

Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

	Produc	t overview			
Product Name	Syphilis (T.P.) coupling protein	Catalog Number	GRJCPS201		
Date of Manufacture	Specific date	Lot Number	Specific lot number		
Immunogen	Т1		I		
Species	Mouse	Expressed Host	N/A		
Tag	N/A	Clone number	1G1		
lsotype	lgG1	Molecular weight	150kDa		
Product buffer solution	10mM PB+150mM NaCl+0.1% ProClin300,pH7.4	Preservative	ProClin300		
Storage Conditions	-20±5°C, Avoid multiple freeze/thaw cycles	Date of Expiration	Shelf life:36 months		
Applications	Detection	Platforms tested	GICA		
	Parameters t	ested on each lot	•		
Product appearance	Liquid				
Conc.determined by	UV absorption	Concentration /Recommended titer	Specific Concentration		
Purification	Protein A chromatography+lon- 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: 了, 2 · 以子 Management representative

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