

Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

Product overview			
Product Name	HCV recombinant antigen	Catalog Number	GRJHCVS205
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	N/A
Product buffer solution	20mM PB+0.1%SDS+3mM EDTA+10%Glycerol+1mM DTT pH8.0	Preservative	N/A
Storage Conditions	-20±5°C, Avoid multiple freeze/thaw cycles	Date of Expiration	Shelf life:36 months
Applications	Detection	Platforms tested	N/A
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 <input checked="" type="checkbox"/> No <input type="checkbox"/>
Clinical specificity	1. No color reaction was observed in the internal negative control samples. 2. In testing internal control samples, the deviation of colorimetric level in test group from the control group was well within±0.5C.		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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