FDA-Approved CDx

QIAGEN and Boehringer Ingelheim: FDA Approves QIAGEN's TheraScreen EGFR as CDx for Boehringer Ingelheim's NSCLC Drug

Submission announced January 15, 2013; agreement announced May 29, 2009 by Boehringer Ingelheim and DxS [since then acquired by QIAGEN]. US FDA Approval date: July 12, 2013

therascreen® EGFR RGQ PCR Kit (*therascreen* EGFR test), developed by Qiagen for use alongside afatinib (Gilotrif) a cancer drug developed by Boehringer Ingelheim and predecessor DxS, and granted Priority Review by FDA as a proposed treatment for patients with locally advanced or metastatic NSCLC, with an EGFR mutation detected by an FDA-approved test. In Europe, diagnostic is CE-marked and available for diagnostic use. In Japan, diagnostic has received regulatory approval. The test identifies EGFR mutation-positive patients eligible for treatment with Gilotrif. Financial terms: Not disclosed.

FDA Approves Roche EGFR Mutation CDx for NSCLC

Announced May 15, 2013

The US FDA approved Roche Molecular Systems' cobas® EGFR Mutation Test as a companion diagnostic for erlotinib (Tarceva), the cancer drug it also approved for the first-line treatment of metastatic non-small cell lung cancer (NSCLC) patients whose tumors show EGFR exon 19 deletions or exon 21 substitution mutations. The agency stated that it based these approvals on the results of a randomized, multicenter, open-label trial comparing erlotinib to platinum-based doublet chemotherapy in patients with metastatic NSCLC whose tumors showed EGFR exon 19 deletions or exon 21 (L858R) substitution mutations. The agency noted that Roche's cobas is the first companion diagnostic it has approved to detect gene mutation associated with a type of lung cancer, adding that EGFR mutations are exhibited in about 10% of NSCLC cases. Tarceva, which is co-marketed by Genentech and Astellas Pharma US [a subsidiary of Tokyo-based Astellas Pharma], received initial FDA approval in November 2004 for the treatment of patients with locally-advanced or metastatic NSCLC after failure of at least one prior chemotherapeutic regimen. Roche's RT-PCR-based cobas EGFR test is for the qualitative detection and quantification of exon 19 deletion or exon 21 substitution mutations in the EGFR gene derived from FFPE tumor tissue from NSCLC patients.

Inform Her2/Neu

Sponsor/Developer: Roche (Ventana Medical Systems)

Intended Use/Indications for Use: Fluorescence in situ hybridization (FISH) DNA probe assay determines the qualitative presence of Her2/Neu gene amplification on formalin-fixed, paraffin embedded human breast tissue. Stratifies breast cancer patients who have had a priori invasive, localized breast carcinoma and who are lymph node-negative, according to risk for recurrence or disease-related death.

PathVysion Her2 DNA Probe Kit

Sponsor/Developer: Abbott (Abbott Molecular)

Intended Use/Indications for Use: Detects amplification of the Her2/neu gene via FISH in formalin-fixed, paraffin-embedded human breast cancer tissue specimens. Predicts disease-free and overall survival in patients with stage II, node-positive breast cancer treated with adjuvant

cyclophosphamide, doxorubicin, and 5-fluorouracil (CAF) chemotherapy. Assesses patients for whom herceptin (trastuzumab) treatment is being considered.

Pathway ANTI-Her2/NEU (4B5)
Sponsor/Developer: Roche (Ventana Medical Systems)
Intended Use/Indications for Use: Mouse monoclonal antibody intended for laboratory use for the semi-quantitative detection of c-erbB-2 antigen in sections of formalin-fixed, paraffin-embedded normal and neoplastic tissue on a Ventana automated immunohistochemistry slide-staining device. Assists in assessment of breast cancer patients for whom Herceptin treatment is being considered.

DAKO EGFR PharmDx Kit
Sponsor/Developer: Agilent Technologies (Dako)
Intended Use/Indications for Use: Qualitative immunohistochemical (IHC) kit system to identify epidermal growth factor receptor (EGFR) expression in normal and neoplastic tissues routinely fixed for histological evaluation EGFR pharmDx specifically detects the EGFR (Her1) protein in EGFR-expressing cells. Assists in identifying colorectal cancer patients eligible for treatment with Erbitux (cetuximab) or Vectibix (panitumumab).

