

**KRISHGEN BioSystems**

OUR REAGENTS, YOUR RESEARCH

# 360+ BIOSIMILARS ELISA

specific, validated assays for detection of monoclonal antibody drugs for pharmacokinetic studies and therapeutic drug monitoring

**measure free, bound and total drug concentrations in serum and plasma**

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At Krishgen, our dedicated team is focused on identifying and prioritizing the most relevant targets and the latest mAb or bsAb drugs in the pipeline to provide cutting-edge assay solutions.

From target discovery to IVD or clinical phase analysis, we can support you at every stage of your monoclonal antibody / biosimilar drug research with the right products for your needs. To ensure the best performance when possible, we test and validate our products in the most relevant models in both healthy and diseased tissue and assays.

The range of Pharmacokinetics (PK) ELISA Kits for the quantification of serum and plasma protein drug levels to provide accurate pharmacokinetic (PK) data that will help optimize drug dosing regimens. These mAb-based ELISA are developed for use with biosimilars and biologics.

## Popular ELISA for Pharmacokinetic (PK) and Anti-Drug Antibody Estimation

### ANTI-TNF ALPHA AND INFLAMMATION BLOCKER MABS

INFLIXIMAB  
ETANERCEPT  
CERTOLIZUMAB  
USTEKINUMAB  
NATALIZUMAB  
VEDOLIZUMAB

ADALIMUMAB  
GOLIMUMAB  
VEDOLIZUMAB  
TOCILIZUMAB  
ALEMTUZUMAB

### ANTI-CANCER MABS

BEVACIZUMAB  
TRASTUZUMAB  
DARATUMUMAB  
PANITUMUMAB

RITUXIMAB  
CETUXIMAB  
OBINUTUZUMAB

### IMMUNE CHECKPOINT BLOCKER MABS (PD-1, PD-L1, CTLA4)

ATEZOLIZUMAB  
PEMBROLIZUMAB  
DURVALUMAB  
RELATLIMAB

IPILIMUMAB  
NIVOLUMAB  
TREMELIMUMAB  
AVELUMAB

### OSTEOPOROSIS MABS

DENOSUMAB

### ANTI-ALERGEN MABS

OMALIZUMAB

### AMD MABS

RANIBIZUMAB  
BEVACIZUMAB

#### Other ELISA available from Krishgen:

- Immune Checkpoint
- Bispecific Antibody
- Neutralizing Antibodies to mAbs
- Peptide Drugs
- Cytokine and Biomarker
- Antibody Drug Conjugates
- Neuro-Degenerative Markers
- GLP-1 Agonists



- Krishgen mAb ELISA employ anti-idiotypic monoclonal antibodies in a sandwich assay format, ensuring exceptional specificity and sensitivity in drug detection, even at low concentrations.
- All validation, verification and lot releases for these ELISA are performed according to best-in-class scientific guidelines (ICH M10, version July 2022) – including a stringent seven-point validation to ensure quality and robustness lot-over-lot.
- Where available, validation of the kit against international standards from NIBSC / WHO.
- To ensure no matrix interference and reproducible dilutional linearity, we run several serum and plasma spiking experiments at various dilutions to optimize. Inter and intra assay CV in accordance with FDA & EMEA requirements CV <10%.
- Ship at ambient temperature, with lyophilized / stabilized reagents.



Our manufacturing lab is ISO 13485 and CDSCO (India) certified, with Class 7 / Class 8 cleanrooms and Air Handling Units to reduce contamination. Automated plate coating lines and handling equipment further reduce lot variation.

## POPULAR PUBLICATIONS USING KRISHGEN PK ELISA

**JAMA Oncology | Brief Report**  
**Association of High Levels of Antidrug Antibodies Against Atezolizumab With Clinical Outcomes and T-Cell Responses in Patients With Hepatocellular Carcinoma**

Chun Kim, MD, PhD, Hanah Yang, PhD, Ehsan Kim, MD, Baodan Kang, MD, Hyeonung Kim, MD, Hyunho Kim, MD, Won Suk Lee, PhD, Sanghoon Jung, MD, Ho Young Lim, MD, PhD, Jaeyoung Ohn, MD, Hong Jae Choi, MD, PhD

**IMPORTANCE:** Administration of atezolizumab could be immunogenic and induce undesirable antidrug antibody (ADA) responses. This may interfere with atezolizumab-mediated actions, affecting drug clearance and serum concentration or inducing antibody neutralization.

