
"trace & catch"
MATRIKS
BIOTEK
innovation for health & wellness

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innovation for health & wellness

Matriks Biotek "Trace and Catch"

Matriks Biotek Ltd. Sti., as a biotechnology company founded in 2002 and is celebrating its 11 years in the business. Production oriented company is committed to R&D and innovation of immune based, molecules and tools that will help well being.
In the market for 6 years and present in 30 countries with our products and over 25 pharmaceutical companies have used or using our products with confidence.
The use of biologics, mainly humanized recombinant monoclonal antibodies, in certain diseases as pharmaceutical drugs elicits the question of effectiveness in each individually treated person. Monitoring drug levels and antibodies plays an emerging role in the management of lack- or loss of response to recombinant and/or humanized antibodies (i.e., to confirm treatment continuation, adjustment to dose, provide a rationale for switching to another agent or to a different class of biological agent). Major areas of interest are as follows;

- Biologics testing
- Biotherapeutics and novel markers for diseases
- Inflammation and Immunology
- Obesity, type II diabetes and cardiovascular diease
- Infectious diseases
- Oncology

Some features of our SHIKARI® Elisa kits:
• Our kits are in 96 well format and you can run as much as 90 samples from each kit.
• Time saver: Short incubation times (55-200 min)
• Immediate delivery (1-5 days all over the world)
• Low sample volumes (10-25 μl)
• All liquid and stabilized ready to use reagents.
• Minimum expiry date of 9 months and delivery is at room temperature.
• Inter and intra assay reproducibility is <8.
• High recovery rates (%97-98), including bevacizumab (%99).
• Highly specific hTNF elisa kits: very low background and peroxidase labelled conjugate.
• Each kit is optimized for Cmax-Cmin values of the drugs when measuring especially trough levels. Researchers can also estimate infliximab, etanercept, adalimumab, bevacizumab, rituximab and trastuzumab levels in human, mouse, rat and monkey serum or plasma samples for pharmacokinetic studies.
• Specific infliximab, etanercept, rituximab elisa kits are monoclonal antibody (capture) based kits that does not cross react with counterpart TNF blockers.
• Kits are suitable for biosimilar work.

NİSSERT

SERTİFİKA / CERTIFICATE

EC DECLARATION OF CONFORMITY

MATRİKS BİOTEK

innovation for health & wellness

NİSSERT ULUSLARARASI SERTİFİKASYON ve DENETİM HİZMETLERİ LTD. ŞTİ. declares that the product:

Product Brand: SHIKARI
Product Name: SHIKARI QS-INFLIXI, SHIKARI Q-INFLIXI, SHIKARI Q-ATI, SHIKARI Q-ADA, SHIKARI S-ATA, SHIKARI Q-ETA, SHIKARI S-ATE, SHIKARI Q-TNF, SHIKARI Q-sTNF-RII, SHIKARI Q-BEVA, SHIKARI S-ATB, SHIKARI Q-RITUX, SHIKARI S-ATR, SHIKARI Q-TRAS, SHIKARI S-ATT
of MATRİKS BİYOTEKNOLOJİ SAN. VE TİC. CO. LTD., is in compliance with the essential requirements and other relevant provisions of In Vitro Diagnostic Medical Device Directive (98/79/EC) Annex III Not List A or B, Article 9.
The product is marked on a voluntary basis with the CE Mark according to the Council Directive 98/79/EC relating to In Vitro Diagnostic Medical Device Directive. It confirms that the tested equipment complies with the principal safety requirements of the directive.

CE

Certificate No: NİS 1305-01
Issuing Date and Place: 07.05.2013, ANKARA

The Technical Construction File required by this Directive is maintained at the corporate headquarter, Gazi Üniversitesi Gölbaşı Yerleşkesi Teknoplaza Binası (B Blok Zemin Kat BZ17) 06830 Gölbaşı / ANKARA / TÜRKİYE of MATRİKS BİYOTEKNOLOJİ CO. LTD.
This certificate is valid until 06.05.2016.

