

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 $OD > 100.0mIU/mL$ 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 Huc

Date: Apr. 21, 2020

