

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: HSV 1/2 IgG EIA Test Kit

PURCHASE NO.: 37740068A

BATCH NO.: 1912656

EXPIRATION DATE: 2021/06/26

QUANTITY: 5kits

SPECIFICATION		STANDARD	CONCLUSION
Physics Check		No sediment or floccule ,and the color meets the requirements.	Complies
Blank Well		OD< 0.050 (450nm/630nm) or OD< 0.100 (450nm)	Complies
Positive Control		OD \geq 1.500	Complies
Cut-Off Control		OD \geq 0.150	Complies
Negative Control		OD<0.100	Complies
Sensitivity	QCO	OD \geq 0.150	Complies
	L1	OD \geq Cut-Off Value	Complies
	L2	OD \geq Cut-Off Value	Complies
	M	OD \geq 0.800	Complies
Accordance of Specificity Standard		OD<Cut-off Value	Complies
Precision		CV<15%,OD>1.1* Cut-Off OD	Complies

Quality Department: Hedy Zhang

Date: Sep. 23, 2020

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: CMV IgM EIA Test Kit

PURCHASE NO.: 37740068A

BATCH NO.: 2003718

EXPIRATION DATE: 2021/10/12

QUANTITY: 20kits

SPECIFICATION		STANDARD	CONCLUSION
Physical Inspection		No obvious precipitates or floccules in liquid component and the color meets requirement.	Complies
Blank Well		OD<0.050(450nm/630nm) or OD<0.100(450nm)	Complies
Negative Control		OD<0.150	Complies
Positive Control		OD>0.500	Complies
Cutoff Control		OD > 0.150	Complies
Sensitivity Standard	L	OD > 0.150	Complies
	M	OD> 0.500	Complies
	H	OD > 1.000	Complies
Negative Standard		OD<Cut-Off Control	Complies
Precision Standard		CV<15%, OD>1.1* Cut-Off OD	Complies

Quality Department: Hedy zhang

Date: Sep. 23, 2021

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: HSV 1/2 IgM EIA Test Kit

PURCHASE NO.: 37740068A

BATCH NO.: 2001660

EXPIRATION DATE: 2021/06/30

QUANTITY: 3kits

SPECIFICATION		STANDARD	CONCLUSION
Physics Check		Liquid should be clear without precipitate, the components of the kit should be complete, no leakage of liquid.	Complies
Blank Well		OD < 0.050 (450nm/630nm) or OD < 0.100 (450nm)	Complies
Positive Control		OD ≥ 0.800	Complies
Cut-off Control		OD ≥ 0.150	Complies
Negative Control		OD < 0.100	Complies
Sensitivity	QCO	OD ≥ 0.150	Complies
	L1	OD ≥ Cut-Off Value	Complies
	L2	OD ≥ Cut-Off Value	Complies
	M	OD ≥ 0.300	Complies
Accordance of Control Standard		OD < Cut-off Value	Complies
Precision		CV < 15%, OD ≥ 1.1 * CO	Complies

Quality Department: Hedy Zhang

Date: Sep. 23, 2020