

Therapeutic drug monitoring of anti-TNF α drug levels and antibodies in inflammatory bowel disease: the LISA-TRACKER assay (and alternative technologies identified during scoping)

LISA-TRACKER assays (Theradiag) are enzyme linked immunoassays (ELISAs) for the quantitative determination of anti-tumour necrosis factor-alpha (anti-TNF α) drug levels and antibodies against anti-TNF α . The LISA-TRACKER assays are indicated for use in patients with inflammatory bowel disease that require treatment with anti-TNF α . Infliximab and adalimumab are anti-TNF α currently recommended as treatment options for people with severe active inflammatory bowel disease. Although these therapies bring benefits to many patients with inflammatory bowel disease, a large proportion of patients lose response over time. This loss of response is thought to be due to the formation of antibodies to anti-TNF α drugs, and fluctuations in circulating drug levels. The use of LISA-TRACKER assays would allow clinicians to monitor levels of anti-TNF α drug and antibodies against anti-TNF α in patient sera. This may allow optimisation of a patient's treatment regimen, for example, increasing or decreasing the drug dose, or switching to an alternative anti-TNF α . This could lead to better health outcomes and improved quality of life. The NICE Diagnostics Assessment Programme will assess the clinical and cost-effectiveness of the LISA-TRACKER assays (and alternative technologies identified during scoping) in order to make recommendations on their use in the NHS.