HER2/neu blood test, 1/14

January 2014—With the recent acquisition by Nuclea Biotechnologies of Wilex (Oncogene Science), Nuclea will begin its foray into the GMP manufacturing and marketing of the FDA 510(k)-cleared HER2/neu blood test out of its facility in Cambridge, Mass. The test is available as an in vitro diagnostic in the U.S., Canada, and Europe (CE mark).

The Centers for Medicare and Medicaid Services approved the serum HER2/neu test for reimbursement from Medicare part B. The AMA has approved a CPT code (HER2/neu oncoprotein: 83950) for HER2/neu oncoprotein testing.

Nuclea Biotechnologies, *413-749-4705*