FINAL REPORT

Clinical Performance Evaluation of

Mindray Automated Chemiluminescence Analyzer: CL-1000i

Evaluated by

Uniwersyteckie Centrum Kliniczne – Gdański Uniwersytet Medyczny
st. Dębinki 7, 80-952 Gdańsk, Poland
TEL: +48 58 727 05 05

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1 Overview

1.1 Background of Uniwersyteckie Centrum Kliniczne

The Uniwersyteckie Centrum Kliniczne (University Clinical Center), also known as UCK Gdańsk, is one of the largest hospitals and took second place in the third edition of the World's Best Hospitals 2021 ranking in Poland. It was established by the Gdański Uniwersytet Medyczny (Medical University of Gdańsk) in 1945. Since then, they have been providing medical services, offering patients comprehensive diagnostics and treatment.

Cooperation with the university gives them access to the latest technologies, global medical knowledge and clinical trials. The offer of the UCK Gdańsk includes a full range of medical services: advanced diagnostics, various surgical procedures, rehabilitation and palliative care. They have most of the specialties that are available in the area of medical services with comprehensive treatment. In addition to typically therapeutic activities, they also run educational programs, emphasizing disease prevention. Besides, UCK Gdańsk was accredited by ISO9001:2015, ISO 14001:2015 and ISO 45001:2018.

1.2 Purpose

CL-1000i is an automated immunoassay analyzer, which is designed and manufactured by Shenzhen Mindray Bio-Medical Electronics Co. Ltd. The purpose of the below study was to evaluate the possibility of applying Mindray CL-1000i system in clinical immunology practice at our laboratory. Method comparison was performed with our routine testing system Abbott Alinity i.

1.3 Instrument and Test Evaluation

1.3.1 Candicate instrument: CL-1000i (provided by Mindray)

1.3.2 Comparative instrument: Alinity i (Abbott)

1.3.3 Tests for method comparison: 5 tests including TPSA, cTnI, TSH, T3 and T4

1.4 Basic information of instrument, meterials and reagents

1.4.1 Mindray instrument serial No: BG7-0C000065

1.4.2 All material instrument, reagents, calibrators, control materials, substrate, wash buffer, sample cups, sample tubes, cuvette were provided by Mindray.

1.4.3 All infrastructure, laboratory facilities, samples and other laboratory material were provided by UCK Gdańsk.

1.4.4 Reagents, calibrators, control materials and consumables

Type	Parameter	Bottle Type	Lot number
Reagent	TPSA	2x50 Tests	2022009112
	cTnI	2x50 Tests	2022050111
	TSH	2x50 Tests	2022070111
	T3	2x50 Tests	2022040111
	T4	2x50 Tests	2022008011
Control	TUMOR M1	3x5ml	2022040111
	TUMOR M2	3x5ml	2022040111
	CARDIAC 1	3x2ml	2022080101
	CARDIAC 2	3x2ml	2022080101
	THYROID 1	3x5ml	2022030100
	THYROID 2	3x5ml	2022030100
Calibrator	PSA CAL	3x2ml	2022070111
	cTnI CAL	3x2ml	2022080101
	TSH CAL	3x2ml	2022020100
	T3 CAL	3x2ml	2022070111
	T4 CAL	3x2ml	2022070111

1.4.5 Duration

The evaluation was carried out within the period of 21st Feb. 2023 to 3rd Apr. 2023.

