

BioSim™ anti-Golimumab (Simponi®) (Human) ELISA Kit

rev04/20

(Catalog # E4393-100, 100 assays, Store at 4°C)

I. Introduction:

Golimumab (Simponi®) is a human immunoglobulin G1κ monoclonal antibody which is specific for pro-inflammatory cytokine, tumor necrosis factor-α (TNFα). Elevated levels of TNF are 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. Golimumab binds to both the soluble and transmembrane bioactive forms of human TNF and prevent TNF from binding to its receptors and finally inhibits biological activity of TNF. However, some patients develop unwanted immunogenicity, which leads to production of anti-drug-antibodies (ADAs) inactivating the therapeutic effects of the treatment and, in rare cases, inducing adverse effects. BioVision's BioSim™ anti-Golimumab ELISA kit is designed to detect the antibody against Golimumab with high specificity and sensitivity in biological matrices.

II. Application:

This ELISA kit is used for *in vitro* qualitative determination of antibody against Golimumab in serum and plasma
 Cross Reactivity: Golimumab (Simponi®) infusion camouflages/masks the presence of antibody to Golimumab (ATG) in serum/plasma samples. Therefore, blood sampling time is critical for detection of ATG. It is convenient to obtain blood sample just before the infusion or at least 2 weeks after the infusion of Golimumab.

III. Sample Type:

Human serum and plasma

IV. Kit Contents:

Components	E4393-100	Part No.
Micro ELISA Plate	1 plate	E4393-100-1
Positive Control	0.3 ml	E4393-100-2
Negative Control	1 ml	E4393-100-3
Assay Buffer	12 ml	E4393-100-4
Peroxidase Conjugate	12 ml	E4393-100-5
TMB substrate (Avoid light)	12 ml	E4393-100-6
Stop Solution	12 ml	E4393-100-7
Wash buffer (20X)	50 ml	E4393-100-8
Plate sealers	2	E4393-100-9

V. User Supplied Reagents and Equipment:

- Microplate reader capable of measuring absorbance at 450 nm
- Precision pipettes with disposable tips
- Clean eppendorf tubes for preparing standards or sample dilutions
- Absorbent paper

VI. Storage and Handling:

The entire kit may be stored at 4°C for up to 12 months from the date of shipment.

VII. Reagent and Sample Preparation:

Note: Before using the kit, spin tubes and bring down all components to the bottom of tubes.

1. **Wash Buffer:** Dilute the 20X Wash Buffer to 1X solution in ddH₂O (10 ml of Wash Buffer stock to 190 ml of ddH₂O). Mix the 1X solution thoroughly by vortex manually. The working stock can be stable for 2 weeks after preparation at 4°C.
2. **Sample preparation:** The usual precautions for venipuncture should be observed. Samples are stable at 4°C for 7 days and -20°C for 6 months. Avoid freeze-and-thaw cycle.

VIII. Assay Protocol:

Note: Bring all reagents, microplate and samples to room temperature 15 minutes prior to the assay.

It is recommended that all standards and samples be run at least in duplicate.

A standard curve must be run with each assay.

1. Prepare all reagents, samples and standards as instructed in section VII.
2. Pipette 100 µl of **Assay Buffer** into each of the wells to be used.
3. Add 10 µl of **negative controls** (2 wells), **positive controls**, and **samples** into appropriate wells. Cover wells and incubate for 60 minutes at room temperature (RT).
4. Discard incubation solution. Wash plate 3 times each with 300 µl of diluted **Wash Buffer**. Remove excess solution by tapping the inverted plate on a paper towel.
5. Add 100 µl of **Peroxidase Conjugate** into each well. Cover wells with adhesive plate sealer and incubate at RT for 60 minutes.
6. Discard the solution and wash the wells as step 3.
7. Add 100 µl of 1X **TMB substrate** solution and incubate the plate in dark at RT for 20 minutes

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8. Add 100 µl of **Stop solution** to stop the reaction
9. Read the absorbance in micro plate reader set to 450 nm within 20 minutes. (reference wavelength to 650 nm)

IX. QUALITATIVE INTERPRETATION:

- For the run to be valid, the OD 450/650 nm of positive control should be >1.5 and the OD 450/650 nm of each negative control should be <0.15. In case of any deviation the following technical issues (but not limited to) should be reviewed: Expiration dates of reagents, storage conditions, pipettes, devices, incubation conditions, washing methods, etc.
- If “Sample OD_{450/650} / Negative Control OD_{450/650}” is < 3, the sample is NEGATIVE for Antibody to Golimumab.
- If “Sample OD_{450/650} / Negative Control OD_{450/650}” is ≥ 3, the sample is POSITIVE for Antibody to Golimumab.

