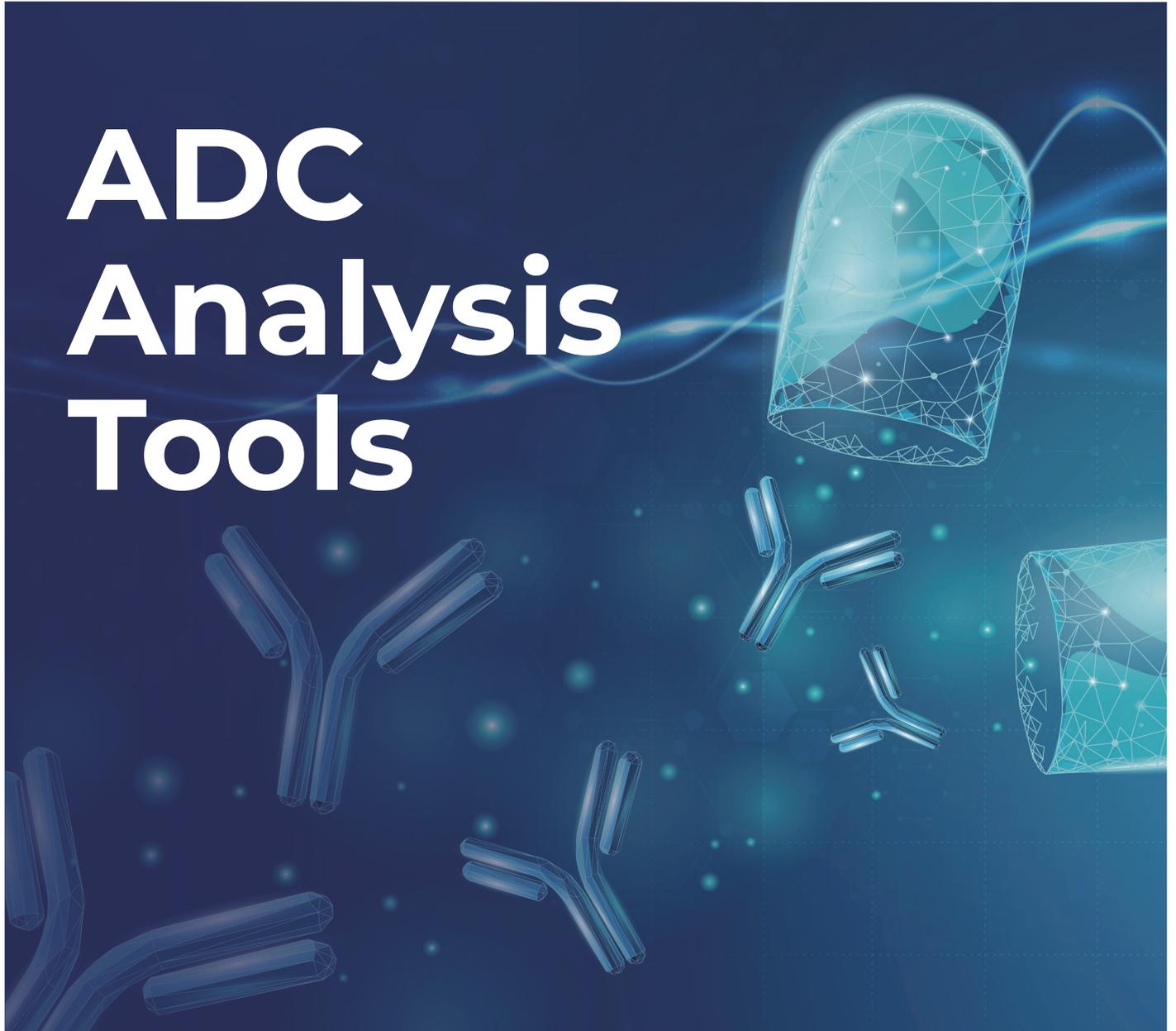


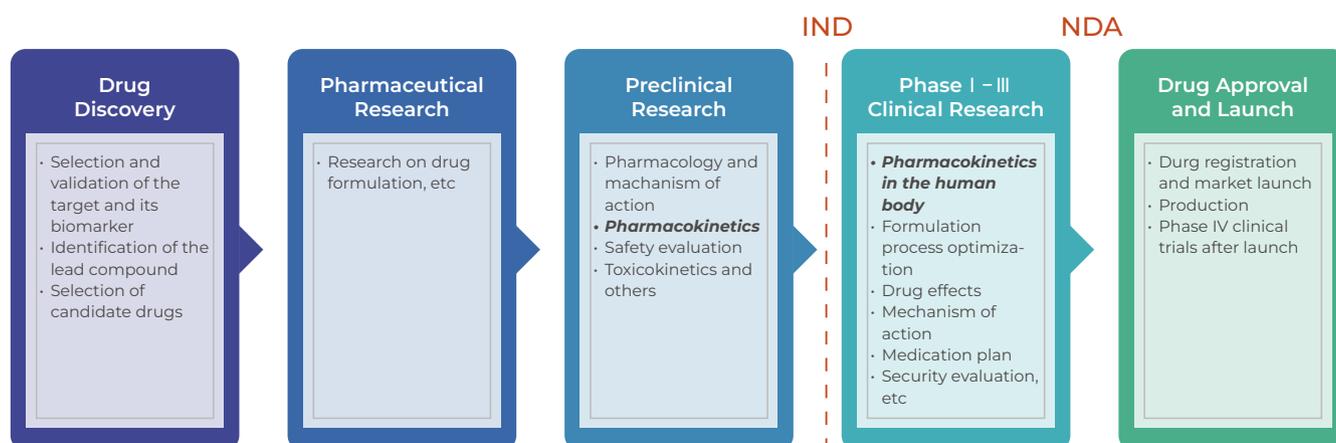
ADC Analysis Tools



PK and ADA Analysis Tools help you better explore the process of drug metabolism and the impact of drug immune reactions



Background



Pharmacokinetic (PK) and Immunogenicity (ADA Assay) are critical components in the drug development lifecycle. FDA, NMPA, and other regulatory agencies require proof of the effectiveness and safety of the drugs in animal models before drugs enter clinical research. Therefore, it is essential to study the pharmacokinetics of drugs and to conduct immunogenicity risk assessment during the IND stage and Phase I clinical trials.

GenScript provides PK and ADA assay kits for preclinical and clinical analysis of drugs, as well as raw materials for method development and establishment of PK and ADA Assay. GenScript's products and services will help you better study the drug metabolism, evaluate drug distribution and metabolism in vivo, and detect the risk of immune reactions caused by drugs.

As your drug development partner, GenScript can provide early guidance for clinical research by developing and establishing reliable non-clinical analytical assessment methods to enhance drug safety and efficacy. GenScript is dedicated to offering high-quality, dependable reagent products and method development support to assist you in achieving success in the drug development process.

Kits Development and Validation

GenScript PK/ADA kits are developed and validated according to FDA and NMPA regulations, and accuracy of kits is evaluated according to the guidance document CLSI EP05-A3 to ensure its accuracy and reliability. GenScript PK/ADA kits can satisfy the needs of PK and ADA research during preclinical and clinical research.

Index:

ICH M10



FDA



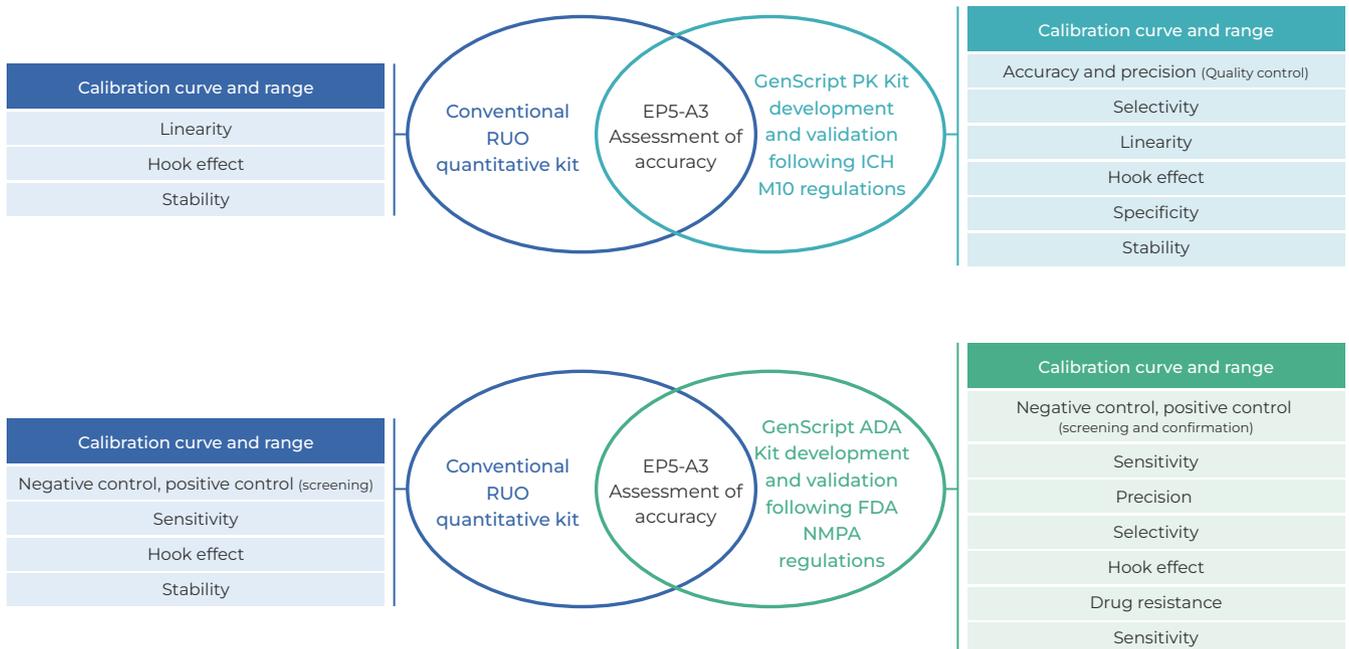
NMPA



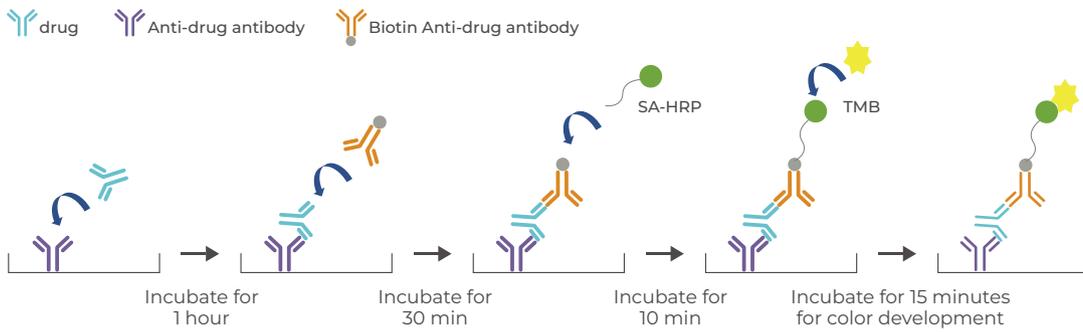
EP05-A3



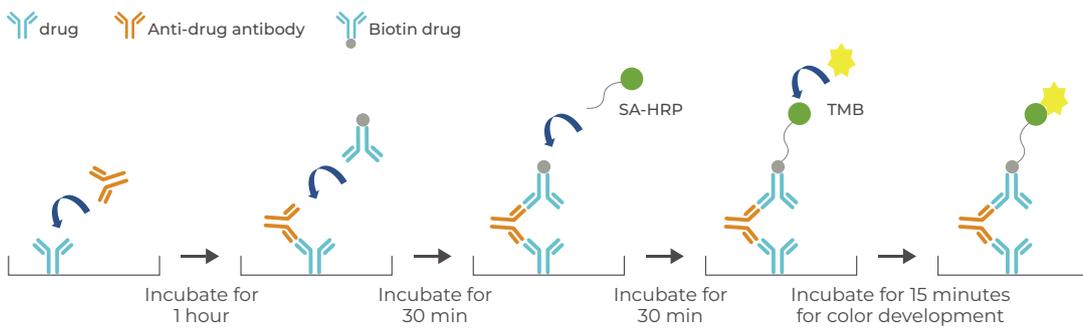
Verification Indicators



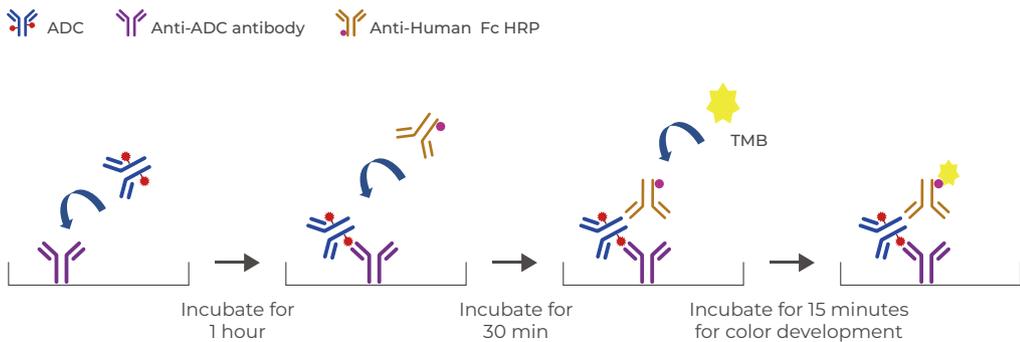
Schematic diagram of the reaction



Pharmacokinetic ELISA Kit



Immunogenicity ELISA Kit (Bridging ELISA)



ADC Pharmacokinetics ELISA Kit

Features



Minimize risk

Minimize the risk of replacing raw materials



Save time

Save the time for raw materials selection and method development