2 Acceptance Criteria

2.1 Effectiveness evaluation index and evaluation method

2.1.1 Precision (between days)

Acceptance criteria: CV%<10% (except cTnI, as the value of the control material or pooled sample is less than 0.5, then take the SD<0.05 as the acceptance criteria)

2.1.2 Quantitative evaluation

Regarding the evaluation method of EP9-A2, the method comparison results of the quantitative parameters (TPSA, cTnI, TSH, T3 and T4 on Mindray CL-1000i and the reference instrument Abbott Alinitiy i) were analyzed by correlation analysis and regression analysis. The fitting equation, correlation index R^2 and slope of the regression analysis are given in the form of y=a+bx.

a) Acceptance criteria: Pearson correlation coefficient>0.9

The linear correlation analysis on the measured values of Mindray CL-1000i and the reference instrument Abbott Alinity i, generates the correlation coefficient. If the hypothesis test makes that the correlation coefficient is equal to zero. And then the correlation coefficient R>0.9, it can be inferred that the method comparison results of Mindray CL-1000i and the reference instrument Abbott Alinity i have a good correlation. Pearson correlation analysis can be properly used for quantitative analysis.

b) Perform linear regression analysis and draw a scatter plot

Carry out linear regression analysis on the measured values of Mindray CL-1000i and the reference instrument Abbott Alinity i, and gerenates the linear regression equation, regression coefficient (slope) and its 95% confidence interval.

3 Statistical Analysis Guildlines and Statistical Software

3.1 Quantitative analysis

This report is based on an Excel database, and the statistical analysis is processed with SPSS20.0® and MedCalc (V22.009). For quantitative evaluation, Pearson simple correlation analysis and linear regression analysis were used for correlation analysis; Routine statistical test adopts two-sided test (except TPSA). α=0.05 is taken as the statistical test level, the constant and regression coefficient of each parameter is estimated by 95% confidence interval.
(Reference：Bowker AH. A test for symmetry in contingency tables. J. Amer. Statist. Assoc. 1948：43：572-574)

3.2 Outlier analysis:

This Excel database is processed with MedCalc(V22.009) for outlier detection by using ESD test.

The ESD test is a method for detecting outliers by testing one or more outliers in a univariate data set that obeys an approximately normal distribution.

First, assume that there are outliers, and the probability of outliers cannot exceed 5%. Set the upper limit of potential outliers according to the outlier probability and the total number of samples, and round down the integer as the number of outliers.

For example, If the total number of samples is 75, the upper limit of outliers=75*5%=3.75, and the upper limit of outliers is 3.

Note: it will not be showed in this report if there is no outlier of the raw data.

4 The results of CL-1000i analyzer evaluation

4.1 Precision results

4.1.1 Sample

a) Mindray internal quality control materials: 2 levels

b) Pooled sera: 3 levels

4.1.2 Precision results (between days)

TPSA					
No.	Tumor M 1	Tumor M 2	Pooled Sample 1	Pooled Sample 2	Pooled Sample 3
1	0.954	12.775	0.366	8.501	25.467
2	0.94	12.542	0.369	8.585	25.136
3	0.97	12.781	0.376	8.519	25.529
4	0.973	12.834	0.368	8.473	25.342
5	1.005	13.601	0.37	8.634	25.373
6	0.927	11.566			
7	0.902	11.711			
8	0.904	11.645			
Mean	0.947	12.432	0.370	8.542	25.369
SD	0.033	0.677	0.003	0.059	0.134
CV	**3.53%**	**5.45%**	**0.91%**	**0.69%**	**0.53%**
Conclusion	**Pass**	**Pass**	**Pass**	**Pass**	**Pass**

cTnI					
No.	CARDIAC 1	CARDIAC 2	Pooled Sample 1	Pooled Sample 2	Pooled Sample 3
1	0.286	14.884	0.023	4.703	14.912
2	0.281	14.167	0.023	4.674	14.806
3	0.269	13.656	0.022	4.655	14.643

4	0.21	11.614	0.029	4.691	14.734
5	0.207	11.718	0.023	4.712	14.692
6	0.252	11.836			
7	0.251	11.829			
Mean	0.251	12.815	0.024	4.687	14.757
SD	**0.029**	1.276	**0.003**	0.020	0.094
CV	11.74%	9.96%	10.54%	0.44%	0.64%
Conclusion	**Pass**	**Pass**	**Pass**	**Pass**	**Pass**

