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Research Article

Assessment of analytical process performance using the Six Sigma method: A comparison of two biochemistry analyzers

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Abstract

Objectives: Six Sigma is a method of quality management analysis that integrates accuracy and precision of measurement, error identification, and process improvement. The aim of this study was to evaluate the analytical process performance of routine biochemical tests performed with 2 biochemistry analyzers in our laboratory according to Six Sigma methodology and compare the findings.

Methods: Internal quality control (IQC) data of routine biochemical analytes used for 3 months in 2 Abbott Architect c16000 analyzers (Abbott Diagnostics Inc., Lake Forest, IL, USA) were extracted and the mean, SD, coefficient of variation %, bias % and sigma values were calculated. The performance of the analytes was classified according to the sigma level: <3 demonstrated poor performance, 3-6 was graded as acceptable, and >6 indicated good performance.

Results: For both analyzers, 2 levels IQC sigma values of chloride and sodium were <3, while the levels of alkaline phosphatase, aspartate aminotransferase, amylase, creatine kinase, iron, gamma-glutamyl transferase, and magnesium were >6; and the sigma values of total bilirubin, phosphorus, glucose, high-density lipoprotein-cholesterol, total cholesterol, calcium, creatinine, and total protein were determined to be within the acceptable range of 3-6. Amylase and creatine kinase were the best performers on both analyzers, while sodium had the lowest sigma values.

Conclusion: Six Sigma is a good method to evaluate the analytical process performance of a clinical laboratory. Quality control measures should be implemented for parameters with low sigma values.

Keywords: Laboratories, quality control, six sigma

Clinical laboratory reports play a critical role in clinical decisions about patients. Therefore, clinical laboratories should evaluate process performance and minimize laboratory errors in order to produce the most accurate and reproducible test results possible. There are 3 basic stages in the total test process of medical laboratories: pre-analytical, analytical, post-analytical. It has been reported that 30% to 75% of laboratory errors occur in the pre-analytical phase, 9% to 55% in the post-analytical phase, and 4% to 30% in the analytical phase [1].

Laboratories should evaluate their process performance according to scientifically accepted quality criteria. This assessment includes the percentage of sample errors and rejections in the pre-analytical phase, the accuracy and precision measurement of test results in the analytical phase, and critical values reporting and test turnaround times in the post-analytic phase [2].

Clinical laboratories approve the validity of the analysis process according to quality control procedures for each analyte. Quality control consists of internal quality control (IQC) and external quality control (EQC) measures. IQC generally employs 2 or 3 levels of clinical decision points and daily IQC results are interpreted using control charts, such as the Levy-Jennings and Westgard rules. EQC samples are provided to clinical chemistry laboratories by an external agency once a month for use in analyzing and reporting [1].

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Analytical process errors comprise systematic and random errors that have basic parameters such as inaccuracy and imprecision. These parameters are expressed as bias and coefficient of variation (CV), respectively. Total error (TE) can be calculated using bias and CV for each test (TE=Bias+1.65CV) [3]. The allowable total error (TEa) is a parameter provided by reports such as the US Clinical Laboratory Implementation Amendments 1988 (CLIA'88) and the German RiliBÄK [4, 5]. Evaluation of the process performance of a clinical laboratory is essential for comparison with laboratories around the world and to ensure high quality standards. During the analytical phase, variables can be assessed according to quality control and calibration procedures [6]. Analytical process performance can be evaluated using process sigma levels, quality indicators, and patient test results [7].

Six Sigma is a quality management method that integrates accurate and precision evaluation, error identification, and process improvement. The Six Sigma method has been used in hospital quality management since 1999 [8]. The universal application steps are to define, measure, analyze, develop, and control. The sigma value can be calculated by laboratories using the TEa and bias and CV % levels [sigma=(TEa %-bias %) /CV %]. A higher sigma level reflects greater consistency and stability of laboratory tests. A low sigma value indicates poor quality, defined as defects per million opportunities (DPMO). The process sigma values according to DPMO recorded in this study are shown in Table 1 [9].

Bias and SD values, which are the criteria of accuracy and repeatability, are obtained from IQC or EQC programs regularly used in clinical laboratories. While some studies suggest calculating the bias values using IQC data, others recommend using EQC data [1, 10-12].

