

# PharmaGenie Therapeutic Antibodies & Biosimilar ELISA

European manufactured ELISA in ISO 13485 accredited facility according CE IVD standards

# ASPIRE TO CURE



Infliximab (Remicade®) | Infliximab (Remsima®) | Adalimumab (Humira®) | Etanercept (Enbrel®) | Golimumab (Simponi®) | Certolizumab (Cimzia®) | Vedolizumab (Entyvio®) | Ustekinumab (Stelara®) | Ramucirumab (Cyramza®) | Bevacizumab (Avastin®) | Rituximab (Rituxan®, Mabthera®) | Trastuzumab (Herceptin®, Herclon®) | Cetuximab (Erbitux®) | Denosumab (Prolia®) | Anti-Filgrastim | Omalizumab (Xolair®) Ranibizumab (Lucentis®) | Avelumab (Bavencio®) | Nivolumab (Opdivo®) | Pembrolizumab (Keytruda®) | Ipilimumab (Yervoy®)

#### PharmaGenie Therapeutic Antibodies & Biosimilar ELISA

The Assay Genie Therapeutic Antibody, Biosimilar & Anti-Drug Antibody (ADA) ELISA kits are a premium range of kits designed to detect free therapeutic antibodies, biosimilars and Anti-Drug Antibodies in serum & plasma samples.

These kits use the highest quality components and are manufactured under ISO 13485 quality systems according to CE IVD standards.

#### **Key Features**

#### **Premium Quality Validated Assays**

- Manufactured in Europe under ISO 13485 quality systems
- · Kits for Research-Use-Only
- · Inter and intra assay CV meet requirements for FDA & EMEA
- Validation, verification and lot release performed according to best-in-class scientific quidelines and literature

#### **Quantitative & Qualitative Screening Kits**

- Quantitative ELISA kits for the measurement of the World's leading therapeutic antibodies & biosimilars

  Ouglitative kits applying the sergening of
  - Qualitative kits enabling the screening of deleterious ADAs
  - Dual kits allowing for the screening of ADAs and free therapeutic antibodies

#### **Optimized Format & Protocol**

- Use as little as 10ul sample per well excellent for clinical, mouse, rat & primate samples
- Get your results in as little as 55 minutes for some kits
- All kits shipped at room temperature







### PharmaGenie Therapeutic Antibodies & Biosimilar ELISA | Essential Data

#### Adalimumab (Humira®) ELISA

#### 2.248 2,5 2 1,287 MEAN OD 1,5 1 0.5 0.204 0.055 0 300ng/ml 1000ng/ml 0ng/ml 100ng/ml 30ng/ml STANDARD CONCENTRATION

#### Etanercept (Enbrel®) ELISA

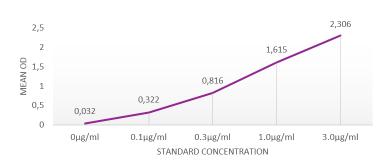


Figure 1: Standard curves for PharmaGenie Adalimumab (Humira) and Etanercept (Enbrel) Quantitative ELISA

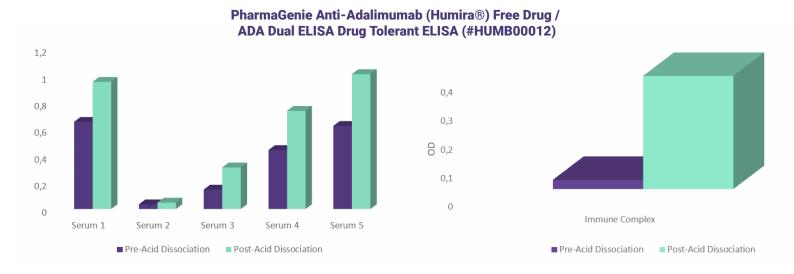


Figure 2: PharmaGenie Anti-Adalimumab (Humira®) Free Drug/ADA Dual ELISA Drug Tolerant Assay: This unique kit enables the detection of Free and Total Anti-Drug Antibodies (ADA) to Adalimumab simultaneously on the same plate. OD values before acid treatment measure "free" ADA (Purple bars) and after acid treatment represent "total" ADA values (free and bound - Green bars). Increase in OD after acid treatment is indicative of Anti-Adalimumab antibodies complexed with Adalimumab that cannot be measured by classical double antigen ADA tests that typically measure "free" ADA.

