

Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

Product overview			
Product Name	HCV recombinant antigen	Catalog Number	GRCHCVS303
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	33kDa
Product buffer solution	25mMTris-Hcl+500mMNaCl+3mMEDTA, pH7.5	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	Affinity chromatography+Ion exchange chromatography	Purity	≥95%
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. 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"/>
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

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管理者代表:
Management representative

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