

Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

Product overview					
Product Name	Anti-Malaria pLDH monoclonal antibody	Catalog Number	BRJMALS210		
Date of Manufacture	Specific date	Lot Number	Specifi	Specific lot number	
Immunogen	Recombinant Malaria pLDH protein				
Species	Mouse	Expressed Host	СНО		
Тад	N/A	Clone number	25C7		
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	GICA		
	Parameters t	ested on each lot			
Product appearance	Liquid				
Conc.determined by	UV absorption	Concentration /Recommended titer	Specific Concentration		
Purification	Protein G 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 0.5C.		in the	Yes√ No□	
Clinical specificity	There is no false positive in testing 50 negative samples.			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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