

Matriks Biotechnology

Ankara, Turkey · est. 2002

Matrix Biotek SL

Barcelona, Spain · est. 2025

SHIKARI® ELISA Kits — Recent Scientific Publications

Peer-reviewed research from June 2026 using Matriks Biotechnology assay products

200+

Publications

40+

Countries

30+

Pharma Clients

132

ELISA Kits

45

Biologics Covered

Recent Publications Featuring SHIKARI® ELISA Kits

This document summarises five recent peer-reviewed and preprint publications (2025–2026) that directly utilised SHIKARI® drug-monitoring and immunogenicity ELISA kits by Matriks Biotechnology, or featured Matriks experts as peer reviewers. Studies span oncology, rheumatology and ophthalmology across multiple countries.

#	Publication	Area	SHIKARI® Kit	Year
1	ATZ-ADA in Hepatocellular Carcinoma	Oncology	S-ATAT	2026
2	Nivolumab PLGA Nanoparticles — NSCLC	Lung Cancer	Q-NIVO	2025
3	ADA in Japanese RA Patients (5 biologics)	Rheumatology	Q-ADA / Q-INFLIXI / Q-GOL / Q-ETA	2026
4	Anti-EpCAM Single-Domain Antibodies	Cancer Biology	Expert Peer Review	2025
5	Ranibizumab in Human Breast Milk	Ophthalmology	Ranibizumab ELISA Kit	2026

SHIKARI® kits are globally the first and leading commercial ELISA portfolio for biotherapy drug monitoring (TDM) and immunogenicity (ADA/NAb) assessment. All products are ISO 13485:2016 certified, RUO-grade, and validated to industry standards.

1

Clinical Significance of Anti-Atezolizumab Antibodies in Patients With Unresectable Hepatocellular Carcinoma Treated With Atezolizumab Plus Bevacizumab



Ouchi K, Inoue J et al. | *Hepatology Research* 2026 | DOI: 10.1111/hepr.70162

Kit(s) used: SHIKARI® S-ATAT — Anti-Atezolizumab ELISA (Matriks Biotechnology, Ankara)

Hepatology Research · Wiley · 2026 · Open Access

Key Findings

- **34% ADA positivity** — ATZ-ADAs (OD \geq 0.40) detected in 17 of 50 unresectable HCC patients receiving atezolizumab + bevacizumab (ATZ/BEV) at Tohoku University Hospital (2020–2024).
- **Significantly shorter PFS in ADA+ patients: 3.8 vs. 9.4 months** (HR = 2.24, p = 0.03). Overall survival not significantly different.
- **Higher ATZ-ADA in progressive disease:** median OD 0.43 (PD) vs. 0.37 (disease control, p = 0.02).
- **Post-treatment ADA rise is the key signal:** Δ ATZ-ADA baseline→cycle 3 significantly higher in PD group (+0.05 vs. -0.03, p = 0.03). Pre-existing ADAs were NOT associated with outcome.
- ROC cut-off OD 0.40 — AUC 0.69, sensitivity 75%, specificity 79%.
- ATZ-ADAs proposed as a **practical predictive biomarker** to guide treatment sequencing in HCC.

Original Abstract

Aim: ATZ/BEV is the recommended first-line HCC therapy, but ADAs against ATZ may impair efficacy. This study evaluates ATZ-ADA incidence and clinical significance in 50 unresectable HCC patients. **Methods:** Serum ELISA at baseline and cycle 3 using SHIKARI S-ATAT. Tumour response by mRECIST; survival by Kaplan–Meier. **Results:** ATZ-ADAs detected in 34% of patients. Median ATZ-ADA higher in PD vs. disease-control (0.46 vs. 0.37, p=0.02). PFS significantly shorter in ADA-positive group (3.8 vs. 9.4 months, HR=2.24, p=0.03); OS not significantly different. **Conclusions:** ATZ-ADAs are a promising biomarker for predicting treatment response and optimising therapeutic strategies in unresectable HCC.

Clinical relevance: Confirms that SHIKARI® S-ATAT reliably detects functionally relevant ADAs during routine clinical monitoring. The cycle-3 sampling window is actionable within standard infusion scheduling, supporting routine ADA testing in HCC management pathways.