More professional

Develop the kit products according to FDA and NMPA regulations



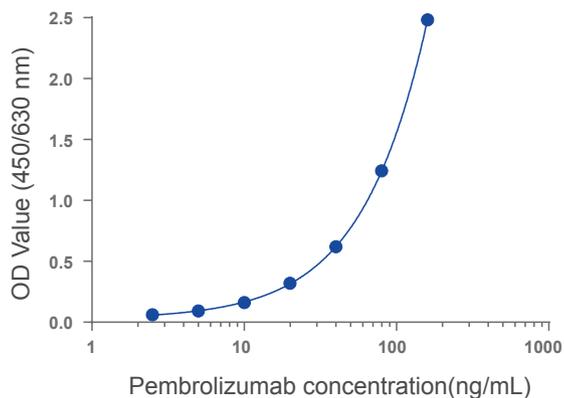
Easier to Operate

Easy to operate and reduce operating errors

Applications

PK— L00968 Pembrolizumab Pharmacokinetic ELISA Kit

Pembrolizumab Standard Curve

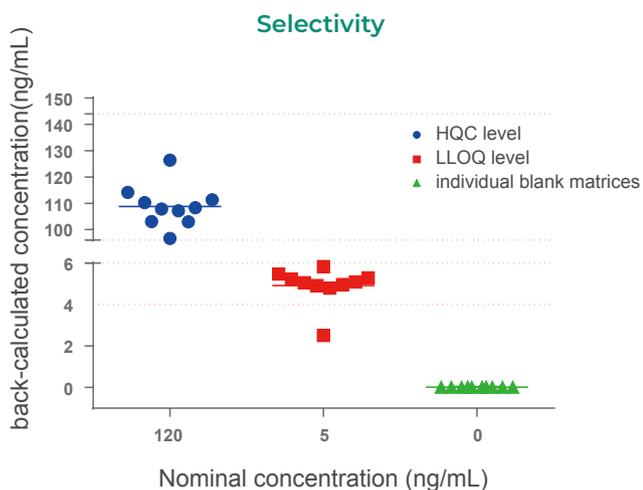


Set 6 concentration points, standard curve range 160-2.5 ng/mL (MRD (Minimum Required Dilution) = concentration before 1:100 dilution), sensitivity: 5 ng/mL.

