Why measure infliximab (IFX) drug levels and antibodies to infliximab (ATI)?

Evidence from the Inflammatory Bowel Disease literature

1. To examine the reason for loss/lack of response to treatment and determine subsequent management.
2. To optimize dose to give the best chance of remission whilst reducing the risk of adverse effects.

Testing algorithm and suggested interpretation for the scenario of loss/lack of response to treatment

ATI will only be performed if IFX is <2 mg/L

The presence of IFX in concentrations >2 mg/L interferes with the detection of ATI therefore ATI will not be performed if the drug level is higher than this. The ATI will be automatically performed if the IFX level is <2 mg/L.
Consent to charges for testing

**Infliximab (IFX) level**

If this is the only test which is performed, there will be no charge over Medicare (no gap). This test is performed at a loss to the laboratory. However, testing will not begin without consent in advance to the charge for ATI testing, if required (see below).

**Antibodies to infliximab (ATI)**

ATI are NOT covered by the Medicare benefits schedule (MBS).

There will be a charge (currently $140) for ATI if this test is deemed to be required according to the algorithm above.

… Except Inflectra

However, if the brand of infliximab called Inflectra has been prescribed, no payment is required. Testing is provided (IFX level and ATI if required) as part of the distributor’s care program for patients receiving Inflectra.

No consent form is required in this case.

**Specimen requirement**

5 ml blood in a serum tube will be sufficient for both tests. The serum sample should be kept refrigerated.

**References and further reading**


Department of Immunology, Sydney South West Pathology Service (Liverpool Hospital)

Supervising Immunologist: Dr Catherine Toong

Phone: (02) 8738 5068 (laboratory)

Specimen reception: Cnr Campbell & Forbes St, Liverpool, NSW 2170. Ph: (02) 8738 5045. Fax: (02) 8738 9465
### Site of Collection
- [ ] Liverpool
- [ ] Bankstown
- [ ] Campbelltown
- [ ] Camden
- [ ] Fairfield
- [ ] Bowral

### PATIENT DETAILS
- **Patient Identifier (MRN):**
- **Date of Birth:** ...
- **Sex:** M/F
- **Surname:**
- **First name:**
- **No. and Street:**
- **Suburb / Town:**
- **Post Code:**
- **Ward/Clinic:**
- **Account Address [if different from above]:**

### TESTS REQUESTED
- **Tests:**
  - Inflliximab trough level and antibodies (SSWPS Liverpool)
  - [ ] Inflectra
  - [ ] Remicade/other brand – Attach consent form
  - **Dose:**
  - **Interval:**

### CLINICAL NOTES
- **Indication for testing:**
- **Loss of response:**
- **Other (e.g. adverse drug reaction):** specify:
- [ ] Clinical: CDAI
- [ ] Biochemical: CRP
- [ ] Faecal calprotectin
- [ ] Endoscopic recurrence
- [ ] Recurrence on imaging

### MEDICARE ASSIGNMENT
- **Patient's Signature:**
- **Medicare Number:**
- **Date:** ...

### COLLECTION DATE
- **EDTA:**
- **CIT:**
- **PLAIN:**
- **HEP:**
- **FLUOR:**
- **PY EDITA:**
- **URINE SPOT:**
- **CSF:**
- **FAECES SPOT:**
- **3 DAY:**
- **SWAB:**
- **SPUTUM:**
- **BC:**
- **SLIDE:**
- **HIST FORMALIN:**
- **OTHER:**
- **CHECKED BY:**

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**Oracle number:** xxxxxx
Patient Consent for Non Rebateable (nonmbs) Test/s

Please print all details clearly

I ________________________ (Patient name) understand that my medical practitioner has requested a pathology test(s) that are not covered by Medicare Australia, Department of Veteran Affairs or a private health fund.

I understand that I will receive an invoice from Sydney South West Pathology Service or another pathology service depending on the test performed.

I agree to accept all responsibility for any out of pocket expenses for the test(s) as requested.

Signature: _________________________ Date: ____________ Amount: $_____.

<table>
<thead>
<tr>
<th>Test</th>
<th>Description</th>
<th>Cost</th>
<th>Required</th>
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<tbody>
<tr>
<td>N02085</td>
<td>ADH (Vasopressin) – MBS Unlisted Hormone Test</td>
<td>$30.70</td>
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<tr>
<td>N02085</td>
<td>Adiponectin – MBS Unlisted Hormone Test</td>
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<td>N05235</td>
<td>Allergy Array – Allergen Component Microarray</td>
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<td>N05305</td>
<td>Antibodies to infliximab (Remicade)</td>
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<td>N02051</td>
<td>Apolipoprotein A1</td>
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<td>N02050</td>
<td>Apolipoprotein E Genotype</td>
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<td>N02010</td>
<td>Bile Acids – Miscellaneous Fluid</td>
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<td>N02010</td>
<td>Bile Acids (If not pregnant or limit 3 reached)</td>
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<td>N09012</td>
<td>Carbohydrate Deficient Transferrin</td>
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<td>Cholinesterase Genotyping Screen – BCHE Butyrylcholinesterase</td>
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<td>Interleukin 6 (IL6)</td>
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<td>VLDL Triglycerides (Ultracentrifuged)</td>
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Price list as at 31 March 2016 (Prices are subject to change)