2

Codelivery of Nivolumab and Galunisertib by EGFR-Targeted Spherical Polymeric Nanoparticles for Effective Treatment of Non-small Cell Lung Cancer

Kaplan M, Tavukçuoğlu E et al. | SSRN Preprint 2025 | Hacettepe University, Ankara



Kit(s) used: SHIKARI® Q-NIVO — Nivolumab Quantification ELISA
(Matriks Biotechnology)

SSRN Preprint · Hacettepe University · TÜBİTAK
Grant 119R055 · 2025

Key Findings

- **Novel PLGA nanosystem** co-loading nivolumab (anti-PD-1) + galunisertib (TGF- β inhibitor) in EGFR-targeted spherical NPs for NSCLC tumour microenvironment delivery.
- **Q-NIVO ELISA used to quantify nivolumab** encapsulation efficiency: 70.9%. Particle size 166–198 nm, PDI < 0.2 — optimal for EPR-mediated tumour accumulation.
- **pH-responsive release:** Complete galunisertib release at pH 5.5 (tumour) within 48 h vs. 70% at physiological pH 7.4 — site-specific delivery confirmed.
- **Nivolumab bioactivity preserved** after nanoencapsulation: PD-1 blocking capacity equivalent to free nivolumab ($p > 0.05$).
- **Tumour volume reduction** statistically significant in targeted-NP group ($p < 0.01$). Elevated IFN- γ , TNF- α , sFASL, IL-2; reduced Treg infiltration.
- **Improved safety:** Diarrhoea with free drug solution; absent with targeted NP formulation.

Original Abstract

A novel nanosystem co-loading galunisertib (TGF- β inhibitor) and nivolumab (PD-1 inhibitor) into spherical PLGA/PLGA-His/PLGA-PEG nanoparticles conjugated with anti-EGFR for targeted delivery. In vitro studies showed pH-dependent drug release, preserved PD-1 blocking, and tumour-specific cytotoxicity. In vivo biodistribution in humanised nude mice confirmed higher tumour accumulation with anti-EGFR-targeted NPs. Targeted co-drug-loaded NPs significantly reduced tumour size vs. non-targeted NPs, with improved tolerability and enhanced cytokine immune profiles.

Note: This Hacettepe University study (TÜBİTAK-funded) demonstrates Q-NIVO's utility beyond clinical TDM — validating its application in nanoformulation development and preclinical pharmacology.

3

Evaluation of Anti-Drug Antibodies Against Therapeutic Monoclonal Antibodies and Related Products in Japanese RA Patients and Their Clinical Impact

Shibata H, Nishimura K et al. | *Eur. J. Pharm. Sci.* 216 (2026) 107357 | NIHS Japan



Kit(s) used: SHIKARI® Q-ADA (Adalimumab) · Q-INFLIXI (Infliximab) · Q-GOL (Golimumab) · Q-ETA (Etanercept)

European Journal of Pharmaceutical Sciences · Elsevier · 2026 · Open Access

Key Findings

- **197 Japanese RA patients** across 5 biologics: IFX, ADM, GLM, TCZ, ETN — four SHIKARI® drug-level kits used for serum free-drug measurement.
- **ADA positivity rates:** ETN 69.8% · IFX 18.5% · ADM 28.6% · GLM 22.7% · TCZ 5.6%. No neutralising antibodies detected in any sample.
- **MTX reduces ADA formation** in ADM-treated patients. No effect for TCZ or ETN.
- **Route matters for TCZ:** 100% of ADA-positive samples from S.C. patients; 0% from I.V. group ($p < 0.05$).
- **HLA-DRB1*04:01** significantly higher in ETN-ADA+ patients (8/43 vs. 0/20, $p=0.047$) — novel pharmacogenomic risk factor.
- **Lower trough concentrations** in ADA+ samples for ADM, GLM, TCZ — ADA-driven clearance confirmed.

Original Abstract

Biopharmaceuticals are widely used in RA. ADA levels were measured in 197 Japanese RA patients (IFX, ADM, GLM, TCZ, ETN) using bridging ECL assays and SHIKARI® drug-level ELISA kits. ADA positivity varied by drug. Concomitant MTX reduced ADA in ADM-treated patients; S.C. administration significantly increased ADA for TCZ. HLA-DRB1*04:01 was associated with ETN-ADA positivity. Lower free-drug concentrations found in ADA-positive samples for ADM, GLM and TCZ. No neutralising ADA detected; residual drug bioactivity remained intact in all ADA-positive samples.

Multi-kit validation: This NIHS Japan study uses four SHIKARI® kits simultaneously in a single real-world cohort — a strong endorsement of the product range's breadth for comparative immunogenicity research across multiple RA biologics.

