

Additional Resources - Diagnostics Research and Development

- [Clinical Cancer Research: CCR Focus, Volume 18, Issue 6 - Scientific and Regulatory Challenges in the Development of Molecular Diagnostics](#)
The articles in this CCR Focus section on molecular diagnosis discuss the development and use of markers to guide cancer clinical decisions.
- Pepe MS, Etzioni R, Feng Z, et al. [Phases of biomarker development for early detection of cancer](#). *J Natl Cancer Inst*. 2001;93(14):1054-1061.
- Hayes DF. [Biomarker validation and testing](#). *Mol Oncol*. 2015;9(5):960-966. doi:10.1016/j.molonc.2014.10.004
- Masucci GV, Cesano A, Hawtin R, et al. [Validation of biomarkers to predict response to immunotherapy in cancer: Volume I - pre-analytical and analytical validation](#). *J Immunother Cancer*. 2016;4:76. Published 2016 Nov 15. doi:10.1186/s40425-016-0178-1
- Dobbin KK, Cesano A, Alvarez J, Hawtin R, Janetzki S, Kirsch I, Masucci GV, Robbins PB, Selvan SR, Streicher HZ, Zhang J, Butterfield LH, Thurin M. [Validation of biomarkers to predict response to immunotherapy in cancer: Volume II - clinical validation and regulatory considerations](#). *J Immunother Cancer*. 2016 Nov 15;4:77.