TSH				
No.	Thyroid 1	Thyroid 2	Pooled Sample 1	Pooled Sample 2
1	0.671	33.413	0.125	33.75
2	0.665	33.334	0.12	32.407
3	0.663	33.71	0.12	33.579
4	0.664	33.258	0.112	32.934
5	0.702	34.709	0.114	33.087
6	0.667	33.55		
7	0.657	32.817		
8	0.671	32.445		
Mean	0.670	33.542	0.118	33.151
SD	0.013	0.625	0.005	0.479
CV	**1.91%**	**1.86%**	**3.95%**	**1.44%**
Conclusion	**Pass**	**Pass**	**Pass**	**Pass**

T3					
No.	Thyroid 1	Thyroid 2	Pooled Sample 1	Pooled Sample 2	Pooled Sample 3
1	2.25	9.04	0.95	2.13	7.54
2	2.32	9.24	0.95	2.23	7.55
3	2.3	9.07	0.96	2.2	7.7
4	2.3	8.81	0.93	2.15	7.53
5	2.22	8.74	0.96	2.18	7.62
6	2.24	9.07			
7	2.2	8.84			
8	2.26	9.04			
Mean	2.261	8.973	0.950	2.178	7.588
SD	0.040	0.157	0.011	0.035	0.064
CV	**1.75%**	**1.75%**	**1.15%**	**1.63%**	**0.85%**
Conclusion	**Pass**	**Pass**	**Pass**	**Pass**	**Pass**

T4					
No.	Thyroid 1	Thyroid 2	Pooled Sample 1	Pooled Sample 2	Pooled Sample 3
1	0.84	2.64	0.34	0.71	2.9
2	0.75	2.46	0.32	0.7	2.89
3	0.74	2.49	0.33	0.7	2.92
4	0.74	2.48	0.33	0.7	2.91
5	0.7	2.36	0.34	0.71	2.86
6	0.77	2.48			
7	0.77	2.49			
8	0.78	2.55			
Mean	0.759	2.486	0.332	0.704	2.896
SD	0.038	0.074	0.007	0.005	0.021
CV	**5.00%**	**2.99%**	**2.25%**	**0.70%**	**0.71%**
Conclusion	**Pass**	**Pass**	**Pass**	**Pass**	**Pass**

4.2 Method comparison

4.2.1 Statistical Analysis Datasets

The candidate instrument CL-1000i all tested the number of samples of each parameter as follows: TPSA-47 samples, cTnI-50 samples, TSH-53 samples, T3-47 samples, T4-47 samples.

After removing all the samples exceeding the detection ranges, the number of the samples for each parameter for final analysis is as follows：TPSA-45 samples, cTnI-50 samples, TSH-52 samples, T3-45 samples.

After removing the outliers of Mindray 2.12 and the outlier of Abbott 0.34 (calculated by MedCalc), the number of T4 is 45.

4.2.2 Results of method comparison

a) Correlation and regression analysis of TPSA test results

Parameter	n	mean	std	max	min	p25	p75	t	P
Mindray_TPSA	45	3.2978	6.505	35.65	0.013	0.431	2.975	3.401	0.001
Abbott_Tpsa	45	3.369	6.607	35.62	0.003	0.445	3.081		
Pearson				r_p =0.997 / P =0.000					
Linear regression				Y=-0.009+0.982x					
95%CI of intercept and slope				a[-0.184，0.166]，b[0.958，1.005]					