**OBJECTIVE:** To determine the clinical and immunological associations of highly elevated ADA levels with clinical outcomes after atezolizumab treatment in patients with advanced hepatocellular carcinoma.

**DESIGN, SETTING, AND PARTICIPANTS:** This cohort with advanced HCC treated with first-line Atezolizumab T-center validation cohort: 153 patients from 4 centers.

**EXPOSURES:** Serum ADA levels at pretreatment and during treatment were analyzed using competitive enzyme-linked immunosorbent assay (ELISA) and flow cytometry.

**MAIN RESULTS AND MEASURES:** Overall ADA-positive outcomes and T-cell functions.

**RESULTS:** After excluding patients with inadequate response, 132 patients (discovery cohort: 50 patients; validation cohort: 82 patients) were analyzed, and robust ADA identified in 23 (17.4%) of the patients. Patients with ADA levels (median [IQR], 65.2 [9.520-61] ng/mL, 0 [0-1075] ng/mL). In both discovery and validation cohorts, patients with high ADA levels had significantly lower overall survival (OS) (P = .001) and progression-free survival (PFS) (P = .001) compared with patients with low ADA levels.

**CONCLUSIONS:** High ADA levels were associated with a reduced response rate (OR = 2.09, 95% CI = 1.02-4.28) and worse OS (HR = 1.76, 95% CI = 1.02-2.99) compared with patients with low ADA levels.

**Supplemental content:**

### Atezolizumab ELISA

**OPEN** **The use of therapeutic drug monitoring for early identification of vedolizumab response in Saudi Arabian patients with inflammatory bowel disease**

Doaa Ambersary<sup>1</sup>, Mahmoud Mousli<sup>2,3,4,5</sup>, Yousef Omer<sup>6,7,8</sup>, Omar Saadiah<sup>9,10</sup>, Rana Bokhary<sup>11,12</sup>, Ahmed Esnat<sup>1</sup>, Mohammed Alsiem<sup>1</sup>, Ahmed Shaker<sup>1</sup>, Ramu Engang<sup>1</sup> & Sameer Alharthi<sup>13,14</sup>

**OBJECTIVE:** To evaluate the utility of vedolizumab therapeutic drug monitoring (TDM) in Saudi Arabian patients with Crohn's disease (CD) and ulcerative colitis (UC) to identify early responders and non-responders.

**DESIGN:** A retrospective cohort study.

**SETTING:** King Fahad Hospital for Specialized Care, Riyadh, Saudi Arabia.

**PARTICIPANTS:** 100 Saudi Arabian patients with CD and UC treated with vedolizumab.

**MEASUREMENTS AND MAIN RESULTS:** The median vedolizumab concentration at 4 weeks was 1.7 µg/mL (IQR 0.5-5.0 µg/mL). Patients with concentrations < 1.0 µg/mL were considered non-responders, while those > 1.0 µg/mL were considered responders. The response rate was significantly higher in the responder group (P < 0.001).

**CONCLUSIONS:** Vedolizumab TDM is a useful tool for early identification of responders and non-responders in Saudi Arabian patients with inflammatory bowel disease.

### Vedolizumab ELISA

**Carbohydrate Polymers**  
Volume 267, 1 September 2021, 118217

**Chitosan coated nanoparticles for efficient delivery of bevacizumab in the posterior ocular tissues via subconjunctival administration**

Jayamanti Pandit, Yasmin Sultana

**Abstract:** In several ocular diseases, vascular endothelial growth factor (VEGF) is upregulated. Bevacizumab, a drug for diabetic retinopathy (DR), poly (lactide-co-glycolic acid) (PLGA) nanoparticles (NPs) were developed for the delivery of bevacizumab to posterior ocular tissues. The penetration of NP through sclera was studied by confocal laser scanning microscopy (CLSM). For pharmacokinetic study...

