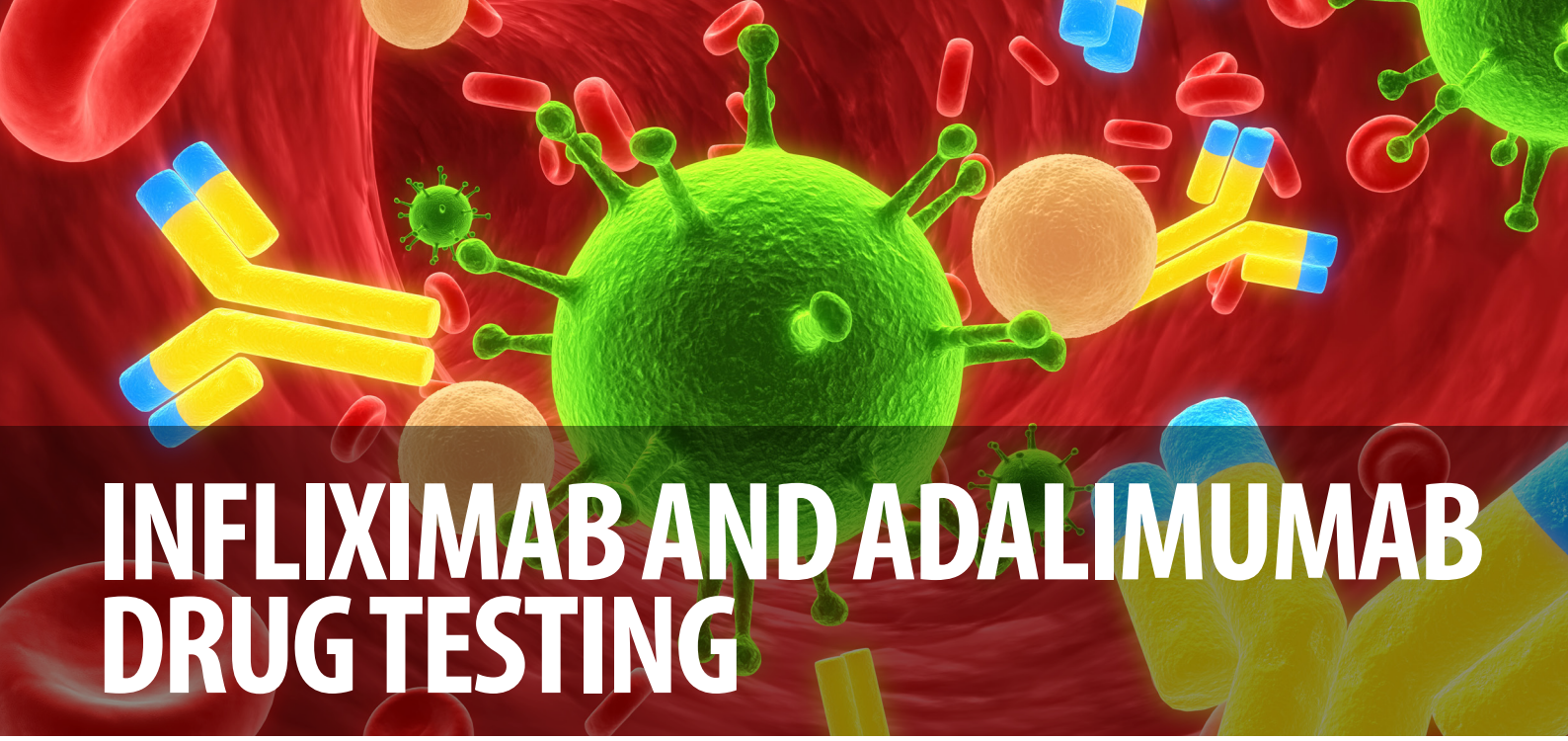


INFLIXIMAB AND ADALIMUMAB DRUG TESTING

Measurement of drug levels for anti-TNFα monoclonal antibodies - Infliximab and Adalimumab

TNFα 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-TNFα 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 patients with an inadequate response, as those 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-TNFα drug levels, additional testing for anti-drug antibodies (ADA) may help guide further management decisions.

Dorevitch Pathology is pleased to be able to announce that therapeutic drug monitoring for two of the most frequently used anti-TNFα monoclonal agents, infliximab and adalimumab **will now be bulk billed.** These tests are performed in-house using an enzyme-linked immunosorbant assay (ELISA) with a turn around time of 1-2 weeks for levels.

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 to 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-TNFα drug is specified.

