

INFLIXIMAB AND ADALIMUMAB DRUG LEVEL TESTING

Measurement of drug levels for anti-TNF α monoclonal antibodies - Infiximab and Adalimumab

TNF α is a cytokine implicated in the pathogenesis of many systemic autoimmune diseases, including Rheumatoid Arthritis, Crohn's Disease, Ulcerative Colitis, and Psoriasis, amongst others. The use of anti-TNF α biological agents such as infliximab and adalimumab have revolutionised the management of these conditions, and increased the likelihood of achieving meaningful disease control. However, not all patients respond to these agents (primary non-responders), and some individuals may lose response after initial success (secondary loss of response) or have adverse reactions to these agents. Measurement of drug levels may assist in the management of those patients with an inadequate response as those patients with loss of response typically have lower drug levels than those who have maintained a good clinical response. In some patients, loss of response may be due to the development of anti-drug antibodies. In patients with undetectable anti-TNF α drug levels, additional testing for anti-drug antibodies (ADA) may help guide further management decisions.

Dorevitch Pathology is pleased to be able to announce the introduction of therapeutic drug monitoring for two of the most frequently used anti-TNF α monoclonal agents, infliximab and adalimumab. These tests will be performed in-house from November 28th 2016 and will be measured using an enzyme-linked immunosorbant assay (ELISA).

Whilst suggested therapeutic ranges will be reported, it is important to note that this data is largely derived from studies in inflammatory bowel disease and there is only minimal literature available supporting the upper limit of the therapeutic ranges, especially for adalimumab. These therapeutic ranges are only applicable for trough samples. In order to allow appropriate application of therapeutic ranges and to ensure appropriate test selection, testing will only be performed on samples where the specific anti-TNF α drug is specified.

Billing

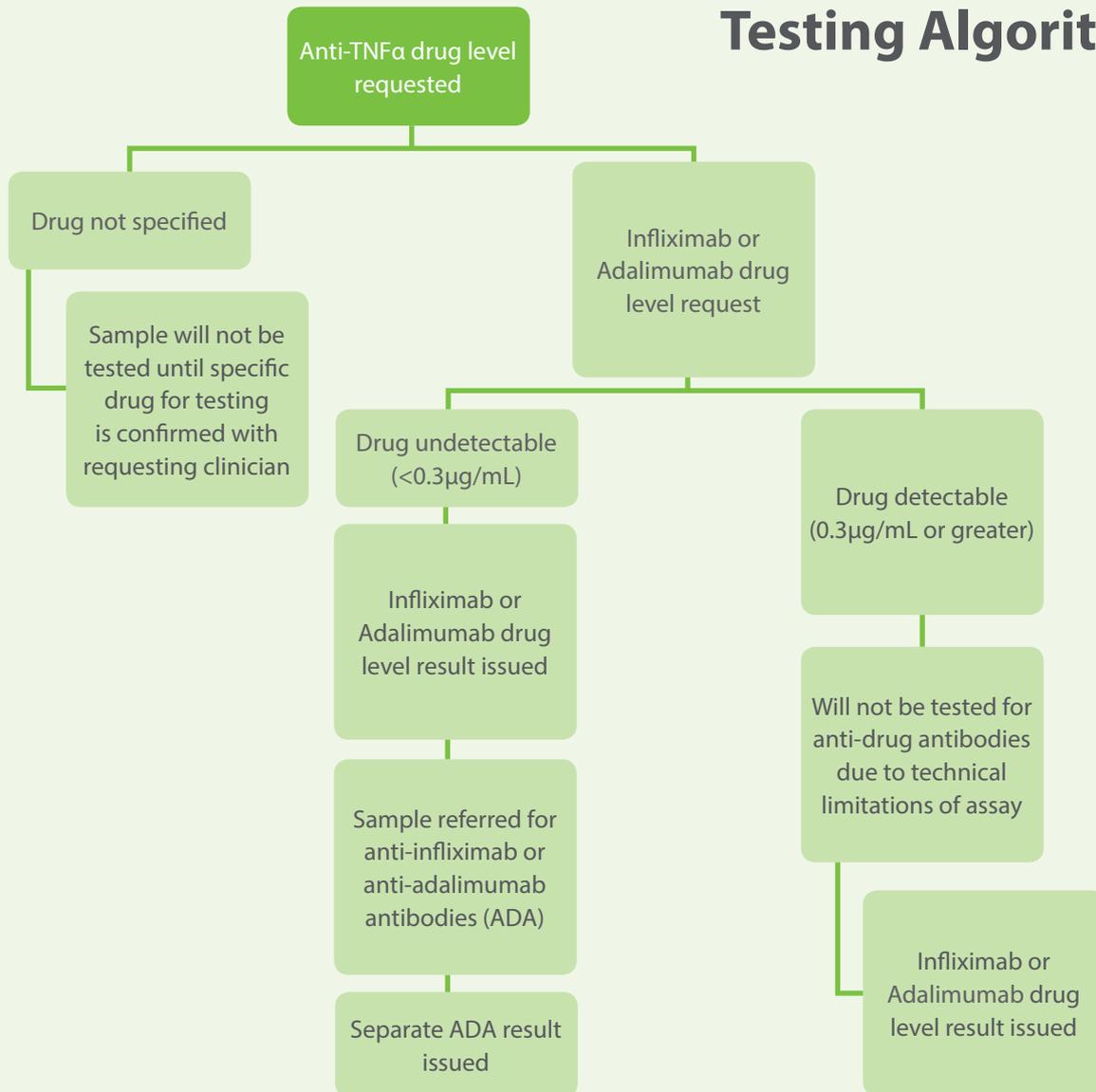
There is currently no medicare rebate available for this test and therefore all requests will be privately billed.

Testing algorithm

All samples with an undetectable infliximab or adalimumab level will automatically undergo testing for ADA. Testing for ADA will be undertaken at an external laboratory, and a separate report will be issued for this test.

Due to technical limitations of the assay methodology, anti-TNF α blocking antibodies are unable to be testing in samples with a detectable drug level (i.e. 0.3 μ g/mL or above). This includes samples within the subtherapeutic range (see over page).

Testing Algorithm



Request:

Infliximab or Remicade drug levels

Additional information required:

Date and time of last dose

Sample type: Serum

Container: SST 8.5mL (BD Vacutainer)

Reported as: $\mu\text{g/mL}$

Reference interval: $<3\mu\text{g/mL}$ Subtherapeutic
 $3-7\mu\text{g/mL}$ Therapeutic
 $>7\mu\text{g/mL}$ Suprathereapeutic

Billing: This test does not currently attract a Medicare rebate and patients will incur an out-of-pocket charge for this test.

Request:

Adalimumab or Humira drug levels

Additional information required:

Date and time of last dose

Sample type: Serum

Container: SST 8.5mL (BD Vacutainer)

Reported as: $\mu\text{g/mL}$

Reference interval: $<4.9\mu\text{g/mL}$ Subtherapeutic
 $4.9-8\mu\text{g/mL}$ Therapeutic
 $>8\mu\text{g/mL}$ Suprathereapeutic

Billing: This test does not currently attract a Medicare rebate and patients will incur an out-of-pocket charge for this test.

For further enquiries regarding these tests, please contact Immunopathology on 03 9244 0286

Dr Katherine Nicholls, Head of Immunopathology