Considerations for IHC biomarker testing workflows

SAMPLE IHC TESTING WORKFLOW

Presentation and Sample Acquisition → **Diagnostic Work-up** → **Reporting**

Test request > Sample prep > Pre-analytics > Post-analytics

Presentation and Referral — Sample Collection and Test Ordering — Testing — Result Interpretation — Accurate Reporting
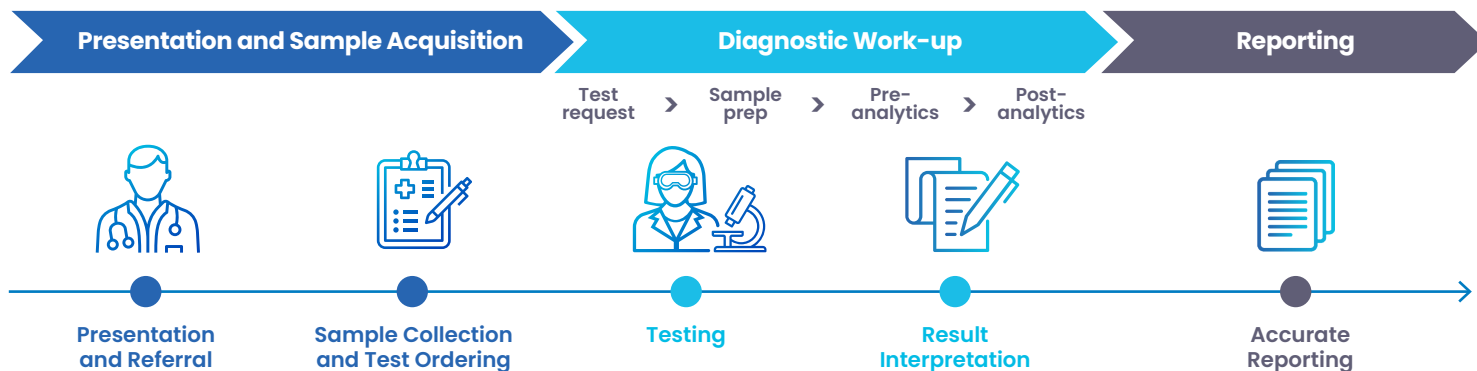
BIOPSY

Sample integrity and size

- **For gastric/GEJ cancers, it is recommended to obtain 5–8 biopsies** to conduct histological interpretation and biomarker testing[1,2]
- **Obtaining sufficient and quality tumor tissue** during biopsy is critical for biomarker testing and avoiding re-biopsy[1,2]
- **Coordination with the multidisciplinary team** enables adequate biopsy samples and optimizes the completeness of biomarker testing[3]

PROCESSING

Epitope stability

- **Sectioned tissue** should be stained immediately, as antigenicity may diminish over time[4]

Pre-analytics

- Routinely processed, formalin-fixed paraffin embedded tissues are suitable for detection where **10% neutral-buffered formalin** is the recommended fixative for optimal IHC staining[5,6]

TURNAROUND TIME

- **Turnaround time** of IHC can be somewhat mitigated **by testing with IHC reflexively** once gastric/GEJ cancer samples have been collected[7]

REPORTING CONSIDERATIONS

- **Specimen type and pre-analytics,** like specimen, fixation time, time spent in formalin, and quality control[8,9]
- **Testing methodology,** like antibody clone used, test type[8]
- **IHC Interpretation:** Percentage of tumor cells exhibiting moderate (2+) to strong (3+) membranous staining[8,10]
- **Any additional comments or interpretation challenges**[8]

Consider including qualitative and semi-qualitative IHC results (e.g., stain intensity and percentage of stained tumor cells) in pathology reports to aid in comprehensive, clear documentation

---

GEJ, gastroesophageal junction; IHC, immunohistochemistry.

References: 1. West NP, et al. *Clin Oncol (R Coll Radiol)*. 2024;36(11):701-709. **2.** Tsimberidou AM, et al. *JCO Oncol Pract*. 2024;20:761-766. **3.** De Las Casas LE, et al. *Am J Clin Pathol*. 2021;155:781-792. **4.** Potts EM, et al. *J Vis Exp*. 2021. doi:10.3791/61622. **5.** Magaki S, et al. *Methods Mol Biol*. 2019;1897:289-298. **6.** Perry C, et al. *J Histochem Cytochem*. 2016;64:425-440. **7.** Anand K, et al. *Clin Lung Cancer*. 2020;21:437-442. **8.** Bartley AN, et al. *Arch Pathol Lab Med*. 2016;140:1345-1363. **9.** Goldsmith JD, et al. *Arch Pathol Lab Med*. 2024;148:e111-e153. **10.** Rha SY, et al. *JCO Precis Oncol*. 2025;9:e2400710.

AMGEN