

## Certificate of Analysis

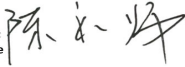
Number: FAPON-FR-T0-017

Edition: B.2

Product overview			
<b>Product Name</b>	Anti-Malaria HRP II monoclonal antibody	<b>Catalog Number</b>	BRCMALS106
<b>Date of Manufacture</b>	Specific date	<b>Lot Number</b>	Specific lot number
<b>Immunogen</b>	Recombinant Plasmodium falciparum HRP-II protein		
<b>Species</b>	Mouse	<b>Expressed Host</b>	CHO
<b>Tag</b>	N/A	<b>Clone number</b>	35A2
<b>Isotype</b>	IgG1	<b>Molecular weight</b>	150kDa
<b>Product buffer solution</b>	10mM PB+150mM NaCl+0.1% ProClin300,pH7.4	<b>Preservative</b>	ProClin300
<b>Storage Conditions</b>	-20±5°C, Avoid multiple freeze/thaw cycles	<b>Date of Expiration</b>	Shelf life:36 months
<b>Applications</b>	Capture	<b>Platforms tested</b>	GICA
Parameters tested on each lot			
<b>Product appearance</b>	Liquid		
<b>Conc.determined by</b>	UV absorption	<b>Concentration /Recommended titer</b>	Specific Concentration
<b>Purification</b>	Protein A chromatography	<b>Purity</b>	≥90%
<b>Performance:</b>			
Items	Passing criteria		Qualified or not
<b>Immunoreactivity</b>	At the same working concentration, the deviation of the activity in the test group from the control group is within ± 0.5C.		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>Clinical specificity</b>	1. No color reaction was observed in the internal negative control samples. 2. Positivity and negativity rate was observed to be same between the test group of 20 clinical samples and the control group. In blood samples that tested either positive or negative, the deviation of colorimetric level in test group from the control group was well within±0.5.		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>Product stability</b>	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

管理者代表:  
Management representative



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