On Behalf of Nissert

Adres: Gimat 3. Blok No:29 PK 06370
Macunköy Ankara – Türkiye
Tel: 0312–397 60 09–397 07 87
Faks: 0312–397 00 58 E-mail: nissert@nissert.com

ITC

Management Systems Certification Body No. 3002
Institute for Testing and Certification, Inc.
třída Tomáše Bati 299, 764 21 Zlín, Czech Republic
www.itczlin.cz

CERTIFICATE

No. 13 0179 SJ

We confirm on the basis of a performed audit that company

Matriks Biyoteknoloji Sanayi ve Ticaret Limited Şirketi
Gazi Üniversitesi Gölbaşı Yerleşkesi Teknoplaza Binası B Blok Zemin Kat BZ17 06830 Gölbaşı, Ankara, Turkey

has implemented and documented a functional quality management system in compliance with the requirements of the standard

ISO 13485:2003

Covering the following activities:

Production, sales and storage of Elisa Kit

The Certificate is issued on the basis of the results mentioned in Audit Report No. 233403175/2012. The Certificate validity is conditioned by positive results of surveillance audits, which the certified company committed to undergo.

S 3002

Date of Issue: 28. 05. 2013
Valid until: 28. 05. 2016

Ing. Pavel Vaněk
Head of Certification Body

We offer specific SHIKARI® Elisa kits for:

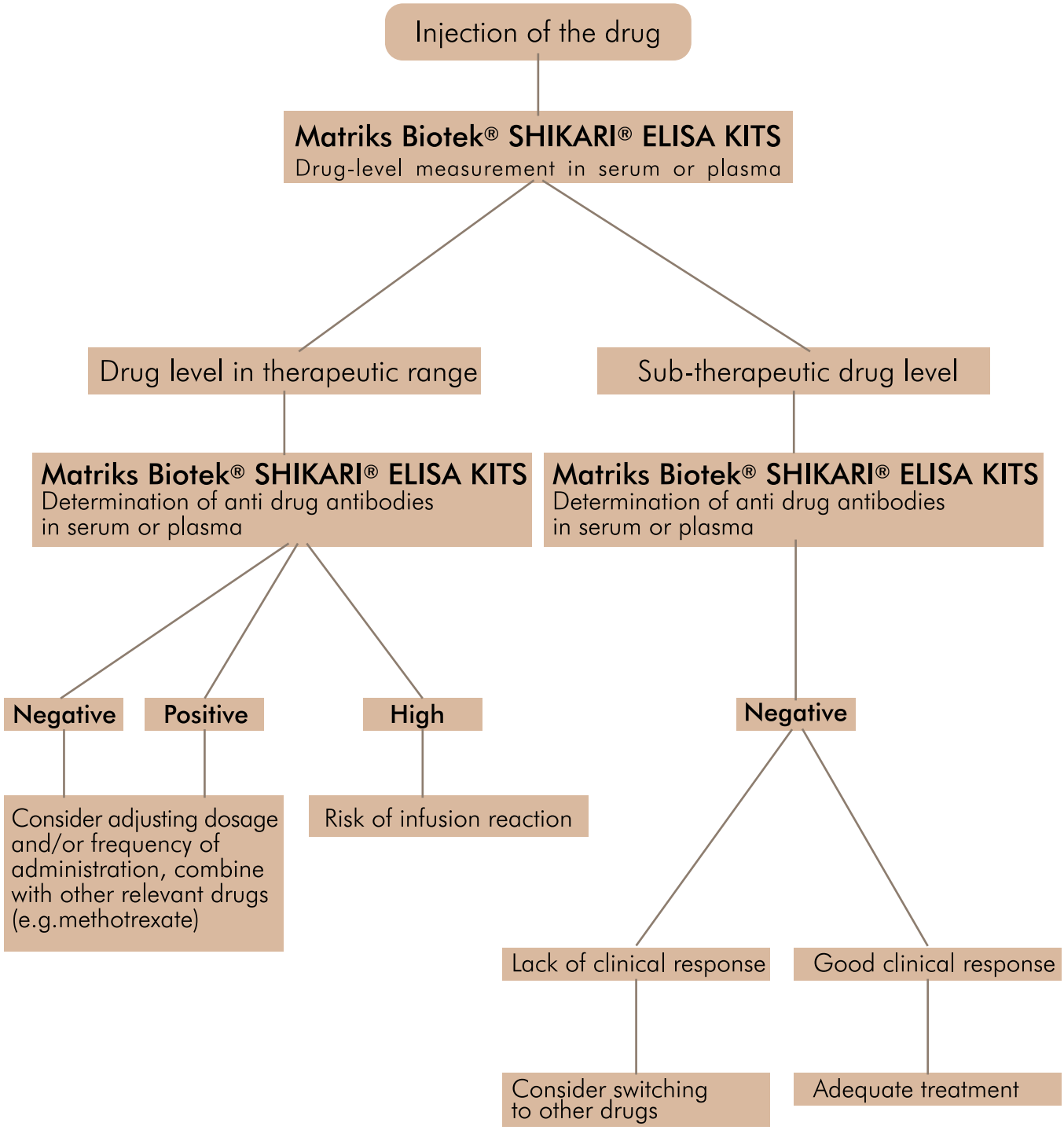
1. The quantitative determination of TNF blockers, Anti-TNF blockers (Infliximab, Adalimumab and Etanercept), human TNF alpha and TNF receptor II.