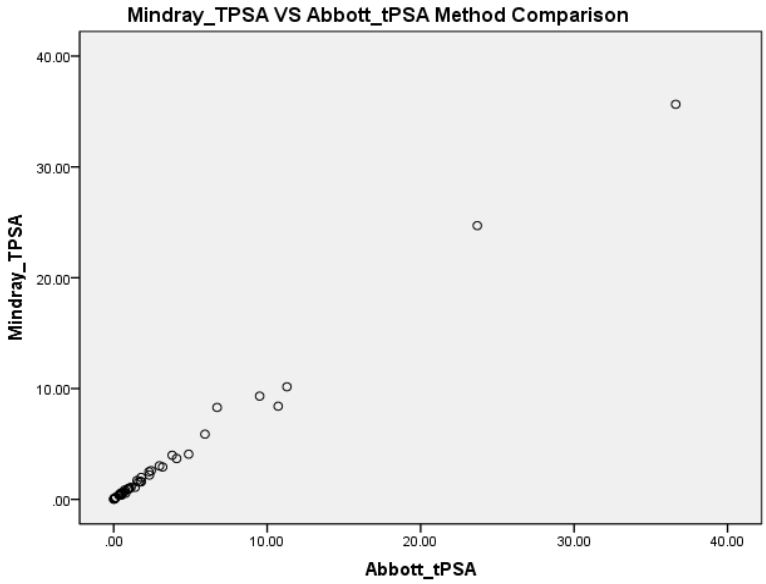

Figure 1 TPSA raw data scatter plot

It can be seen from the above table that the overall concentration of TSH was determined by the candidate instrument Mindray CL-1000i was 3.2978±6.505 ng/mL, and the reference instrument Abbott Alinity i was 3.369±6.607 ng/mL, there was statistically significant difference between the two grouped values (t = 3.401, P =0.001). The Pearson correlation coefficient between the candidate instrument and the reference instrument is r_p = 0.997 (P <0.001), and the concentration results of the two instruments have a strong correlation. The regression equation Y=-0.009+0.982x, the linear relationship is established (P <0.001), the regression coefficient is 0.982, close to 1, and its 95%CI is (0.958, 1.005); the intercept is -0.009, close to 0. Its 95%CI is (-0.184, 0.166). From the above results, it can be inferred that the quantitative results of the candidate instrument and the reference instrument are almost the same.

b) Correlation and regression analysis of cTnI test results

Parameter	n	mean	std	max	min	p25	p75	t	P
Mindray_cTnI	50	8.235	24.453	150.24	0.011	0.154	5.232	2.381	0.021
Abbott_hsTnI	50	9.899	31.428	195.17	0.0062	0.1238	6.2744		
Pearson				r_p =0.999/ P =0.000					
Linear regression				Y=0.543+0.777x					
95%CI of intercept and slope				a[0.162，0.924]，b[0.765，0.789]					

