WCC and NC Range Action
WCC ≥3.5 x 10⁹/L and NC ≥ 2.0 x 10⁹/L Clozapine therapy can continue or be titrated upwards as required
WCC 3.0-3.5 x 10⁹/L and/or NC 1.5-2.0 x 10⁹/L Requires increasing frequency of monitoring; to twice weekly
WCC<3.0 x 10⁹/L and/or NC < 1.5 x 10⁹/L STOP clozapine immediately and repeat blood test within 24 hours. Contact Consultant Psychiatrist and arrange urgent medical review.

Specific instructions for completing clozapine participant protocol - white cell
If the participants blood results fall within the upper range (as indicated in the table above) please follow these instructions:
- Participants on a weekly/monthly protocol should continue to have their clinical review observations documented on their current form (either Clozapine Commencement Form, Clozapine Participant Protocol - Weekly or Clozapine Participant Protocol - Recommended as required)
- Continue twice weekly white cell (WCC) and neutrophil (NC) counts until either:
  - WCC ≥ 3.0 x 10⁹/L and NC ≥ 2.0 x 10⁹/L - Resume pre-interruption monitoring protocol
  - and/or NC < 1.5 x 10⁹/L - Cease clozapine and commence red range monitoring protocol immediately

Specific instructions for completing clozapine participant protocol - neutrophil
If the participants blood results fall within the upper range (as indicated in the table above) please follow these instructions:
- Contact consultant psychiatrist
- Cease clozapine immediately
- Repeat white cell (WCC) and neutrophil (NC) counts within 24 hours
- Notify consultant haematologist of the clozapine manufacturer’s protocol
- Continue daily white cell (WCC) and neutrophil (NC) counts until either:
  - 1. WCC ≥ 3.0 x 10⁹/L and NC ≥ 1.5 x 10⁹/L - proceed with twice weekly blood monitoring until
  - 2. WCC ≥ 3.5 x 10⁹/L and NC ≥ 2.0 x 10⁹/L - proceed with weekly blood monitoring for four (4) weeks
- Clozapine must not be restarted unless authorised by the clozapine manufacturer’s consultant haematologist.

General instructions for completing clozapine management forms
- This form is designed for medical officers to document the results of tests required for the monitoring of local clozapine coordinator for more information.
- Doctors prescribing clozapine must be registered with the monitoring provider (refer to your
- The full completion of this form is the minimum requirement for all participants prescribed clozapine under the TGA endorsed clozapine management protocols. More intensive monitoring may be required as clinically indicated or under individual local health network protocols.
- All entries must be completed with a date, signature, name, designation and time
- Incomplete entries are not valid; all losses in each section must be completed and each section signed off.
- Plans for dealing with abnormal results should be documented in the medical record.
- Please use the comments section (in the box on the right side of this form) to indicate blood tests out of the normal range e.g. WCC range, amber range.

Cardiac Monitoring Guidelines
- Weekly monitoring for 6 weeks or as long as symptoms persisted.
- For 1st 28 days At all times Educate participants and carers to report flu-like symptoms, GI upsets, dizziness or chest pain.
- First 28 days At all times Educate participants and carers to report flu-like symptoms, GI upsets, dizziness or chest pain.
- For echocardiogram review register:
- Cardiac Monitoring Guidelines
- Urgent echocardiography.:
- RESULTS ENTERED INTO THE RELEVANT CLOZAPINE MANUFACTURER’S DATABASE BY CENTRE PERSONNEL OR ONTO A PAPER BLOOD COUNT FORM WHICH IS THEN FAXED TO PHARMACY.
- Medication dispensed by pharmacist after they review the blood results and prescription
- Results entered into the relevant clozapine manufacturer’s database by centre personnel or onto a paper Blood Count Form which is then faxed to pharmacy
- If applicable, a completed paper Blood Count Form should be attached to the clozapine manufacturer’s consumer monitoring database provider.
- If a blood count is not received by the clozapine manufacturer’s database provider within 48 hours after the blood due date; an alert will be generated by the clozapine database provider and an appropriate letter faxed & emailed to the Centre Co-ordinator, the Medical Officer and the Pharmaceutical who signed the most recent Blood Count Form.
- If the participant has discontinued clozapine for any reason or there has been any therapy interruption greater than 72 hours, white cell count should be fast to the clozapine manufacturer database provider.

Monitoring requirements for participants prescribed clozapine
In order to comply with the TGA endorsed clozapine protocol, it is imperative that:
- The Medical Officer reviews the current white cell (WCC) and neutrophil counts before writing a clozapine prescription.
- The participant is clinically assessed for signs and symptoms of infection before being given a clozapine prescription.
- White cell counts and prompted weekly for the first 28 days and then every 28 days thereafter providing results remain in the green range (WCC 3.0-5.0 x10⁹/L and neutrophil count > 2.0 x10⁹/L).
- The decision to move a participant with normal neutrophils monitoring to 4-weekly monitoring should be guided by the clozapine manufacturer’s Consultant Haematologist.

