

## **Certificate of Analysis**

Number: FAPON-FR-T0-017 Edition: B.2

Product overview					
Product Name	Ant-Cyfra21-1 monoclonal antibody	Catalog Number	BEJCYFS101		
Date of Manufacture	Specific date	Lot Number	Specific lot number		
Immunogen	N/A				
Species	Mouse	Expressed Host	СНО		
Tag	N/A	Clone number	22C4		
Isotype	lgG2b	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	ELISA、CLIA		
Parameters tested 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 c	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 ± 15%.			Yes√ No□	
Clinical specificity	The slope was within range of 0.75-1.2 and R^2 is not less than 0.85, when the results of the test group.			Yes√ No□	
Product stability	N/A			Yes□ No□	
Miscellaneous	N/A			Yes□ No□	
Remark	N/A				
Conclusion	Pass√ Fail □				

Quality signature	N/A	Quality inspection date	N/A

管理者代表: 人 人 Management representative

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