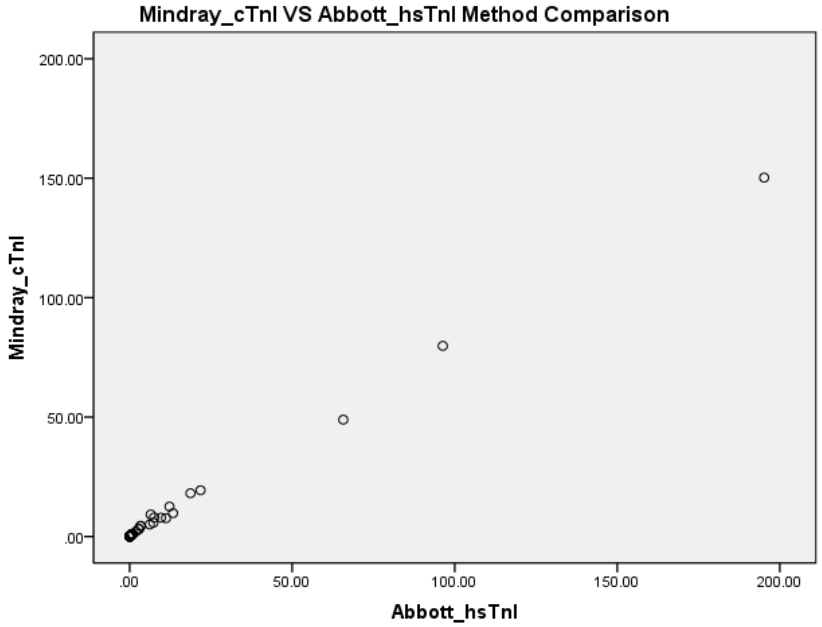

Figure 2 cTnI raw data scatter plot

It can be seen from the above table that the overall concentration of TSH was determined by the candidate instrument Mindray CL-1000i was 8.235±24.453 ng/mL, and the reference instrument Abbott Alinity i was 9.899±31.428 ng/mL, there was not statistically significant difference between the two grouped values (t = 2.381, P =0.021). The Pearson correlation coefficient between the candidate instrument and the reference instrument is r_p = 0.999 (P <0.001), and the concentration results of the two instruments have a strong correlation. The regression equation Y=0.543+0.777x, the linear relationship is established (P <0.001), the regression coefficient is 0.777 and its 95%CI is (0.765, 0.789); the intercept is 0.543, close to 0. Its 95%CI is (0.162, 0.924).

Because Mindray cTnI is normal TnI, Abbott cTnI is high sensitive one, that's why the slope of the linear regression equation is not close to 1, while there is no discrepancy result. So it can be inferred that the quantitative results of the candidate instrument and the reference instrument can both be used for diagnosis.

c) Correlation and regression analysis of TSH test results

Parameter	n	mean	std	max	min	p25	p75	t	P
Mindray_TSH	52	5.6415	7.9026	31.27	0.04	1.1783	4.631	5.148	0.000
Abbott_TSH	52	3.9317	5.4284	23.2	0.1	0.9582	3.3108		
Pearson				r_p =0.983/ P =0.000					
Linear regression				Y=0.013+1.431x					
95%CI of intercept and slope				a[-0.488，0.515]，b[1.356，1.507]					

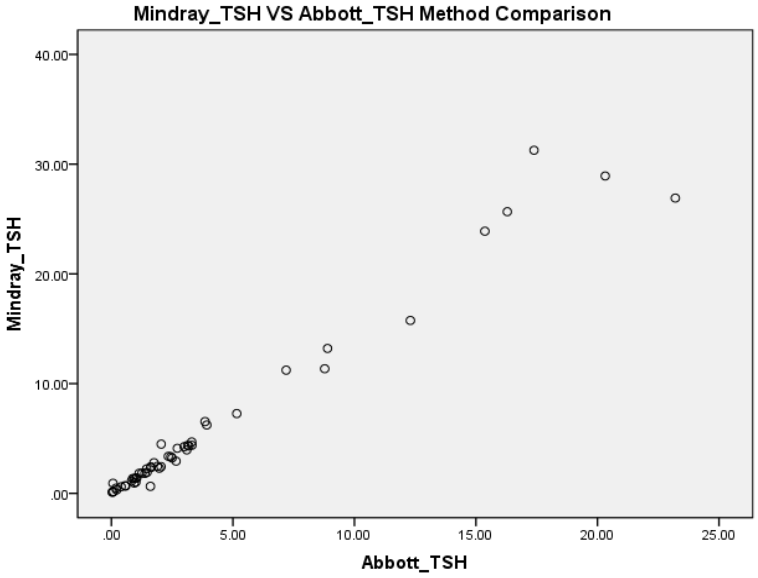

Figure 3 TSH raw data scatter plot

It can be seen from the above table that the overall concentration of TSH was determined by the candidate instrument Mindray CL-1000i was 5.6415±7.9026 uU/mL, and the reference instrument Abbott Alinity i was 3.9317±5.4284 uU/mL, there was statistically significant difference between the two grouped values (t = 5.148, P =0.000). The Pearson correlation coefficient between the candidate instrument and the reference instrument is r_p = 0.983 (P <0.001), and the concentration results of the two instruments have a strong correlation. The regression equation Y=0.013+1.431x, the linear relationship is established (P <0.001), the regression coefficient is 1.431 and its 95%CI is (1.356, 1.507); the intercept is 0.013, close to 0. Its 95%CI is (-0.488, 0.515).

