RESEARCH ARTICLE

Performance evaluation of a chemiluminescence microparticle immunoassay for CK-MB

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Background: To verify and evaluate the performance characteristics of a creatine kinase phosphokinase isoenzymes MB (CK-MB) assay kit, which produced by Xiamen Innodx Biotech Co. Ltd.

Methods: Evaluation was carried out according to "Guidelines for principle of analysis performance evaluation of in vitro diagnostic reagent." The performance parameters included detection limit, linearity range, reportable range, recovery test, precision verification, interference test, cross-reactivity, matrix effect, and method comparison.

Results: The detection limit was 0.1 ng/mL. The assay had clinical linearity over range of 0.1 ng/mL-500 ng/mL. Reportable range was from 0.1 ng/mL to 1000 ng/mL. The average percent of recovery was 99.66%. The coefficient of variation (CV) for within-run and between-run of low CK-MB sample was 5.55% and 6.16%, respectively. As for high-level sample, it was 7.88% and 7.80%. In medical decision level, the relative deviation (Bias) of all interference tests was lower than 15%. When the sample had mild-hemolysis; hemoglobin ≤ 15 g/L; triglyceride ≤ 17 mmol/L; bilirubin ≤ 427.5 μ mol/L; rheumatoid factor ≤ 206 U/mL, there was no significant interference to be found. Moreover, assay kit had no cross-reaction with CK-MM and CK-BB. At last, total diagnostic accuracy of kit was 93.24%, when compared with refer kit.

Conclusion: Overall the results of the verification study indicated the performance of kit is met the requirements of the clinical test.

KEYWORDS

chemiluminescence microparticle immunoassay, CK-MB, evaluation, kit, performance

1 | INTRODUCTION

Creatine kinase (CK), also known as creatine phosphokinase (CPK), is an enzyme that expressed by various tissues and cell types.

Abbreviations: ADL, average deviation from linearity; AMI, acute myocardial infarction; CFDA, China Food and Drug Administration; CK-MB, creatine kinase MB; CLSI-EP, Clinical and Laboratory Standards Institute-Evaluation Protocols; CPK, creatine phosphokinase; CV, coefficient of variation; RLU, relative light units; SD, standard deviation.

Creatine kinase is a dimer consist of two subunits which can be either M or B. The name originates from the various combinations of the M (muscle) and brain (brain) isoforms. Therefore, there are three different isoenzymes: CK-MM, CK-BB, and CK-MB.¹ CK-MM mainly exists in all kinds of muscle cells, CK-BB mainly exists in the part of the brain cells, and CK-MB mainly exists in the myocardial cells. Skeletal muscle cell expresses CK-MM (98%) and CK-MB (1%). In contrast, myocardium cell expresses CK-MM at

70% and CK-MB at 25%-30%; CK-BB is predominantly expressed in brain and smooth muscle, including vascular and uterine tissue.² CK-MB accounted for about 15%-20% of the total creatine kinase and almost exists in the myocardial cells, this characteristic makes it possess high-diagnostic value of acute myocardial infarction (AMI).³

In 1955, Oliver⁴ first developed spectrophotometric method to detection of activity for CK. Until 1960, Dreyfus et al suggested that creatine kinase is a diagnostic biomarker in serum for myocardial infarct.⁵ Roe et al use the zone electrophoresis method to identify and quantify the CK-MB in serum or plasma. The activity of enzyme in the serum or plasma was unstable and imprecise to respond to the actual level. Therefore, the measurement of CK-MB mass was applied, which was more sensitive and rapid than CK-MB activity assay. And detection of CK-MB mass concentration is more suitable than determination of enzyme activity for AMI patients.⁶ The chemiluminescence immunoassay is a commendatory method of detecting the concentration of enzyme.

