

Certificate of Analysis

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

	Produc	t overview			
Product Name	Anti-CA242 monoclonal antibody	Catalog Number	BECCA242S102		
Date of Manufacture	Specific date	Lot Number	Specific lot number		
Immunogen	N/A		'		
Species	Mouse	Expressed Host	N/A		
Tag	N/A	Clone number	2C2		
Isotype	lgG1	Molecular weight	150kDa		
Product buffer solution	20mM CB+150mM NaCl+0.1% ProClin300,pH6.0	Preservative	ProClin300		
Storage Conditions	-20±5°C, Avoid multiple freeze/thaw cycles	Date of Expiration	Shelf life:36 months		
Applications	Capture,Detection	Platforms tested	ELISA、CLIA		
	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 ± 15%.		Yes√ No□		
Clinical specificity	 Internal negative control samples did not show any positivity during testing. 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 and in the 30 positive samples were compared. 			Yes√ No⊓	
Product stability	When accelerated stability testing at 37°C was performend, No change in specificity testing of the internal controls samples was observed and the change in activity was not higher than 20%.			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: Management representative	χ -	X
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