2. The quantitative determination of VEGF blocker and Anti-VEGF blocker (Bevacizumab).

3. The quantitative determination of CD20 (Rituximab).

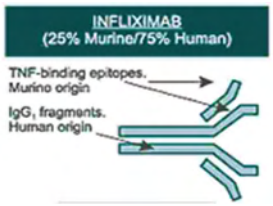
4. The quantitative determination of HER2 (Trastuzumab).

Matriks Biotek is now certified for quality management system ISO 13485:2003. All of the SHIKARI® products from Matriks Biotek are marked with the CE IVD Mark according to Councel Directive 98/79/EC relating to In Vitro Medical Device Directive.



Keep monitoring drug-levels and antibodies against drug with
SHIKARI® ELISA KITS for PRECISE TREATMENT!
For more information, please visit
www.matriksbiotek.com

INFLIXIMAB



Infliximab (Remicade®) is a chimeric monoclonal antibody and used to treat autoimmune disorders. Infliximab reduces the amount of active human tumor necrosis
factor alpha (hTNFα) in the body by binding to it and preventing it from signaling the receptors for TNFα on the surface of various cell types. TNFα is one of thekey cytokines that triggers and sustains the inflammatory reactions. Infliximab is used for the treatment of psoriasis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis, ulcerative colitis, and approved by FDA.

SHIKARI® QS-INFLIXI: Enzyme immunoassay for the specific quantitative determination of Infliximab (Remicade®) in serum, plasma and other biological fluids

SHIKARI® Q-INFLIXI: Enzyme immunoassay for the quantitative determination of infliximab (Remicade®) in serum and plasma.

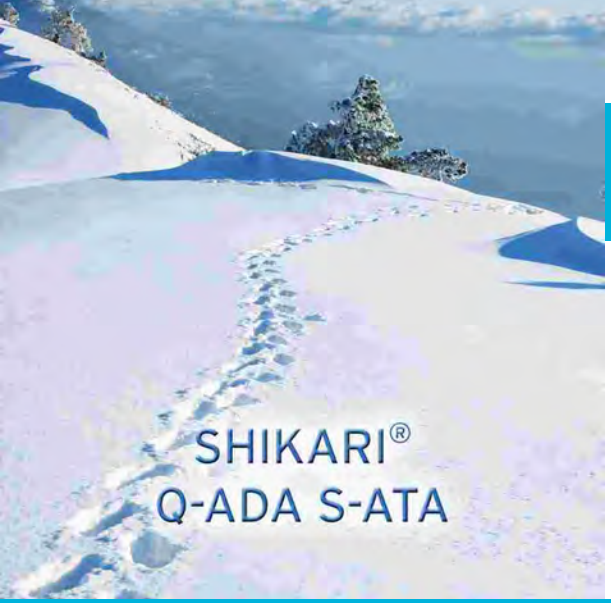
SHIKARI® Q-ATI: Enzyme immunoassay for the quantitative and qualitative determination of specific antibodies to infliximab in human serum and plasma.

Follow-up your patient's trough infliximab levels, dose response to infliximab with QS-INFLIXI or Q-INFLIXI, depending on your needs, and adjust dose when needed.