DAKO C-KIT PharmDx
Sponsor/Developer: Agilent Technologies (Dako)
Intended Use/Indications for Use: Qualitative IHC kit system used on the Dako Autostainer for the identification of c-kit protein/CD 117 antigen (c-kit protein) expression in normal and neoplastic formalin-fixed paraffin-embedded tissues for histological evaluation. The c-Kit pharmDX rabbit polyclonal antibodies specifically detect the c-kit protein in CD 117 antigen-expressing cells. Assists in differential diagnosis of gastrointestinal stromal tumors (GIST). After diagnosis of GIST, results from c-Kit pharmDx may be used as an aid in identifying those patients eligible for treatment with Gleevec/Glivec (imatinib mesylate).

InSite Her2/NEU Kit
Sponsor/Developer: Biogenex Laboratories
Intended Use/Indications for Use: For use in IHC assays to semi-quantitatively localize by light microscopy the overexpression of Her2/neu (i.e., c-erbB-2) in formalin-fixed, paraffin-embedded normal and neoplastic tissue sections. Assists in the assessment of breast cancer patients for whom Herceptin (trastuzumab) therapy is being considered.

SPOT-Light Her2 CISH Kit
Sponsor/Developer: Life Technologies (being acquired by Thermo Fisher Scientific for $15.8 billion)
Intended Use/Indications for Use: Intended to quantitatively determine Her2 gene amplification in formalin-fixed, paraffin-embedded (FFPE) breast carcinoma tissue sections using chromogenic in situ hybridization (CISH) and brightfield microscopy. Assists in the assessment of patients for whom Herceptin (trastuzumab) treatment is being considered.

Bond Oracle Her2 IHC System
Sponsor/Developer: Leica Biosystems
Intended Use/Indications for Use: Semi-quantitative IHC assay to determine Her2 (human epidermal growth factor receptor 2) oncoprotein status in formalin-fixed, paraffin-embedded breast cancer tissue processed for histological evaluation following automated staining on the bond-max slide staining instrument. Assists in the assessment of patients for whom Herceptin (trastuzumab) treatment is being considered.

Her2 CISH PharmDx Kit
Sponsor/Developer: Agilent Technologies (Dako)
Intended Use/Indications for Use: Intended for dual-color chromogenic visualization of signals achieved with directly labeled in situ hybridization probes targeting the Her2 gene and centromeric region of chromosome 17. Designed to quantitatively determine Her2 gene status in formalin-fixed, paraffin-embedded breast cancer tissue specimens. Assists in the assessment of patients for whom Herceptin (trastuzumab) treatment is being considered.

INFORM Her2 DUAL ISH DNA Probe Cocktail
Sponsor/Developer: Roche (Ventana Medical Systems)
Intended Use/Indications for Use: Intended for determining Her2 gene status by enumeration of the ratio of the Her2 gene to Chromosome 17. The Her2 and Chromosome 17 probes are detected using two-color CISH in formalin-fixed, paraffin-embedded human breast cancer tissue specimens following staining on Ventana BenchMark XT automated slide stainers (using NexES software), by light microscopy. Assists in the assessment of patients for whom Herceptin (trastuzumab) treatment is being considered.

VYSIS ALK Break Apart FISH Probe Kit
Sponsor/Developer: Abbott (Abbott Molecular)
Intended Use/Indications for Use: Qualitative test to detect rearrangements involving the anaplastic lymphoma receptor tyrosine kinase (ALK) crizotinib. Gene via FISH in FFPE non-small cell lung cancer (NSCLC) tissue specimens to aid in identifying patients eligible for treatment with Xalkori (crizotinib). For prescription use only.

COBAS 4800 BRAF V600 Mutation Test
Sponsor/Developer: Roche Molecular Systems
Intended Use/Indications for Use: Intended for the qualitative detection of the BRAF V600E mutation in DNA extracted from formalin-fixed, paraffin-embedded human melanoma tissue. Real-time PCR test intended to assist in selecting melanoma patients whose tumors carry the BRAF V600E mutation for treatment with vemurafenib.

