

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: HBsAg EIA Test Kit

PURCHASE NO.: 37740068A

BATCH NO.: 2004721

EXPIRATION DATE: 2021/11/12

QUANTITY: 50kits

SPECIFICATION		STANDARD	CONCLUSION
Physics Check		No visible deposit or floccules in solution.	Complies
Blank well		OD< 0.100 (450nm) OD< 0.050 (450/630)	Complies
Sensitivity	Ad0.2 ng/ml	OD $\geq$ 0.100	Complies
	Ad0.5 ng/ml	OD $\geq$ 0.150	Complies
	Ad1.0 ng/ml	OD $\geq$ 0.250	Complies
	Ay0.2 ng/ml	OD $\geq$ 0.100	Complies
	Ay0.5 ng/ml	OD $\geq$ 0.150	Complies
Coincidence of Specificity Standard		100/100	Complies
High Positive Standard		OD $\geq$ 3.000	Complies
Negative Control		OD<0.100	Complies
Positive Control		OD>1.000	Complies
Precision		CV<15%	Complies

Quality Department: Hedy zhang

Date: Sep. 23, 2020

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: HCV Antibody EIA Test Kit

PURCHASE NO.: 37740068A

BATCH NO.: 2004722

EXPIRATION DATE: 2022/02/11

QUANTITY: 50kits

SPECIFICATION		STANDARD	CONCLUSION
Physics Check		No visible deposit or floccules in solution.	Complies
Blank Well		OD < 0.100 (450nm) OD < 0.050 (450/630 nm)	Complies
Sensitivity	H (n=2)	OD ≥ 2.500	Complies
	M (n=2)	OD ≥ 1.500	Complies
	L1 (n=2)	OD ≥ 0.150	Complies
	L2 (n=2)	OD ≥ 0.150	Complies
	L3 (n=2)	OD ≥ 0.150	Complies
Negative Control		OD < 0.100	Complies
Positive Control		OD > 1.000	Complies
Coincidence of specificity standard		≥ 99/100	Complies
Precision		CV < 15%	Complies

Quality Department: Hedy Zhang

Date: Sep. 23, 2020

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Toxoplasma IgG EIA Test Kit

PURCHASE NO.: 37740068A

BATCH NO.: 2003678

EXPIRATION DATE: 2021/09/22

QUANTITY: 20kits

SPECIFICATION		STANDARD	CONCLUSION
Appearance		No obvious sediments or floccules in liquid component and color meets requirement	Complies
Blank		OD<0.050(450nm/630nm) or OD<0.100(450nm)	Complies
Sensitivity Standard	200IU/ml	OD>1.000	Complies
	50IU/ml	10 IU/ml OD< OD < 200 IU/ml OD	Complies
	10IU/ml	0.150 < OD < 0.450	Complies
Compliance of Negative Standard		$\geq 19/20$ and $\geq 16/20$ (OD<0.100)	Complies
Calibrator 1 #		OD<0.100	Complies
Calibrator 2 #		OD>0.150	Complies
Calibrator 3 #		Calibrator2#OD<OD<Calibrator4#OD	Complies
Calibrator 4 #		OD>1.000	Complies
R value		≥ 0.98	Complies
Precision		CV<15%, OD>1.1* Calibrator 2#OD.	Complies

Quality Department: Hedy Zhang

Date: Sep. 23, 2020

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: H. pylori Antigen EIA Test Kit

PURCHASE NO.: 37740068A

BATCH NO.: 2004725

EXPIRATION DATE: 2021/11/06

QUANTITY: 13kits

SPECIFICATION		STANDARD	CONCLUSION
Physics Check		No sediment or floccule	Complies
Blank Well		OD < 0.050 (450nm/630nm) or OD < 0.100 (450nm)	Complies
Calibrators	Calibrator 1#	OD < 0.100	Complies
	Calibrator 2#	OD > 0.150	Complies
	Calibrator 3#	OD > 0.500	Complies
	Calibrator 4#	OD > 1.000	Complies
	R	≥ 0.98	Complies
Sensitivity	Q0.1	OD ≥ 0.200	Complies
	Q0.5	OD ≥ 0.600	Complies
	P	OD > (Calibrator 1# + Calibrator 2#) / 2 OD	Complies
Accordance of Specificity Standard		OD < (Calibrator 1# + Calibrator 2#) / 2 OD	Complies
Precision		CV < 15%	Complies

