

Certificate of Analysis

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

	Produc	t overview							
Product Name	HCV biotinylated recombinant antigen	Catalog Number GEEH		HCVS202					
Date of Manufacture	Specific date	Lot Number	Specifi	c 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	25mM Tris-HCl+ 0.1% SDS+5mMEDTA,pH8.0+50% Glycerol	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	N/A						
	Parameters tested on each lot								
Product appearance	Liquid								
Conc.determined by	N/A	Concentration /Recommended titer	Specific Concentration						
Purification	N/A	Purity	N/A						
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 ± 10%.			Yes√ No□					
Clinical specificity	 There is no positive result in testing all negative internal control samples. In testing internal control samples, the deviation of the specificity in the test group from the control group is not more than 3 sample. 			Yes√ No□					
Product stability	When accelerated stability testing at 37°C was performend, No change in specificity testing of the internal controls samples was observed and the change in activity was not higher than 15%.			Yes√ No□					

Miscellaneous	N/A					Yes□ No□
Remark	N/A					
Conclusion	Pa	ass√	Fail □			
Quality signature	N/A			Quality inspection date	N/A	

管理者代表: Management representative	34	χ-	X
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