Herceptest™
Sponsor/Developer: Agilent Technologies (Dako)
Intended Use/Indications for Use: Semi-quantitative immunocytochemical assay to determine Her2 protein overexpression in breast cancer tissues routinely processed for histological evaluation and formalin-fixed, paraffin-embedded cancer tissue from patients with metastatic gastric or gastroesophageal junction adenocarcinoma. Assists in assessment of patients for whom

Herceptin (trastuzumab) treatment is being considered and for breast cancer patients for whom Perjeta (pertuzumab) treatment is being considered (see Herceptin and Perjeta package inserts); and for patients with Her2-positive metastatic breast cancer who have received prior treatment with Herceptin (trastuzumab) and a taxane chemotherapy, for whom Kadcyla (ado-trastuzumab emtansine) treatment is being considered.

Her2 FISH PharmDx Kit
Sponsor/Developer: Agilent Technologies (Dako)
Intended Use/Indications for Use: FISH assay designed to quantitatively determine Her2 gene amplification in FFPE breast cancer tissue specimens and FFPE specimens from patients with metastatic gastric or gastroesophageal junction adenocarcinoma. Assists in the assessment of patients for whom Herceptin (trastuzumab) treatment is being considered; for breast cancer patients for whom Perjeta (pertuzumab) treatment is being considered (see Herceptin and Perjeta package inserts); and for patients with Her2-positive metastatic breast cancer who have received prior treatment with Herceptin (trastuzumab) and a taxane chemotherapy, for whom Kadcyla (ado-trastuzumab emtansine) treatment is being considered.

therascreen **KRAS RGQ PCR Kit**
Sponsor/Developer: QIAGEN
Intended Use/Indications for Use: Real-time qualitative PCR assay used on the Rotor-Gene Q MDx instrument for the detection of seven somatic mutations in the human KRAS oncogene, using DNA extracted from FFPE colorectal cancer (CRC) tissue. Assists in the identification of CRC patients for treatment with Erbitux (cetuximab) based on a KRAS no mutation detected test result.

HER2 IQFISH Assay
Sponsor/Developer: Agilent Technologies (Dako)
Intended Use/Indications for Use: FDA approved HER2 IQFISH pharmDx assay is a FISH assay based on Dako's "instant quality in situ hybridization" buffer chemistry for reducing cancer diagnosis turnaround time to 3.5 hours from the current 2 day protocol.

SELECTBIO

CDx under Development/Partnerships in the Space

Life Tech Inks Companion Dx Alliance with Merck Serono

Agreement announced July 16, 2013

Life Technologies has inked a companion diagnostics deal with pharmaceutical firm Merck Serono for an undisclosed oncology target and eventually other therapeutic areas. Under the non-exclusive agreement, Life Tech will employ a wide range of its technology platforms, including next-generation sequencing, Sanger sequencing, qPCR, and flow cytometry. Life Tech said that if the alliance is successful, the firms would sign another agreement, under which the firm would commercialize the companion diagnostics in agreed-upon territories. The partners would also work to simultaneously seek regulatory approval of Merck's drug and Life Technologies' companion diagnostic. Financial and other terms of the agreement were not disclosed.

QIAGEN Licenses two Biomarkers for CDx Development

Agreement announced May 31, 2013

QIAGEN announced two licensing deals aimed at developing companion diagnostic tests for glioblastoma, lymphoma, and other cancers. In one deal, QIAGEN has licensed an option on FGFR-TACC fusion genes from Columbia University. QIAGEN plans to develop a diagnostic test based on the biomarker for doctors to use in identifying patients who may benefit from targeted treatments currently under development. QIAGEN also has an exclusive license option with the BC Cancer Agency, based in Vancouver, British Columbia, for the EZH2 Y641 mutation biomarker. QIAGEN plans on developing a companion diagnostic based on that biomarker for selecting patients who would benefit from EZH2-targeted therapies being developed. Financial and other deal terms were not disclosed.

Foundation Medicine and Memorial Sloan-Kettering Cancer Center

Agreement announced May 2, 2013

Collaboration to co-develop a new molecular diagnostic intended to match patients with blood cancers to targeted therapies or clinical trials. Diagnostic will be based on technology, methods, and computational algorithms developed by Foundation Medicine, which says it intends to commercialize the test internationally. Leukemia, lymphoma, and myeloma specialists at Memorial Sloan-Kettering will provide clinical and genomic expertise to assist in product development. Foundation Medicine said it expects by year's end to launch the new diagnostic, which will use both DNA and RNA sequencing to identify genomic alterations characteristic of hematologic malignancies. Drugs and specific forms of cancer not disclosed.
Financial terms not disclosed.

