Humanized Anti-IgE (Xolair/Omalizumab) Assay Kits

Immunoglobulin E (IgE) is an immunoglobulin isotype that is found only in mammals. It is a monomeric antibody with 4 Ig-like domains. Its main function is immunity to parasites. IgE is commonly involved with allergies when present in high amounts in the body. It is especially associated with type I hypersensitivity. IgE is an important target for the treatments for allergy and asthma. IgE elicits an immune response by binding to Fc receptors found on the surface of mast cells and basophils. Fc receptors are of two types: FcεRI, the high-affinity IgE receptor and FcεRII, also known as CD23, is the low-affinity IgE receptor.

Omalizumab (**Xolair, Genentech/Novartis**) is a recombinant DNA-derived humanized IgG1k monoclonal antibody. Xolair is a glycosylated monoclonal antibody (~149 kda) produced in Chinese hamster ovary cells (CHO) suspension culture. Xolair inhibits the binding of IgE to the high-affinity IgE receptor (FceRI) on the surface of mast cells and basophils. It is approved for patients with moderate-to-severe or severe allergic asthma, which is caused by hypersensitivity reactions to certain harmless environmental substances. The drug is administered subcutaneously once every 2 or 4 weeks (150 to 375 mg). Like other protein and antibody drugs, omalizumab causes anaphylaxis (a life-threatening systemic allergic reaction) in 1 to 2 patients per 1,000. Antibodies to Xolair were detected in approximately 1/1723 (< 0.1%) of patients treated with Xolair. **Gomiliximab (IDEC Pharmaceuticals Corporation.)** is a monoclonal IgG1 antibody acting as an immunosuppressive drug for the treatment of allergic asthma. It targets the low affinity IgE receptor (FcεRII). The drug is a chimeric antibody from Macaca irus and Homo sapiens.

Omalizumab inhibits the binding of IgE to the high-affinity IgE receptor FcεRI by binding to an epitope on IgE that overlaps with the site to which FcεRI binds. This feature is critical to omalizumab's pharmacological effects because a typical anti-IgE antibody can cross-link cell surface FcεRI-bound IgE and induce mediator release from basophils and mast cells. Although the binding peptide sequence on IgE that is used to bind to low affinity IgE receptor (FcεRII) is different from the sequence used to bind to FcεRI, omalizumab, by steric hindrance, also prevents binding of IgE to FcεRII.

IgE plays a role in a natural defense against parasitic diseases, treatment is usually not recommended when living in environments where the presence of parasites is common. IgE might play an important role in the immune system's recognition of cancer cells,[3] so indiscriminate blocking of IgE /receptor interaction might have unforeseen problems. There is a possible small increased risk of cancer in those taking omalizumab. Concerns have also been raised about possible induction of Churg-Strauss syndrome, nasal polyps, andadrenal insufficiency. Therefore, it is extremely critical to assess the IgE concentrations in the patient before and after the treatments with anti-IgE drugs such as Xoliar. However, it is not known what IgE, free or Xoliar-bound, is being measured by the current IgE ELISA kits.

ADI has developed new ELISA kits that measure **total IgE** (free and Xolair-bound) and more importantly "**Free IgE** (Xolair-unbound)" in patients treated with Xolair. Highly sensitive ELISA kits were also developed to measure the concentration of Xolair in human or animal sera that measure "**Free Xolair or IgE-unbound or Active Xolair**". ADI has also developed ELISA kits to detect antibodies to Xolair (**Human Anti-Xolair Antibodies**) in patients receiving long-term treatments. These kits will be useful to develop better immunotherapeutics. We are also working to develop assays that may predict patients who are likely to respond to Xolair therapy and who may be more prone to develop antibodies.

Catalog#	Product Description	Features
200-410-XLG	Xolair/Omalizumab ELISA Kit for human, 96 tests	**Range** 0-250 ng/ml; **Sensitivity** ~1 ng/ml **Samples** (**100 ul**; 1:10000, serum/plasma **Time:** 105 min assay (60+30+15) at room temp
200-420-XLG	Human Anti-Xolair/Omalizumab Antibody ELISA Kit, 96 tests	**Range** 0-50 ng/ml; **Sensitivity** ~0.25 ng/ml **Samples** (**100 ul**; 1:10-1:100, serum/plasma **Time:** 105 min assay (60+30+15) at room temp
200-430-XET	Human IgE (Total; Free and Xolair-bound) ELISA Kit for Xolair-treated samples, 96 tests	**Range** 0-50 IU/ml; **Sensitivity** ~3 ng/ml **Samples** (**100 ul**; 1:10-1:100, serum/plasma **Time:** 105 min assay (60+30+15) at room temp
200-440-XEF	Human IgE (Free; Xolair unbound) ELISA Kit for Xolair-treated samples, 96 tests	**Range** 0-200 IU/ml; **Sensitivity** ~10 IU/ml **Samples** (**100 ul**; 1:5, serum/plasma **Time:** 105 min assay (60+30+15) at room temp

ADI is also offering custom testing of animal or human samples for Xolair, antibodies to Xolair, and IgE measurements.

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