

Certificate of Analysis

Number: FAPON-FR-T0-017

Edition: B.2

Product overview			
Product Name	Anti-ETG monoclonal antibody	Catalog Number	BRJETGP101
Date of Manufacture	Specific date	Lot Number	Specific lot number
Immunogen	N/A		
Species	N/A	Expressed Host	CHO
Tag	N/A	Clone number	22F6
Isotype	IgG	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 tested on each lot			
Product appearance	Liquid		
Conc.determined by	Protein A chromatography	Concentration /Recommended titer	Specific Concentration
Purification	Protein A chromatography+Ion- exchange chromatography	Purity	≥90%
Performance:			
Items	Passing criteria		Qualified or not
Immunoreactivity	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 <input checked="" type="checkbox"/> No <input type="checkbox"/>
Clinical specificity	The 10 negative urine samples tested true negative.		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

广东省东莞市松山湖台湾高科技园花莲路5号
No.5 Hualian Road, Taiwan High-tech industrial park, Songshan Lake, Dongguan, Guangdong, 523808, China
0769-22898885 marketcn@fapon.com (国内/Domestic) market@fapon.com (国际/International) www.faponbiotech.com