Serum clozapine level register (Refer to complete results in medical record under investigations)
- Refers to serum clozapine levels which are required if the participant is pharmacologically at risk of serious side effects. There are also additional monitoring requirements depending on the period of interruption. See table below.

<table>
<thead>
<tr>
<th>Date of ECG Test</th>
<th>Date test results reviewed</th>
<th>Time test results reviewed</th>
<th>Reviewed by Signature</th>
<th>Reviewed by Name (please print)</th>
<th>Reviewed by Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>/ / /</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of echocardiogram test</th>
<th>Date test results reviewed</th>
<th>Time test results reviewed</th>
<th>Reviewed by Signature</th>
<th>Reviewed by Name (please print)</th>
<th>Reviewed by Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>/ / /</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of clozapine test</th>
<th>Date test results reviewed</th>
<th>Time test results reviewed</th>
<th>Results</th>
<th>Reviewed by Signature</th>
<th>Reviewed by Name (please print)</th>
<th>Reviewed by Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>/ / /</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# CLOZAPINE INVESTIGATION REVIEW & PRESCRIPTION RECORD

**MR75D**

**Hospital/site:** ..................................................

**Date bloods taken** | **Date bloods reviewed** | **Time bloods reviewed** | **Type of test** | **Results** | **Comments** | **Prescription written** | **Number of days** | **Dose (mg)** | **Signature** | **Name (please print)** | **Designation**
--- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | ---
| | | | | | | | | | | | | |

**Precription Number**

- Number of days
- Dose (mg)
- Signature
- Name (please print)
- Designation

**Normal ranges for blood testing**

- **Fasting lipids**
  - **Cholesterol**
    - Adult: <5.3 mmol/L
    - 0 - 18 years: <4.5 mmol/L
  - **LDL**
    - Adult: <3.7 mmol/L
    - 2 - 18 years: <2.9 mmol/L
  - **HDL**
    - Male: 0.9 - 2.0 mmol/L
    - Female: 1.0 - 2.2 mmol/L
    - 2 - 18 years: 1.0 - 1.92 mmol/L

- **Triglycerides**
  - Adult: <1.7 mmol/L
  - 0 - 18 years: <1.9 mmol/L
  - 0 - 18 years: <4.5 mmol/L

- **Troponin T**
  - Myocardial damage indicated & Troponin T > 100 ng/mL.
  - Any detectable troponin is a risk factor for future cardiac events.

- **Fasting glucose**
  - 0 - 3 months: Fast or non-fasting: 2.6 - 7.0 mmol/L
  - 3 months - 15 years: Fast: 3.0 - 5.5 mmol/L
  - 15 years - adults: Fast: 3.2 - 5.5 mmol/L

**Clozapine level**

- 500 - 600 ug/mL (12 hour trough)

**PLEASE NOTE:** While the therapeutic serum clozapine range is advised to be 350-600 mg/mL for some participants the range required for beneficial therapy can be in the upper range of this level. At these levels discussion with a psychiatrist and careful monitoring for dose related side effects is advised.

**Waiver of Necessity for Clozapine therapy**

- Requires increasing frequency of monitoring, upwards as required
- Clozapine therapy can continue or be titrated
- Requires increasing frequency of monitoring, in 14 day window
- STOP clozapine immediately and repeat blood test
- Consult treating psychiatrist
- Consult Clozapine Psychiatric or endocrinology service

**Please note these ranges are an SA Pathology guide only and may change depending on the laboratory used.

**WCC and NC**

- **WCC <3.0 x 10⁹/L and/or NC <1.5 x 10⁹/L**
- **WCC >3.0 x 10⁹/L and/or NC >1.5 x 10⁹/L**

**Clozapine therapy can be in the upper range of this level.

**Ranges and Action**

- **GREEN**
  - WCC and NC Range
  - WCC <3.0 x 10⁹/L and/or NC <1.5 x 10⁹/L
  - WCC >3.0 x 10⁹/L and/or NC >1.5 x 10⁹/L

- **AMBER**
  - WCC >3.0 - 4.0 x 10⁹/L and/or NC >1.5 - 1.9 x 10⁹/L
  - WCC >4.0 - 6.0 x 10⁹/L and/or NC >1.9 - 2.4 x 10⁹/L

- **RED**
  - WCC >4.0 - 6.0 x 10⁹/L and/or NC >2.4 - 3.0 x 10⁹/L
  - WCC >6.0 x 10⁹/L and/or NC >3.0 x 10⁹/L

**Blood test Normal Range**

- **C-Reactive Protein (CRP)**
  - 0 - 10 mg/L

**Adverse Event Protocols for Management**

- STOP Clozapine immediately and repeat blood test
- Consult treating psychiatrist
- Consult Clozapine Psychiatric or endocrinology service
- Requires increasing frequency of monitoring, in 14 day window

**CAUTION: increases in WCC range may indicate a sepsis related event**