

Division of Laboratory Medicine

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 α 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: Not established

Frequency of analysis: As required

Specimen transport: At room temperature

Additional/special requirements:

Factors affecting the test: None

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Method: ELISA method

Participation in EQA scheme: No formal EQA scheme. Sample exchange to be set up.

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.

ICE reference:

- Infliximab drug level (not Inflectra)
- Infliximab drug (Inflectra only)

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-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 total anti-infliximab antibody levels

Volume and sample type: Serum

Units: AU/mL (arbitrary units per mL)

Turnaround time: Not established

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Frequency of analysis: As required

Specimen transport: At room temperature

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 to be set up.

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.

ICE reference:

- Infliximab antibody level (not Inflectra)
- Infliximab antibody (Inflectra only)

Adalimumab Drug Levels

General information

Adalimumab is a fully human therapeutic monoclonal antibody directed against TNF α 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>

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Laboratory information

Analyte: This assay measures infliximab 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

Method: ELISA method

Participation in EQA scheme: No formal EQA scheme. Sample exchange to be set up.

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.

ICE reference: Adalimumab

Anti-Adalimumab Antibody levels

General information

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

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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 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

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. Sample exchange to be set up.

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.

ICE reference: Adalimumab antibodies

(Last updated September 2020)