4

Novel Human Single-Domain Antibodies Exert Potent Anti-Tumor Activity by Targeting EGF-like Repeat Epitope of EpCAM

Zhou X, Liu Z, Zhang W et al. | *Front. Pharmacol.* 2025 | DOI: 10.3389/fphar.2025.1530268



Kit(s) used: Matriks Biotechnology contribution: Gamze Eda Yildirim (Matriks Biotechnology Co.) — expert peer reviewer

Frontiers in Pharmacology · Frontiers Media · February 2025 · Open Access

Key Findings

- **Target — EpCAM:** Cancer stem cell marker overexpressed in breast, prostate, colon, liver and oesophageal cancers; associated with invasion, metastasis and chemoresistance.
- **Five fully human anti-EpCAM sdAbs** isolated by phage display targeting the EGF-like repeat epitope on the EpCAM extracellular domain.
- **Selective tumour binding:** All five sdAbs bound DU145, PC3 and MCF-7 cancer cell lines but NOT 293T or 3T3 non-cancerous cells.
- **Potent in vitro activity:** Significant inhibition of proliferation, migration and invasion; induction of apoptosis across all three cancer lines.
- **~70% in vivo tumour reduction** (aEP3D4, aEP4G2) — comparable to cisplatin ($p < 0.05$); Ki67 downregulation + caspase-3 activation confirmed by IHC.
- At ~15 kDa, sdAbs offer superior tumour penetration and minimal immunogenicity vs. conventional mAbs.

Original Abstract

Introduction: EpCAM is a key cancer stem cell marker and promising therapeutic target. Conventional anti-EpCAM mAbs have shown limited clinical efficacy. Single-domain antibodies (sdAbs) offer advantages including smaller size for tumour penetration and reduced immunogenicity. **Methods:** A critical EGF-like repeat epitope on the EpCAM extracellular domain was selected for screening a fully human sdAb phage library. **Results:** Five sdAbs specifically bound the EpCAM peptide and cancer cell lines but not non-cancer controls. Two sdAbs (aEP3D4, aEP4G2) potently reduced tumour volume in a xenograft model. **Discussion:** Targeting EpCAM's EGF-like epitope with sdAbs is a promising cancer therapy approach.

Strategic note: Although this study does not cite a SHIKARI® product, Matriks Biotechnology's expert peer-review contribution to *Frontiers in Pharmacology* reflects the company's recognised authority in the broader therapeutic antibody field.

5

VEGF-A and Drug Level in Serum and Human Breast Milk of a Lactating Woman After Intravitreal Injection of Ranibizumab: A Case Report



Zhang J, Niu B et al. | *Front. Med.* 13:1730208, 2026 | DOI: 10.3389/fmed.2026.1730208

Kit(s) used: Ranibizumab ELISA Kit (Matriks Biotechnology, Turkey) — validated in serum and breast milk matrices

Frontiers in Medicine · Frontiers Media · January 2026
· Open Access

Key Findings

- **First reported use** of the Matriks Biotechnology Ranibizumab ELISA kit in a **breast milk matrix** — extending validated application beyond standard serum/plasma.
- **Serum PK:** Peak ranibizumab 15.35 ng/mL at Day 1; 9.64 ng/mL at Week 4.
- **Breast milk drug level:** Peak 3.14 ng/mL at Day 1 (~1/5th of serum). All values below in vitro IC_{50} for VEGF (11–27 ng/mL) — limited pharmacological risk to infant.
- **VEGF-A in breast milk:** Baseline 29.49 ng/mL → nadir 12.75 ng/mL at Day 3 (**57% decrease**) → recovered to 25.56 ng/mL at Week 4.
- Intra-assay CV < 15% for all time points — excellent reproducibility confirmed in breast milk.
- **No developmental abnormalities** in infant. Ranibizumab preferred over bevacizumab/afibercept in lactating patients due to its shorter systemic half-life (Fab-only structure, no Fc).

Original Abstract

Background: Evidence on anti-VEGF excretion in breast milk is very limited. **Case presentation:** A 30-year-old lactating woman received IVR 0.5 mg ranibizumab for cystoid macular oedema (BRVO). Serial serum and breast milk samples collected over 4 weeks. Ranibizumab peaked at 15.35 ng/mL in serum and 3.14 ng/mL in breast milk on Day 1. Serum VEGF-A remained stably low. Breast milk VEGF-A decreased 57% at Day 3, recovered by Week 4. **Conclusion:** Systemic exposure to ranibizumab following IVR is detectable in breast milk. Additional evaluation is recommended when anti-VEGF therapy is necessary in lactating patients.

Clinical significance: This case report validates the Matriks Biotechnology Ranibizumab ELISA kit's performance in breast milk — a challenging matrix with high lipid content. Breast milk levels remain below pharmacological thresholds throughout 4-week monitoring, providing practical safety reassurance for ophthalmologists managing lactating patients.