In this study, the analytical process performance of routine biochemical tests performed using 2 biochemistry analyzers in our laboratory was evaluated using Six Sigma methodology and compared.

Materials and Methods

The present study was conducted between January 1, 2020 and March 30, 2020 in the clinical chemistry laboratory of Adiyaman University Research and Education Hospital. The IQC data of 2 Abbott Architect c16000 analyzers (Abbott Diagnostics Inc., Lake Forest, IL, USA) were extracted for the following parameters: albumin (Alb), alkaline phosphatase (ALP), alanine aminotransferase (ALT), aspartate aminotransferase (AST), amylase (AMY), direct bilirubin (DBIL), total bilirubin (TBIL), creatine kinase (CK), iron (Fe), phosphorus (P), gamma-glutamyl transferase (GGT), glucose (Glc), high-density lipoprotein-cholesterol (HDL-Cholesterol), total cholesterol, calcium (Ca), chloride (Cl), creatinine (CREA), lactate dehydrogenase (LD), lipase, magnesium (Mg), potassium (K), sodium (Na), total protein (TP), triglyceride (TG), uric acid (UA), and urea. The daily level 1 (normal concentration) and level 2 (abnormal concentration) IQC material used was Technopath MultiChem S Plus (Lot: 18609180; Technopath Life Sciences, Ballina, Co. Tipperary, Ireland) and was applied according to the manufacturer's instructions.

Table 1. Process sigma level according to defects per million opportunities

Sigma level	DPMO
1	691462
2	308538
3	66807
4	6210
5	233
6	3.4

DPMO: Defects per million opportunities.

IQC level 1 (n=65 for each test) and IQC level 2 (n=65 for each test) data were obtained from the laboratory information system. The target mean values of the IQC material were those specified by the IQC material manufacturer and the target TEa levels were determined according to the CLIA'88. The CLIA total error criteria can be freely accessed at http://www.westgard.com.

The laboratory mean, SD, CV %, bias %, and sigma values were calculated for all of the analytes and the performance was graded according to the sigma level (<3: poor performance, 3-6: acceptable, >6: good performance).

The statistical analysis was performed using Microsoft Office Excel 2007 (Microsoft Corp., Redmond, WA, USA). Non-acceptable control data were excluded from the study. The mean, SD, CV %, bias %, and sigma values of the acceptable control data were calculated using the following the formulas:

CV %=SD/Mean×100

Bias %=(Laboratory mean-Target Mean)/Target Mean×100

Sigma=(TEa-Bias)/CV

Results

The target mean, TEa level, laboratory mean, SD, CV %, bias %, and sigma values for IQC level 1 and level 2 of the tests run on the first Abbott Architect c16000 analyzer are shown in Table 2, and results for the second Abbott Architect c16000 analyzer are shown in Table 3. Table 4 shows the distribution of analytes grouped according to the calculated sigma values.

The sigma values of Alb, DBIL, Cl, Na, urea, and TG for IQC level 1 and the sigma values of Alb, Cl, and Na for IQC level 2 were <3 on the first analyzer. The sigma values of Cl and Na for IQC level 1, and the sigma values of Alb, DBIL, Cl, and Na for IQC level 2 were <3 on analyzer 2.

The sigma values of ALT, TBIL, P, Glc, HDL-cholesterol, total cholesterol, Ca, CREA, TP, and UA for IQC level 1, and the sigma values of DBIL, TBIL, P, Glc, HDL-cholesterol, total cholesterol,

Table 2. Analyzer 1: Target mean values provided by the manufacturer and the calculated laboratory mean, SD, CV %, bias %, and process sigma level of internal quality controls calculated in our laboratory

