

Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

Product overview			
Product Name	Anti AFP recombinant antibody	Catalog Number	BECAFPS108
Date of Manufacture	Specific date	Lot Number	Specific lot number
Immunogen	N/A		
Species	N/A	Expressed Host	CHO
Tag	N/A	Clone number	27C9
Isotype	IgG1	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	Capture	Platforms tested	N/A
Parameters tested on each lot			
Product appearance	Liquid		
Conc.determined by	UV absorption	Concentration /Recommended titer	Specific Concentration
Purification	Protein A chromatography+Ion-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 <input checked="" type="checkbox"/> No <input type="checkbox"/>
Clinical specificity	The slope was within range of 0.75-1.2 and R ² is not less than 0.85, when compared to the control group values.		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
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 <input checked="" type="checkbox"/> No <input type="checkbox"/>
Miscellaneous	N/A		Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	N/A		

Conclusion	Pass <input checked="" type="checkbox"/>	Fail <input type="checkbox"/>	
Quality signature	N/A	Quality inspection date	N/A

管理者代表: 
Management representative

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