

## Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

Product overview			
<b>Product Name</b>	H. pylori (HP) recombinant antigen	<b>Catalog Number</b>	GECHPI401
<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>	68kDa
<b>Product buffer solution</b>	10mM PB+0.01%SDS+5mMEDTA,pH7.4	<b>Preservative</b>	N/A
<b>Storage Conditions</b>	-20±5°C, Avoid multiple freeze/thaw cycles	<b>Date of Expiration</b>	Shelf life:36 months
<b>Applications</b>	Capture	<b>Platforms tested</b>	GICA
Parameters tested on each lot			
<b>Product appearance</b>	Liquid		
<b>Conc.determined by</b>	UV absorption	<b>Concentration /Recommended titer</b>	Specific Concentration
<b>Purification</b>	Ion-exchange 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>	1. There is no color reaction in negative internal control samples. 2. In testing the internal control samples, 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		

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

管理者代表:   
Management representative

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