

Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

Product overview			
Product Name	Cytomegalovirus IgM quality control	Catalog Number	BENCMVN102
Date of Manufacture	Specific date	Lot Number	Specific lot number
Immunogen	N/A		
Species	N/A	Expressed Host	CHO
Tag	N/A	Clone number	30C1
Isotype	IgM	Molecular weight	900kDa
Product buffer solution	10mM PB+150mM NaCl+0.1% ProClin300,pH7.2	Preservative	ProClin300
Storage Conditions	-20±5°C, Avoid multiple freeze/thaw cycles	Date of Expiration	Shelf life:36 months
Applications	Control	Platforms tested	ELISA、CLIA
Parameters tested on each lot			
Product appearance	Liquid		
Conc.determined by	N/A	Concentration /Recommended titer	Specific Concentration
Purification	N/A	Purity	N/A
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 <input checked="" type="checkbox"/> No <input type="checkbox"/>	
Clinical specificity	N/A	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Product stability	When accelerated stability testing at 37°C was performed, No change in specificity testing of the internal controls samples was observed and the change in activity was not higher than 15%.	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
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管理者代表: 
Management representative

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