

Zolbetuximab High-Sensitivity ELISA

---- A Powerful Tool for PK Research

Zolbetuximab (trade name VYLOY®) is a first-in-class chimeric (mouse/human) IgG1 monoclonal antibody that targets the tight-junction protein Claudin 18.2 (CLDN18.2). This protein is highly expressed in a variety of gastrointestinal tumors—especially gastric and gastro-esophageal junction adenocarcinomas—while its expression in normal tissues is restricted, making it a promising tumor-specific target. Zolbetuximab binds to the first extracellular loop of CLDN18.2 and mobilizes the immune system to attack tumor cells primarily through two mechanisms, antibody-dependent cellular cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC).

Using Zolbetuximab-specific antibodies as coating and detection reagents, we have developed a highly sensitive ELISA kit for quantifying free Zolbetuximab. The lower limit of detection is 0.13 ng/mL, providing a reliable tool for pharmacokinetic studies of the drug.

Key specifications of the kit:

- **Detection range:** 0.39 - 50 ng/mL
- **Sensitivity:** 0.13 ng/mL
- **Species reactivity:** universal
- **Sample types:** serum, plasma, tissue lysates, and other biological fluid samples.

Zolbetuximab standard curve

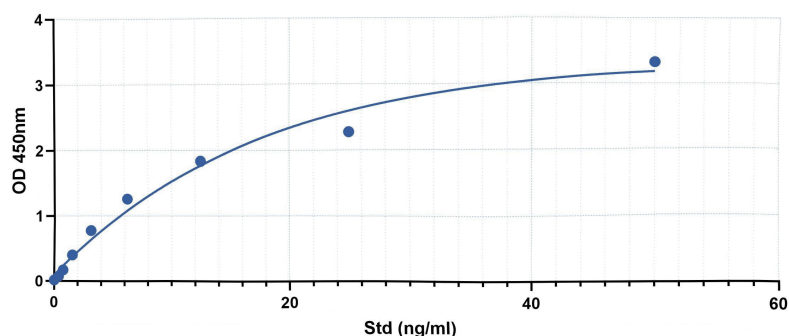


Figure 1 Zolbetuximab standard curve

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Table 1 Zolbetuximab standard data

Std Conc. (ng/ml)	OD _{450nm}
50	3.3314
25	2.2741
12.5	1.8396
6.25	1.2591
3.125	0.7758
1.56	0.401
0.78	0.1705
0.390	0.0748
0	0.0162

Validate data - Limit of Detection

Table 2 Determination of LOD (Limit of Detection)

OD _{450nm}	Blank sample-0 ng/ml		
0.0162	0.013		
0.0268	0.014	Mean	0.0167
0.0126	0.0161	SD	0.0041
0.0176	0.0191	Mean+2*SD	0.0248
0.0151	0.016	LOD	0.13 ng/ml

Validate data - Precision

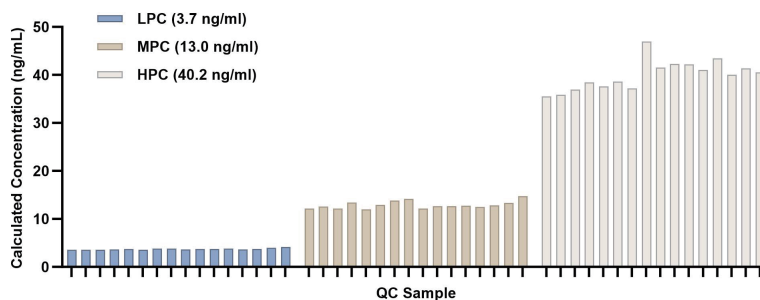


Figure 2 Calculated concentrations of QC samples for CV determination

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Table 3 QC samples for CV determination

Replication	LPC (ng/ml)	MPC (ng/ml)	HPC (ng/ml)
1	3.568	12.199	35.559
2	3.568	12.549	35.85
3	3.623	12.151	36.96
4	3.634	13.399	38.431
5	3.71	12.026	37.664
6	3.623	12.953	38.66
7	3.808	13.838	37.178
8	3.797	14.199	46.952
9	3.634	12.199	41.558
10	3.721	12.661	42.327
11	3.786	12.693	42.171
12	3.808	12.791	41.055
13	3.634	12.469	43.436
14	3.753	12.856	40.075
15	3.983	13.349	41.406
16	4.193	14.725	40.561
CV (Coefficient of Variation)			
	4%	6%	8%

Cat	Product
DEIASL523-H	Human Zolbetuximab ELISA Kit - High Sensitivity

Creative Diagnostics

Zolbetuximab High-Sensitivity ELISA



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