

Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

Product overview					
Product Name	Anti-CKMB monoclonal antibody	Catalog Number	BRJCKMBS105		
Date of Manufacture	Specific date	Lot Number	Specific lot number		
Immunogen	Recombinant human creatine kinase MB				
Species	Mouse	Expressed Host	СНО		
Тад	N/A	Clone number	35C9		
lsotype	lgG1	Molecular weight	150kDa		
Product buffer solution	10mM PB+150mM NaCl+0.1% ProClin300,pH7.4	Preservative	ProClin300		
Storage Conditions	-20±5°C, Avoid multiple freeze/thaw cycles	Date of Expiration	Shelf life:36 months		
Applications	Detection	Platforms tested	FIA		
	Parameters to	ested on each lot			
Product appearance	Liquid				
Conc.determined by	UV absorption	Concentration /Recommended titer	Specific Concentration		
Purification	Protein A chromatography+lon- exchange chromatography	Purity	≥90%		
Performance:					
Items	Passing criteria			Qualified or not	
Immunoreactivity	At the same working concentration, the deviation of the activity in the test group from the control group is within \pm 15%.		Yes√ No□		
Clinical specificity	N/A			Yes□ No□	
Product stability	N/A			Yes□ No□	
Miscellaneous	N/A			Yes□ No□	
Remark	N/A				
Conclusion	Pass√ Fail □		_		

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Quality signature	N/A	Quality inspection date	N/A
管理者代表: Management representative	·KP		
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