

Anti-idiotypic Antibodies

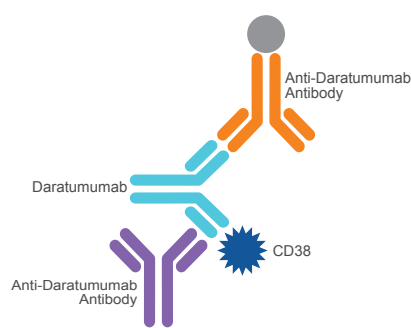
Support PK and immunogenicity study of biosimilars

Anti-idiotypic antibodies

An antibody that binds to the idiotype (variable region) of another antibody is called an anti-idiotypic antibody (anti-ID Abs). This feature can be used to measure therapeutic antibody concentration in pre-clinical and clinical studies. When a patient is treated with an antibody drug, a severe immune response might occur and result in devastating consequences in the body. Anti-idiotypic antibodies are also commonly used as a reference standard for antibody drug immunogenicity (immune response, IR) studies. GenScript's catalog of anti-ID Abs will help support your development of biosimilars, providing patients with affordable alternatives to innovative drugs currently on the market.

Applications

- Pharmacokinetic (PK) studies: Used to measure the drug level in patient samples



Schematic image of total Daratumumab or the biosimilar (free, partially bound, fully bound) PK study.

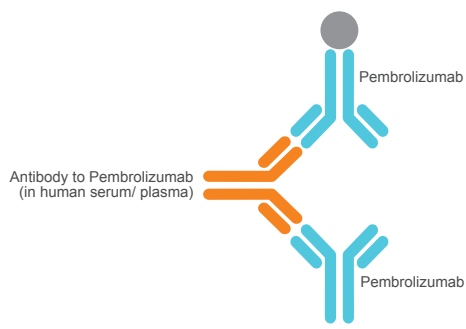
The assay was developed by using Anti-Daratumumab Antibody, mAb, Mouse (Cat.No. A01996) as capture antibody and Anti-Daratumumab Antibody (6A3), mAb, Mouse (Cat.No. A01997) as the detection antibody.

Note: A01977 was labeled with Biotin in this assay.

Sensitivity	39 pg/ml
Detection Range	78-1250 pg/ml
Test Samples	Human serum/plasma, mouse serum/plasma

Figure 1. Example of Bridging ELISA-based PK assay

- Immunogenicity (anti-drug antibody, ADA) assays: Used as a positive control or reference standards



Schematic image of Pembrolizumab or the biosimilar immunogenicity assay.

Anti-Pembrolizumab Antibody, pAb, Rabbit (Cat.No. A01846) can be used as positive control for the standard curve.

Sensitivity	0.20 ng/ml
Detection Range	1.56-100 ng/ml
Test Samples	Human serum/plasma (EDTA), mouse serum, rat serum/plasma (heparin), rabbit serum/plasma (heparin)

Figure 2. Example of Bridging ELISA-based ADA assay

Features

• High Specificity

Binding specificity of Anti-Trastuzumab antibody

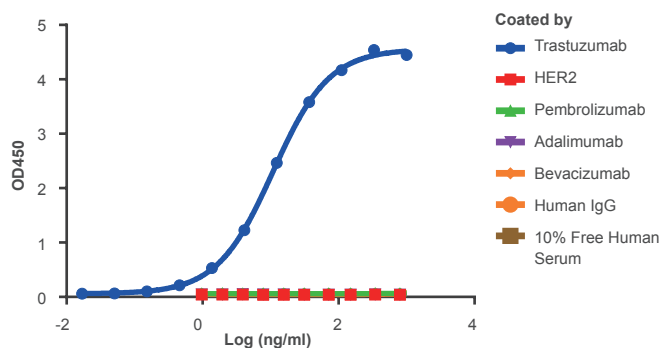


Figure 3. High specificity of Anti-Trastuzumab antibody to Trastuzumab.

The binding specificity of Anti-Trastuzumab Antibody (15H2), mAb, Mouse (A02033) to Trastuzumab was studied using indirect ELISA. No cross-reactivity was noted with human IgG, 10% free human serum, and other antibody drugs shown in the figure.

