Guardant360 CDx OK’d as companion diagnostic for Enhertu

Aug. 23, 2022–Guardant Health announced that the FDA has approved its Guardant360 CDx liquid biopsy test as a companion diagnostic to select patients with unresectable or metastatic HER2 (ERBB2)-mutant non-small cell lung cancer whose tumors have activating HER2 mutations (single nucleotide variants and exon 20 insertions) for treatment with Enhertu. Enhertu (fam-trastuzumab deruxtecan-nxki) is a HER2-directed antibody drug conjugate developed by Daiichi Sankyo and AstraZeneca.

Guardant360 CDx provides comprehensive genomic results from a blood draw in seven days and covers all genes recommended by the National Comprehensive Cancer Network.