### Bevacizumab ELISA

**Histological and Immunohistochemical Retinal Changes Following the Intravitreal Injection of Aflibercept, Bevacizumab and Ranibizumab in Newborn Rabbits**

Duygu Cizmeci, Ayşe Tuğba Berk, Serap Çeliker Akkoc, Turay Yılmaz, Belirli Ergül Ergül & Çiğdem Yılmaz

Pages 115-121 | Received 11 Nov 2015, Accepted 06 Mar 2016, Published online 17 Jun 2016

**ABSTRACT:** Purpose: To analyze the retinal effects of the VEGF inhibitors (aflibercept, bevacizumab and ranibizumab) in newborn rabbits. Methods: Eight eyes of 28 two-week-old Newborn rabbits received intravitreal injection of 0.025 mg aflibercept (group I), 0.05 mg bevacizumab (group II), 0.05 mg ranibizumab (group III), six 0.3125 mg bevacizumab (group IV) intravitreally. Blood samples were examined by light microscopy as staining to evaluate the level of apoptosis at retinal. Light microscopic evaluation did not show any significant changes in the retinal tissue. Positive TUNEL staining was present in 16.75 ± 0.56% of the eyes resulted in groups I, II, III, IV, detected by caspase-3 staining was as follows: 1.37% in Group III, 24.4 ± 2.7% in Group IV, was found to be statistically higher in all anti-apoptosis (p = 0.028, p = 0.009, p = 0.01, p = 0.01, respectively). Serum

### Ranibizumab ELISA

**A Prospective, Randomized, Double-blind, Comparative Clinical Study of Efficacy and Safety of a Biosimilar Adalimumab with Innovator Product in Patients with Active Rheumatoid Arthritis on a Stable Dose of Methotrexate**

Prasad Apsangkar, Sunil Chaudhry, Manoj Nalk, Shashank Dooghare, Jamila Joseph

**Abstract:** Objective: The objective of this study was to compare efficacy, safety, and immunogenicity between the biosimilar adalimumab (Abimab) and the reference innovator product in moderate to severe rheumatoid arthritis (RA) patients on stable dose of methotrexate (MTX). Methods: Patients with moderate to severe active RA (n = 106) on a stable dose of MTX were randomized to biosimilar adalimumab (Abimab) (study arm) or reference innovator adalimumab (reference arm) 40 mg every 2 weeks. The primary endpoint was proportion of patients who achieved ACR20 at 24 weeks. Secondary endpoints included ACR50, ACR70, and patients who achieved DAS28-ESR1 ≤ 3.2. Results: Out of 106 patients, 53 patients were in the study arm and 53 patients were in the reference arm. There were no significant differences between the two groups in terms of efficacy, safety, and immunogenicity. Conclusion: The efficacy and safety of Abimab were comparable to the reference innovator product. Key Words: double-blind, efficacy, safety, immunogenicity.

### Adalimumab ELISA

**Published: 06 October 2021**

**Oral Delivery of Peptide Formulations and Their Cellular Evaluation**

Saurabh Patil, Kritika Gupta, Ashish Pandit, Bhushan Desai, Siegfried Gschlieser, Prajakti Dandekar, G. & Ratnesh Jain

**Abstract:** The development of peptide-based formulations presents numerous challenges to the formulation due to their complexity, delicate nature, and instability in the harsh environment factors. To date, the common formulation routes are intramuscular, intravenous, and subcutaneous. However, these routes enable improved patient compliance and reduce the risk of infection. The development of a novel systemic approach for novel delivery of therapeutic peptides. Insulin, glargine, teriparatide, liraglutide, leuprolide were formulated with various combinations of permeation enhancers and administered orally to animals using enteric coated capsules. Enzyme activity for proteolytic enzymes was assessed, also blood plasma concentration and bioavailability of peptides obtained from the animal study were compared to commercial formulations.

### Liraglutide ELISA

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