Test (Unit)	IQC level	Target mean	TEa % (CLIA'88)	Laboratory mean	Laboratory SD	Laboratory CV %	Laboratory bias %	Sigma level
Albumin (g/L)	QC1	0.03	10	0.031	0.001	2.91	3.13	2.36
	QC2	0.036	10	0.038	0.001	2.81	5.03	1.77
Alkaline phosphatase (IU/L)	QC1	68.5	30	67.93	3.2	4.71	-0.83	6.55
	QC2	183.5	30	193.97	6.13	3.16	5.7	7.69
Alanine aminotransferase (IU/L)	QC1	21.5	20	19.44	1.83	9.43	-9.6	3.14
	QC2	108	20	105.79	2.3	2.17	-2.04	10.16
Aspartate aminotransferase (IU/L)	QC1	37.5	20	38.81	1.06	2.73	3.5	6.04
	QC2	135.5	20	140.67	2.55	1.81	3.81	8.93
Amylase (U/L)	QC1	38	30	38.15	1.06	2.79	0.40	10.61
	QC2	112.5	30	117.43	2.94	2.51	4.38	10.22
Direct bilirubin (µmol/L)	QC1	38.1	20	36.55	3.46	9.48	-3.83	2.52
	QC2	110.5	20	104.37	8.6	8.24	-5.55	3.1
Total bilirubin (µmol/L)	QC1	81.33	20	71.91	4.64	6.46	-11.58	4.89
	QC2	253.71	20	227.77	15.64	6.87	-10.23	4.4
Creatine kinase (IU/L)	QC1	68	30	63.91	1.99	3.11	-6.02	11.57
	QC2	238	30	235.82	5.05	2.14	-0.92	14.45
Iron (µmol/L)	QC1	4.54	20	4.48	0.15	3.34	-1.26	6.36
	QC2	5.6	20	5.48	0.15	2.8	-2.25	7.94
Phosphorus (mg/dL)	QC1	2.25	15	2.34	0.06	2.72	4.03	4.04
	QC2	4.3	14.8	4.45	0.13	2.81	3.45	4.03
Gamma-glutamyl transferase (U/L)	QC1	25	17.9	20.05	1.24	6.19	-19.81	6.1
	QC2	69.5	17.4	65.5	1.82	2.77	-5.76	8.35
Glucose (mmol/L)	QC1	2.78	10	2.75	0.09	3.1	-0.92	3.52
	QC2	7.16	10	7.07	0.16	2.2	-1.31	5.14
HDL-cholesterol (mmol/L)	QC1	1.44	30	1.42	0.08	5.73	-1.42	5.48
	QC2	2.22	30	2.15	0.13	6.27	-3.32	5.31
Total cholesterol (mmol/L)	QC1	5	10	5.04	0.11	2.12	0.85	4.31
	QC2	8.38	10	8.5	0.2	2.36	1.45	3.62
Calcium (mmol/L)	QC1	0.35	11.3	0.35	0.01	2.55	-0.88	4.78
	QC2	0.53	7.4	0.54	0.01	2.25	0.5	3.07
Chloride (mmol/L)	QC1	84.5	5	86.28	1.52	1.76	2.11	1.65
	QC2	99	5	101.55	1.88	1.85	2.57	1.31
Creatinine (µmol/L)	QC1	54.81	15	54.64	1.51	2.77	-0.31	5.53
	QC2	179.45	15	180.09	5.4	3	0.36	4.88
Lactate dehydrogenase (U/L)	QC1	111	20	105.59	3.63	3.44	-4.87	7.24
	QC2	230	20	237.93	8	3.36	3.45	4.93
Lipase (U/L)	QC1	25.5	30	24.72	1.31	5.29	-3.06	6.25
	QC2	70	30	68.81	3.16	4.6	-1.7	6.9
Magnesium (mmol/L)	QC1	0.08	25	0.078	0.002	3.1	-3.03	9.04
	QC2	0.144	25	0.137	0.003	2.56	-4.66	11.6
Potassium (mmol/L)	QC1	2.55	13.9	2.53	0.06	2.27	-0.9	6.52
	QC2	4.25	7	4.25	0.08	1.88	-0.09	3.77
Sodium (mmol/L)	QC1	113	2.7	113.76	1.88	1.65	0.67	1.23
	QC2	146.5	2.9	148.36	2.63	1.77	1.27	0.92
Total protein (g/L)	QC1	46.5	10	47.19	0.75	1.59	1.49	5.36
	QC2	57	10	57.77	0.99	1.72	1.35	5.04
Triglyceride (mmol/L)	QC1	3.83	25	4.1	0.35	8.42	6.96	2.14
	QC2	9.38	25	9.63	0.47	4.93	2.69	4.53
Uric acid (mmol/L)	QC1	0.14	17	0.15	0.004	2.56	6.1	4.26
	QC2	0.31	17	0.32	0.01	2.09	2.62	6.86
Urea (mmol/L)	QC1	0.94	9	0.96	0.04	4.62	1.91	1.53
	QC2	4.77	9	4.78	0.1	2.07	0.13	4.29

CLIA'88: Clinical Laboratory Implementation Amendments 1988; CV: Coefficient of variation; IQC: Internal quality control; TEa: Total allowable error; QC: Quality control; HDL: high-density lipoprotein.

