

Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

Product overview			
Product Name	HIV-2 gp36 recombinant antigen	Catalog Number	GRCHIVS202
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	32.4kDa
Product buffer solution	20mMTris-HCl+5mMEDTA,pH8.5	Preservative	N/A
Storage Conditions	2~8°C	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	≥85%
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 <input checked="" type="checkbox"/> No <input type="checkbox"/>
Clinical specificity	1. No color reaction was observed in the internal negative control samples.2. Positivity and negativity rate was observed to be same between the test group of 20 clinical samples and the control group.In blood samples that tested either positive or negative,the deviation of colorimetric level in test group from the control group was well within ± 0.5 .		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Product stability	N/A		Yes <input type="checkbox"/> No <input type="checkbox"/>
Miscellaneous	N/A		Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	N/A		

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

管理者代表: 
Management representative

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