In this study, the test kit detects the concentration of CK-MB by chemiluminescence immunoassay, a method what based on double-antibody sandwich ELISA method has high specificity and sensitivity. We evaluated the performance of CK-MB assay kit (chemiluminescence immunoassay Xiamen Innodx Biotech Co. Ltd) and compared to the commercial CK-MB assay kit (electro-chemiluminescence immunoassay, Roche).

2 | MATERIALS AND METHOD

2.1 | Clinical sample collection

All the samples, a total of 296 sample (143 patients, 153 healthy volunteers), were collected from the Xiamen University Affiliated Zhongshan Hospital, from December 2013 to April 2014. The serum or EDTA plasma samples were separated by centrifugation (3000 × g, 10 minutes) and stored at 4°C until used. All the information of samples were anonymous until the end of detection.

2.2 | Reagents and instruments

2.2.1 | Reagents

(i) Test kit: CK-MB assay kit (chemiluminescence immunoassay, Xiamen Innodx Biotech Co. Ltd, Xiamen, China), Lot number: RM2012121701, RM2012121801, RM2012121901. (ii) Compared kit: CK-MB assay kit (electro-chemiluminescence immunoassay, Roche, Basel, Switzerland), Lot number: 174104-01. (iii) Zero-level CK-MB calibration solution, Lot number: 2012122001. (iv) Series of calibration solution (L1~L8, concentration 0.1 ng/mL, 0.2 ng/mL, 0.8 ng/mL, 5 ng/mL, 20 ng/mL, 50 ng/mL, 250 ng/mL, 500 ng/mL, Lot number: 2012122001. (v) Interferential substances: bilirubin (Aladdin Chemistry Co. Ltd, Shanghai, China), Lot number: 39340; triglyceride (Aladdin Chemistry Co. Ltd, Shanghai, China), Lot number: 55543; rheumatoid factor (bioryt, Cambridge, United Kingdom), Lot number: D6987.

2.2.2 | Instruments

(i) Caris200 (automated chemiluminescent immunoassay, UMIC, Xiamen, China). (ii) COBAS E170 (automated electro-chemiluminescent immunoassay, Roche, Basel, Switzerland).

2.3 | Method

All performance evaluation mainly referred to the "Guidelines for principle of analysis performance evaluation of in vitro diagnostic reagent",⁷ which formulated by the China Food and Drug Administration (CFDA). The guidelines were amended by the protocol of the Clinical and Laboratory Standards Institute (CLSI). Specifically, limited detection according to CLSI EP17-A,⁸ linearity and reportable range according to CLSI EP6-A,⁹ precision according to CLSI EP5-A,¹⁰ interference test according to CLSI EP7-A,¹¹ matrix effects test according to CLSI EP14-A2,¹² and method comparison according to CLSI EP9-A2.¹³

2.4 | Functional sensitivity: detection limit

We detected the calibration solution L1-L8 in duplicate and made a kit dose-response curve fitting (four parameters). The mean and standard deviation (SD) of the 0 level calibration solution was calculated by 20

FIGURE 1 The four parameters kit dose-response curve fitting of test kit, and equation was $y = (3123000 - 70) / [1 + (x/734.9) - 1.01] + 70$. Transformed the values of raw RLU to values of concentration (ng/mL) by the equation

FIGURE 2 The scatter diagram of linearity detection. The solid line represents the line of scatter; the dotted line represents the regression line

consecutive measurements. Subsequently, obtained the mean +2 SD of relative light units (RLU) and calculated the actual concentration correspondingly, based on dose-response curve fitting, which average of 20 dates was detection limit.

2.5 | Linearity range

Series of calibration solution (L1-L8, concentration 0.1 ng/mL, 0.2 ng/mL, 0.8 ng/mL, 5 ng/mL, 20 ng/mL, 50 ng/mL, 250 ng/mL, and 500 ng/mL) was detected in quadruplicate by test kit, and multiple regression models were selected to linearity analysis. All raw dates show as RLU and transform as relevant concentration by the calibration curve. Made a scatter diagram (X: theoretical

concentration, Y: instrumental concentration). The multiple regression model was established and obtained three orders equations. The linearity of measurements was evaluated by the t test of regression coefficient B3. As for linearity evaluation base on clinical criteria was judged by ADL (average deviation from linearity).

