

BIOMARKER INFORMATION SHEET

PD-L1 testing for Solid Tumours

Awanui Labs has four experienced pathologists trained in reading PD-L1 immunohistochemistry since June 2017. The indications in New Zealand (as of January 2026) according to the type of malignancy are summarised as follows (including the scoring system and cut-off points as per registrational trial).

Malignancy	Registrational trial	Cut-off points	
Non-small cell lung cancer	KEYNOTE-042; IMPower 010	TPS \geq 1%	TPS < 1%
	KEYNOTE-024	TPS \geq 50%	TPS < 50%
Metastatic Triple negative breast cancer	KEYNOTE 355	CPS \geq 10	CPS < 10
Metastatic or recurrent Head and neck squamous cell carcinoma (mucosal origin)	KEYNOTE 048	CPS \geq 1	CPS < 1
Metastatic Cervical cancer	KEYNOTE 158	CPS \geq 1	CPS < 1
Metastatic Gastric or OGJ adenocarcinoma	KEYNOTE 811, KEYNOTE 859	CPS \geq 1	CPS < 1
	Checkmate 649	CPS \geq 5	CPS < 5
	RATIONALE-305	TAP \geq 5%	TAP < 5%
Metastatic Oesophageal squamous cell carcinoma	KEYNOTE 590	CPS \geq 10	CPS < 10
	Checkmate 648	TPS \geq 1%	TPS < 1%
	RATIONALE-306	TAP \geq 5%	TAP < 5%

TPS (Tumour Proportion Score); CPS (Combined Positive Score); TAP (Tumour Area Positivity)

March 2026 update: with the anticipated MedSafe approval of tislelizumab, TAP as per the RATIONALE trials has been added for Metastatic Gastric or OGJ adenocarcinoma and Metastatic Oesophageal squamous cell carcinoma.

Please note that Health New Zealand only funds testing for non-small cell lung cancer, Metastatic Triple negative breast cancer and Metastatic or recurrent Head and neck squamous cell carcinoma (mucosal origin). All other indications require patient consent and payment.

For other indications not listed above and enquiries, please contact: Dr Michael Lau (michael.lau@awanuilabs.co.nz 03-474 8322) or Dr Martha Nicholson (martha.nicholson@awanuilabs.co.nz, 03-474 8319) or Dr Cody Ross (cody.ross@awanuilabs.co.nz)

Methodology

PD-L1 immunohistochemistry is performed on FFPE sections using Roche clone SP263 (TPS) or Dako clone 22C3 (CPS)

Referral and sample requirements

Please ask the source pathology laboratory to send the following:

- FFPE tissue block of tumour
NOTE: cytology (including cell blocks) and decalcified samples are NOT suitable for CPS; A minimum of 100 cells on tissue section is required
- Copy of the original pathology report from source laboratory (including specimen type, date and time collected laboratory specimen number)
- The Awanui Biomarker Request Form completed by the referring oncologist (NOTE: Biomarker Consent and Payment Form may be required according to the indication listed on the form)
To: Anatomical Pathology – Level 2
Awanui Laboratories (Dunedin) - Plunket House
472 George St, Dunedin 9016

Expected turnaround time: 2-3 working days upon receipt of sample in Awanui Labs (Dunedin).

Molecular testing for Solid Tumours

Awanui Labs has evaluated and validated the Biocartis Idylla analyser (and accompanying immunohistochemistry) for the following Health New Zealand approved indications:

- **Non-squamous Non-small cell lung cancer:** *EGFR* mutation analysis, and **PD-L1** immunohistochemistry followed by **ALK (D5F3 clone)** and **ROS1 (SP384 clone)** immunohistochemistry if no *EGFR* mutations are detected. If **ROS1 (SP384 clone)** immunohistochemistry shows a positive reaction, confirmatory molecular testing will then be performed, and a supplementary report will be subsequently issued.
- **Metastatic left-sided Colorectal Carcinoma:** *KRAS/BRAF/NRAS* mutation analysis plus **HER2 (4B5 clone)** immunohistochemistry
- **Metastatic Melanoma (stage III/IV):** *BRAF* mutation analysis.

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Methodology

Molecular testing (PCR; polymerase chain reaction) is performed on FFPE sections using the Biocartis analyser. HER2 immunohistochemistry is performed on FFPE sections using Roche clone 4B5.

Referral and sample requirements

Please ask the source pathology laboratory to send the following:

1. FFPE tissue block of tumour
NOTE: decalcified samples are NOT suitable for molecular testing
2. Copy of the original pathology report from source laboratory (including specimen type, date and time collected laboratory specimen number)
3. The Awanui Biomarker Request Form completed by the referring oncologist

To: Anatomical Pathology – Level 2
Awanui Laboratories (Dunedin)
Plunket House
472 George St
Dunedin 9016

Expected turnaround time: 2-5 working days upon receipt of sample in Awanui Labs (Dunedin).