

Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

Product overview			
Product Name	Rubella recombinant antigen	Catalog Number	GECRVC103
Date of Manufacture	Specific date	Lot Number	Specific lot number
Immunogen	N/A		
Species	N/A	Expressed Host	CHO
Tag	N/A	Clone number	N/A
Isotype	N/A	Molecular weight	57kD and 40kDa
Product buffer solution	10mM Tris+150mM NaCl+1mM EDTA,pH8.0	Preservative	N/A
Storage Conditions	-20±5°C, Avoid multiple freeze/thaw cycles	Date of Expiration	Shelf life:36 months
Applications	Capture,Detection	Platforms tested	ELISA、CLIA
Parameters tested on each lot			
Product appearance	Liquid		
Conc.determined by	UV absorption	Concentration /Recommended titer	Specific Concentration
Purification	Affinity 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 ± 10%.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
Clinical specificity	In testing 200 clinical blood samples, the deviation of the specificity in the test group from the control group is not more than 2 samples.	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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