

## **Certificate of Analysis**

Number: FAPON-FR-T0-017 Edition: B.2

Product overview						
Product Name	Dengue recombinant antigen	Catalog Number	GRJDENC301			
Date of Manufacture	Specific date	Lot Number	Specific lot number			
Immunogen	N/A		I			
Species	N/A	Expressed Host	E.coli			
Tag	His	Clone number	N/A			
Isotype	N/A	Molecular weight	18.5kDa			
Product buffer solution	20mM PB+50mM NaCl+0.1% P300,pH7.4	Preservative	ProClin300			
Storage Conditions	-20±5°C, Avoid multiple freeze/thaw cycles	Date of Expiration	Shelf life:24 months			
Applications	Detection	Platforms tested	GICA			
Parameters tested on each lot						
Product appearance	Liquid					
Conc.determined by	SDS-PAGE electrophoresis+ activity conc	Concentration /Recommended titer	Specific Concentration			
Purification	Affinity 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 $\pm$ 0.5C.			Yes√ No□		
Clinical specificity	In testing 50 clinical samples, the positivity rate/negativity rate in the test group is the same as the control group. In the blood samples tested positive/negative, the deviation of the colorimetric level in the test group from the control group is within $\pm 0.5$ .			Yes√ No□		
Product stability	N/A			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: 人 人 人

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