Abbott (Abbott Molecular) and Epizyme

Agreement announced April 18, 2013

Companies to co-develop diagnostic for Epizyme drug candidate EPZ-5676, an inhibitor targeting the DOT1L histone methyltransferase for mixed lineage leukemia (MLL-r), a subtype of both acute myeloid leukemia and acute lymphoblastic leukemia. Diagnostic will apply Abbott's FISH technology to detect MLL genetic alterations that lead to the cancer-causing function of DOT1L. Epizyme will use Abbott's FISH-based diagnostic to help identify eligible

patients for EPZ-5676.
Financial terms not disclosed.

PrimeraDx and Quest Diagnostics
Agreement announced March 26, 2013
Nonexclusive agreement to co-develop and commercialize diagnostics that will apply Primera Dx's ICEPlex System assay-development platform in early-phase biomarker and drug development studies and clinical trials with biotechnology, pharmaceutical, and medical device clients of Quest Diagnostics Clinical Trials. Companies said they expect initial collaborations to focus on cancer, "although they may also explore opportunities in infectious diseases, genetics and other conditions." Specific drugs and cancer indications not disclosed.
Financial terms not disclosed.

Merck, Luminex Partner to Advance Companion Test for Alzheimer's Drug
Agreement announced March 13, 2013
Merck and Luminex said that they will work together to develop a companion test for Merck's investigational BACE inhibitor for Alzheimer's Disease, MK-8931. The diagnostic, which will operate on Luminex's xMAP platform, will be used to stratify patients into clinical trials involving MK-8931. According to the companies, Luminex will be in charge of developing, garnering regulatory approval, and commercializing the companion test. Researchers involved in development of the drug will use the test to identify patients with mild cognitive impairment who are at heightened risk of developing Alzheimer's based on the concentration levels of the biomarkers amyloid-beta42 and t-tau in their cerebrospinal fluid. The companies did not disclose the financial terms of the deal.

Lab21, IntegraGen Co-developing CDx for Colorectal Cancer Therapy
Agreement announced February 22, 2013
Lab21 announced an agreement with IntegraGen to develop a microRNA-based assay to identify colorectal cancer patients who may best respond to EGFR-inhibitor therapy. Lab21 will develop an assay based on its SPARQ PCR technology to detect the expression level of a microRNA biomarker called hsa-miR-31-3p. IntegraGen and its academic partners discovered and patented the biomarker, which has shown an ability to predict EGFR-inhibitor response in KRAS wild-type patients with metastatic colorectal cancer. Lab21 said that most patients with the cancer are already screened and stratified by determining mutations in the KRAS gene. About 40% of patients have a KRAS mutation and are not suitable for treatment with EGFR inhibitors. Of the remaining cancer patients without a KRAS mutation and who are eligible for EGFR-inhibitor therapy, only 50-60% respond to the therapy. microRNA expression testing would provide an additional level of stratification and further help clinicians identify those patients who would be best candidates for the therapy, improving outcomes while saving costs to the healthcare system.

Janssen Biotech, Pharmacyclics Explore Abbott FISH Technology as CDx for CLL
Agreement announced February 21, 2013
Abbott has announced a collaboration to explore the use of its FISH technology as a companion diagnostic for an investigational new drug being developed by J&J's Janssen Biotech and Pharmacyclics for treating chronic lymphocytic leukemia (CLL).

Abbott will develop a FISH-based test for identifying high-risk CLL patients with a deletion within chromosome 17p and who may respond to ibrutinib, a small-molecule inhibitor of Bruton tyrosine kinase. Janssen and Pharmacyclics are developing ibrutinib for several B-cell malignancies including CLL. Patients with a deletion within chromosome 17p respond poorly to chemoimmunotherapy and have limited therapeutic options. Being able to detect the deletion would identify a patient population with a high unmet medical need. Abbott's Vysis CLL FISH Probe Kit will be used for investigational use only as part of the deal in order to determine genetic marker status. The kit, which was cleared by the FDA in 2011, targets multiple genes, such as TP53 within the deleted 17p region, and is used to determine the prognosis of CLL patients.

QIAGEN and Eli Lilly
Agreement announced February 13, 2013
"Master collaboration" entailing development and commercialization of companion diagnostics that will apply Qiagen's Rotor-Gene Q platform for use alongside "Lilly investigational and approved medicines across all therapeutic areas."
Financial terms not disclosed.

