

Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

Product overview			
Product Name	Heterophilic Immunoglobulin Elimination Reagent	Catalog Number	HIER-E-014
Date of Manufacture	Specific date	Lot Number	Specific lot number
Immunogen	N/A		
Species	Mouse	Expressed Host	CHO
Tag	N/A	Clone number	N/A
Isotype	IgG1	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	Blocking Heterophilic Antibody Interference	Platforms tested	FIA、GICA
Parameters tested on each lot			
Product appearance	Liquid		
Conc.determined by	UV absorption	Concentration /Recommended titer	Specific Concentration
Purification	Protein A chromatography	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 <input checked="" type="checkbox"/> No <input type="checkbox"/>
Clinical specificity	The deviation of the background signal reduction/elimination (OD of the false positive in the test group is 30% higher than the control group) 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	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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