Note: 10% free human serum refers to T3/T4 Free human serum, lipid stripped.

Anti-Trastuzumab Antibody specificity

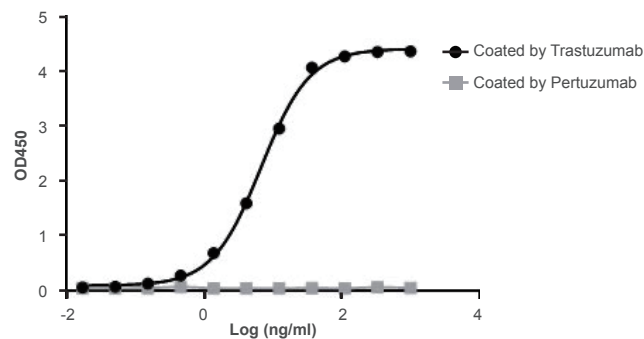


Figure 4. High specificity of Anti-Trastuzumab to Trastuzumab.

The binding specificity of Anti-Trastuzumab Antibody (15H2), mAb, Mouse (A02033) to Trastuzumab was studied using indirect ELISA. No cross-reactivity with Pertuzumab was observed.

Anti-Pertuzumab Antibody specificity

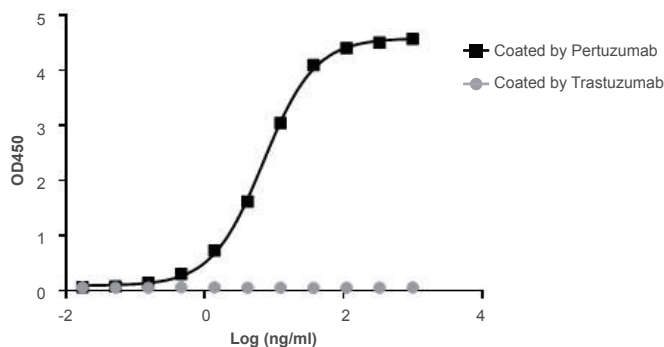


Figure 5. High specificity of Anti-Pertuzumab to Pertuzumab.

The binding specificity of Anti-Pertuzumab Antibody (1A3), mAb, Mouse (A02150) to Pertuzumab was studied using indirect ELISA. No cross-reactivity with Trastuzumab was observed.

Pertuzumab, trastuzumab, and hyaluronidase-zzxf is approved to be given with docetaxel or other chemotherapy agents to treat breast cancer that is HER2 positive. It is used as neoadjuvant therapy (to shrink the tumor before surgery) in adults with locally advanced, inflammatory, or early-stage breast cancer. Therefore, the specificity of anti-pertuzumab or anti-trastuzumab antibodies is important in PK assays for patients who receives both pertuzumab and trastuzumab treatments.

• High Affinity

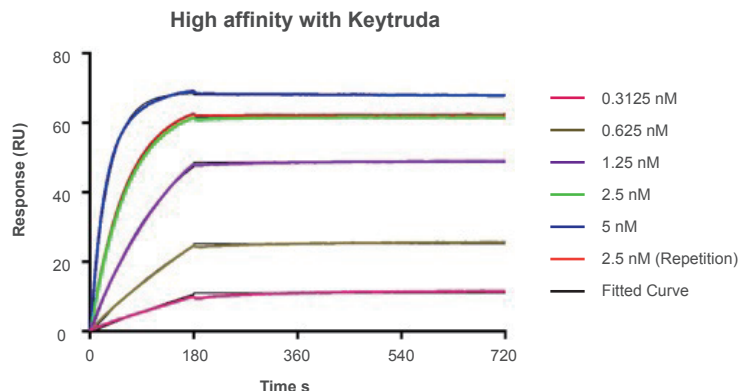


Figure 6. High affinity of Anti-Pembrolizumab antibody with Keytruda.

