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Boditech MED INC

43, Geodudanji 1-gil, Dongnae-myeon
 Chuncheon-si, Gangwon-do, 24398.
 South Korea
 23, January 2024

To whom it may concern,

We, Boditech Med Inc., (Address: 43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, 24398, Republic of Korea), hereby declare that,

1. Linearity

Item	R value	
AFIAS D-Dimer Neo	0.9774	
AFIAS β-HCG Plus	0.9955	
AFIAS Cardiac Triple	Tn-I	0.9850
	CK-MB	0.9860
	Myoglobin	0.9900

2. Sensitivity

Item	Sensitivity		
AFIAS D-Dimer Neo	LOB(Limit of Blank)	8.23 ng/mL	
	LOD(Limit of Detection)	17.5 ng/mL	
	LOQ(Limit of Quantitation)	50.0 ng/mL	
AFIAS β-HCG Plus	LOB(Limit of Blank)	0.10 mIU/mL	
	LOD(Limit of Detection)	0.50 mIU/mL	
	LOQ(Limit of Quantitation)	1.80 mIU/mL	
AFIAS Cardiac Triple	Tn-I	LOB(Limit of Blank)	0.008 ng/mL
		LOD(Limit of Detection)	0.01 ng/mL
		LOQ(Limit of Quantitation)	0.03 ng/mL

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	CK-MB	LOB(Limit of Blank)	0.67 ng/mL
		LOD(Limit of Detection)	1.31 ng/mL
		LOQ(Limit of Quantitation)	3.00 ng/mL
	Myoglobin	LOB(Limit of Blank)	1.25 ng/mL
		LOD(Limit of Detection)	1.64 ng/mL
		LOQ(Limit of Quantitation)	5.00 ng/mL

3. Specificity

1) Cross-reactivity

Item	Cross-reactants	Concentration	
AFIAS D-Dimer Neo	Fibrinogen	10 g/L	
	Troponin Complex	1,000 ng/mL	
	CK-MB	1,000 ng/mL	
	NT-proBNP	100 ng/mL	
	Myoglobin	3,000 ng/mL	
AFIAS β-HCG Plus	hTSH	500 uIU/mL	
	hFSH	1,000 mIU/mL	
	hLH	1,000 mIU/mL	
AFIAS Cardiac Triple	Tn-I	CK-MB	1,000 ng/mL
		D-Dimer	20,000 ng/mL
		NT-proBNP	1,000 ng/mL
		Myoglobin	2,000 ng/mL
	CK-MB	Troponin Complex	1,000 ng/mL
		D-Dimer	20,000 ng/mL
		NT-proBNP	1,000 ng/mL
		Myoglobin	2,000 ng/mL
	Myoglobin	Troponin Complex	1,000 ng/mL
		CK-MB	1,000 ng/mL
		D-Dimer	20,000 ng/mL
		NT-proBNP	1,000 ng/mL

2) Interference

Item	Cross-reactants	Concentration
AFIAS D-Dimer Neo	Bilirubin (unconjugated)	700 µmol/L
	Cholesterol	13 mmol/L
	Glucose	60 mmol/L
	Hemoglobin	10 g/L
	Ascorbic acid	300 µmol/L
	Triglyceride, total	37 mmol/L
	Sodium citrate	2 mg/mL
AFIAS β-HCG Plus	D-Glucose	60 mM/L
	L-Ascorbic	0.2 mM/L
	Bilirubin	0.4 mM/L
	Hemoglobin	2 g/L
	Cholesterol	13 mM/L
	Triglyceride	40 mM/L
	Progesterone	1,000 nmol/L
	Testosterone	1,200 ng/dL
	PRL	1,000 mIU/mL
	PTH	70 ng/mL
AFIAS Cardiac Triple	L-Ascorbic acid	350 µmol/L
	Bilirubin	350 µmol/L
	Cholesterol	13 mmol/L
	D-Glucose	1,000 mg/dL
	Hemoglobin	2 g/L
	Triglyceride mixture	500 mg/dL
	EDTA	3.4 µmol/L
	Heparin	3,000 U/L
Sodium citrate	2 mg/mL	

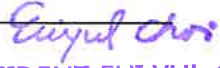
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For and of behalf of the Boditech Med Inc.

Signature

43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gangwon-do, South Korea

Boditech Med Inc.



PRESIDENT EUI YUL CHOI