Put It on the Board

Paige HER2Complete receives CE-IVD and UKCA designations

July 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.

“AI brings a transformational approach to diagnostics and allows us to identify low levels of HER2 in tissue that we would not be able to detect using current assays,” David Klimstra, MD, Paige founder and chief medical officer, said in a statement. He added, “We are working to enable the next generation of HER2 testing to provide the information physicians need to guide the use of next-generation HER2 therapy. We believe that this assay will allow us to reliably identify increased likelihood of HER2 expression, even on samples where HER2 expression was misclassified by legacy diagnostics as low or null.”

Paige announced a month earlier, 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. The Paige Prostate Biomarker Suite was developed using the same underlying technology from Paige Prostate Detect, which was developed with histology image data from tens of thousands of patients and was already CE-IVD and UKCA marked and approved by the Food and Drug Administration.

Sysmex receives FDA clearance for residual WBC counting

Sysmex America has received FDA clearance for the addition of residual white blood cell counting to its XN-10 Automated Hematology Analyzer with Blood Bank mode. This is the first automated hematology analyzer to be FDA cleared for residual WBC counting. The latest analyzer supports red blood cell and platelet component testing along with residual white blood cell counting in a single sample aspiration.

The XN-10 with Blood Bank mode features analysis of blood components with four different selectable profiles: two profiles for RBC concentrates and two for platelet concentrates.

Available as a single module (XN-1000BB) or twin co-primary analyzers (XN-2000BB), the scalable hematology analyzer may be installed as a tabletop analyzer or placed on wagons, and either model may be made even more efficient with the addition of the RU-20 reagent unit, the company said in its June 15 press release.