

Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

	Produc	t overview		
Product Name	NSE recombinant antibody	Catalog Number	BENNSEN103	
Date of Manufacture	Specific date	Lot Number	Specific lot number	
Immunogen	N/A		1	
Species	Mouse	Expressed Host	СНО	
Тад	N/A	Clone number	N/A	
Isotype	lgG1	Molecular weight	150kDa	
Product buffer solution	10mM PB+150mM NaCl+0.1% ProClin300,pH7.4	Preservative	ProClin300	
Storage Conditions	2~8°C	Date of Expiration	Shelf life:36 months	
Applications	Detection	Platforms tested	ELISA、CLIA	
	Parameters t	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	A comparison of the test group (y) with the control group (x) gives the following correlation: The slope is within the range of $0.75-1.2$, and R^2 is not less than 0.85.			Yes√ No□
Product stability	In the accelerated stability test at 37 °C for 3 days, the change in activity is not higher than 10%. In the accelerated stability test at 37 °C for 7 days, the change in activity is 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: 了, 2 · 以子 Management representative

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