

## Laboratory Medicine Care Division

### Immunology

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

The Immunology department uses ELISA assays to measure the following:

- Infliximab drug levels
- Anti-Infliximab antibody levels
- Adalimumab drug levels
- Anti-Adalimumab antibody levels

## Infliximab Drug Levels

### General information

Infliximab 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/infliximab-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 infliximab drug levels

**Volume and sample type:** Serum

**Units:** mg/L

**Turnaround time (calendar days from sample receipt to authorised result):** Median - 10

**Frequency of analysis:** As required

**Specimen transport:** At room temperature

**Additional/special requirements:**

**Factors affecting the test:** None

## Laboratory Medicine Care Division

### Immunology

**Method:** ELISA method

**Participation in EQA scheme:** Pilot UK NEQAS for Anti-TNF Drugs and Antibodies

### 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 (calendar days from sample receipt to authorised result):** Median - 10

**Frequency of analysis:** As required

**Specimen transport:** At room temperature

## Laboratory Medicine Care Division

### 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:** Pilot UK NEQAS for Anti-TNF Drugs and Antibodies

### 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 (calendar days from sample receipt to authorised result):** Median - 10

## Laboratory Medicine Care Division

### 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:** Pilot UK NEQAS for Anti-TNF Drugs and Antibodies

### 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

## Laboratory Medicine Care Division

### Immunology

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

**Turnaround time (calendar days from sample receipt to authorised result):** Median - 10

**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:** Pilot UK NEQAS for Anti-TNF Drugs and Antibodies

### 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.

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