

Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

Product overview			
Product Name	Anti-cTnI monoclonal antibody	Catalog Number	BRNCTNIN113
Date of Manufacture	Specific date	Lot Number	Specific lot number
Immunogen	Recombinant human cTnI		
Species	Mouse	Expressed Host	CHO
Tag	N/A	Clone number	23C12
Isotype	IgG1	Molecular weight	150 kDa
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, FIA, GICA
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	FIA platform: When the quality control concentration is equivalent, the reading value deviation of the batch to be tested and the control batch for the same quality control is less than ±10%.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
Clinical specificity	In testing all negative controls, the background signal in the test group is not 10% higher than the control group.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
Product stability	N/A	Yes <input 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
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管理者代表: 
Management representative

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