

## Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

Product overview			
<b>Product Name</b>	Dengue recombinant antigen	<b>Catalog Number</b>	BA-DENII0033
<b>Date of Manufacture</b>	Specific date	<b>Lot Number</b>	Specific lot number
<b>Immunogen</b>	N/A		
<b>Species</b>	N/A	<b>Expressed Host</b>	E.coli
<b>Tag</b>	His	<b>Clone number</b>	N/A
<b>Isotype</b>	N/A	<b>Molecular weight</b>	18.7kDa
<b>Product buffer solution</b>	20mMPB+50mMNaCl+0.1% P300, pH7.4	<b>Preservative</b>	ProClin300
<b>Storage Conditions</b>	-20±5°C, Avoid multiple freeze/thaw cycles	<b>Date of Expiration</b>	Shelf life:24 months
<b>Applications</b>	Detection	<b>Platforms tested</b>	GICA
Parameters tested on each lot			
<b>Product appearance</b>	Liquid		
<b>Conc.determined by</b>	SDS-PAGE electrophoresis+ activity conc	<b>Concentration /Recommended titer</b>	Specific Concentration
<b>Purification</b>	Affinity chromatography	<b>Purity</b>	≥90%
<b>Performance:</b>			
Items	Passing criteria		Qualified or not
<b>Immunoreactivity</b>	At the same working concentration, the deviation of the activity in the test group from the control group is within ± 0.5C.		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>Clinical specificity</b>	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 ±0.5.		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>Product stability</b>	N/A		Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Miscellaneous</b>	N/A		Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Remark</b>	N/A		

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

管理者代表:   
Management representative

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