Agilent Technologies (Dako) and Pfizer
Agreement announced February 12, 2013
Collaboration to entail "research, development, and commercialization as well as advisory services" in the development of "various" companion diagnostics. Dako specializes in tissue-based cancer diagnostics, though drugs and specific cancer indications were undisclosed.
Financial terms not disclosed.

Agilent Technologies (Dako) and Eli Lilly
Agreement announced January 7, 2013
Master Framework Agreement to develop companion diagnostics "to identify patients who may be more likely to benefit from an investigational oncology medicine currently under development by Lilly." Drugs and specific cancer indications not disclosed. Oncology is the collaboration's initial focus. Lilly will be exclusively responsible for development and registration of therapeutics, including clinical trials. Dako will be responsible for developing and registering the diagnostic with FDA.
Financial terms not disclosed.

Skuldtech and AB Science
Plans for companion diagnostic announced November 6, 2012
Commercialization planned for diagnostic for use alongside the latter's drug candidate masitinib, an oral tyrosine kinase inhibitor (TKI) for which AB Science has applied to the European Medicines Agency for marketing authorization. Diagnostic will use a set of blood markers discovered by Skuldtech to predict a higher survival rate in pancreatic cancer patients from a drop of blood. Markers discovered during Phase III trial assessing efficacy of masitinib plus gemcitabine—the current standard of care—compared with gemcitabine alone. AB Science will retain full rights to the markers upon FDA marketing authorization of masitinib, which has been

designated an orphan drug by FDA and EMA.
Financial terms not disclosed.

QIAGEN and Bayer HealthCare
Agreement announced October 25, 2012
Collaboration where Qiagen will develop, manufacture, and commercialize diagnostics alongside "targeted anticancer therapies developed by Bayer HealthCare, which are currently in early development." Specific drugs and cancer indications undisclosed. Diagnostics will apply Qiagen's QIAsymphony platform to identify "specific tumor markers." Qiagen said the first collaborations will entail development of companion diagnostics to identify patients "who may respond to therapies in clinically unmet disease classifications." Qiagen also said the companies will also collaborate on development of "technologies for patient profiling which may result in innovative research-use-only products for exploratory and translational medicine." Over the agreement's five-year period, Bayer said, it and Qiagen may launch further projects to develop diagnostic tests "in support of additional targeted therapies."
Financial terms not disclosed.

Life Technologies (being acquired by Thermo Fisher Scientific) and Bristol-Myers Squibb
Agreement announced September 17, 2012
Master Development Agreement Collaboration—the second between the companies—covers an initial oncology project, and a long-term partnership "across a potentially broad range of Life instrument platforms and a wide range of therapeutic areas." Specific drugs and cancer indications undisclosed. In oncology, "hundreds of agents are currently in clinical trials, and we see strong market opportunity in the robust expansion this will mean for the companion diagnostics space," Ronnie Andrews, president of medical sciences at Life Technologies, said in a statement.
Financial terms not disclosed.

PrimeraDx and Eli Lilly
Agreement announced June 26, 2012
"Multi-year" collaboration to develop diagnostic that will apply Primera Dx's ICEPlex System assay-development platform to identify multiple DNA and RNA biomarkers: "Our early focus will be in oncology," Andrew Schade, M.D., Ph.D., senior director, Clinical Diagnostics Laboratory at Lilly, said in a statement, adding that what is learned would be applied later "across therapeutic areas." Drugs and specific cancer indications undisclosed.
Financial terms not disclosed.

Genomic Health and OncoMed Pharmaceuticals
Agreement announced May 2, 2012
Collaboration to discover biomarkers designed to help identify subsets of patients that will more likely respond to cancer therapeutics, targeting the Notch, Wnt, and other pathways critical to the spread of cancer stem cells. OncoMed providing Genomic Health with breast, prostate, colon, and lung tumor samples, some of which will include OncoMed's proprietary xenograft models derived from freshly resected human cancers.
Financial terms not disclosed.

Roche (Ventana Medical Systems) and Seattle Genetics and Takeda Pharmaceutical (Millennium: The Takeda Oncology Company)
Agreement announced April 12, 2012
Ventana to develop, manufacture, and commercialize diagnostic for use alongside Adcetris (brentuximab vedotin), jointly developed by Seattle Genetics and Millennium. Diagnostic will be designed to detect CD30 expression levels in tissue specimens, and thus identify additional patients who might benefit from Adcetris. The antibody-drug conjugate was approved by FDA in 2011 for relapsed Hodgkin lymphoma and systemic anaplastic large call lymphoma.
Financial terms not disclosed.