Figure 3: PharmaGenie Anti-Adalimumab (Humira®) Free Drug/ADA Dual ELISA Drug Tolerant Assay: The immune complex is composed of Adalimumab bound to an Anti-Adalimumab human monoclonal antibody at an equimolar ratio. This drug tolerant assay uses acid dissociation (Green Bar) to measure the levels of bound ADA that can otherwise not be measured by traditional drug sensitivity assays (Purple bar) as Adalimumab is in a complex with Anti-Adalimumab antibodies thus preventing detection.



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## PharmaGenie Therapeutic Antibodies, Biosimilar and ADA ELISA

Code	Product	Kit type
HUMB00001	Infliximab (Remicade®) ELISA	Quantitative Therapeutic Antibody ELISA
HUMB00002	Anti-Infliximab (Remicade®) ELISA	Anti-Drug Antibody (ADA) Screening - Qualitative
HUMB00003	Anti-Infliximab (Remicade®) ADA Quantitative ELISA	Anti-Drug Antibody (ADA) Screening - Quantitative
HUMB00004	Anti-Infliximab (Remicade®) Free Drug/ADA Dual ELISA	Free Drug & Anti-Drug Antibody (ADA) Semi-Quantitative
HUMB00005	Infliximab (Remsima®) ELISA	Quantitative Therapeutic Antibody ELISA
HUMB00006	Anti-Infliximab (Remsima®) ADA Qualitative ELISA	Anti-Drug Antibody (ADA) Screening - Qualitative
HUMB00007	Anti-Infliximab (Remsima®) ADA Quantitative ELISA	Anti-Drug Antibody (ADA) Screening - Quantitative
HUMB00008	Anti-Infliximab (Remsima®) ADA Semi-Quantitative ELISA	Anti-Drug Antibody (ADA) Screening - Semi-Quantitative
HUMB00009	Adalimumab (Humira®) ELISA	Quantitative Therapeutic Antibody ELISA
HUMB00010	Anti-Adalimumab (Humira®) ADA Qualitative ELISA	Anti-Drug Antibody (ADA) Screening - Qualitative
HUMB00011	Anti-Adalimumab (Humira®) ADA Quantitative ELISA	Anti-Drug Antibody (ADA) Screening - Quantitative
HUMB00012	Anti-Adalimumab (Humira®) Free Drug/ADA Dual ELISA	Free Drug & Anti-Drug Antibody (ADA) Semi-Quantitative
HUMB00013	Etanercept (Enbrel®) ELISA	Quantitative Therapeutic Antibody ELISA
HUMB00014	Anti-Etanercept (Enbrel®) ADA Qualitative ELISA	Anti-Drug Antibody (ADA) Screening - Qualitative
HUMB00015	Golimumab (Simponi®) ELISA	Quantitative Therapeutic Antibody ELISA
HUMB00016	Anti-Golimumab (Simponi®) ADA Qualitative ELISA	Anti-Drug Antibody (ADA) Screening - Qualitative
HUMB00017	Certolizumab (Cimzia®) ELISA	Quantitative Therapeutic Antibody ELISA
HUMB00018	Vedolizumab (Entyvio®) ELISA	Quantitative Therapeutic Antibody ELISA
HUMB00019	Anti-Vedolizumab (Entyvio®) ADA Qualitative ELISA	Anti-Drug Antibody (ADA) Screening - Qualitative
HUMB00020	Ustekinumab (Stelara®) ELISA	Quantitative Therapeutic Antibody ELISA
HUMB00021	Anti-Ustekinumab (Stelara®) ADA Qualitative ELISA	Anti-Drug Antibody (ADA) Screening - Qualitative
