

The CHTN has set a policy that all five adult divisions will provide the following biomarkers free of charge to investigators upon request if they are not already a part of the pathology report. These biomarker methods conform to CAP CLIA standards.

- 1. Breast DCIS ER IHC
- 2. Breast Invasive ductal or lobular carcinoma ER IHC
- 3. Breast Invasive ductal or lobular carcinoma PR IHC
- 4. Breast Invasive ductal or lobular carcinoma HER2 IHC
- 5. Breast Invasive ductal or lobular carcinoma HER2 FISH (if needed)
- 6. GI Tract NET Ki-67
- 7. Colon/Rectum Adenocarcinoma MSI IHC for MLH1, MSH2, MSH6 and PMS2
- 8. GIST CD117 IHC or Molecular
- 9. Lung Adenocarcinoma PD-L1
- 10. Lung Adenocarcinoma ALK
- 11. Uterus/Endometrial Other than Serous MSI IHC for MLH1, MSH2, MSH6 and PMS2
- 12. Head and Neck SCC Oropharyngeal p16

In addition, CHTN notes that, while not uniform across adult divisions, some divisions clinically perform even more biomarkers or molecular testing. This data, if available, could also be provided to investigators upon request. Examples include ThyroSeq molecular panel testing performed on thyroid tumors at Eastern and Southern Divisions, HER2 testing on esophageal tumors performed by Eastern, Western, and Mid-Atlantic Divisions, with additional PD-L1 and MSI-IHC testing performed on esophageal tumors by Mid-Atlantic Division, and HER2, EBV, and MSI testing performed on gastric tumors by Western, Southern, and Mid-Atlantic Divisions (EBV testing is also performed on these tumors by Midwestern Division), and BRAF testing performed on melanoma tumors by Southern, Midwestern, Mid-Atlantic, and Eastern Divisions.

The Pediatric Division performs molecular panel testing in hematologic malignancies, targeted microarray, DNA ploidy and N-MYC testing in neuroblastoma, targeted microarray testing in Wilm's tumor, N-MYC and C-MYC FISH testing in medulloblastoma, and specific gene fusion assays related to Ewing sarcoma, synovial sarcoma, desmoplastic small round cell tumor, and congenital fibrosarcoma/cellular mesoblastic nephroma.