Mindray TSH is 35% higher than Abbott TSH averagely, that's why the slope of the linear regression equation is not close to 1, while there is no discrepancy result. So it can be inferred that the quantitative results of the candidate instrument and the reference instrument can both be used for supporting diagnosis of thyroid diseases.

d) Correlation and regression analysis of T3 test results

Parameter	n	mean	std	max	min	p25	p75	t	P
Mindray_T3	45	2.7951	1.0594	7.72	1.35	2.24	3.115	17.699	0.000
Abbott_T3	45	2.6167	0.96	7.06	1.4	2.08	2.905		
Pearson				r_p =0.979/ P =0.000					
Linear regression				Y=-0.031+1.08x					
95%CI of intercept and slope				a[-0.225, 0.162], b[1.011, 1.15]					

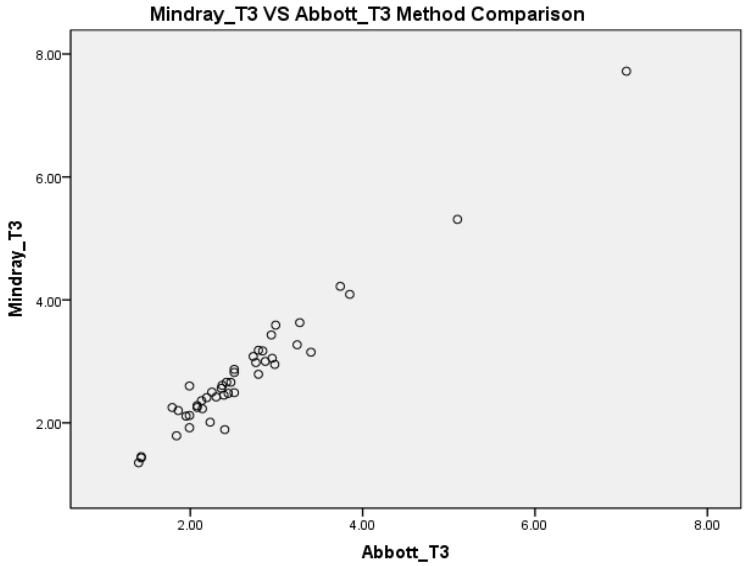

Figure 4 T3 raw data scatter plot

It can be seen from the above table that the overall concentration of T3 was determined by the candidate instrument Mindray CL-1000i was 2.7951±1.0594 pg/mL, and the reference instrument Abbott Alinity i was 2.6167±0.96 pg/mL, there was statistically significant difference between the two grouped values (t = 17.699, P =0.000). The Pearson correlation coefficient between the candidate instrument and the reference instrument is r_p = 0.979 (P <0.001), and the concentration results of the two instruments have a strong correlation. The regression equation Y=-0.031+1.08x, the linear relationship is established (P <0.001), the regression coefficient is 1.08, close to 1, and its 95%CI is (1.011, 1.15); the intercept is -0.031, close to 0. Its 95%CI is (-0.225, 0.162). From the above results, it can be inferred that the quantitative results of the candidate instrument and the reference instrument are almost the same.

e) Correlation and regression analysis of T3 test results

Parameter	n	mean	std	max	min	p25	p75	t	P
Mindray_T4	45	0.8944	0.22419	1.43	0.31	0.745	1.045	26.763	0.000
Abbott_T4	45	0.9789	0.18255	1.39	0.44	0.88	1.11		
Pearson				r_p =0.931/ P =0.000					
Linear regression				Y=-0.225+1.14x					
95%CI of intercept and slope				a[-0.362，-0.088]，b[1.006，1.281]					

