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Donna Roscoe is a Scientific Reviewer in the Immunology Branch in FDA's Office of In Vitro Diagnostic Device Evaluation and Safety. She reviews *in vitro* diagnostic devices related to companion diagnostics, cancer, and genetics applications. She leads the Division's Tumor Marker Working Group, and is on the CLSI committee for the upcoming molecular diagnostic methods for nonhematological cancers document. Prior to coming to the FDA, Dr. Roscoe worked for several start-up companies and the National Center for Biotechnology Information (NCBI). Dr. Roscoe was a post-doctoral fellow in the clinical cancer research Laboratory of Molecular Biology at the National Cancer Institute (NCI) at NIH.