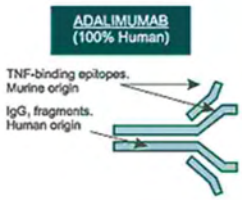
Matriks Biotek SHIKARI® QS-INFLIXI ELISA is developed for specific measurement of Infliximab (Remicade®) in sera, plasma and other biological fluids by the advantage of using a site-directed monoclonal antibody specific for Infliximab (Remicade®) only. The user-friendly Matriks Biotek SHIKARI® Specific Infliximab ELISA is the first and only ELISA kit for the quantitative determination of Infliximab (Remicade®) at uppermost specificity.

Check anti-infliximab antibodies in your patients sera with Q-ATI, escalate the dose or combine with (e.g.) methotrexate when needed.

	QS-INFLIXI	Q-INFLIXI	Q-ATI
	Specific Infliximab(Remicade®) monoclonal based quantitative analyses	Free Infliximab (Remicade®) quantitative analyses	Infliximab(Remicade®) antibodies qualitative and quantitative analyses
Required Volume (µl)	10	10	10
Total Time (min)	75	55	140
Sample	Serum, plasma and other biological fluids	Serum, plasma	Serum, plasma
Sample Number	96	96	96
Dedection Limit (ng/mL)	20	30	30
Spike Recovery (%)	97	97	97
Shelf Life (year)	1	1	9



ADALIMUMAB



Adalimumab (Humira®) is a recombinant human IgG1 monoclonal antibody specific for human tumor necrosis factor alpha (TNF-a). Adalimumab (Humira®) was created using phage display technology resulting in an antibody with human derived heavy and light chain variable regions and human IgG1:k constant regions. Adalimumab (Humira®) is produced by recombinant DNA technology in a mammalian cell expression system and is purified by a process that includes specific viral inactivation and removal steps. It consists of 1330 amino acids and has a molecular weight of approximately 148 kilodaltons.

Adalimumab (Humira®) binds specifically to (TNF-α) and blocks its interaction with the p55 and p75 cell surface TNF receptors. Adalimumab (Humira®) also lyses surface TNFexpressing cells in vitro in the presence of complement. Adalimumab (Humira®) does not bind or inactivate lymphotoxin (TNF-beta). TNF is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Elevated levels of TNFare found in the synovial fluid of rheumatoid arthritis, including juvenile idiopathic arthritis, psoriatic arthritis, and ankylosing spondylitis patients and play an important role in both the pathologic inflammation and the joint destruction that are hallmarks of these diseases. Increased levels of TNF are also found in psoriasis (Ps) plaques.

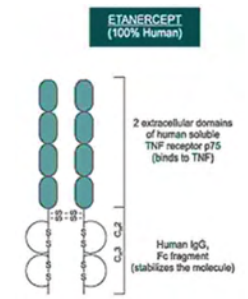
SHIKARI® Q-ADA: Enzyme immunoassay for the quantitative determination of free adalimumab (Humira®) in serum and plasma.
The Matriks Biotek SHIKARI® Q-ADA ELISA has been especially developed for the quantitative analysis of free adalimumab in serum and plasma samples.

SHIKARI® S-ATA: Enzyme immunoassay for the qualitative determination (screening) of antibodies to adalimumab in serum and plasma.

Adalimumab (Humira®) was associated to the development of anti-Adalimumab antibodies, even some were reported to be neutralizing, in various percentages of patients during therapy with the drug Humira®. This might lead to severe complications. The Matriks Biotek SHIKARI® S-ATA ELISA Kit can be efficiently used for monitoring anti-Adalimumab antibodies during therapy and offers the clinician a tool for decision on possible preventive measures such as possible addition of immunosuppressive drug to reduce anti-Adalimumab antibodies.

