

PD-L1 and Molecular Testing for Solid Tumours

Southern Community Laboratories (SCL) has been offering 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 for the following indications:

- Non-Small Cell Lung Cancer (NSCLC) since June 2017 using Tumour Proportion Score (TPS)
- Triple-Negative Breast Cancer (TNBC) since July 2019 using Immune Cells (IC) score
- Combined Positive Score (CPS) for the following indications: Urothelial Carcinoma (UC), Gastric Carcinoma (GC) and Head and Neck Squamous Cell Carcinoma (HNSCC)
- For other indications and enquiries, please contact:
Dr Michael Lau (michael.lau@sclabs.co.nz; 03-4748322)
Dr Martha Nicholson (martha.nicholson@sclabs.co.nz; 03-4748319)

Methodology

PD-L1 immunohistochemistry (performed on FFPE sections using Roche clone SP263 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

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 lab (including specimen type, date and time collected, laboratory specimen number)
3. PD-L1 request form completed by referring oncologist.
<https://www.sclabs.co.nz/index.php/clinicians/oncol>
NSCLC: form through MSD (DPOC.NZ@merck.com)
TNBC: <https://www.sclabs.co.nz/index.php/clinicians/oncol>
Other indications: <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

SCL Biomarker Consent and payment form

<https://www.sclabs.co.nz/index.php/clinicians/oncol>

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

- NSCLC: TPS including referral cut-off points
- TNBC: IC including referral cut-off points
- UC, GC, HNSCC: CPS including referral cut-off points
- Other indications; dependent on tumour type

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; 03-4733034)

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>

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Consent and payment form

<https://www.sclabs.co.nz/index.php/clinicians/oncol>

(Please note that EGFR +/- ALK D5F3 is funded through the District Health Boards and a payment form is not required)

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