

Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

Product overview			
Product Name	Syphilis (T.P.) TP15 recombinant antigen	Catalog Number	GECTPS101
Date of Manufacture	Specific date	Lot Number	Specific lot number
Immunogen	N/A		
Species	N/A	Expressed Host	E.coli
Tag	N/A	Clone number	N/A
Isotype	N/A	Molecular weight	41.5 kDa
Product buffer solution	25mM Tris-HCl+0.1% SDS+5mMEDTA,pH8.0	Preservative	N/A
Storage Conditions	2~8°C	Date of Expiration	Shelf life:36 months
Applications	Capture	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	≥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 ± 10%.		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Clinical specificity	1. There is no positive result in testing all negative internal control samples. 2. In testing internal control samples, the deviation of the specificity in the test group from the control group is not more than 1 sample.		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Product stability	When accelerated stability testing at 37°C was performed, No change in specificity testing of the internal controls samples was observed and the change in activity was not higher than 10%.		Yes <input checked="" 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	

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管理者代表:
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