

## Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

Product overview			
<b>Product Name</b>	HBe recombinant antigen	<b>Catalog Number</b>	GENHBVN201
<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>	34kDa
<b>Product buffer solution</b>	20mM Tris, pH8.5	<b>Preservative</b>	N/A
<b>Storage Conditions</b>	2~8°C	<b>Date of Expiration</b>	Shelf life:36 months
<b>Applications</b>	Neutralization antigen	<b>Platforms tested</b>	N/A
Parameters tested on each lot			
<b>Product appearance</b>	Liquid		
<b>Conc.determined by</b>	N/A	<b>Concentration /Recommended titer</b>	Specific Concentration
<b>Purification</b>	N/A	<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 $\pm 10\%$ .	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
<b>Clinical specificity</b>	N/A	Yes <input type="checkbox"/> No <input type="checkbox"/>	
<b>Product stability</b>	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 20%.	Yes <input checked="" 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>	Pass <input checked="" type="checkbox"/> Fail <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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