Quality Department: Hedy Zhang

Date: Sep. 23, 2020

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: HBcAb EIA Test Kit

PURCHASE NO.: 37740068A

BATCH NO.: 2008762

EXPIRATION DATE: 2021/11/08

QUANTITY: 11kits

SPECIFICATION	STANDARD	CONCLUSION
Appearance	No visible deposit or floccules in liquid component	Complies
Negative Control	$OD > 1.000$	Complies
Positive Control	$OD < 0.080$	Complies
QCO reference	$0.500 \leq QCO/Cutoff\ value \leq 1.500$	Complies
Compliance rate of negative reference	15/15	Complies
Compliance rate of positive references	15/15	Complies
Precision criteria	$CV < 20\%$	Complies

Quality Department: Hedy zhang

Date: Sep. 23, 2020

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: HSV 1 IgG EIA Test Kit

PURCHASE NO.: 37740068A

BATCH NO.: 2008763

EXPIRATION DATE: 2022/01/07

QUANTITY: 11kits

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 $\geq$ 0.200	Complies
Negative Control		OD<0.100	Complies
Sensitivity	QCO	OD $\geq$ 0.200	Complies
	L	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 $\geq$ 1.1*Cut-Off OD	Complies

Quality Department: Hedy Zhang

Date: Sep. 23, 2020

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Toxoplasma IgM EIA Test Kit

PURCHASE NO.: 37740068A

BATCH NO.: 2003699

EXPIRATION DATE: 2021/08/20

QUANTITY: 20kits

SPECIFICATION		STANDARD	CONCLUSION
Appearance		No obvious sediments or floccules in liquid component and color meets requirement	Complies
Blank		OD<0.050 (450nm/630nm) or OD<0.100 (450nm)	Complies
Sensitivity Standard	ToxoM-H	OD>0.500	Complies
	ToxoM-M	OD>0.300	Complies
	ToxoM-L	OD>0.200	Complies
Compliance of Negative Standard		$\geq 19/20$	Complies
Negative Control		OD<0.200	Complies
Cutoff Control		OD>0.200	Complies
Positive Control		OD>0.500	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: HSV 1 IgM EIA Test Kit

PURCHASE NO.: 37740068A

BATCH NO.: 1912665

EXPIRATION DATE: 2021/05/04

QUANTITY: 13kits

SPECIFICATION		STANDARD	CONCLUSION
Physics Check		Liquid should be clear without precipitate, the components of the kit should be complete, without no leakage of liquid.	Complies
Positive Control		$OD > 0.800$	Complies
Negative Control		$OD < 0.100$	Complies
Cut-Off Control		$OD \geq 0.150$	Complies
Accordance of positive reference		6/6	Complies
Accordance of negative reference		10/10	Complies
Minimum Detection Limit	S1	Negative	Complies
	S2	Negative, Positive or equivocal	Complies
	S3	Positive	Complies
	S4	Positive	Complies
Precision		$CV \leq 15\%$, $OD \geq \text{Cut-Off OD}$	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, 2020

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Total T4 EIA Test Kit

PURCHASE NO.: 37740068A

BATCH NO.: 2003705

EXPIRATION DATE: 2021/07/29

QUANTITY: 5kits

SPECIFICATION		STANDARD	CONCLUSION
Physics Check		No sediment or floccule	Complies
Calibrator	Calibrator 1	$OD \geq 1.800$	Complies
	Calibrator 6	$OD < 0.400$	Complies
QL		$0.50 \leq R \leq 1.50$	Complies
QM		$0.70 \leq R \leq 1.30$	Complies
QH		$0.73 \leq R \leq 1.30$	Complies
QN1-QN8		$\leq 15.0 \mu\text{g/dL}$ (8/8)	Complies
QH1-QH2		$> 15.0 \mu\text{g/dL}$ (2/2)	Complies
Precision		$CV \leq 15\%$	Complies

Quality Department: Hedy zhang

Date: Sep. 23, 2020

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Free T4 EIA Test Kit

PURCHASE NO.: 37740068A

BATCH NO.: 2008764

EXPIRATION DATE: 2021/06/24

QUANTITY: 2kits

SPECIFICATION	STANDARD	CONCLUSION
Physics Check	No sediment or floccule	Complies
Calibrator1#	$OD \geq 1.800$	Complies
Calibrator 6#	$OD \leq 0.400$	Complies
QL	$0.44 \leq R \leq 1.33$	Complies
QM	$0.66 \leq R \leq 1.34$	Complies
QH	$0.66 \leq R \leq 1.34$	Complies
QN1-QN8	Concentration $\leq 2\text{ng/dL}$ (8/8)	Complies
QH1,QH2	Concentration $> 2\text{ng/dL}$ (2/2)	Complies
Precision	$CV \leq 15\%$	Complies