2.6 | Reportable range

Randomly selected a sample from samples had been quantified by Roche Cobas E170 and identified as low CK-MB concentration. Low-level samples (3.14 ng/mL) were diluted with 5% bovine serum albumin into 5 levels concentrations (recorded as Y1, Y2, Y3, Y4, and Y5). Those concentrations were nearly lower linear range limited

TABLE 1 The polynomial regression equation of linearity test

Order	Equation	Relevant coefficient	ADL
First	$y = 0.9142x + 3.6682$	$r = .9989$	-
Second	$y = 0.0016x^2 + 0.9168x + 3.6698$	$r = .9989$	0.1%
Third	$y = -0.043x^3 + 0.1119x^2 + 0.9328x + 3.5902$	$r = .9998$	1.1%

ADL, average deviation from linearity.

TABLE 2 The determination of low-level samples for reportable range

RLU	Y1 (ng/mL)	Y2 (ng/mL)	Y3 (ng/mL)	Y4 (ng/mL)	Y5 (ng/mL)
RLU1	0.21	0.15	0.12	0.10	0.07
RLU2	0.28	0.14	0.12	0.11	0.09
RLU3	0.23	0.15	0.12	0.11	0.08
RLU4	0.22	0.16	0.10	0.10	0.09
RLU5	0.26	0.15	0.11	0.10	0.08
RLU6	0.24	0.15	0.10	0.11	0.09
RLU7	0.26	0.15	0.10	0.10	0.08
RLU8	0.27	0.14	0.12	0.09	0.09
RLU9	0.26	0.18	0.10	0.08	0.09
RLU10	0.27	0.16	0.11	0.09	0.08
AVE	0.25	0.15	0.11	0.10	0.08
SD	0.023	0.010	0.010	0.009	0.007
CV%	9.25%	6.40%	8.95%	9.39%	7.86%

The serum samples at low level: Y1, Y2, Y3, Y4, and Y5.

CV, coefficient of variation; RLU, relative light units; SD, standard deviation.

TABLE 3 The determination of high-level samples for reportable range

	H1 (ng/mL)	H2 (ng/mL)	H3 (ng/mL)
RLU1	247.10	226.84	229.00
RLU2	238.05	238.48	238.52
RLU3	254.90	257.11	226.24
AVE	246.68	240.81	231.25
Dilution ratio	2	3	5
Restore concentration	493.37	722.43	1156.27
Theoretical concentration	500	750	1250
Relevant bias(10%)	-1.33%	-3.68%	-7.50%

The serum samples at high level: H1, H2, H3.

TABLE 4 Analytical precision of the test kit assay

Lot number	Low CK-MB concentration				High CK-MB concentration			
	AVE (ng/mL)	MAX (ng/mL)	MIN (ng/mL)	Within-run CV	AVE (ng/mL)	MAX (ng/mL)	MIN (ng/mL)	Within-run CV
RM2012121701	5.01	5.64	4.41	7.11%	49.92	55.81	44.00	6.35%
RM2012121801	4.85	5.25	4.05	6.45%	49.84	54.74	44.43	5.74%
RM2012121901	4.84	5.58	4.38	5.78%	48.96	52.96	41.89	6.45%
Between-run CV	6.56%					6.14%		

(0.1 ng/mL). Similarly, diluted high CK-MB concentration samples (450 ng/mL) were nearly upper 1/3 linear range and recorded as H1, H2, and H3. In a round, low-concentration samples and high-concentration samples repeatedly detected 10 times and 3 times, respectively.

2.7 | Recovery test

Three different CK-MB concentration samples were measured in triplicates (A1: high sample (83.17 ng/mL), A2: low sample (1.34 ng/mL), A3:1/10 A1 mixed with 9/10 A2). The percentage ratio between the measured and estimated concentrations was calculated and acceptable range between 90 and 110%.

