

## Therapeutic Drug Monitoring of anti-TNF therapies Infiximab and Adalimumab

The Immunology department uses ELISA assays to measure the following:

- Infiximab drug levels
- Anti-Infiximab antibody levels
- Adalimumab drug levels
- Anti-Adalimumab antibody levels

### Infiximab Drug Levels

#### General information

Infiximab is a murine-human chimeric, therapeutic monoclonal antibody directed against TNF $\alpha$  and is used in the treatment of inflammatory diseases including Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis and severe psoriasis.

This is a recently introduced method. For information on these assays please see:

<https://www.exeterlaboratory.com/test/infiximab-drug-levels>

For interpretation of anti-TNF drug and antibody levels please see: <http://tinyurl.com/Exeter-Anti-TNF-Guidelines>

#### Laboratory information

**Analyte:** This assay measures infiximab drug levels

**Volume and sample type:** Serum

**Units:** mg/L

**Turnaround time:** Not established

**Frequency of analysis:** As required

**Specimen transport:** At room temperature

**Additional/special requirements:**

**Factors affecting the test:** None

## Division of Laboratory Medicine

### Immunology

**Method:** ELISA method

**Participation in EQA scheme:** No formal EQA scheme. Sample exchange in place.

### Clinical information

**Reference range and interpretation:**

Cut off levels and ranges have not yet been defined for anti-TNF drug levels. Results for anti-TNF drug levels and antibodies against anti-TNF drugs need to be interpreted by the requesting specialist clinical team in combination with the clinical features

This test has been launched recently in the Immunology department. Once sufficient clinical samples have been tested we will provide local advice.

## Anti-Infliximab antibody levels

### General information

Antibodies directed against infliximab can be associated with treatment failure and can help direct subsequent treatment.

This is a recently introduced method. For information on these assays please see:

<https://www.exeterlaboratory.com/test/infliximab-antibody-levels/>

For interpretation of anti TNF drug and antibody levels please see: <http://tinyurl.com/Exeter-Anti-TNF-Guidelines>

### Laboratory information

**Analyte:** This assay measures total anti-infliximab antibody levels

**Volume and sample type:** Serum

**Units:** AU/mL (arbitrary units per mL)

**Turnaround time:** Not established

**Frequency of analysis:** As required

**Specimen transport:** At room temperature

## Division of Laboratory Medicine

### Immunology

**Additional/special requirements:**

**Factors affecting the test:** Higher concentrations of biotin can lead to falsely low results.

**Method:** ELISA method

**Participation in EQA scheme:** No formal EQA scheme. Sample exchange in place.

### Clinical information

**Reference range and interpretation:**

Results for anti-TNF drug levels and antibodies against anti-TNF drugs need to be interpreted by the requesting specialist clinical team in combination with the clinical features

This test has been launched recently in the Immunology department sufficient clinical samples have been tested we will also provide local advice.

## Adalimumab Drug Levels

### General information

Adalimumab is a fully human therapeutic monoclonal antibody directed against TNF $\alpha$  and is used in the treatment of inflammatory diseases including Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis and severe psoriasis.

This is a recently introduced method. For information on these assays please see:

<https://www.exeterlaboratory.com/test/adalimumab-drug-levels/>

For interpretation of anti-TNF drug and antibody levels please see: <http://tinyurl.com/Exeter-Anti-TNF-Guidelines>

### Laboratory information

**Analyte:** This assay measures adalimumab drug levels

**Volume and sample type:** Serum

**Units:** mg/L

**Turnaround time:** Not established

## Division of Laboratory Medicine

### Immunology

**Frequency of analysis:** As required

**Specimen transport:** At room temperature

**Additional/special requirements:**

**Factors affecting the test:** None

**Method:** ELISA method

**Participation in EQA scheme:** No formal EQA scheme. Internal Quality Assurance in place.

### Clinical information

#### Reference range and interpretation:

Cut off levels and ranges have not yet been defined for anti-TNF drug levels. Results for anti-TNF drug levels and antibodies against anti-TNF drugs need to be interpreted by the requesting specialist clinical team in combination with the clinical features

This test has been launched recently in the Immunology department. Once sufficient clinical samples have been tested we will provide local advice.

## Anti-Adalimumab Antibody levels

### General information

Antibodies directed against adalimumab can be associated with treatment failure and can help direct subsequent treatment.

This is a recently introduced method. For information on these assays please see:

<https://www.exeterlaboratory.com/test/adalimumab-antibody-levels/>

For interpretation of anti TNF drug and antibody levels please see: <http://tinyurl.com/Exeter-Anti-TNF-Guidelines>

### Laboratory information

**Analyte:** This assay measures total anti adalimumab antibody levels

**Volume and sample type:** Serum

## Division of Laboratory Medicine

### Immunology

**Units:** AU/mL (arbitrary units per mL)

**Turnaround time:** Not established

**Frequency of analysis:** As required

**Specimen transport:** At room temperature

**Additional/special requirements:** None

**Factors affecting the test:** High dose biotin may cause false low results for this assay.

**Method:** ELISA method

**Participation in EQA scheme:** No formal EQA scheme. Internal Quality Assurance in place.

### Clinical information

**Reference range and interpretation:**

Results for anti-TNF drug levels and antibodies against anti-TNF drugs need to be interpreted by the requesting specialist clinical team in combination with the clinical features

This test has been launched recently in the Immunology department. Once sufficient clinical samples have been tested we will provide local advice.

**(Last updated October 2023)**