Intra-assay and inter-assay accuracy of the kit

Quality Control	Pembrolizumab (ng/mL)	Intra-assay (n=10)			Inter-assay (n=30)		
		Measured (ng/mL)	CV %	Accuracy %	Measured (ng/mL)	CV %	Accuracy %
P1	120	102.41	6.92	85.34	105.08	2.65	87.57
P2	30	29.58	3.88	98.61	31.00	0.83	103.33
P3	15	16.64	2.99	110.96	17.77	2.71	118.49

Precision of L00968: Intra-batch CV% <7%, Inter-batch CV% <3%

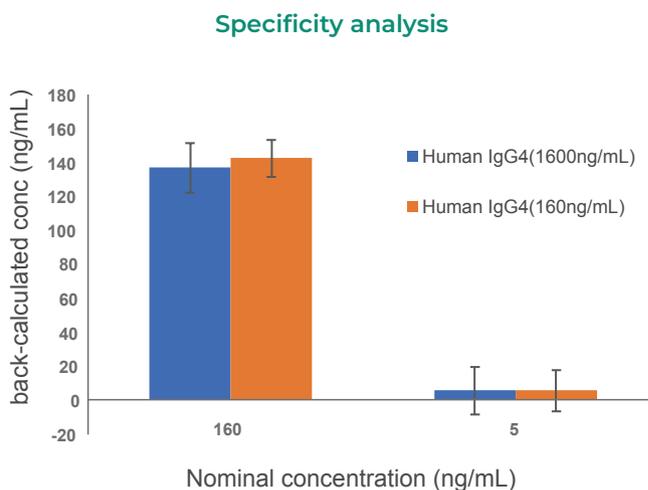


The dashed lines in the figure represent the critical lines of 80% and 120% precision.

HQC (High Quality Control) level selectivity: The precision of 100% blank individual matrices from different sources is 80.5% ~ 105%, and the precision is 0.9% ~ 6.4%.

LLOQ (Lower Limit of Quantification) level selectivity: The precision of 90% blank individual matrices from different sources is 95.8% ~ 116.8%, and the precision is 1.0% ~ 10.6%.

The blank individual matrices from different sources: The signal values of 10 blank individual matrices from different sources are all lower than the LLOQ signal value.



Human IgG4 (1600 ng/mL) was added. The accuracy of Pembrolizumab at ULOQ and LLOQ levels is 85.6% ~ 113.8%, and the precision is 2% ~ 5.1%.

Human IgG4 (160 ng/mL) was added. The accuracy of Pembrolizumab at ULOQ and LLOQ levels is 89.1% ~ 111.9%, and the precision is 0.4% ~ 0.5%.

Hook effect analysis

Pembrolizumab (ng/mL)	Absorbance (OD 450/630nm)			CV%
	Duplicate 1	Duplicate 2	Average	
15,000	5.845	5.323	5.584	6.60
1,500	5.881	5.611	5.746	3.33
750	5.505	5.583	5.544	0.99

The precision of the concentrations of three samples above ULOQ level is not affected by the hook effect (signal suppression caused by high concentration samples).

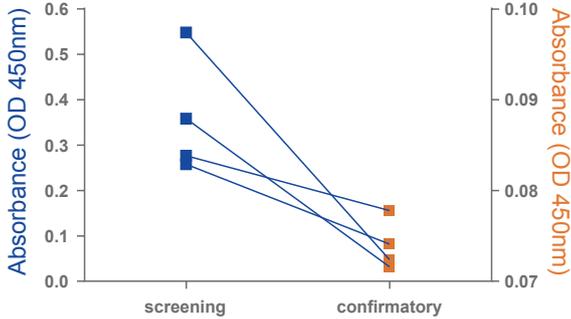
Dilutional linearity analysis

Dilution Factor	Expected Pembrolizumab (ng/mL)	Measured Pembrolizumab (ng/mL)	CV%	Accuracy%
1:2,000	7.5	8.496	0.28	113.28
1:1,000	15	17.215	2.27	114.77
1:100	15	15.406	1.21	102.71
1:50	15	15.597	2.92	103.98

Dilute the standard product by 4 different dilution ratios, after dilution factor correction, the accuracy of each diluted standard product is 102.7% ~ 114.8%, and the precision is 0.28% ~ 2.9%.