Note: The cut-off information provided with this kit can only be considered as a recommendation. Cut-off values must be calculated/set or verified according to scientific standards by the users.

X. RELATED PRODUCTS:

- BioSim™ Rituximab (Mabthera®) (Human) ELISA Kit (Cat. No. E4371-100)
- BioSim™ Adalimumab (Humira®) (Human) ELISA Kit (Cat. No. E4372-100)
- BioSim™ Bevacizumab (Avastin®) (Human) ELISA Kit (Cat. No. E4373-100)
- BioSim™ Etanercept (Enbrel®) (Human) ELISA Kit (Cat. No. E4374-100)
- BioSim™ Infliximab (Remicade®) (Human) ELISA Kit (Cat. No. E4375-100)
- BioSim™ Trastuzumab(Herceptin®)(Human) ELISA Kit (Cat. No. E4376-100)
- BioSim™ Golimumab (Simponi®)(Human) ELISA Kit (Cat. No. E4377-100)
- BioSim™ Infliximab (Remsima®)(Human) ELISA Kit (Cat. No. E4378-100)
- BioSim™ Cetuximab (Erbix®)(Human) ELISA Kit (Cat. No. E4379-100)
- BioSim™ Denosumab (Prolia®)(Human) ELISA Kit (Cat. No. E4380-100)
- BioSim™ Omalizumab (Xolair®)(Human) ELISA Kit (Cat. No. E4381-100)
- BioSim™ Nivolumab (Opdivo®)(Human) ELISA Kit (Cat. No. E4382-100)
- BioSim™ Pembrolizumab (Keytruda®)(Human) ELISA Kit (Cat. No. E4383-100)
- BioSim™ Ipilimumab (Yervoy®)(Human) ELISA Kit (Cat. No. E4384-100)
- BioSim™ Rituximab (Mabthera®) (Human) ELISA Kit (Cat. No. E4385-100)
- BioSim™ Trastuzumab (Herceptin®) (Human) ELISA Kit (Cat. No. E4386-100)
- BioSim™ Infliximab (Remicade®) (Human) ELISA Kit (Cat. No. E4387-100)
- BioSim™ Adalimumab (Humira®) (Human) ELISA Kit (Cat. No. E4388-100)
- BioSim™ Bevacizumab (Avastin®) (Human) ELISA Kit (Cat. No. E4389-100)
- BioSim™ Infliximab (Remsima®) (Human) ELISA Kit (Cat. No. E4390-100)
- BioSim™ Cetuximab (Erbix®) (Human) ELISA Kit (Cat. No. E4391-100)
- BioSim™ Etanercept (Enbrel®) (Human) ELISA Kit (Cat. No. E4392-100)
- BioSim™ Golimumab (Simponi®) (Human) ELISA Kit (Cat. No. E4393-100)
- BioSim™ Denosumab (Prolia®) (Human) ELISA Kit (Cat. No. E4394-100)
- BioSim™ Omalizumab (Xolair®) (Human) ELISA Kit (Cat. No. E4395-100)
- BioSim™ Nivolumab (Opdivo®) (Human) ELISA Kit (Cat. No. E4396-100)
- BioSim™ Pembrolizumab (Keytruda®) (Human) ELISA Kit (Cat. No. E4397-100)
- BioSim™ Ipilimumab (Yervoy®) (Human) ELISA Kit (Cat. No. E4398-100)
- BioSim™ Filgrastim (Herceptin®) (Human) ELISA Kit (Cat. No. E4399-100)

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