

## **Certificate of Analysis**

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

	Produc	t overview				
Product Name	HBe Antibody	Catalog Number	BECHE	BECHBVS207		
Date of Manufacture	Specific date	Lot Number	Specific lot number			
Immunogen	N/A					
Species	N/A	Expressed Host	СНО			
Tag	N/A	Clone number	33C2			
Isotype	lgG2a	Molecular weight	150kDa			
Product buffer solution	10mM PB+150mMNacl+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	N/A			
	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 ± 10%.			Yes√ No□		
Clinical specificity	<ol> <li>There is no positive result in testing all negative internal control samples.</li> <li>In testing internal control samples, the deviation of the specificity in the test group from the control group is not more than 1 sample.</li> </ol>			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 15%.			Yes√ No□		

Miscellaneous	N/A					Yes□ No□
Remark	N/A					
Conclusion	Pa	ass√	Fail □			
Quality signature	N/A			Quality inspection date	N/A	

管理者代表: Management representative	34	χ-	X
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