2.8 | Precision verification

High-level sample and low-level sample were detected by three different batch kits at the same time and repeat 20 times. Precision was evaluated as the coefficient of variation (CV), within-run and between-run imprecision CVs were obtained from the mean and standard deviation of data.

2.9 | Interference test

The effect of mild-hemolysis, hemoglobin, lipemia, bilirubin, and rheumatoid factor on the measurement of CK-MB in serum was assessed in vitro. Serum of normal samples was spiked with different concentrations of the interfering material. The relative bias of each determination was calculated between the before treatment and the after treatment. The maximum allowable relative bias was 15%.

2.10 | Cross-reactivity

Samples with CK-MM (14 000 ng/mL) and CK-BB (29 400 ng/mL) were selected to perform cross-reaction test. Test performance was carried by three different batches of test kit. The values of these tests were obtained and evaluated the cross-reactivity.

2.11 | Matrix effects

A sample was randomly selected, which had high CK-MB in serum, and diluted by kit diluent and serum matrix, respectively, for gradient dilution (0.1 ng/mL to 500 ng/mL). The RLU values of every test were recorded and evaluated the effect of diluent and matrix.

2.12 | Method comparison

A total of 296 anonymous serum samples from routine diagnostic testing were used to perform the method comparison study between test kit and a commercial kit (Roche kit). Another commercial kit (Abbott kit) was used to confirm comparison results, which were different between two kits. Recorded the result of tests and evaluated the consistency between two kits. Samples outside of the measuring range were diluted, and the samples underside of the

TABLE 5 Results of interference test

Interference factor	Bias (%)		
	RM2012121701	RM2012121801	RM2012121901
Mild-hemolysis	10%	-8%	9%
Hemoglobin (g/L)			
3.75	7.08%	12.22%	-12.47%
7.50	-7.16%	8.61%	-14.21%
11.25	-1.85%	12.50%	-9.72%
15.00	-3.92	-5.28	8.73
Triglyceride (mmol/L)			
4.25	-1.06	-2.48	4.58
8.50	-12.66	5.95	-2.89
12.75	-6.07	-5.71	-2.17
17.00	-12.46	5.71	-10.36
Bilirubin (μmol/L)			
106.87	2.01	8.60	-8.33
213.75	9.05	-4.84	7.55
320.62	4.02	6.99	1.04
427.50	1.51	-9.14	0.52
Rheumatoid factor (U/mL)			
51.50	-3.61	-2.56	7.37
103.00	-7.43	5.12	2.63
154.50	-9.13	4.09	1.58
206.00	4.46	-4.60	5.94

TABLE 6 The cross-reactivity of CK isozyme for developed kit

Lot number	Isozyme	Concentration (ng/mL)	Bias%
RM2012121701	CK-MM	14 000	0.0030
	CK-BB	29 400	0.0004
RM2012121801	CK-MM	14 000	0.0264
	CK-BB	29 400	0.0004
RM2012121901	CK-MM	14 000	0.0400
	CK-BB	29 400	0.0007

detect-limitation were excluded. Consistency of two methods was evaluated and presented with a Bland-Altman plot.

2.13 | Statistical analysis

The normal and the abnormal coincidence rates of comparison study were calculated as follows: normal coincidence rate (%) = $a/(a + c) \times 100$, abnormal coincidence rate (%) = $d/(b + d) \times 100$, and total coincidence rate (%) = $a + d/(a + b + c + d) \times 100$; where 'a' is the number of samples what CK-MB in serum be verified as normal by both test kit and reference kit; 'b' is the normal samples in the test kit, but with an abnormal reference kit; 'c' is when the test kit is abnormal and the reference kit normal; and, 'd' is also abnormal for both tests. Statistical analysis and graphics were performed by SPSS 19.0 statistical software package (SPSS, Chicago, IL, USA) and

The effect of diluent and matrix **FIGURE 3** Comparison of effect for different dilutions (matrix and kit dilution) for CK-MB assay at eight different levels that were in linear range (0.1 ng/mL-500 ng/mL)

GraphPad Prism version 5.01 (GraphPad Software, Inc., California, USA). *P*-values <.05 were considered statistically significant.