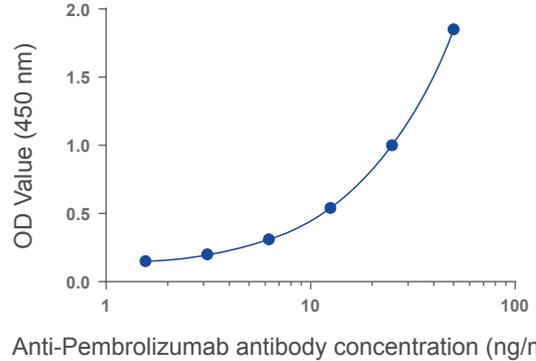
ADA— L00971 Pembrolizumab Immunogenicity Kit (Bridging ELISA)

Positive Control Antibodies Screening



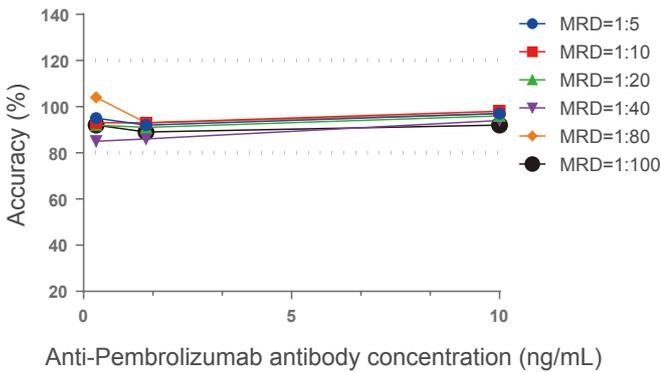
The sensitivity of 4 antibodies is validated to be greater than 20 ng/mL through screening experiments, and results show that all 4 antibodies can be used as positive control antibodies by further validation experiments. Based on the screening and validation results, the antibody with the highest sensitivity is selected as the final positive control antibody for ELISA kit.

Anti-Pembrolizumab Standard Curve



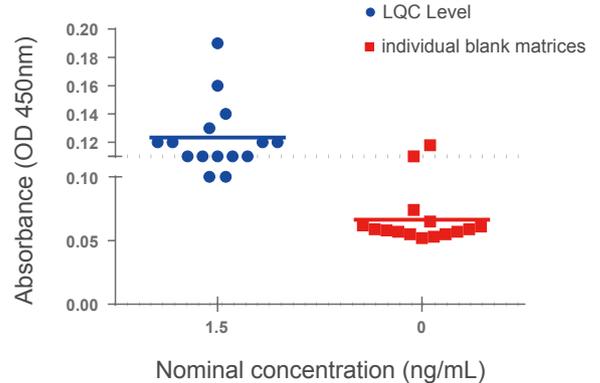
Set 6 concentration points, standard curve range 50-0.78 ng/mL (MRD = concentration before 1:100 dilution), sensitivity: 1.56 ng/mL

MRD Analysis of Detection of Anti-Pembrolizumab in Biological Matrix



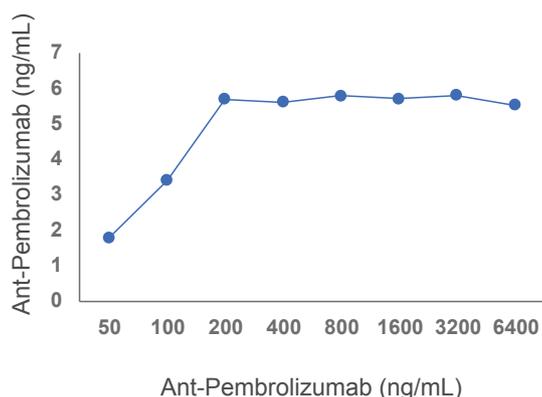
When MRD=1:5, the signal value of the sample prepared with biological matrix is closest to the signal value of the sample prepared with sample diluent.

Selectivity



The dashed line in the figure is the screening critical value line.
 LQC (Low Quality Control) level selectivity: The precision of 87% blank individual matrices from different sources is 0.2% ~ 8.5%, and signal value is not lower than the screening critical value.
 Blank level selectivity: The precision of 87% blank individual matrices from different sources is 0.6% ~ 14.3%, and signal value is lower than the screening critical value.

