PD-L1 and Molecular Testing for Solid Tumours

Ancillary Testing for a number of solid tumour and haematological malignancies.

PD-L1 Testing for Solid Tumours

SCL has five experienced pathologists trained in reading PD-L1 immunohistochemistry since June 2017. The indications in New Zealand (as of April 2021) according to the checkpoint inhibitor and type of malignancy are summarised as follows (including the scoring system and cut-off points):

	Pembrolizumab (Keytruda)			Atezolizumab (Tencentriq)		
Malignancy	SP263 (Ventana) or 22C3 (Dako)			SP142 (Ventana)		
NSCLC	TPS ≥ 50%	TPS 1-49%	TPS < 1%	TC ≥ 50% or IC ≥ 10%	TC or IC ≥ 1%	TC or IC < 1%
	22C3 (Dako)					
TNBC	CPS ≥ 10		CPS <10	IC ≥ 1%		IC < 1%
UC	CPS ≥ 10		CPS <10	IC ≥ 5%		IC < 5%
HNSCC	CPS ≥ 20	CPS 1-20	CPS < 1			

Key: Non-Small Cell Lung Cancer (NSCLC); Triple-Negative Breast Cancer (TNBC); Urothelial Carcinoma (UC); Head and Neck Squamous Cell Carcinoma (HNSCC); Tumour Proportion Score (TPS) = Tumour Cells (TC); Immune Cells (IC); Combined Positive Score (CPS)

- Combined Positive Score (CPS) is available for the following indications: Gastric Carcinoma, Oesophageal Carcinoma, Cervical Carcinoma and others
- For other indications and enquiries, please contact: Dr Michael Lau (michael.lau@sclabs.co.nz; 03-4748322) or Dr Martha Nicholson (martha.nicholson@sclabs.co.nz: 03-4748319)

Methodology

PD-L1 immunohistochemistry (performed on FFPE sections using Roche clone SP263 or SP142 using Ventana Optiview DAB detection system). Note: Agilent clone 22C3 using Dako Autostainer Link 48 is currently the only validated clone for PD-L1 CPS testing and harmonization data with other antibodies is in progress. The Roche clone, however has excellent comparison data (and is validated) in the setting of NSCLC.

Referral and sample requirements

Please ask source pathology laboratory to send the below:

1. 4x slides of 4 micron sections placed at the upper end of coated slides undried (freshly cut FFPE tissue - 100 cells required)

2. Copy of the original pathology report from source laboratory (including specimen type, date and time collected, laboratory specimen number)

3. PD-L1 request form completed by the referring oncologist

All request forms are at https://www.sclabs.co.nz/index.php/clinicians/oncol)

- For atezolizumab (Tencentriq) NSCLC, TNBC, UC (please note that a payment form is not required): use PD-L1 (SP142) Request Form
- For pembrolizumab (Keytruda) NSCLC, UC, HNSCC (please note that a payment form is not required): use MSD PTPAP (PD-L1 Lung Cancer Request Form)
- For pembrolizumab (Keytruda) TNBC: a payment form is required use PDL1 CPS Request Form AND SCL Biomarker Consent & Payment Form
- For other indications, a payment form is required: use PDL1 CPS Request Form AND SCL Biomarker Consent & Payment Form

Expected turnaround time: 2 working days upon receipt of sample. Results will include referral cut-off points.

Address: Anatomical Pathology - Level 2 Southern Community Laboratories Ltd (Dunedin), Plunket House 472 George Street, Dunedin, 9016

Molecular Testing for Solid Tumours

SCL has evaluated and validated the Biocartis Idylla analyser for the following indications:

- Lung adenocarcinoma: EGFR
    - This is reflexively followed by ALK D5F3 immunohistochemistry
- Metastatic melanoma: BRAF
- Metastatic colorectal adenocarcinoma: KRAS/BRAF/NRAS

For enquiries, please contact:

Jenny Grant, HoD, Molecular Pathology (jenny.grant@sclabs.co.nz; 03-470 2934)
Dr Michael Lau (michael.lau@sclabs.co.nz; 03-4748322)

Methodology

Lung adenocarcinoma: EGFR

The Biocartis Idylla ™ EGFR Mutation test detects the presence of 53 somatic mutations in exons 18-21 of the *EGFR* proto-oncogene (G719A/C/S, deletions in exon 19, T790M, S768I, insertions in exon 20, L858R, and L861Q). The Biocartis Idylla ™ EGFR Mutation Test is able to detect allelic frequencies at: ≤ 5% for deletions in exon 19, T790M, S768I, insertions in exon 20, L858R, and L861Q or ≤ 10% for G719A/C/S.

Metastatic melanoma: BRAF

The Biocartis Idylla ™ BRAF Mutation test which detects the presence of V600E/E2/D and V600K/R/M mutations in codon 600 of the *BRAF* gene. The Biocartis Idylla ™ BRAF Mutation Test is able to detect 1% mutant in wild type background.

Metastatic colorectal adenocarcinoma: KRAS/NRAS/BRAF

The Biocartis Idylla ™ KRAS Mutation test detects mutations in exons 2, 3, and 4 (codons 12, 13, 59, 61, 117, and 146) of the *KRAS* oncogene at allelic frequencies ≤ 5%.
The Biocartis Idylla ™ NRAS-BRAF Mutation test detects mutations in codons 12, 13, 59, 61, 117, 146 of the *NRAS* gene and in codon 600 of the *BRAF* gene at the following allelic frequencies: ≤ 5% in codons 12 and 61 of the *NRAS* gene, and in codon 600 the *BRAF* gene; ≤ 10% in codons 13, 59, and 117 of the *NRAS* gene and; ≤ 15% in codon 146 of the *NRAS* gene.

Referral and sample requirements

Pathology laboratory to send the below:

1. FFPE tissue block of tumour
2. Copy of the original pathology report from source lab (including specimen type, date and time collected, laboratory specimen number)
3. Request form completed by referring oncologist.
   https://www.sclabs.co.nz/index.php/clinicians/oncol
4. Consent & Payment form *(Please note that EGFR +/- ALK D5F3 is funded through the District Health Boards and a payment form is not required)*
   https://www.sclabs.co.nz/index.php/clinicians/oncol

Address: Anatomical Pathology - Level 2 Southern Community Laboratories Ltd (Dunedin), Plunket House 472 George Street, Dunedin, 9016

Expected turnaround time: 2-3 working days upon receipt of sample. Results will include the following:

- Lung adenocarcinoma:
    - EGFR: Type of mutation detected or Mutation not detected or Insufficient sample
    - ALK D5F3 immunohistochemistry: Positive or Negative staining
- Metastatic melanoma:
    - BRAF: Type of mutation detected or Mutation not detected or Insufficient sample
- Metastatic colorectal adenocarcinoma:
    - KRAS/BRAF/NRAS: Type of mutation detected or Mutation not detected or Insufficient sample