HTG Molecular Diagnostics and Sanofi
Agreement announced March 30, 2012
Collaborative program to identify biomarkers that may lead to the development of a companion diagnostic to help identify patients most likely to respond to a new Sanofi investigational cancer drug. Drug and specific cancer indications not disclosed. Diagnostic will apply HTG Molecular Diagnostics' qNPA technology measures mRNA and/or miRNA expression in formalin-fixed paraffin embedded tumor samples, allowing clinicians to verify the presence of certain biomarkers relevant to patient selection and therapy.
Financial terms not disclosed.

Myriad Genetics and Teva Pharmaceutical (Cephalon)
Agreement announced March 28, 2012
Collaboration to test for BRCA1 and BRCA2 mutation via Myriad's lead product, BRACAnalysis® on patients before their enrollment in a Phase I/II clinical study for a drug candidate. Drug and specific cancer indication not disclosed.
Financial terms not disclosed.

Abbott (Abbott Molecular) and Merck & Co.
Agreement announced March 6, 2012
Collaboration to evaluate the use of a FISH-based companion diagnostic for use alongside a Merck investigational cancer therapy. Drug and specific cancer indication not disclosed. Abbott agreed to develop a test based on its FISH technology, intended to identify deletions of the TP53 gene in cancer patients. Abbott FISH will be evaluated in clinical trials to help identify patients more likely to respond favorably to the Merck investigational cancer drug.
Financial terms not disclosed.

Biodesix and Kadmon
Agreement announced February 27, 2012
Collaboration to apply Biodesix' VeriStrat® in a Phase III NSCLC study of Kadmon's KD019, a reversible TKI targeting EGFR, Her2, VEGFR2 & 3, and SRC. Trial designed to evaluate KD019 compared to erlotinib in patients with stage IIIB/IV NSCLC who have progressed after first- or second-line chemotherapy.
Financial terms not disclosed.

Agilent Technologies (Dako) and Amgen
Agreement announced February 20, 2012
Collaboration agreement to develop a diagnostic for "an Amgen cancer drug candidate in clinical development" that is also "a rare but deadly cancer." Drug and specific indication not disclosed. Financial terms not disclosed.

Siemens Healthcare Diagnostics and ViiV Healthcare
Agreement announced February 7, 2012
Collaboration to develop a diagnostic for use alongside ViiV's Celsentri/Selzentry® (maraviroc), an experimental CCR5 co-receptor antagonist for CCR5-tropic HIV, in the Phase III MODERN trial [Maraviroc Once daily with Darunavir Enhanced by Ritonavir in a Novel regimen], also known as A4001095. The 96-week trial is designed to comparing its CCR5-inhibitor, Celsentri/Selzentry® (maraviroc), to emtricitabine/tenofovir (Truvada®), both in combination with darunavir/ritonavir. Also being compared in the trial is the performance of a genotypic test with a phenotypic test in identifying randomized patients appropriate for use of Celsentri/Selzentry®. Genotypic tropism testing in the MODERN study is provided by Siemens Healthcare Diagnostics; phenotypic testing (Trofile®), by Monogram Biosciences.
Financial terms not disclosed.

Siemens Healthcare Diagnostics and Tocagen
Agreement announced February 7, 2012
Collaboration to develop diagnostics to support clinical trials related to Tocagen's viral gene therapy (Toca 511 & Toca FC) for primary brain cancer, followed by potential commercialization of the diagnostic tests for therapy monitoring. Tocagen is enrolling patients in clinical trials of Toca 511 (vocimagene amiretrorepvec), for injection & Toca FC (flucytosine), extended-release tablets. Study designed for patients with recurrent high-grade glioma, such as those with glioblastoma multiforme (GBM, Grade 4), who have had prior surgery and chemoradiation. Toca 511 is a retroviral replicating vector designed to deliver a cytosine deaminase (CD) gene selectively to cancer cells. After allowing time for the administered Toca 511 to spread through the tumor, those cancer cells expressing the CD gene may convert the antibiotic flucytosine into the anticancer drug 5-fluorouracil (5-FU).
Financial terms not disclosed.