3 | RESULTS

3.1 | Detection limit

The four parameters kit dose-response curve fitting was presented in Figure 1. In study according to equation of kit dose-response curve

TABLE 7 Results of the test kit and reference kit in clinical samples

		Reference kit		
		Abnormal samples	Normal samples	Total samples
Test kit	Abnormal samples	135	12	147
	Normal samples	8	141	149
	Total samples	143	153	296
Abnormal coincidence rate		Normal coincidence rate		Total coincidence rate
135/143 = 94.41%		141/153 = 92.16%		(135 + 141)/296 = 93.24%

FIGURE 4 (A) The regression line: Innodx (Y) against Roche (X), where Innodx is the test kit and Roche is the reference. (B) Bland-Altman plots of the differences between the 2 methods against their means

fitting ($y = (3123000-70)/[1 + (x/734.9)-1.01]+70$) transformed the RLU to concentration (ng/mL). The lowest analyte concentration was 0.1 ng/mL according to 20 consecutive measurements at the same time, which was the detection limit of the kit.

3.2 | Linearity range

A scatter diagram (Figure 2) was drawn with theoretical concentration (X-axis) and instrumental concentration (Y-axis). Then, the polynomial regression analysis was performed for first-, second-, and third-order polynomials. The result of *t* test for B3 presented that the data were not linear in statistical standard and then, the linearity of data was evaluated in clinical standard. The analysis of regression equation was shown in Table 1, the average deviation from linearity (ADL) of second- and third-order regression equation

was 0.1% and 1.1%, respectively. When the ADL < 5%, the data were accepted as clinical linearity in the measuring range of 0.1 ng/mL ~ 500 ng/mL.

3.3 | Reportable range

The detection of low-level samples (3.14 ng/mL) and high-level samples (450 ng/mL) was depicted in Tables 2 and 3. The CV% of the low-level samples (0.08 ng/mL-0.25 ng/mL) was less than 10% and detection limit was 0.1 ng/mL, so the minimum of reportable range was 0.1 ng/mL. The high-level samples were diluted from 1:2 to 1:5, and the bias of 1:2 diluted sample test was minimum. And recommend maximum dilution ratio was 2. The maximum of reportable range = 2(recommend maximum dilution ratio) * 500 ng/mL (the upper limit of linearity range) = 1000 ng/mL. The reportable range was from 0.1 ng/mL to 1000 ng/mL.

3.4 | Recovery test

The result of recovery test for three independent tests (A1, A2, and A3) was 106.83%, 92.94% and 100.02%, respectively, and within the acceptable range of 90% to 110%.

3.5 | Precision

The imprecision of CV was calculated as equation: $CV\% = SD/\bar{X} \times 100\%$. The test of precision for two different concentration samples was detected by three different batches of kit (Table 4). The within-run and between-run imprecision CV values were both in an acceptable range <10%.

3.6 | Interference test

Those interference factors: hemoglobin, triglyceride, bilirubin, and rheumatoid factor that had several concentrations of were tested and the Bias% of every test was $\leq \pm 15\%$ (Table 5). The result indicated that these common contaminants did not interfere with the test results of CK-MB.

3.7 | Cross-reactivity

Samples with isoenzymes of CK: CK-MM (14 000 ng/mL) and CK-BB (29 400 ng/mL) made no difference to the CK-MB value (Table 6).

3.8 | Matrix effect

There was no significant difference in CM-MB values between samples ($P < .05$), which were diluted by kit diluent and serum matrix, respectively, in the linearity range (Figure 3).

