 6.25 mg/L
Known normal/abnormal Serum samples					
Sample-1	0.013	0.44	0.012	0.42	Upto 0.5 mg/L
Sample-2	0.010	0.34	0.011	0.38	
Sample-3	0.013	0.44	0.012	0.42	
Sample-4	0.009	0.31	0.010	0.35	
Sample-5	0.012	0.41	0.013	0.45	
Linearity					
20 mg/L	0.572	19.40 (97.00%)	0.568	19.70 (98.50%)	± 10%

6.2 Accelerated stability study: D-Dimer.

Time interval= Day-14

Storage Temperature= 37°C

Test	Vanguard Reagent		Reference Reagent		Specification (mg/L)
	ΔAbs./min	Conc (mg/L)	ΔAbs./min	Conc (mg/L)	
Calibrator (11.6 mg/L)	0.336	-	Calibrator (12.0 mg/L)	0.342	-
Controls					
Internal C1	0.064	2.21	0.063	2.21	1.42 - 2.37 mg/L
Internal C2	0.162	5.59	0.155	5.44	3.75 - 6.25 mg/L
Known normal/abnormal Serum samples					
Sample-1	0.011	0.38	0.012	0.42	Upto 0.5 mg/L
Sample-2	0.010	0.35	0.011	0.39	
Sample-3	0.013	0.45	0.014	0.49	
Sample-4	0.009	0.31	0.011	0.39	
Sample-5	0.013	0.45	0.013	0.46	
Linearity					
20 mg/L	0.558	19.26 (96.30%)	0.562	19.16 (95.80%)	± 10%

7.0 Conclusions

- The D-Dimer reagent showed an excellent Coefficient of Correlation (“r”) using as Reference.
- D-Dimer. showed values of “r” was 0.939 displaying the highest degree of correlation between the two sets of reagents.
- The D-Dimer reagent showed an excellent coefficient of Variation (CV %).
- The CV % was found to be in the range of 0.52% and 1.45% displaying a very high level of precision and repeatability.
- The D-Dimer reagent showed an excellent performance even under stressful conditions. The reagents were found to be stable at 37°C for 14 days.

The D-Dimer reagent was thus concluded to be Accurate, Precise and Stable, while using clinical normal and abnormal samples and 3rd Party controls (Level-1 and Level-2).