Table 3. Analyzer 2: Target mean values provided by the manufacturer and the calculated laboratory mean, SD, CV %, bias %, and process sigma level of internal quality controls calculated in our laboratory

Test (Unit)	IQC level	Target mean	TEa % (CLIA'88)	Laboratory mean	Laboratory SD	Laboratory CV %	Laboratory bias %	Sigma level
Albumin (g/L)	QC1	0.03	10	0.031	0.001	2.14	3.21	3.18
	QC2	0.036	10	0.038	0.001	1.9	4.33	2.99
Alkaline phosphatase (IU/L)	QC1	68.5	30	67.33	2.28	3.38	-1.7	9.37
	QC2	183.5	30	192.22	5.76	3	4.75	8.43
Alanine aminotransferase (IU/L)	QC1	21.5	20	19.77	0.86	4.36	-8.05	6.43
	QC2	108	20	103.96	1.4	1.35	-3.74	17.64
Aspartate aminotransferase (IU/L)	QC1	37.5	20	37.42	1.03	2.74	-0.21	7.37
	QC2	135.5	20	137	2.43	1.78	1.11	10.64
Amylase (U/L)	QC1	38	30	38.04	0.45	1.2	0.11	25.01
	QC2	112.5	30	115.77	1.42	1.23	2.91	22.04
Direct bilirubin (µmol/L)	QC1	38.01	20	37.16	2.68	7.2	-2.23	3.09
	QC2	110.5	20	105.38	8.72	8.28	-4.63	2.98
Total bilirubin (µmol/L)	QC1	79.56	20	71.83	5.49	7.64	-9.72	3.89
	QC2	253.71	20	231.17	16.92	7.32	-8.89	3.95
Creatine kinase (IU/L)	QC1	68	30	63	1.76	2.79	-7.35	13.4
	QC2	238	30	233.91	5.02	2.14	-1.72	14.79
Iron (µmol/L)	QC1	4.54	20	4.47	0.09	1.94	-1.54	11.1
	QC2	5.6	20	5.46	0.15	2.77	-2.48	8.1
Phosphorus (mg/dL)	QC1	2.25	15	2.34	0.05	2.15	4.07	5.08
	QC2	4.3	14.8	4.47	0.11	2.49	3.84	4.4
Gamma-glutamyl transferase (U/L)	QC1	25	17.9	19.87	0.68	3.44	-20.51	11.16
	QC2	69.5	17.4	65.63	1.57	2.39	-5.56	9.61
Glucose (mmol/L)	QC1	2.78	10	2.74	0.07	2.69	-1.18	4.16
	QC2	7.16	10	7.07	0.15	2.19	-1.28	5.16
HDL-cholesterol (mmol/L)	QC1	1.44	30	1.42	0.09	6.15	-1.94	5.19
	QC2	2.22	30	2.12	0.12	5.64	-4.71	6.15
Total cholesterol (mmol/L)	QC1	5	10	5.07	0.11	2.1	1.56	4.03
	QC2	8.41	10	8.5	0.22	2.53	1.07	3.53
Calcium (mmol/L)	QC1	0.347	11.3	0.345	0.01	1.88	-0.46	6.25
	QC2	0.533	7.4	0.532	0.01	1.97	-0.27	3.9
Chloride (mmol/L)	QC1	84.5	5	86.52	1.62	1.87	2.4	1.4
	QC2	99	5	101.09	1.8	1.78	2.11	1.62
Creatinine (µmol/L)	QC1	54.81	15	53.72	1.79	3.34	-1.99	5.09
	QC2	179.45	15	178.23	5.43	3.04	-0.68	5.15
Lactate dehydrogenase (U/L)	QC1	111	20	104.52	4.71	4.51	-5.84	5.73
	QC2	230	20	235.29	5.46	2.32	2.3	7.63
Lipase (U/L)	QC1	25.5	30	24.28	1.59	6.57	-4.78	5.3
	QC2	70	30	67.5	3.89	5.76	-3.57	5.83
Magnesium (mmol/L)	QC1	0.08	25	0.078	0.002	2.86	-3.02	9.79
	QC2	0.144	25	0.136	0.004	2.95	-5.49	10.34
Potassium (mmol/L)	QC1	2.55	13.9	2.55	0.07	2.73	-0.13	5.14
	QC2	4.25	7	4.27	0.08	1.98	0.35	3.35
Sodium (mmol/L)	QC1	113	2.7	114.81	2.18	1.9	1.6	0.58
	QC2	146.5	2.9	149.27	2.44	1.64	1.89	0.62
Total protein (g/L)	QC1	46.5	10	47.2	0.82	1.73	1.51	4.91
	QC2	57	10	57.88	0.83	1.44	1.54	5.88
Triglyceride (mmol/L)	QC1	3.83	25	3.97	0.09	2.27	3.58	9.44
	QC2	9.38	25	9.63	0.21	2.23	2.72	9.99
Uric acid (mmol/L)	QC1	0.14	17	0.15	0.004	2.81	6.42	3.77
	QC2	0.31	17	0.32	0.01	2.11	1.88	7.18
Urea (mmol/L)	QC1	0.94	9	0.92	0.03	2.78	-2.55	4.15
	QC2	4.77	9	4.69	0.12	2.62	-1.65	4.06