	Q-ADA Free Adalimumab(Humira®) quantitative analyses	S-ATA Adalimumab(Humira®) antibodies qualitative analyses
Required Volume (µl)	20	10
Total Time (min)	70	140
Sample	Serum, plasma	Serum, plasma
Sample Number	96	96
Dedection Limit (ng/mL)	10	+/-
Spike Recovery (%)	97	-
Shelf Life (year)	1	1

ETANERCEPT



Etanercept (Enbrel®) is a dimeric fusion protein consisting of the extracellular ligand-binding portion of the human 75 kilodalton (p75) tumor necrosis factor receptor (TNFR) linked to the Fc portion of human IgG1. The Fc component of etanercept contains the CH2 domain, the CH3 domain and hinge region, but not the CH1 domain of IgG1. Etanercept consists of 934 amino acids and has an apparent molecular weight of approximately 150 kilodaltons. Etanercept binds specifically to tumor necrosis factor (TNF) and blocks its interaction with cell surface TNF receptors. Elevated levels of TNF are found in involved tissues and fluids of patients with rheumatoid arthritis (RA), psoriatic arthritis, ankylosing spondylitis (AS), and plaque psoriasis. Two distinct receptors for TNF (TNFRs), a 55 kilodalton protein (p55) and a 75 kilodalton protein (p75), exist naturally as monomeric molecules on cell 4 • SHIKARI® Q-ETAsurfaces and in soluble forms. Biological activity of TNF is dependent upon binding to either cell surface TNFR. Etanercept is a dimeric soluble form of the p75 TNF receptor that can bind to two TNF molecules. Etanercept inhibits binding of both TNFα and TNFß (lymphotoxin alpha [LTα]) to cell surface TNFRs, rendering TNF biologically inactive.

SHIKARI® Q-ETA: Enzyme immunoassay for the quantitative determination of Etanercept (Enbrel®) in serum and plasma
Etanercept specific monoclonal antibody based elisa for the quantitative determination of etanercept (Enbrel®) in serum and plasma samples between the Cmin and Cmax range of concentrations as indicated.

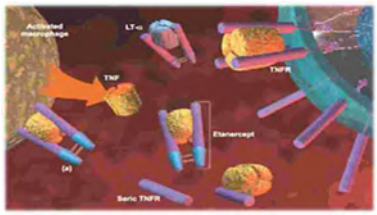
The user-friendly Matriks Biotek SHIKARI® Q-ETA is the first and only ELISA kit in the market for the quantitative determination of etanercept (Enbrel®) at uppermost specificity.

SHIKARI® S-ATE: Enzyme immunoassay for the qualitative determination of antibodies to etanercept(Enbrel®) in serum and plasma

The Matriks Biotek® S-ATE ELISA Kit can be efficiently used for monitoring anti-Etanercept antibodies during therapy and offers the clinician a tool for decision on possible preventive measures such as possible addition of immunosuppressive drug to reduce anti-etanercept antibodies.

	Q-ETA	S-ATE
	Free Etanercept (Enbrel®) mono-clonal based quantitative analyses	Etanercept(Enbrel®) antibodies qualitative analyses
Required Volume (µl)	20	10
Total Time (min)	160	140
Sample	Serum, plasma	Serum, plasma
Sample Number	96	96
Dedection Limit (µg/mL)	0,2	+/-
Spike Recovery (%)	97	-
Shelf Life (year)	1	1

HUMAN TNF & RECEPTORS



SHIKARI® Q-TNF: Enzyme immunoassay for the quantitative determination of Human Tumor Necrosis Factor-alpha (TNF-α) in serum, plasma and cell culture supernatants.

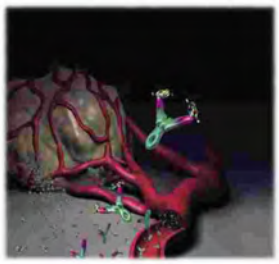
The Matriks Biotek® sensitive and specific TNF-α determination kit is based on double monoclonal antibody sandwich assay where TNF-α is captured with one monoclonal antibody on to solid phase and detected by another monoclonal antibody labeled with horse raddish peroxidase. For more information please refer to Instructions for Use PDF file.

SHIKARI® Q-sTNF-RII: Enzyme linked immunoassay for the quantification of human soluble TNF-RII (p75/80 kDa) from cell culture supernatant, serum, plasma or other body fluids.

This immunoassay has been designed to accurately quantitate the recombinant as well as native human soluble TNF-RII (p75/80). Since the measurement of human sTNF-RII by the Human sTNF-RII Immunoassay is insensitive to added TNF and this measurement corresponds to the total amount of the sTNF-RII present in samples, i.e., the total amount of free sTNF-RII plus the total amount of sTNF-RII bound to TNF.

