

FDA clears Boston Cell Standards IHC controls for HER2, ER, PR

Oct. 6, 2022—[Boston Cell Standards](#) today announced it received 510(k) clearance from the FDA for its IHControls breast cancer panel, positive controls to monitor the performance of the immunohistochemical staining process for HER2, ER, and PR IHC assays. The on-slide staining controls are provided at concentrations that match the linear range of IHC assays. The sensitivity, specificity, reproducibility, stability, and real-world performance of IHControls has been validated and published, the company says.

This is the first FDA 510(k) clearance for immunohistochemistry controls.