CLIA'88: Clinical Laboratory Implementation Amendments 1988; CV: Coefficient of variation; IQC: Internal quality control; TEa: Total allowable error; QC: Quality control; HDL: high-density lipoprotein.

Table 4. Distribution of analytes grouped according to calculated sigma value

	Analyzer 1		Analyzer 2	
Sigma metrics	**QC1**	**QC2**	**QC1**	**QC2**
Group 1 (<3 sigma)	Albumin Direct bilirubin Chloride Sodium Urea Triglyceride	Albumin Chloride Sodium	Chloride Sodium	Albumin Direct bilirubin Chloride Sodium
Group 2 (3-6 sigma)	ALT Total bilirubin Phosphorus Glucose HDL-cholesterol Total cholesterol Calcium Creatinine Total protein Uric acid	Direct bilirubin Total bilirubin Phosphorus Glucose HDL-cholesterol Total cholesterol Calcium Creatinine Lactate dehydrogenase Potassium Total protein Triglyceride Urea	Albumin Direct bilirubin Total bilirubin Phosphorus Glucose HDL-cholesterol Total cholesterol Creatinine Lactate dehydrogenase Lipase Potassium Total protein Uric acid Urea	Total bilirubin Phosphorus Glucose Total cholesterol Calcium Creatinine Lipase Potassium Total protein Urea
Group 3 (>6 sigma)	Alkaline phosphatase AST Amylase Creatine kinase Iron GGT Lactate dehydrogenase Lipase Magnesium Potassium	Alkaline phosphatase ALT AST Amylase Creatine kinase Iron GGT Lipase Magnesium Uric acid	Alkaline phosphatase ALT AST Amylase Creatine kinase Iron GGT Calcium Magnesium Triglyceride	Alkaline phosphatase ALT AST Amylase Creatine kinase Iron GGT HDL-cholesterol Lactate dehydrogenase Magnesium Triglyceride Uric acid

QC: Quality control; ALT: Alanine aminotransferase; AST: Aspartate aminotransferase; GGT: Gamma-glutamyl transferase; HDL: High-density lipoprotein.

Ca, CREA, LD, K, TP, TG, and urea for IQC level 2 were within the acceptable range on analyzer 1 (sigma level: 3-6). For analyzer 2, the sigma values of Alb, DBIL, TBIL, P, Glc, HDL-cholesterol, total cholesterol, CREA, LD, lipase, K, TP, UA, and urea for IQC level 1, and the sigma values of TBIL, P, Glc, total cholesterol, Ca, CREA, lipase, K, TP, and urea for IQC level 2 were within the acceptable range (sigma level: 3-6).