The affinity of MonoRab™ Anti-Pembrolizumab Antibody (90G12F8), mAb, Rabbit (Cat.No. A01853) towards Keytruda was measured by SPR method; $K_d < 10^{-12}$ M.

• High Stability

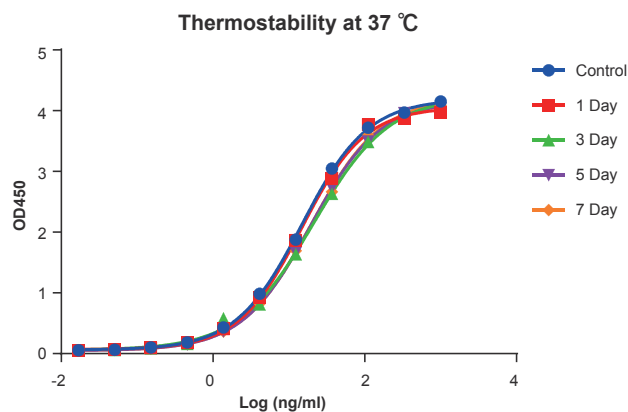


Figure 7. High thermal stability of A02033.

Anti-Trastuzumab Antibody (15H2), mAb, Mouse (A02033, 0.5 mg/ml) was aliquoted and placed at 37°C for different time periods (1, 3, 5, 7 days), along with the control placed at 4°C. No significant loss of binding activity was observed. Trastuzumab (1 µg/ml) was used as coating antigen.

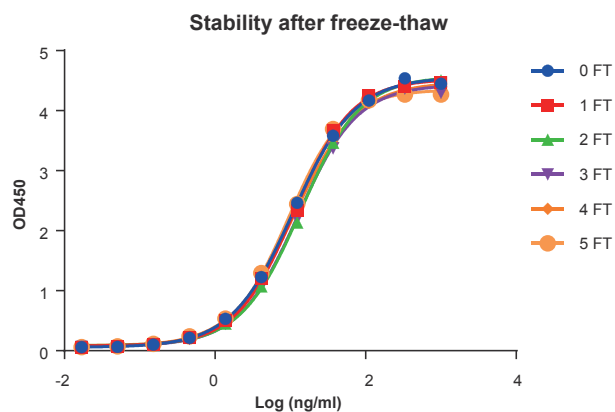


Figure 8. High freeze-thaw stability of A02033.

Anti-Trastuzumab Antibody (15H2), mAb, Mouse (A02033, 0.5 mg/ml) were subjected to the indicated number of freeze-thaw cycles (FT). No significant loss of activity was observed.

Product List

GenScript offers more than 100 anti-ID antibodies identifying 28 blockbuster drug targets.

• Antibody Pairs for PK Study

GenScript has developed various ready-to-use anti-ID antibody pairs for your pharmacokinetic studies. When your study requires extremely high sensitivity, MonoRab™ rabbit monoclonal antibodies are a perfect choice with their picomolar-level immunoassay sensitivity. Additionally, GenScript offers a customized labeling service for detection antibodies.

Drug Target	Antibody	Antibody Type	Capture	Detection-unconjugated	Detection-Biotin conjugated
CD20	Anti-Obinutuzumab	mAb, Mouse	A01945-40	A01946-40	A01947-40
		mAb, Rabbit	A01966-40	A01967-40	
	Anti-Rituximab	mAb, Mouse	A01969-40	A01970-40	A01971-40
		mAb, Rabbit	A01942-40	A01943-40	A01944-40
CD274	Anti-Durvalumab	mAb, Mouse	A02029-40	A02030-40	
CD38	Anti-Daratumumab	mAb, Mouse	A01996-40	A01997-40	
Complement Protein C5	Anti-Eculizumab	mAb, Mouse	A02115-40	A02116-40	
CTLA-4	Anti-Ipilimumab	mAb, Mouse	A01859-40	A01961-40	A01858-40
EGF Receptor	Anti-Cetuximab	mAb, Mouse	A01939-40	A01938-40	
		mAb, Rabbit	A01991-40	A01992-40	
	Anti-Panitumumab	mAb, Mouse	A02100-40	A02099-40	
HER2	Anti-Pertuzumab	mAb, Mouse	A02150-40	A02151-40	
	Anti-Trastuzumab	mAb, Mouse	A02032-40	A02033-40	
Human IgE	Anti-Omalizumab	mAb, Mouse	A02095-40	A02094-40	
IL-12 & IL-23	Anti-Ustekinumab	mAb, Mouse	A02118-40	A02117-40	

