IHC Specimen Instructions

Foundation Medicine offers immunohistochemistry (IHC) testing for PD-L1 as a supplemental test to our portfolio of comprehensive genomic profiling (CGP) tests. Please indicate if you would like PD-L1 testing by making a selection on our test requisition form.

Selecting a Clone

When ordering PD-L1 testing, you will be asked to select the IHC clone(s), as several tumor types have multiple clones that are FDA-approved for different therapies.

- You must select *at least* one clone but may select multiple if appropriate
- Please note: if ordering multiple IHC tests, an additional 4 unstained slides are required per clone selected
- For additional information on clone offerings by tumor type, please visit our website at www.foundationmedicine.com/IHC
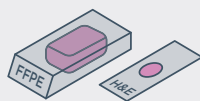
Acceptable Samples

- Formalin-fixed paraffin embedded (FFPE) specimens, including cut slide specimens.
- Use standard fixation methods to preserve nucleic acid integrity. 10% neutral-buffered formalin for 6–72 hours is industry standard. DO NOT use other fixatives (Bouins, B5, AZF, Holland's).
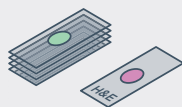- Do not decalcify.

SAMPLE REQUIREMENTS PER IHC CLONE

1 When feasible, please send the block + 1 H&E slide.*

Four unstained slides (positively charged and unbaked at 4–5 microns thick) + 1 H&E slide.†

OR

* When submitting an order for both CGP and IHC testing, only one FFPE block is needed, but note that sample size requirements for CGP testing must be fulfilled in addition to IHC sample requirements.

† For smaller samples, providing the original H&E will preserve material for testing.

TUMOR CELL CONTENT

2 MINIMUM: 100 tumor cells‡

Note: Heavily pigmented melanoma samples are not acceptable. For SP142, 22C3 CPS or 28-8 CPS cytology samples are not acceptable.

‡ Viable and intact tumor cells; degenerating, necrotic, crushed and/or cauterized cells cannot be counted towards 100 tumor cell requirement.

Shipping Instructions

1. Include the sample for IHC testing (along with additional sample needed for Foundation Medicine testing) in the appropriate shipping kit. Be sure the test requisition form, and any other attachments are also included.

2. Place the specimen shipping kit (including samples and paperwork) into the provided clinical shipping pack, first ensuring that primary specimen containers (e.g. blocks, slides) are labeled with two patient-specific identifiers. Seal the shipping pack.

3. Call 800.463.3339 to request a pick-up or drop the package at your site's designated FedEx pick-up location and ship sealed shipping pack to the address indicated on the primary test's specimen instructions.