ALP, ALT (except IQC level 1 on analyzer 1), AST, AMY, CK, Fe, lipase (analyzer 1), GGT, LD (except IQC level 2 on analyzer 1 and IQC level 1 on analyzer 2), Mg, TG (analyzer 2), UA (except IQC level 1 on both analyzers), K (IQC level 1 on analyzer 1), Ca (IQC level 1 on analyzer 2), and HDL-cholesterol (IQC level 2 on analyzer 2) had good performance (sigma level: >6).

Discussion

We evaluated 26 biochemical analytes using the Six Sigma methodology on 2 Abbott Architect c16000 analyzers and we compared IQC level sigma values. For both analyzers, the 2 levels of IQC sigma values of Cl, Na, and Alb (except IQC level 1 on analyzer 2) were <3; the 2 levels of IQC sigma values of ALP, AST, AMY, CK, Fe, GGT, Mg, TG (analyzer 2), ALT (except IQC level 1 on analyzer 1) were >6. The 2 levels of IQC sigma values of TBIL, P, Glc, HDL-cholesterol (except IQC level 2 on analyzer 2), total cholesterol, Ca (except IQC level 1 on analyzer 2), CREA, TP, and urea (except IQC level 1 on analyzer 1) were within the acceptable range (sigma level: 3-6). AMY and CK had the best

sigma metrics on both analyzers, while Na had the lowest sigma values on both analyzers. The sigma values of many analytes were consistent for both analyzers.

Many studies have evaluated analytical performance using the Six Sigma method with different analyzers and parameters, and using internal or external quality controls. Medina et al. [12] evaluated 5 years of IQC data of 2 Abbott Architect c8000 chemistry analyzers. The sigma values of DBIL, CK, HDL-cholesterol, TG, and UA were >6 for 1 analyzer while the values of CK, DBIL, HDL-cholesterol, Mg, TG, and UA were >6 for the second analyzer. The electrolytes Ca, Cl, and Na had an average sigma level of <3 on both devices, while K showed better sigma scores.

Mao et al. [1] and Zhou et al. [13] extracted 5 months' worth of IQC data of biochemical parameters using the AU5800 analyzer (Beckman Coulter Inc., Brea, CA, USA). In the study performed by Mao et al. [1], the sigma values of urea and Na were determined to be <3; and AMY, UA, HDL-cholesterol, TBIL, ALT, TG, AST, ALP, and CREA were >6. Zhou et al. [13] reported that the sigma values of BUN, Ca, ALT, and P were <3, and those of ALP, CK, TG, GGT, and TBIL were >6.

Other studies in the literature that used the Six Sigma method have yielded varied results [10, 11, 14-18]. The differences in sigma values of the analytes may be due to differences in the autoanalyzers, the quality control material, the pre/post-analytical conditions, the period of study, or the method used.

The TEa target levels used to evaluate the analytical process influence the calculated sigma values. It has been noted that the different CLIA and RiliBÄK TEa levels affected the results [4, 5]. In our study, the TEa target values were determined according to the CLIA'88 and the low sigma values of Na and Cl seen may have been due to the low TEa target levels used. A very stringent calibration, IQC, and analyzer maintenance have to be followed for parameters with low sigma values. Simple QC rules are adequate for parameters with high sigma values.

Six Sigma-method applications allow a laboratory to calculate their performance using universal criteria and to compare the results with those of other clinical laboratories around the world. Parameters with low performance can be identified using this analysis and performance should be improved with regulatory activities in order to meet the universal quality criteria. The sigma levels of Na, Cl, and Alb in our study indicated that regulatory activities should be conducted for low concentration and electrolyte tests that were studied with the indirect ion selective electrode method. Fluctuations in the electrolyte results may have been due to contamination or deterioration of the reference electrode. We implemented regulatory activities such as changing the reference solution and performing electrode maintenance more frequently to resolve these problems.

This study has some limitations that should be noted. First, the evaluation period was limited to 3 months. Second, because of the short duration, the EQC-Bias % was not evaluated. We believe that EQC-Bias % data calculated over longer periods would provide statistically more accurate results, and our next goal is to evaluate the EQC as well as the IQC over a longer period as a bias indicator.

In conclusion, the Six Sigma method is an effective form of statistical analysis to evaluate analytical process performance with quality control results. In the present study, the identification and measurement steps of the universal application were performed for biochemistry tests on 2 Abbott Architect c16000 analyzers. The next goal is to perform the analysis, improvement, and control steps to further enhance our analytical process performance.

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