	Q-sTNF-RII	Q-TNF
	TNF-RII quantitative analyses	TNF-α quantitative analyses
Required Volume (µl)	20	50
Total Time (min)	80	200
Sample	Supernatant, serum, plasma and other biological fluids	Supernatant, serum, plasma
Sample Number	96	96
Dedection Limit (ng/mL)	0.08	0,007
Spike Recovery (%)	≥98	≥98
Shelf Life (year)	1	1

BEVACIZUMAB



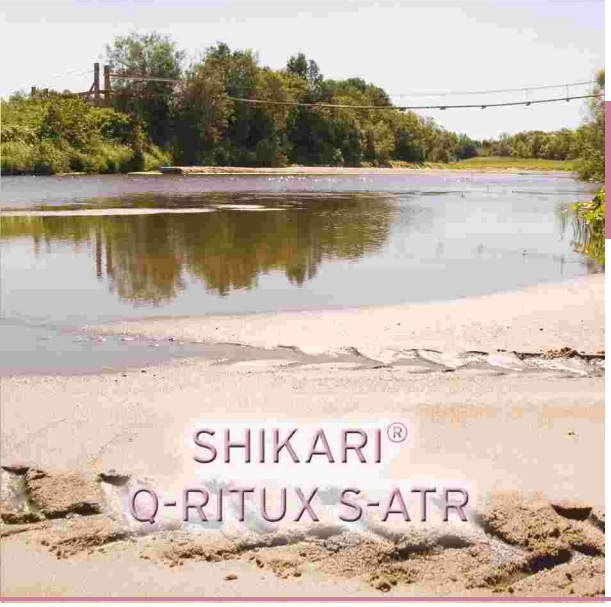
Bevacizumab (Avastin®)is a recombinant human IgG1:k monoclonal antibody specific for all human vascular endothelial growth factor-A (VEGF-A) isoforms. In 1997, the humanization of the murine anti-VEGF Mab A.4.6.1. was reported. Like its murine counterpart, bevacizumab binds to and neutralizes all human VEGF-A isoforms and bioactive proteolytic fragments, but not mouse or rat VEGF. However, bevacizumab was observed to inhibit the growth of human tumor cell lines in nude mice. In addition, studies have demonstrated that bevacizumab, in combination with chemotherapy, resulted in increased survival in patients with previously untreated metastatic colorectal cancer relative to chemotherapy alone, leading to FDA approval of the first anti-angiogenic agent.

SHIKARI® Q-BEVA: Enzyme immunoassay for the quantitative determination of Bevacizumab (Avastin®) in serum and plasma.
The Matriks Biotek® SHIKARI® Q-BEVA Enzyme Immunoassay has been developed for the quantitative analysis of biologically active form of free bevacizumab (Avastin®)* in serum and plasma samples.

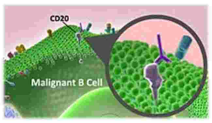
SHIKARI® S-ATB: Enzyme immunoassay for the quantitative determination of antibodies to Bevacizumab (Avastin®)* in serum and plasma.

The Matriks Biotek® S-ATB ELISA Kit can be used for monitoring anti-Bevacizumab antibodies during therapy and offers the clinician a tool for decision on possible preventive measures.

	Q-BEVA Free Bevacizumab (Avastin®) quantitative analyses	**S-ATB** Bevacizumab (Avastin®) antibodies qualitative analyses
Required Volume (µl)	5	25
Total Time (min)	170	140
Sample	Serum, plasma	Serum, plasma
Sample Number	96	96
Dedection Limit (ng/mL)	30	+/-
Spike Recovery (%)	99	-
Shelf Life (year)	1	1