Roche (Ventana Medical Systems) and Bayer HealthCare
Agreement announced January 17, 2012
Strategic collaboration to develop a molecular companion diagnostic test intended to identify patients most likely to benefit from a Bayer antibody-drug conjugate (ADC). Diagnostic will apply Ventana's diagnostic immunohistochemistry platform, designed to analyze the expression level of certain tumor targets serving as biomarkers in clinical studies for patient selection. Ventana agreed to initially develop, manufacture and commercialize a companion diagnostic test for one of Bayer's ADCs. Over five years, however, both parties may launch further projects to develop molecular diagnostic tests in support of additional targeted cancer therapy drugs.
Financial terms not disclosed.

Foundation Medicine and Sanofi
Agreement announced January 10, 2012
Foundation Medicine agreed to use next-gen genomic sequencing and analytic capabilities to identify genetic biomarkers and potential companion diagnostics for select Sanofi oncology drug candidates. Drug candidates and specific cancer indications not disclosed. Collaboration will apply Foundation Medicine's comprehensive cancer genomic test to analyze routine clinical specimens for molecular alterations in approximately 200 cancer-related genes.
Financial terms not disclosed.

Agilent Technologies (Dako) and Amgen
Agreement announced January 10, 2012
Development and collaboration agreement to develop a diagnostic for "an Amgen cancer drug candidate targeted for a rare and deadly cancer" that is also "a low-incidence cancer." Drug and specific indication undisclosed.
Financial terms not disclosed.

Roche (Ventana Medical Systems), Pfizer, and Cell Signaling Technology (CST)
Agreement announced January 9, 2012
Collaboration to develop diagnostic for use alongside Pfizer drug Xalkori. Ventana agreed to develop the first fully automated and standardized immunohistochemistry companion diagnostic for ALK gene rearrangements. Diagnostic will apply CST's D5F3 antibody and Ventana's Optiview DAB detection platforms to measure the associated protein product when an ALK gene rearrangement is present. The diagnostic will be designed to identify NSCLC patients with ALK gene rearrangements who may benefit from the Pfizer drug.
Financial terms not disclosed.

Xenon Pharmaceuticals and Roche (Genentech)
Agreement announced January 9, 2012
Strategic alliance designed to discover and develop companion diagnostics and compounds for pain. Genentech awarded an exclusive license to compounds and a nonexclusive license to diagnostics from Xenon for development and commercialization of products.
Financial terms: Xenon received an undisclosed up-front payment, plus research funding and eligibility for payments tied to undisclosed research, development and commercialization milestones, all totaling $646 million for multiple products and indications. Xenon will receive royalties on sales of products from the collaboration.

Roche (Ventana Medical Systems) and Aeterna Zentaris
Agreement announced January 5, 2012
Companies to develop a companion diagnostic for use alongside Aeterna Zentaris' doxorubicin luteinizing hormone-releasing hormone (LHRH) targeted conjugate compound AEZS-108 against cancer. Announcement cites positive final Phase I results in LHRH-receptor expressing endometrial and ovarian cancer, while raising the possibility of additional indications by adding that LHRH receptors are "are expressed in a significant proportion of endometrial, ovarian, breast, bladder, prostate, and pancreatic tumors."
Financial terms not disclosed.

Roche (Ventana Medical Systems) and Syndax Pharmaceuticals
Agreement announced January 5, 2012
Companies agreed to develop a companion diagnostic for use alongside erlotinib and Syndax' lead drug candidate entinostat. Diagnostic to apply Ventana's in vitro diagnostic kit to measure levels of E-cadherin in epithelial tissues, to identify patients likely to benefit from combination therapy of erlotinib plus entinostat.
Financial terms not disclosed.

Metamark Genetics and Johnson & Johnson (Janssen Biotech)
Agreement announced December 19, 2011
Research, collaboration, and license agreement applying Metamark's discovery platform to identify and characterize specific cancer targets demonstrated to play a causal role in promoting tumor progression and spread. Upon selection of targets, Janssen will receive a limited exclusive license and take responsibility for discovery, development, and commercialization of therapeutic inhibitors for the cancer targets.
Financial terms: Metamark received an undisclosed initial up-front payment from Janssen, and is eligible for near-term milestone payments following initial target validation. Metamark may be eligible to receive up to $365 million in milestone payments across multiple targets, tied to specified but undisclosed development, regulatory, and commercialization goals. Metamark will also be entitled to royalties on worldwide net sales of therapeutics and any associated companion diagnostics upon commercialization.

