BIOMARKER INFORMATION SHEET

(Update November 2026)

PD-L1, claudin 18.2, FOLR1 immunohistochemistry testing for Solid Tumours

Awanui Labs has four experienced pathologists trained in reading oncology biomarker immunohistochemistry (IHC) since June 2017.

The PD-L1 indications in New Zealand 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 ≥ 1%	TPS < 1%
	KEYNOTE-024	TPS ≥ 50%	TPS < 50%
Metastatic Triple negative breast cancer	KEYNOTE 355	CPS ≥ 10	CPS < 10
Metastatic or recurrent Head and neck squamous cell carcinoma (mucosal origin)	KEYNOTE 048	CPS ≥ 1	CPS < 1
Advanced Cervical cancer	KEYNOTE 158	CPS ≥ 1	CPS < 1
Advanced Gastric or OGJ adenocarcinoma	KEYNOTE 811, KEYNOTE 859	CPS ≥ 1	CPS < 1
	Checkmate 649	CPS ≥ 5	CPS < 5
	RATIONALE-305	TAP ≥ 5%	TAP < 5%
Advanced Oesophageal squamous cell carcinoma	KEYNOTE 590	CPS ≥ 10	CPS < 10
	Checkmate 648	TPS ≥ 1%	TPS < 1%
	RATIONALE-306	TAP ≥ 5%	TAP < 5%

TPS (Tumour Proportion Score); CPS (Combined Positive Score); TAP (Tumour Area Positivity)
Please note that Health New Zealand only funds PD-L1 testing for Non-small cell lung cancer, Metastatic Triple negative breast cancer and Metastatic/recurrent Head and neck squamous cell carcinoma (mucosal origin). All other indications require patient consent and payment.

Methodology

PD-L1 IHC is performed on FFPE sections using CE-IVD/FDA approved Roche clone SP263 or Dako clone 22C3.

The claudin 18.2 and FOLR1 indications in New Zealand 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
Advanced HER2 negative Gastric or OGJ Adenocarcinoma (claudin 18.2)	GLOW, SPOTLIGHT	Positive ≥ 75%
Platinum resistant Advanced Ovarian Serous Cancer	SORAYA, MIRASOL	Positive ≥ 75%

Methodology

Claudin 18.2 and FOLR1IHC are performed on FFPE sections using CE-IVD/FDA approved Roche clones respectively.

Referral and sample requirements

Please ask the source pathology laboratory to send the following:

1. FFPE tissue block of tumour

   NOTE: A minimum of 100 cells on tissue section is required. Cytology (including cell blocks) and decalcified samples are NOT suitable for PD-L1 CPS or TAP
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 (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. If ***HER2* (4B5 clone)** immunohistochemistry shows a 2 + positive reaction by HERACLES criteria, confirmatory FISH testing will then be performed, and a supplementary report will be subsequently issued.
- **Metastatic Melanoma (stage III/IV): *BRAF*** mutation analysis.

Awanui Labs has evaluated and validated the Biocartis Idylla analyser (and accompanying immunohistochemistry) for the following indications which require patient consent and payment:

- **Metastatic right-sided Colorectal Carcinoma: *KRAS*/*BRAF*/*NRAS*** mutation analysis plus ***HER2* (4B5 clone)** immunohistochemistry. If ***HER2* (4B5 clone)** immunohistochemistry shows a 2 + positive reaction by HERACLES criteria, confirmatory FISH testing will then be performed, and a supplementary report will be subsequently issued.
- **Advanced Pancreatic ductal adenocarcinoma: *KRAS*/*BRAF*/*NRAS*** mutation analysis

Methodology

Molecular testing (PCR; polymerase chain reaction) is performed on FFPE sections using the Biocartis analyser. HER2 IHC is performed on FFPE sections using CE-IVD/FDA approved 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)

For enquiries, please contact: Dr Michael Lau (michael.lau@awanuilabs.co.nz) or Dr Martha Nicholson (martha.nicholson@awanuilabs.co.nz) or Dr Cody Ross (cody.ross@awanuilabs.co.nz)