RITUXIMAB



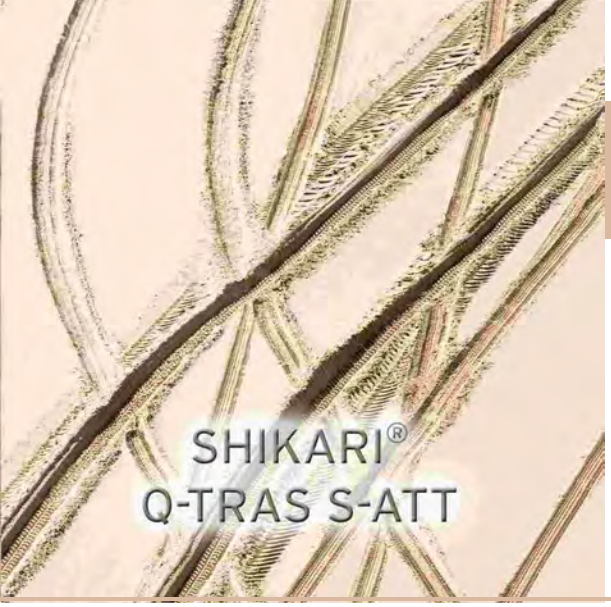
The use of rituximab (Rituxan®, Mabthera®) was associated to the development of anti-rituximab antibodies, even some might be neutralizing, in various percentages of patients during therapy with the drug.
The Matriks Biotek® Rituximab-ELISA and Antibody to Rituximab ELISA Kits can be efficiently used, for monitoring serum through levels and the presence of anti-rituximab antibodies respectively, during therapy and offers the scientist a tool for decision on possible preventive measures. There is no cross reaction with any other proteins present in naïve human serum. In addition, there is no cross reaction with the other therapeutic immunoglobulins tested (infliximab (Remicade®), etanercept (Enbrel®), adalimumab (Humira®), bevacizumab (Avastin®) and trastuzumab (Herceptin®)) at up to 500 µg/mL.

SHIKARI® Q-RITUX: Enzyme immunoassay for the quantitative determination of rituximab in serum, plasma and other biological fluids
The Matriks Biotek Q-RITUX (Rituxan®, Mabthera®) solid phase Elisa is based on rituximab-specific 9F9 monoclonal antibody (mAb). Kit is intended for the qualitative determination of antibodies to rituximab (Rituxan®, Mabthera®) in serum and plasma.

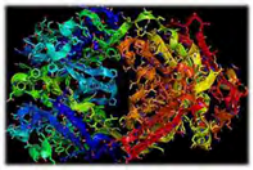
SHIKARI® S-ATR: Enzyme immunoassay for the qualitative determination of antibodies to rituximab in serum and plasma

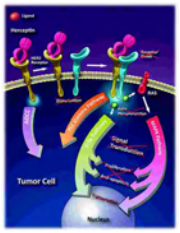
The Matriks Biotek S-ATR (Rituxan®, Mabthera®) Elisa Kit is intended for the qualitative determination of antibodies to rituximab (Rituxan®, Mabthera®) in serum and plasma.

	Q-RITUX Free Rituximab (Rituxan®, Mabthera®) quantitative analyses	**S-ATR** Rituximab (Rituxan®, Mabthera®) antibodies qualitative analyses
Required Volume (µl)	10 µl	10 µl
Total Time (min)	75 min	140 min
Sample	Serum, plasma and other biological fluids	Serum, plasma
Sample Number	96	96
Dedection Limit (ng/mL)	30 ng/mL	+/-
Spike Recovery (%)	98	-
Shelf Life (year)	1	1



TRASTUZUMAB





Trastuzumab (Herclon®, Herceptin®) is a recombinant DNA-derived humanized monoclonal antibody that selectively targets the extracellular domain of the human epidermal growth factor receptor 2 protein (HER2). Trastuzumab has antitumor activity against HER2-positive human breast tumor cells in laboratory models and is active for the treatment of women with HER2- overexpressing breast cancers. On the basis of trastuzumab clinical efficacy, this antibody was approved in 1998 for clinical use for HER2 overexpressing metastatic breast cancer.

The Matriks Biotek® Trastuzumab-ELISA and Antibody to Trastuzumab ELISA Kits can be efficiently used, for monitoring serum through levels and the presence of anti-trastuzumab antibodies respectively, during therapy and offers the scientist a tool for decision on possible preventive measures.

SHIKARI® Q-TRAS: Enzyme immunoassay for the qualitative determination of free Trastuzumab (Herclon®, Herceptin®) in serum and plasma. Matriks Biotek Trastuzumab ELISA has been developed for the quantitative analysis of free trastuzumab in serum and plasma samples at high specificity.