Billing

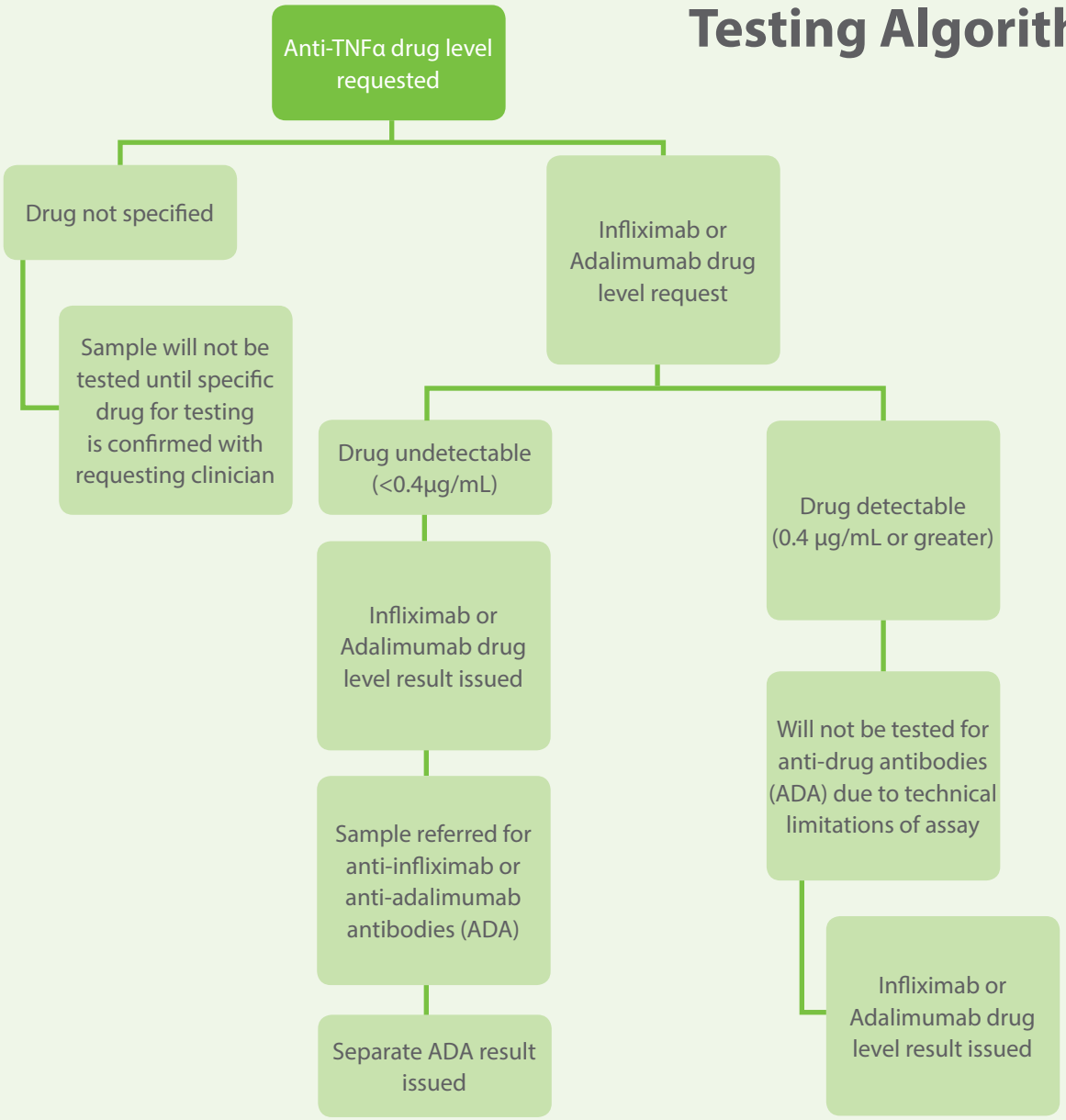
Tests for infliximab or adalimumab will be bulk billed, and any additional antibody testing will come at no cost.

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 further report will be issued for this test. There are no additional charges if ADA testing is required.

Due to technical limitations of the assay methodology, anti- TNFα blocking antibodies are unable to be tested in samples with a detectable drug level (i.e. 0.4µg/mL or above). This includes samples within the subtherapeutic range (see over page).

Testing Algorithm



Request:

Specific information required (or testing may not be performed):

- **Drug name** (Infliximab or Remicade, Inflectra, Adalimumab or Humira)
- **Date and time of last dose**
- **Weight of patient (kg)**
- **Dose (mg)**
- **Age of patient (years)**
- **Condition** (e.g. Crohn's disease, ulcerative colitis)
- **Indication for testing** (Induction, Maintenance in remission, or Maintenance loss of response)

Sample type:	Serum
Container:	SST 8.5mL (BD Vacutainer)
Reported as:	µg/mL
Reference interval:	
Infliximab:	<3µg/mL Subtherapeutic
	3-7µg/mL Therapeutic
	>7µg/mL Supratherapeutic
Adalimumab:	<4.9µg/mL Subtherapeutic
	4.9-8µg/mL Therapeutic
	>8µg/mL Supratherapeutic
Billing:	MBS rebateable

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

Specialist Diagnostic Services, ABN 84 007 190 043 APA No. 000042, trading as Dorevitch Pathology. DP0562V3 25.09.20