FDA clears FISH probes for AML, MDS

Feb. 11, 2019—Oxford Gene Technology has been granted de novo classification by the FDA for eight Cytocell Aquarius hematology fluorescence in situ hybridization probes for acute myeloid leukemia and myelodysplastic syndromes. The eight FISH probes tests are used to detect common chromosomal rearrangements in fixed bone marrow specimens.

“We’re delighted to bring our comprehensive range of FDA-cleared AML and MDS FISH probes to market,” Steve Chatters, director of medical affairs at Oxford Gene Technology, said in a release. “The rigorous FDA de novo pathway requires submission of extensive clinical and performance data from multiple sites, along with robust evidence of the safety and effectiveness of the probes. What this means for customers, particularly in the U.S., is a significant reduction in the validation burden and immediate access to a range of high-quality IVD probes covering a comprehensive set of rearrangements. Our customers will be able to easily and accurately detect pertinent chromosomal rearrangements in fixed bone marrow specimens without needing to complete lengthy validations for every probe prior to use.”