Hook effect analysis



Intra-assay and inter-assay accuracy of the kit

Samples	Anti-Pembrolizumab (ng/mL)	Intra-assay (n=10)			Inter-assay (n=30)		
		Measured (ng/mL)	CV %	Accuracy %	Measured (ng/mL)	CV %	Accuracy %
P1	50	49.27	3.26	98.54	50.96	3.51	102.07
P2	7.5	7.75	4.27	103.37	8.22	4.17	110.32
P3	2.5	2.15	7.27	85.81	2.39	8.07	95.40

As the concentration of Anti-Pembrolizumab increases, the signal value increases. The signal value of high-concentration samples is higher than the signal value of the high point of the standard curve, and there is no significant signal suppression phenomenon. No hook effect is observed within the tested concentration range.

Precision of L00971: intra-assay CV% <8%, inter-assay CV% <9%

Product List

Product Category	Product Name	Cat. No.
Pharmacokinetic ELISA Kit	Pembrolizumab Pharmacokinetic ELISA Kit	L00968
	Bevacizumab Pharmacokinetic ELISA Kit	L00969
	Trastuzumab Pharmacokinetic ELISA Kit	L00970
	Pertuzumab Pharmacokinetic ELISA Kit	L00978
	Dxd ADC Pharmacokinetic ELISA Kit	L00972
	MMAE ADC Pharmacokinetic ELISA Kit	L00991
Immunogenicity Kit (Bridging ELISA)	Pembrolizumab Immunogenicity Kit (Bridging ELISA)	L00971
	Pertuzumab Immunogenicity Kit (Bridging ELISA)	L00979
	Trastuzumab Immunogenicity Kit (Bridging ELISA)	L01007
PEG ELISA Kit	PEGylated Molecule Assay Kit	L00458
ADC Antibody	DXd Antibody (39F4), mAb, Mouse	A02217
	DM1 Antibody (15L2), mAb, Mouse	A02223
	MMAE Antibody (69F7), mAb, Mouse	A02224
	MMAF Antibody (11B8), mAb, Mouse	A02225

Product Category	Product Name	Target
Anti-Idiotypic Antibody	Anti-Abatacept	CTLA-4-Fc
	Anti-Adalimumab	TNF alpha
	Anti-Atezolizumab	PD-L1
	Anti-Avelumab	PD-L1
	Anti-Bevacizumab	VEGF-A
	Anti-Certolizumab pegol	TNF alpha
	Anti-Cetuximab	EGF Receptor
	Anti-Daratumumab	CD38
	Anti-Denosumab	RANK Ligand
	Anti-Dupilumab	IL-4R α
	Anti-Durvalumab	CD274
	Anti-Eculizumab	Complement protein C5
	Anti-Etanercept	TNF alpha
	Anti-Evolocumab	PCSK9
	Anti-Golimumab	TNF alpha
	Anti-Infliximab	TNF alpha
	Anti-Ipilimumab	CTLA-4
	Anti-Ixekizumab	IL-17A
	Anti-Lecanemab	amyloid β
	Anti-Mosunetuzumab	CD3
	Anti-Nivolumab	PD-1
	Anti-Obinutuzumab	CD20
	Anti-Ocrelizumab	CD20
	Anti-Omalizumab	Human IgE
	Anti-OKT3	CD3
	Anti-Palivizumab	RSV F
	Anti-Panitumumab	EGF Receptor
	Anti-Pembrolizumab	PD-1
Anti-Pertuzumab	HER2	

Product Category	Product Name	Target
Anti-Idiotypic Antibody	Anti-Ranibizumab	VEGF-A
	Anti-Rituximab	CD20
	Anti-Sarilumab	IL-6 Receptor
	Anti-Secukinumab	IL-17A
	Anti-Teclistamab	BCMAxCD3
	Anti-Tocilizumab	IL-6 Receptor
	Anti-Trastuzumab	HER2
	Anti-Ustekinumab	IL-12 & IL-23
	Anti-Zolbetuximab	Claudin 18.2

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Pharmacokinetics and immunogenicity analysis
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