

Does the guidance of IVDMA intend to regulate a laboratory technical component (such as a molecular method), or statistical analysis of testing result (algorithm), or the clinical application of the test (whether the test is proper for diagnosis/prediction of a specific disease)?

Will FDA guide the criteria of the IVDMA testing specificity and sensitivity in diagnosis and prediction of diseases? The minimum number of patient specimens used in testing validation? The statistical methods employed to generate the algorithm?

If a molecular test of 5-gene expression panel reports a summary of data generated from a real-time PCR machine after standard calculation (such as $\Delta\Delta C_t$ values) and then indicates the likelihood of certain disease activity (such as an autoimmune disease), will this test be considered as an IVDMA?

Will the cost of premarket and postmarket requirements for IVDMA tests be a concern in the future development of new clinical tests after the implementation of the guidance?