HUMB00022	Ramucirumab (Cyramza®) ELISA	Quantitative Therapeutic Antibody ELISA
HUMB00023	Anti-Ramucirumab (Cyramza®) ADA Qualitative ELISA	Anti-Drug Antibody (ADA) Screening - Qualitative
HUMB00024	Bevacizumab (Avastin®) ELISA	Quantitative Therapeutic Antibody ELISA
HUMB00025	Anti-Bevacizumab (Avastin®) ADA Qualitative ELISA	Anti-Drug Antibody (ADA) Screening - Qualitative
HUMB00026	Anti-Bevacizumab (Avastin®) ADA Quantitative ELISA	Anti-Drug Antibody (ADA) Screening - Quantitative
HUMB00027	Rituximab (Rituxan®, Mabthera®) ELISA	Quantitative Therapeutic Antibody ELISA
HUMB00028	Anti-Rituximab (Rituxan®, Mabthera®) ADA Qualitative ELISA	Anti-Drug Antibody (ADA) Screening - Qualitative
HUMB00029	Anti-Rituximab (Rituxan®, Mabthera®) ADA Quantitative ELISA	Anti-Drug Antibody (ADA) Screening - Quantitative
HUMB00030	Trastuzumab (Herceptin®, Herclon®) ELISA	Quantitative Therapeutic Antibody ELISA
HUMB00031	Anti-Trastuzumab (Herceptin®, Herclon®) ADA Qualitative ELISA	Anti-Drug Antibody (ADA) Screening - Qualitative
HUMB00032	Anti-Trastuzumab (Herceptin®, Herclon®) ADA Quantitative ELISA	Anti-Drug Antibody (ADA) Screening - Quantitative
HUMB00033	Cetuximab (Erbitux®) ELISA	Quantitative Therapeutic Antibody ELISA
HUMB00034	Anti-Cetuximab (Erbitux®) ADA Qualitative ELISA	Anti-Drug Antibody (ADA) Screening - Qualitative
HUMB00035	Anti-Cetuximab (Erbitux®) ADA Quantitative ELISA	Anti-Drug Antibody (ADA) Screening - Quantitative
HUMB00036	Denosumab (Prolia®) ELISA	Quantitative Therapeutic Antibody ELISA
HUMB00037	Anti-Denosumab (Prolia®) ADA Qualitative ELISA	Anti-Drug Antibody (ADA) Screening - Qualitative
HUMB00038	Anti-Filgrastim ADA Quantitative ELISA	Anti-Drug Antibody (ADA) Screening - Quantitative
HUMB00039	Omalizumab (Xolair®) ELISA	Quantitative Therapeutic Antibody ELISA
HUMB00040	Anti-Omalizumab (Xolair®) ADA Qualitative ELISA	Anti-Drug Antibody (ADA) Screening - Qualitative
HUMB00041	Ranibizumab (Lucentis®) ELISA	Quantitative Therapeutic Antibody ELISA
HUMB00042	Avelumab (Bavencio®) ELISA	Quantitative Therapeutic Antibody ELISA
HUMB00043	Anti-Avelumab (Bavencio®) ADA Qualitative ELISA	Anti-Drug Antibody (ADA) Screening - Qualitative
HUMB00044	Nivolumab (Opdivo®) ELISA	Quantitative Therapeutic Antibody ELISA
HUMB00045	Anti-Nivolumab (Opdivo®) ADA Qualitative ELISA	Anti-Drug Antibody (ADA) Screening - Qualitative
HUMB00046	Pembrolizumab (Keytruda®) ELISA	Quantitative Therapeutic Antibody ELISA
HUMB00047	Anti-Pembrolizumab (Keytruda®) ADA Qualitative ELISA	Anti-Drug Antibody (ADA) Screening - Qualitative
HUMB00048	Ipilimumab (Yervoy®) ELISA	Quantitative Therapeutic Antibody ELISA
HUMB00049	Anti-Ipilimumab (Yervoy®) ADA Qualitative ELISA	Anti-Drug Antibody (ADA) Screening - Qualitative