Quality Department: Hedy zhang

Date: Sep. 23, 2020

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: HSV 2 IgG EIA Test Kit

PURCHASE NO.: 37740068A

BATCH NO.: 2006743

EXPIRATION DATE: 2021/12/18

QUANTITY: 13kits

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
Sensitivity	L	OD $\geq$ Cut-Off Value	Complies
	M	OD $\geq$ 0.400	Complies
Accordance of Specificity Standard		OD <Cut-Off Value	Complies
Positive Control		OD $\geq$ 0.800	Complies
Negative Control		OD<0.100	Complies
Cut-Off Control		0.150 $\leq$ OD $\leq$ 0.400	Complies
Precision		CV<15%, OD $\geq$ 1.1* Cut-Off OD	Complies

Quality Department: Hedy Zhang

Date: Sep. 23, 2020

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: HSV 2 IgM EIA Test Kit

PURCHASE NO.: 37740068A

BATCH NO.: 2004727

EXPIRATION DATE: 2021/09/01

QUANTITY: 13kits

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
Sensitivity	L	OD $\geq$ Cut-Off Value	Complies
	M	OD $\geq$ 0.400	Complies
Accordance of Specificity Standard		OD <Cut-Off Value	Complies
Positive Control		OD $\geq$ 0.800	Complies
Negative Control		OD<0.100	Complies
Cut-Off Control		OD $\geq$ 0.150	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: H.pylori IgG EIA Test Kit

PURCHASE NO.: 37740068A

BATCH NO.: 2003703

EXPIRATION DATE: 2021/10/14

QUANTITY: 15kits

SPECIFICATION		STANDARD	CONCLUSION
Physics Check		No sediment or floccule	Complies
Blank Well		OD < 0.050 (450nm/630nm) or OD < 0.100 (450nm)	Complies
Calibrators	Calibrator 1#	OD < 0.100	Complies
	Calibrator 2#	OD > 0.150	Complies
	Calibrator 6#	OD > 1.000	Complies
	R	≥ 0.98	Complies
Sensitivity	Negative	Conc. < 5AU/mL(8/8)	Complies
	Positive	Conc. > 5AU/mL(5/5)	Complies
	Minimum Detection Limit	Conc. < 5AU/mL	Complies
PRECISION		CV < 15%	Complies

Quality Department: Hedy Zhang

Date: Sep. 23, 2020

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: HBsAb Quantitative EIA Test Kit

PURCHASE NO.: 37740066B

BATCH NO.: 2003706

EXPIRATION DATE: 2021/03/04

QUANTITY: 33kits

SPECIFICATION		STANDARD	CONCLUSION
Appearance		No obvious sediments or floccules in liquid component and color meets requirement	Complies
Sensitivity Standard	10mIU/mL	$0.105 < OD < 0.400$	Complies
	100mIU/mL	$0.500 < OD < 1.600$	Complies
	200mIU/mL	$OD > 1.200$ and $OD > 100.0 \text{ mIU/mL}$ OD	Complies
Compliance of Negative Standard		$OD < \text{Calibrator 2\# } OD$	Complies
Calibrator 1#		$OD < 0.105$	Complies
Calibrator 2#		$OD > 0.105$	Complies
Calibrator 3#		$OD > 0.250$	Complies
Calibrator 4#		$OD > 0.500$	Complies
Calibrator 5#		$OD > 1.000$	Complies
R value		$R > 0.98$	Complies
Precision		$CV < 15\%$	Complies
The above results based on evaluation on the whole kit with all components manufactured by ACON			

Quality Department: Antony. Hu

Date: Apr. 21, 2020

ACON BIOTECH (HANGZHOU) CO.,LTD

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Total PSA EIA Test Kit

PURCHASE NO.: 37740066A

BATCH NO.: 1912663

EXPIRATION DATE: 2021/01/05

QUANTITY: 30kits

SPECIFICATION		STANDARD	CONCLUSION
Physics Check		No sediment or floccule	Complies
Blank Well		$OD \leq 0.050$	Complies
Calibrators	Calibrator 1#	$OD \leq 0.050$	Complies
	Calibrator 2#	$OD \geq 0.060$	Complies
	Calibrator 6#	$OD \geq 2.000$	Complies
Sensitivity	Q4	$2.3\text{ng/mL} \leq \text{concentration} \leq 5.7\text{ng/mL}$	Complies
	Q20	$13\text{ng/mL} \leq \text{concentration} \leq 27\text{ng/mL}$	Complies
	Q50	$32.5\text{ng/mL} \leq \text{concentration} \leq 67.5\text{ng/mL}$	Complies
	QN1-QN10	$\text{concentration} < 4\text{ng/mL}$	Complies
Precision		$CV \leq 15\%$	Complies

Quality Department: Antong. Hu

Date: Mar. 05, 2020