Drug Target	Antibody	Antibody Type	Capture	Detection-unconjugated	Detection-Biotin conjugated
IL-17A	Anti-Secukinumab	mAb, Mouse	A02152-40	A02153-40	
IL-4Rα	Anti-Dupilumab	mAb, Mouse	A02098-40	A02097-40	
IL-6 Receptor	Anti-Tocilizumab	mAb, Mouse	A01978-40	A01979-40	A01980-40
	Anti-Sarilumab	mAb, Mouse	A02042-40	A02043-40	
PD-1	Anti-Nivolumab	mAb, Mouse	A01847-40	A01965-40	A01848-40
		mAb, Rabbit		A01988-40	A01989-40
	Anti-Pembrolizumab	mAb, Rabbit	A02008-40	A02007-40	
PD-L1	Anti-Atezolizumab	mAb, Mouse	A01948-40	A01949-40	A01950-40
		mAb, Rabbit	A01984-40	A01985-40	A01986-40
	Anti-Avelumab	mAb, Mouse	A02121-40	A02120-40	
RANK Ligand	Anti-Denosumab	mAb, Mouse	A02101-40	A02102-40	
RSV F	Anti-Palivizumab	mAb, Mouse	A02112-40	A02111-40	
TNF alpha	Anti-Adalimumab	mAb, Mouse	A01954-40	A01955-40	A01956-40
		mAb, Rabbit	A01921-40	A01922-40	
	Anti-Etanercept	mAb, Mouse	A02114-40	A02113-40	
	Anti-Infliximab	mAb, Mouse	A02040-40	A02041-40	
VEGF-A	Anti-Bevacizumab	mAb, Mouse	A01975-40	A01976-40	A01977-40
		mAb, Rabbit	A01895-40	A01962-40	A01896-40
	Anti-Ranibizumab	mAb, Mouse	A02035-40	A02036-40	

• Antibodies for Immunogenicity Assays

Polyclonal antibodies can highly simulate anti-drug antibodies *in vivo* due to their capacity to identify multiple epitopes. This makes polyclonal antibodies an ideal choice as positive controls for immunogenicity studies.

Drug Target	Antibody	Antibody Type	Cat. No.
CD20	Anti-Obinutuzumab	pAb, Rabbit	A01933-40
	Anti-Rituximab	pAb, Rabbit	A01918-40
CD274	Anti-Durvalumab	pAb, Rabbit	A02010-40
EGF Receptor	Anti-Cetuximab	pAb, Rabbit	A01993-40
	Anti-Panitumumab	pAb, Rabbit	A02063-40
Human IgE	Anti-Omalizumab	pAb, Rabbit	A02060-40
IL-12 & IL-23	Anti-Ustekinumab	pAb, Rabbit	A02123-40
IL-4R α	Anti-Dupilumab	pAb, Rabbit	A02062-40
IL-6 Receptor	Anti-Tocilizumab	pAb, Rabbit	A01932-40
	Anti-Sarilumab	pAb, Rabbit	A02122-40
PD-1	Anti-Nivolumab	pAb, Rabbit	A01931-40
	Anti-Pembrolizumab	pAb, Rabbit	A01846-40
RSV F	Anti-Palivizumab	pAb, Rabbit	A02064-40
TNF alpha	Anti-Adalimumab	pAb, Rabbit	A01886-40
	Anti-Golimumab	pAb, Rabbit	A02093-40
	Anti-Infliximab	pAb, Rabbit	A02061-40
VEGF-A	Anti-Bevacizumab	pAb, Rabbit	A01887-40
	Anti-Ranibizumab	pAb, Rabbit	A02037-40

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