3.9 | Method comparison

The total coincidence rate of two methods was 93.24% (276/296), and the normal coincidence rate and abnormal coincidence rate were 92.16% (141/153) and 94.41% (135/143), respectively (Table 7). Values of three samples were outside of detection limit of Roche kit and excluded the study of relevant analysis. And the regression equation which was obtained by the linear regression model was $y = 0.9134x + 0.0081$, $r = .958$ (Figure 4A,B).

4 | DISCUSSION

CK-MB was as classical biomarkers of AMI. Although CK-MB is more concentrated in the myocardium, it also exists in skeletal muscle partly. And its elevations occur in a number of clinical diseases, including myocardial infarction, myopathy, and renal injury.¹⁴ CK-MB first appears 4–6 hours after infarction onset, peaks at 24 hours, and returns to normal in 48–72 hours.¹⁵ Its value in the early and late (>72 hours) diagnosis of AMI is limited. However, the release dynamics was helpful to diagnose reinfarction of AMI. There was a clear association between concentrations of enzyme and short-term clinical outcome, including risk of death, reinfarction, and emergency revascularization.¹⁶

In this study, we evaluated the performance of the CM-MB assay (Innodox) and compared with the similar assay (Roche). The Innodox CK-MB assay kit was based on double antibodies sandwich ELISA. The solid phase carrier of kit was nanometer magnetic particle; it could not only increase the reaction sensitivity but also greatly improves the anti-interference ability of the test. On the other hand, the assay used acridinium ester as chemiluminescent label has advantages of low background.

In this study, the performance evaluation was according to instructions from the “Guiding principles on performance analysis of diagnostic reagents in vitro.” And the CLSI files were referred to for relevant standard procedures, too. The limit of determination was 0.1 ng/mL, better than Roche kit (0.3 ng/mL). And the reportable range of developed kit was greater than Roche kit. It means test kit has a more sensitivity method to detect CM-MB. Those results indicated that Innodox kit can more precisely detect the CK-MB concentration in patient serum and reflect the physiological change in vivo timely, which help early diagnosis and treating accurately. In this study, we evaluated the degree of potential interference of abnormal clinical samples that could result from hemoglobin (15 g/L), triglyceride (17 mmol/L), bilirubin (427.5 μmol/L), and rheumatoid factor (206 U/mL). No significant analytical interference was observed in interference test. Cross-reactivity

evaluation revealed that the test product did not provide false-positive readings when incubated with CK-MM (14 000 ng/mL) and CK-BB (29 400 ng/mL).

In this comparison test, 2 commercial assay kits were chosen. One is the Roche assay, which is an electro-chemiluminescence immunoassay. The other is the Abbott assay, which is used to confirm the comparison results. The Innodox kit had a great consistency with Roche kit, and total coincidence rate was 93.24%. Potential differences among the assays could be explained by the detection method used.

5 | CONCLUSION

In conclusion, the evaluation of this kit demonstrated excellent diagnostic performance and fulfilled the requirement for clinical routine diagnosis. At the same time, Innodox kit was cheap than other commercial kits that was helpful for reducing the heavy burdens of patients.

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AUTHORS' CONTRIBUTIONS

Xu Fei-hai and Zhang Zhong-ying participated in the design of this study. Lin Zhi-yuan carried out the study and collected important background information and the statistical analysis. Fang Yi-zhen, Jin Hong-wei, Lin Hua-yue, Dai Zhang, Luo Qing, Li Hong-wei, Lin Yan-ling, and Gao Lei provided assistance for data acquisition, data analysis, and statistical analysis.

AVAILABILITY OF DATA AND MATERIALS

Not applicable.

ETHICAL APPROVAL AND CONSENT TO PARTICIPATE

This study has been cleared by the Xiamen University Affiliated Zhongshan Hospital Ethics Review Board for human studies, and that patients have signed informed consent.

CONSENT FOR PUBLICATION

All authors read and approved the final manuscript for publication.

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