

[Paige HER2Complete gets CE-IVD, UKCA marks](#)

written by CAP TODAY
June 30, 2022

June 30, 2022—[Paige](#) has received CE-IVD and UKCA (UK Conformity Assessed) marks for its HER2Complete artificial intelligence software. In a recent study, HER2Complete was able to detect levels of HER2 expression in HER2-negative (IHC-0) and HER2-low (IHC 1+/2+) H&E-stained tissue samples, Paige said in announcing the news.

Paige deploys HER2Complete to detect HER2 expression based on protein and mRNA levels on digital images of H&E-stained tissue samples. The company says recent work has shown that HER2Complete can also identify HER2 expression in patients currently classified as IHC negative, in addition to expression in HER2-low patients, and that this approach complements existing IHC testing to potentially identify true HER2-expressing breast cancers without the need for special staining approaches and with a rapid turnaround using only the diagnostic biopsy or resection slides.

Paige announced in May that it received CE-IVD and UKCA marks for the Paige Prostate Biomarker Suite, designed to assist in the detection of androgen receptor, TP53, RB1, and PTEN biomarkers.



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