Fully subsidised genomic testing for patients with CLL

As a result of the generous philanthropic funding provided to establish the Wilson Centre for Lymphoma Genomics, the Molecular Haematology Laboratory at the Peter MacCallum Cancer Centre is pleased to be able to provide fully subsidised TP53 and IGHV mutation testing for patients with chronic lymphocytic leukaemia (CLL) over the period commencing 16 April 2018 until 30 June 2021.

The most important molecular considerations for treatment strategy in patients with untreated CLL are TP53 status (*i.e.* wildtype or inactivated by either deletion (del(17p)) or mutation) and IGHV mutation status (*i.e.* mutated or unmutated). As a result, testing of TP53/IGHV mutational status is now recommended as part of standard-of-care in patients with CLL (Hallek et al., Blood, 2018).

TP53 inactivation (by deletion or mutation) is associated with inferior outcomes when treated with fludarabine, cyclophosphamide and rituximab (FCR) chemoimmunotherapy. However, these patients may have improved outcomes when treated with novel agents (such as BTK inhibitors or BH3-mimetic agents) that may be accessible through clinical trials or compassionate access. By contrast, the absence of del(17p)/TP53 mutation combined with a mutated IGHV sequence is generally associated with favourable outcomes and long-term remissions with FCR therapy.

By providing fully subsidised TP53 and IGHV mutation testing we hope to support patients with CLL to attain the most appropriate upfront treatment.

Patient eligibility

To be eligible patients must:

- be aged < 70
- have a diagnosis of CLL meeting conventional criteria for treatment
- have no known del(17p) by cytogenetics or FISH (or TP53 mutation)
- not have been previously treated for CLL and are being considered for chemoimmunotherapy

Testing

5-10 ml of peripheral blood in EDTA should be sent to the Peter MacCallum Cancer Centre with this completed form. A report will be issued to the referring haematologist within four weeks. Genetic tests do not distinguish between somatic and germline variants. Germline variants with significant implications for both the patient and their family may be detected. Please ensure that you and your patient understand this possibility before testing is requested. **Please note, del(17p) testing is not included and should be requested separately.**

Patient details:		**Requesting haematologist details:**
☐ **Patient eligible (see criteria above)**		Name:
		Hospital/Lab:
Surname:	❑ M ❑ F	Provider no:
First name:	DOB:	Report to (fax or email):
Address:		
		Signature: Date: __/__/____
Clinical notes:		**Send sample to:**
		Pathology – Specimen Reception (Level 4) **Peter MacCallum Cancer Centre** **305 Grattan Street** **MELBOURNE VIC 3000**