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 TNFα 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

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

Method: ELISA method

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

Clinical information

Reference range and interpretation for IBD (1,2):

Interpretation of drug levels based on outcomes (remission)

- **Week 6 (Induction):** A dose-response association was observed where drug concentrations up to **30–35 mg/L** were associated with increasing remission at week 14.
- **Week 14 (Post-induction):**
    - The initial study identified **7 mg/L** as the optimal concentration associated with remission at both week 14 and week 54.
    - Follow-up data over 3 years refined this range, suggesting an optimal threshold of **6.1–10.0 mg/L** at week 14 to predict remission at any later timepoint.
- **Week 54 (Maintenance):** To ensure remission at subsequent timepoints (years 2 and 3), the optimal minimal concentration was estimated to be **3.6–4.5 mg/L**.

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

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/

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

Additional/special requirements:

Factors affecting the test: High dose biotin supplementation 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

Adalimumab Drug Levels

General information

Adalimumab is a fully human therapeutic monoclonal antibody directed against TNFα 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/

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

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 for IBD (1,2):

Interpretation of drug levels based on outcomes (remission)

- **Week 14 (Post-induction):**
  - The initial study identified **12 mg/L** as the optimal concentration associated with remission at both week 14 and week 54.
  - Long-term follow-up data (3 years) identified an optimal threshold of **10.1–12.0 mg/L** at week 14 to predict remission at later timepoints.
- **Week 54 (Maintenance):** To ensure remission at subsequent timepoints, drug concentrations should be maintained at **more than 10 mg/L**.

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

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/

Laboratory information

Analyte: This assay measures total anti adalimumab 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

Additional/special requirements: None

Factors affecting the test: High dose biotin supplementation 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 for IBD:

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

Summary of target drug levels associated with remission in IBD

Drug	Timepoint	Target Concentration Range
Infliximab	**Week 14**	**6.1–10.0 mg/L**
	Week 54	**3.6–4.5 mg/L**
Adalimumab	**Week 14**	**10.1–12.0 mg/L**
	Week 54	**>10 mg/L**

References

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2. Chanchlani, N., Lin, S., Bewshea, C., Hamilton, B., Thomas, A., Smith, R., Roberts, C., Bishara, M., Nice, R., Lees, C. W., Sebastian, S., Irving, P. M., Russell, R. K., McDonald, T. J., Goodhand, J. R., Ahmad, T., Kennedy, N. A., Patel, V., Mazhar, Z., … Gore, S. (2024). Mechanisms and management of loss of response to anti-TNF therapy for patients with Crohn's disease: 3-year data from the prospective, multicentre PANTS cohort study. *The Lancet Gastroenterology & Hepatology*, *9*(6), 521–538. https://doi.org/10.1016/S2468-1253(24)00044-X

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