

Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

Product overview							
Product Name	Anti-Human IgG monoclonal antibody	Catalog Number	BENIGGI101				
Date of Manufacture	Specific date	Lot Number	Specific lot number				
Immunogen	Human IgG(FC)						
Species	Mouse	Expressed Host	N/A				
Тад	N/A	Clone number	1H8				
Isotype	lgG1	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	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 10%.			Yes√ No□			
Clinical specificity	 There is no positive result in testing all negative internal control samples. In testing internal control samples, the deviation of the specificity in the test group from the control group is not more than 3 sample. 			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	Pass√	Fail 🗆			
Quality signature	N/A		Quality inspection date	N/A	

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