Anti-TNF drugs (Adalimumab, Infliximab) and anti-drug antibodies User Information

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Clinical Indications

Adalimumab and Infliximab are all drugs which inhibit the activity of tumour necrosis factor alpha (TNF-α). They are licensed for a number of clinical conditions, which include Gastroenterology (Crohn's disease, ulcerative colitis), Rheumatology (rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, juvenile idiopathic arthritis) and Dermatology (severe plaque psoriasis).

The measurement of anti-TNF drugs and drug associated antibodies are useful tools in managing patients who fail to respond (primary non-response) or initially respond followed by loss of response (secondary non-response) to treatment. Monitoring drug levels and anti-drug antibodies allows for a personalised approach to drug optimisation by appropriate dose escalation/de-escalation, drug switching/withdrawal, re-introduction after drug interruption, adherence to therapy or confirmation of drug reactions.

Patient preparation / other factors

Trough (pre-dose/pre-infusion) samples are recommended.

Specimen Type

Serum (SST tube or plain) sample is preferred sample. Plasma (Lithium heparin, citrate or EDTA) is also acceptable.

Volume required

Minimum 500 µL

Sample Handling

Centrifuge sample at 3000 rpm for 10 minutes, aliquot serum or plasma and store at 2-8°C until transport.

Storage Conditions

Samples should be stored at 2–8°C. If transport is to be delayed over 5 days please freeze samples at -20°C until dispatch by post.

Address for Sample Transport

Please send samples to:

Synnovis Blackfriars Hub

Central Specimen Reception

41-43 Friars Bridge Court

Blackfriars Road

London

SE1 8NZ

Specimen Transport to Lab

1st Class Post

Assays available (anti-TNF alpha)

Infliximab (Remicade®)

Infliximab biosimilars: Inflectra™, Remsima™, Flixabi™ Zessly™

Adalimumab (Humira®)

Adalimumab biosimilars: Imraldi™, Amgevita™ Idacio™ Hyrimoz™

Assays available but not in routine service

The following assays are not currently in routine service however we hope to expand our repertoire to include them in the near future. In the meantime, analysis can be arranged if required – please contact the laboratory to discuss.

Etanercept (Enbrel®)

Etanercept biosimilars: Eticovo™, Erelzi™

Golimumab (Simponi®)

Vedolizumab (Entyvio®) (anti- α4β7 integrin)

Certolizumab Pegol (Cimzia®)

Ustekinumab (Stelara®) (anti-IL12/23 IgG1 kappa human monoclonal antibody)

Results line/reports

0204 513 7300 / customerservices@synnovis.co.uk

Laboratory contacts for results discussion

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External Quality Control

Infliximab/adalimumab drug and anti-drug antibody assays are in the SKML biologics EQA scheme and the UKNEQAS anti-TNF pilot scheme.

Target Ranges - guidance

Infliximab

Suggested target drug concentrations for intravenous infliximab in the treatment of IBD:

Induction/post-induction:
Week 2 infliximab concentration to target: 20 - 25µg/mL
Week 6 infliximab concentration to target: 15 - 20µg/mL
Week 14 infliximab concentration to target: 7 - 10µg/mL
Maintenance infliximab concentration to target: 5 - 10µg/mL

Important note: Target infliximab concentrations are based on *Cheifetz et al. (2021) and apply only to intra-venous infliximab in inflammatory bowel disease. Therapeutic levels for subcutaneous infliximab have not been established. All therapeutic drug monitoring thresholds are estimates based on population data. Results should always be interpreted in the context of the clinical situation.

*Cheifetz et al, Am J Gastroenterol 2021;116:2014-2025.

Adalimumab

Adalimumab target concentrations:
Induction/post-induction:
Week 4 therapeutic target: 8 – 12µg/mL
Maintenance therapeutic target: at least 8 – 12µg/mL

Important note: Target adalimumab concentrations are based on Cheifetz et al (Am J Gastroenterol 2021; 116:2014-2025) and apply only to inflammatory bowel disease. All therapeutic drug monitoring thresholds are estimates based on population data. Results should always be interpreted in the context of the clinical situation.

Anti-drug antibody reference ranges

Anti-Infliximab antibodies - ≤10 ng/mL

Anti-Adalimumab antibodies - ≤10 ng/mL

Please note, full interpretation requires complete clinical information: drug dosage/frequency, previous exposure to other biologics, time of sampling, duration of therapy and clinical assessment.

Turnaround Time

14 working days. Urgent analysis can be arranged – please contact the laboratory to discuss.

Additional Information/Interpretive comments

Analysis of free anti-drug antibody is provided as a reflex test where clinically indicated, i.e. when anti-TNFα drug result is in the sub-therapeutic range.

Anti-drug antibodies may be neutralising or non-neutralising depending on which part of the anti-TNF drug they are directed against (idiotype or non-idiotype). CLIA assays in routine clinical use are not capable of distinguishing neutralising from non-neutralising anti-drug antibodies. Both neutralising and non-neutralising antibodies will accelerate drug clearance leading to sub-therapeutic drug levels.