MDx Health and Celldex
Agreement announced December 2, 2011
Companies agreed to use MDxHealth's epigenetic MGMT test during recruitment of patients for Phase III global clinical study of Celldex' immunotherapeutic vaccine rindopepimut in newly diagnosed GBM. Diagnostic will be used to determine the methylation status of the MGMT promotor gene in patients enrolled in the rindopepimut study.
Financial terms not disclosed.

Abbott (Abbott Molecular) and GlaxoSmithKline
Agreement expanded November 28, 2011 and March 3, 2010; originally announced July 13, 2009
Collaboration to develop diagnostic to support GSK's cancer immunotherapy research program by identifying specific DNA sequences to guide physicians in determining patient benefit from specific drugs. Expanded agreement entails development of a PCR test for use on the Abbott m2000rtTM instrument to screen NSCLC tumors for the expression of the PRAME antigen of melanoma, expressed in most NSCLC cases as well as other cancer types, including melanoma, breast, ovarian, and bladder cancer. Earlier agreements focused on the development of PCR tests to screen NSCLC and melanoma tumors for expression of the MAGE-A3 antigen, in a large variety of cancers, including melanoma, NSCLC, head and neck, and bladder cancer.
Financial terms not disclosed.

Agilent Technologies (Dako) and Bristol-Myers Squibb
Agreement announced November 9, 2011, by BMS and Dako, acquired last year by Agilent

Broad Framework Agreement to develop diagnostics intended to identify patients more likely to benefit from treatment with investigational drug candidates under development by BMS. Drugs and indications not disclosed. Expansion of a collaboration launched in 2008.
Financial terms not disclosed.

Life Technologies (being acquired by Thermo Fisher Scientific) and GlaxoSmithKline
Agreement announced October 25, 2011
Collaboration designed to develop a companion diagnostic to a GSK candidate cancer immunotherapy. Life will apply its Taqman® Array Card technology to develop a qPCR-based diagnostic assay for GSK's MAGE-A3 cancer immunotherapy candidate, designed to identify patients likely to benefit from the experimental drug, now in Phase II development for melanoma and NSCLC, and Phase I for bladder cancer.
Financial terms not disclosed.

Foundation Medicine and Johnson & Johnson
Agreement announced October 25, 2011
Collaboration designed to apply Foundation Medicine's clinical cancer genomic test to identify potential biomarkers to support J&J Pharmaceutical Research and Development oncology clinical development programs. Drug candidates and specific cancer indications not disclosed. Diagnostic uses next-generation sequencing to analyze routine clinical specimens for molecular alterations in more than 200 cancer-related genes.
Financial terms not disclosed.

QIAGEN and Eli Lilly
Agreement announced September 6, 2011
Partnership to develop diagnostic for use alongside Eli Lilly's JAK2 inhibitor blood cancers candidate, which targets the Janus kinase 2, or JAK2, gene associated with myeloproliferative neoplasms. The PCR-based diagnostic will apply Qiagen's Rotor-Gene Q platform to qualitatively and quantitatively test for JAK2 V617F mutation, in order to identify patients most likely to benefit from the pathway inhibitor. Qiagen initially licensed the JAK2 inhibitor from Ipogen before acquiring the French company later in 2011.
Financial terms not disclosed.

Skyline Diagnostics and Clavis Pharma
Agreement announced September 6, 2011
Research agreement, under which Skyline agreed to investigate gene expression biomarkers for selection of individual acute myeloid leukemia (AML) patients that may benefit from an experimental drug then being developed by Clavis. All development of elacytarabine was halted April 1 after the elaidic acid derivative of cytarabine failed the CLAVELA Phase III study, showing no significant improvement in overall survival among patients with relapsed/refractory AML randomized to either the drug candidate or a treatment of the investigator's choice.
Financial terms not disclosed.

QIAGEN and Pfizer
Agreement announced August 16, 2011

Partnership to develop diagnostic for use alongside investigational compound dacomitinib (PF-00299804), an oral Her1, Her2, and Her4 TKI now in Phase III clinical trials for NSCLC. As of April 22, ARCHER 1050 trial was recruiting participants, while the Phase III ARCHER 109 trial was active but not recruiting as of April 9, according to ClinicalTrials.gov. Pfizer is co-developing the drug with The SFJ Pharmaceuticals Group. Diagnostic will apply Qiagen's KRAS assay technology to identify patients with wild-type KRAS who are generally most likely to respond to EGFR inhibitor therapy.
Financial terms not disclosed.