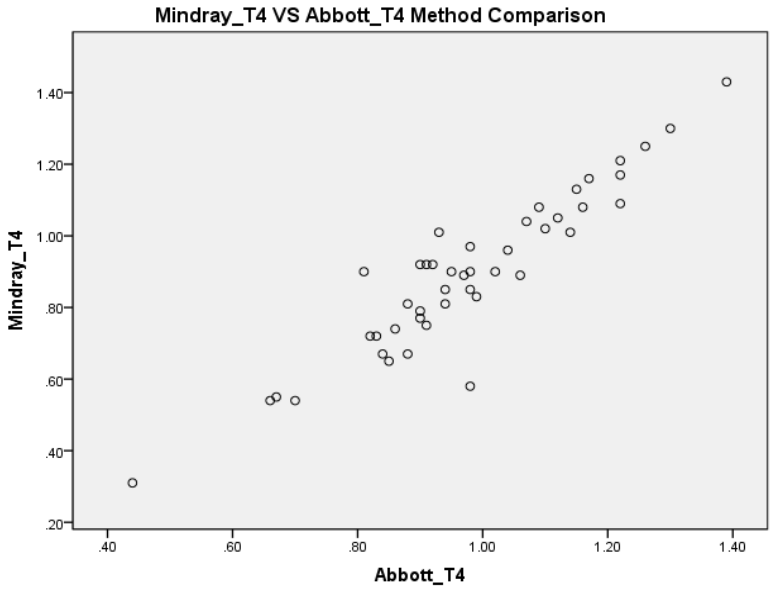

Figure 5 T4 raw data scatter plot

It can be seen from the above table that the overall concentration of T4 was determined by the candidate instrument Mindray CL-1000i was 0.8944±0.22419 ng/dL, and the reference instrument Abbott Alinity i was 0.9789±0.18255 ng/dL, there was statistically significant difference between the two grouped values (t = 26.763, P =0.000). The Pearson correlation coefficient between the candidate instrument and the reference instrument is r_p = 0.931 (P <0.001), and the concentration results of the two instruments have a strong correlation. The regression equation Y=-0.225+1.14x, the linear relationship is established (P <0.001), the regression coefficient is 1.14, close to 1, and its 95%CI is (1.006, 1.281); the intercept is -0.225, close to 0. Its 95%CI is (-0.362, -0.088). From the above results, it can be inferred that the quantitative results of the candidate instrument and the reference instrument are almost the same.

5 Conclusion

CL-1000i for determining immunology assays was evaluated in accordance with the Clinical Laboratory Standards Institute (CLSI) guidelines by Uniwersyteckie Centrum Kliniczne, Poland.

The performance evaluation includes precision study, method comparison with Abbott Alinity i. The 5 tests including TPSA, cTnI, TSH, T3 and T4 were evaluated. During the evaluation period, the operators were trained and familiar with operation of the instrument systems, maintenance procedures, methods of sample preparation, running calibration and performing quality control.

The results of the performance evaluation for CL-1000i analyzer were all acceptable according to CL series' criteria. We conclude that CL-1000i analyzer gives precise, accurate and reliable results that comparable with the current routine method and it meets the expectations in clinical use. The software of CL-1000i system is intuitive and user-friendly.

Uniwersyteckie Centrum Kliniczne
st. Dębinki 7, 80-952 Gdańsk
TEL: +48 58 727 05 05

31th Jul 2023

The performance of Mindray C-L1000i immunoassay system was evaluated at Uniwersyteckie Centrum Kliniczne - Gdański Uniwersytet Medyczny, Poland, from February to April, 2023.

During the evaluation, we have tested the calibration, controls, precision (between days) and method comparison with Abbott Alinity i.

In our opinion, the performance of Mindray CL-1000i automated chemiluminescence analyzer is satisfactory on the set critieria and analyzer compares favorably with Abbott Alinity i and meets the need of testing in the clinical laboratory.

In addition, software functionalities of CL-1000i were exercised to determine ease of use and usability of the functions.

We conclude that CL-1000i is a competent analyzer to provide reliable and accurate diagnostric results.

KAROLINA RYBARCZYK-KAPTURSKA, PhD

Assistant Laboratory Diagnostician

Uniwersyteckie Centrum Kliniczne - Gdański Uniwersytet Medyczny