

IHC Specimen Instructions

Foundation Medicine offers immunohistochemistry (IHC) testing as a supplemental test to our portfolio of comprehensive genomic profiling (CGP) tests. Please select the appropriate test(s) at the time of ordering.



Selecting a Test

When ordering IHC testing, you will be asked to select the appropriate IHC test(s). Please note, several tumor types have multiple IHC tests that are FDA-approved for different therapies.

- You must select *at least* one test but may select multiple if appropriate.
- IHC testing requires 1 H&E and a formalin-fixed paraffin embedded (FFPE) tissue block (strongly preferred) or 4 unstained slides per each test.
- For additional information on test offerings by tumor type, please visit our website at www.foundationmedicine.com/IHC.



Acceptable Samples

- FFPE blocks are preferred, but unstained cut slide specimens are acceptable.
- 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).
- For IHC testing, please follow appropriate cold ischemia and fixation guidelines.
- Do not decalcify.



Cut Section Storage Recommendations

False-negative results may be caused by degradation of the antigen in tissue over time. Results should be interpreted with caution when specimens are not stained within the cut section storage recommendations. When stored at room temperature, it is generally recommended that cut sections should be stained within one month of sectioning. For more specific details, see the manufacturer's individual package insert.



SAMPLE REQUIREMENTS PER IHC TEST

- 1** For optimal processing please send the block + 1 H&E slide.*

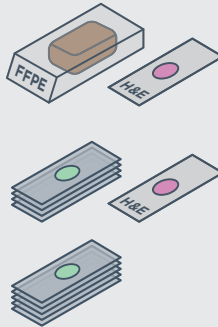
OR

For PD-L1: Four unstained slides (positively charged and unbaked at 4–5 microns thick) + 1 H&E slide.†

For FOLR1: Four unstained slides (positively charged and unbaked at 4–5 microns thick), but 5 are preferred.

For HER2: Four unstained slides (positively charged and unbaked at 4–5 microns thick), but 5 are preferred.

For CLDN18: Four unstained slides (positively charged and unbaked at 4–5 microns thick), but 5 are preferred.



* When submitting an order for both CGP and IHC testing, one FFPE block is needed, two are preferred. 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: For certain PD-L1 tests (e.g., SP142, 22C3 CPS scoring, or 28-8 CPS scoring), cytology fluid samples are not recommended due to the requirement for tumor-associated stroma. A majority of hematolymphoid tumors are not recommended for PD-L1 testing due to inability to distinguish tumor cells from non-tumor immune cells.

‡ 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 sample for CGP testing, utilizing a Foundation Medicine shipping kit with the corresponding test(s) ordered. Kit packaging includes prepaid waybill; utilizing the kit and waybill ensures the most efficient shipping, tracking, and handling of the specimen at the most appropriate Foundation Medicine lab site. Please only use one kit per patient.
2. Place the specimen shipping kit (including samples, test requisition form, corresponding pathology report, and any other relevant paperwork) into the provided clinical shipping pack. Ensure that primary specimen containers (e.g. blocks, slides) are labeled with two patient-specific identifiers. Seal the shipping pack.
3. Drop off the sealed package at your site's designated FedEx pick-up location. To request a pick-up, contact FedEx by calling 800.463.3339 or visiting www.Fedex.com.