Anti-TNFα Drugs (Biologics)

The Reference Chemistry Laboratory at Viapath, Guy's and St Thomas' Hospital is the first to introduce anti-TNFα and anti-drug antibody testing in the UK. Our service is backed by innovative research in collaboration with the Gastroenterology and Dermatology clinical teams at GSTT. The introduction of anti-TNFα drug and anti-drug antibody monitoring may allow clinicians to personalise therapy for better patient care and associated savings on drug costs.

TNFα antagonists (biologic drugs):
NICE guidance makes recommendations about the use of biologic drugs based on clinical and cost-effectiveness. Biologic drugs are recommended for the treatment of inflammatory disease in Rheumatology, Dermatology and Gastroenterology but restricted to patients who have an active, and moderate or severe form of their inflammatory condition, and who have contraindications to or whose condition is not responding to conventional treatments and/or pharmacotherapy.

Infliximab (Remicade®): Infliximab is a TNFα blocker indicated for inflammatory bowel disease (incorporating Crohn's disease and ulcerative colitis), rheumatoid arthiritis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis.

Adalimumab (Humira®): Adalimumab is a TNFα blocker indicated for rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis and Crohn's disease.

Etanercept (Enbrel®): Etanercept is a TNFα blocker indicated for rheumatoid arthritis, spondylitis, psoriatic arthritis, plaque psoriasis, juvenile arthritis and other rheumatic conditions.

Immunogenicity of anti-TNFα drugs:
Biologics are highly effective at inducing and maintaining remission however significant proportion of patients will not respond or will lose response.

- Patients can develop antibodies against the drug which neutralise the therapeutic effect of the anti-TNFα drug.
- Sub therapeutic levels of drug correlate to loss of response
- Measurement of drug and anti-drug antibody levels may aid individualisation of therapy

Clinical indications for measurement* may include:

- Primary treatment failure (non-response)
- Secondary loss of response
- Prediction of infusion reactions
- Adherence to therapy
- Reintroduction after drug interruption

* Please note that clinical validity and utility in psoriasis is not established and is currently subjected to research.

A quick guide to personalising anti-TNFα therapy:
Drug effectiveness based on drug and anti-drug antibody levels and clinical response:

- **Good response** - therapeutic levels of drug and no anti-drug antibody detected
- **Limited clinical response** - sub-therapeutic levels of drug and no anti-drug antibody detected; *consider dose escalation* OR sub-therapeutic levels of drug and high levels of anti-drug antibody detected; *may suggest the drug no longer effective for the patient, consider change anti-TNFα agent although may also be worth considering adding an immunomodulator*
- **No response** - therapeutic levels of drug; *disease activity may not be TNF-dependent and/or symptoms may not be due to active disease, suggest change drug type or look for alternative cause of symptoms*

Please note test interpretation requires full clinical information

Synonyms/ Key words	Infliximab (Remicade®) and Anti-Infiximab Antibodies Adalimumab (Humira®) and Anti-Adalimumab antibodies Etanercept (Enbrel®) and Anti-Etanercept antibodies Certolizumab Pegol (Cimzia®), HACA
Test description	Automated ELISA assay for the simultaneous analysis of both anti-TNFα drug and anti-drug antibody. The assays allows detection of the free anti-TNFα drugs currently prescribed, including Infliximab, Adalimumab, Etanercept and Certolizumab
Laboratory Service	Reference Chemistry, Biochemical Sciences, St Thomas' Hospital
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Clinical Contacts	Ms Zehra Arkir Tel: 020 7188 1253 Email: Zehra.Arkir@viapath.co.uk Mr Nick Unsworth or Mrs Gillian Richards Tel: 020 7188 1264 Email: Gillian.Richards@viapath.co.uk or Nick.Unsworth@viapath.co.uk
Chief Biomedical Scientist	Mark Dunsford Tel: 020 7188 1523
Download Referral Form	Email or call clinical contacts for referral form
Sample required	Serum or plasma sample required. Collect blood into a serum separation (SST™), plain or lithium heparin tube, preferably shortly before drug administration (trough levels for infliximab).
-Additional Information/ Special sample instructions	Centrifuge sample at 3000 rpm for 10 minutes, aliquot serum or plasma and keep in fridge until transport. If transport is going to be delayed over 5 days freeze at -20°C. Post the sample to GSTS by first class post. Minimum 300µL serum or plasma required for both drug and anti-drug antibody analysis.
Turnround Time	< 2 weeks
Interpretation	Tailored interpretation based on clinical history
Call in advance	For Certolizumab requests only. Email or call clinical contacts.
Cost	On application (discounts could be available for significant workloads)