

Certificate of Analysis

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

Product overview						
Product Name	H.pylori recombinant antigen	Catalog Number	GRNHPS102			
Date of Manufacture	Specific date	Lot Number	Specific lot number			
Immunogen	N/A					
Species	N/A	Expressed Host	E.coli			
Tag	N/A	Clone number	N/A			
Isotype	N/A	Molecular weight	64.6kDa			
Product buffer solution	10mM PB+0.01%SDS+5mMEDTA, pH7.4	Preservative	N/A			
Storage Conditions	-20±5°C, Avoid multiple freeze/thaw cycles	Date of Expiration	Shelf life:36 months			
Applications	N/A	Platforms tested	GICA			
Parameters tested on each lot						
Product appearance	Liquid					
Conc.determined by	N/A	Concentration /Recommended titer	Specific Concentration			
Purification	N/A	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 ±0.5C.			Yes√ No□		
Clinical specificity	 There is no color reaction in negative internal control samples. 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√ 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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