SHIKARI® S-ATT: Enzyme immunoassay for the qualitative determination of antibodies to trastuzumab in serum and plasma. The Matriks Biotek Antibody to Trastuzumab (Herclon®, Herceptin®) Enzyme-Linked-Immuno-Sorbent-Assay (ELISA) Kit is intended for the qualitative determination of antibodies to Trastuzumab in serum and plasma.

	Q-TRAS Free Trastuzumab (Herclon®, Herceptin®) quantitative analyses	S-ATT Trastuzumab (Herclon®, Herceptin®) antibodies qualitative analyses
Required Volume (µl)	10	10
Total Time (min)	70	120
Sample	Serum, plasma	Serum, plasma
Sample Number	96	96
Dedection Limit (ng/mL)	10	+/-
Spike Recovery (%)	98	-
Shelf Life (year)	1	1

SHIKARI® Elisa Kits are travelling the world!

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You can order directly from us.
For detailed information and distribution, please check out **www.matriksbiotek.com**

REFERENCE CODE	PRODUCT NAME	DESCRIPTION
TR-QS-INFLIXIv1	SHIKARI QS-INFLIXI	Enzyme immunoassay for the specific quantitative determination of Infliximab (Remicade®) in serum, plasma and other biological fluids
TR-Q-INFLIXIv2	SHIKARI Q-INFLIXI	Enzyme immunoassay for the quantitative determination of infliximab (Remicade®) in serum and plasma.
TR-ATIv4	SHIKARI Q-ATI	Enzyme immunoassay for the quantitative and qualitative determination of specific antibodies to infliximab in human serum and plasma.
TR-ADAv1	SHIKARI Q-ADA	Enzyme immunoassay for the quantitative determination of free adalimumab (Humira®) in serum and plasma
TR-A-ADAv1	SHIKARI S-ATA	Enzyme immunoassay for the qualitative determination (screening) of antibodies to adalimumab in serum and plasma.
TR-ETAv1	SHIKARI Q-ETA	Enzyme immunoassay for the quantitative determination of Etanercept (Enbrel®) in serum and plasma
TR-AETAv2	SHIKARI S-ATE	Enzyme immunoassay for the qualitative determination of antibodies to etanercept(Enbrel®) in serum and plasma
TR-TNFv1	SHIKARI Q-TNF	Enzyme immunoassay for the quantitative determination of Human Tumor Necrosis Factor-alpha (TNF-α) in serum, plasma and cell culture supernatants.
TR-sTNF-RIIv1	SHIKARI Q-sTNF-RII	Enzyme linked immunoassay for the quantification of human soluble TNF-RII (p75/80 kDa) from cell culture supernatant, serum, plasma or other body fluids.
TR-BEVAv1	SHIKARI Q-BEVA	Enzyme immunoassay for the quantitative determination of Bevacizumab(Avastin®) in serum and plasma.
TR-ABEVAv1	SHIKARI S-ATB	Enzyme immunoassay for the quantitative determination of antibodies to Bevacizumab (Avastin®)* in serum and plasma.
TR-RTXv1	SHIKARI Q-RITUX	Enzyme immunoassay for the quantitative determination of rituximab in serum, plasma and other biological fluids
TR-ARTXv1	SHIKARI S-ATR	Enzyme immunoassay for the qualitative determination of antibodies to rituximab in serum and plasma
TR-TRASv1	SHIKARI Q-TRAS	Enzyme immunoassay for the qualitative determination of antibodies to trastuzumab in serum and plasma
TR-ATRASv1	SHIKARI S-ATT	Enzyme immunoassay for the qualitative determination of antibodies to trastuzumab in serum and plasma

We can send you a proforma invoice and relevant information for bank transfer according to amount of kits you require.

Delivery is immediately after prepayment.
Our delivery process is on room temperature.
All of our kits are for 96 samples.

Our kits have been widely used for clinical and pharmacokinetic purposes.

PUBLICATIONS DONE BY USING MATRIKS BIOTEK SHIKARI® ELISA KITS

1. Malickova K, et al, Monitoring patients treated with infliximab: Assessing Anti-Infliximab antibodies, Czech Republic (2009)

2. Adisen E, et al, Anti-infliximab antibody status and its relation to clinical response in psoriatic patients: A pilot study, Journal of Dermatology (2010)

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