

Certificate of Analysis

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

Product overview					
Product Name	HIV-I antigen	Catalog Number	GRCHIVS117		
Date of Manufacture	Specific date	Lot Number	Specific lot number		
Immunogen	N/A				
Species	N/A	Expressed Host	E.coli		
Tag	His	Clone number	N/A		
Isotype	N/A	Molecular weight	15.8kDa		
Product buffer solution	20mM Tris-HCl+1mM EDTA,pH8.0	Preservative	N/A		
Storage Conditions	-20±5°C, Avoid multiple freeze/thaw cycles	Date of Expiration	Shelf life:36 months		
Applications	Capture	Platforms tested	GICA		
Parameters tested on each lot					
Product appearance	Liquid				
Conc.determined by	UV absorption	Concentration /Recommended titer	Specific Concentration		
Purification	Ion-exchange 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	 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 Management representative

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