SELECTED PERSONALIZED MEDICINE GENETIC TESTS WITH RESPECT TO DRUGS AND/OR DISEASE
AS OF MAY 2014

Drug Name (Brand name)	Test/Kit	Indication
Cardiovascular (CV)		
	AlloMap Molecular Expression Testing	**Heart Transplant:** Aid in the identification of heart transplant recipients with stable allograft function who have a low probability of moderate/severe acute cellular rejection (ACR) at the time of testing in conjunction with standard clinical assessment.
	Corus® CAD	**Obstructive Coronary Artery Disease:** Gene expression test is a decision-making tool that can help identify patients unlikely to have obstructive CAD and help determine appropriate next steps.
	Familion® 5-gene profile	**CV:** Guides prevention and drug selection for patients with inherited cardiac channelopathies such as Long QT Syndrome (LQTS), which can lead to cardiac rhythm abnormalities.
Statins *	SINM PhyzioType™	**CV:** Predicts risk of statin-induced neuro-myopathy, based on a patient's combinatorial genotype for 50 genes.
Warfarin * (Coumadin®)	eQ-PCR LC Warfarin Genotyping kit	Genotyping single nucleotide polymorphisms (SNPs) in the cytochrome P450 enzyme gene *CYP2C9* known as *CYP2C9*2* (C430T), *CYP2C9*3* (A1075C), and a SNP in the vitamin K epoxide reductase complex 1 gene (*VKORC1*) known as *VKORC1* (-1639G>A).
	eSensor Warfarin Sensitivity Test	Detection and genotyping of *CYP450* 2C9 (*2 and *3) and *VKORC1* (-1639G>A)
	Gentris Rapid Genotyping Assay - *CYP2C9* & *VKORCI*	Intended to detect the presence of *CYP2C9* *2 and *3 and *VKORC1* 1173 C>T alleles. Information about the *CYP2C9* and *VKORC1* genotypes may be used as an aid in the identification of patients with greater risk for warfarin sensitivity.
	INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin	Identify *CYP450* 2C9 and *VKORC1* genetic variants.
	PGx Predict™	**CV:** Determines *CYP2C9* and *VKORC1* genotypes to predict likelihood of adverse events with warfarin therapy.
	Verigene Warfarin Metabolism Nucleic Acid Test and Verigene System	The two most common alleles of CYP2C9 that affect warfarin metabolism are *CYP2C9*2* (also known as R144C) and *CYP2C9*3* (also known as I359L). The *VKORC1* gene, located on the short arm of human chromosome 16 (16p11.2), encodes the *VKORC1* protein which plays an essential role in gamma-carboxylation of Vitamin K-dependent blood clotting factors.
Drug metabolism		
	AmpliChip CYP450 microarray	Detection of gene variations — including deletions and duplications — for the *CYP2D6* and *CYP2C19* genes, the expressed enzymes play a major role in the metabolism of an estimated 25% of all prescription drugs.
	INFINITI *CYP2C19* Assay	Determining therapeutic strategy for therapeutics that are metabolized by the *CYP450 2C19* gene product, specifically *2, *3, *17.
	Verigene *CYP2C 19* Nucleic Acid Test	Identifies a patient's CYP2C19 *2, *3 and *17 genotype.
	xTAG® *CYP2D6* Kit	*Determine therapeutic strategy for therapeutics that are metabolized by the CYP2D6 gene product.*

Drug Name (Brand name)	Test/Kit	Indication
Genetic disease		
	AneuVysion	Detect alpha satellite sequences in the centromere regions of chromosomes 18, X, and Y, and LSI 13/21 probe to detect the 13q14 region and the 21q22.13 to 21q22.2 region.
	CEP 8 Spectrumorange DNA Probe Kit	Detect AT rich alpha satellite sequences in the centromere region of chromosome 8 in conjunction with routine diagnostic cytogenetic testing.
	eSensor® CF Genotyping Test	**Cystic Fibrosis:** Provide patients with accurate genetic carrier screening results. Panel includes 23 ACOG/ACMG recommended mutations.
	xTAG Cystic Fibrosis 39 Kit v2 xTAG Cystic Fibrosis 60 Kit v2	**Cystic Fibrosis:** Test for the most prevalent CFTR gene mutations in a variety of populations. Tests a patient for only the 23 CFTR mutations recommended by the ACMG/ACOG or to also test for an additional 16 (with the xTAG Cystic Fibrosis (*CFTR*) 39 kit v2) or an additional 37 (with the xTAG Cystic Fibrosis *(CFTR)* 60 kit v2) of the world's most common and North American-prevalent mutations.
	Verigene® CFTR and Verigene® CFTR PolyT Nucleic Acid Tests	**Cystic Fibrosis:** Panel includes mutations and variants recommended by the 2004 American College of Medical Genetics (ACMG) and the 2005 American College of Obstetricians and Gynecologists (ACOG). It provides information intended to be used for carrier testing in adults of reproductive age and in confirmatory diagnostic testing of newborns and children.
	InPlex CF Molecular Test	**Cystic Fibrosis:** Tests for twenty-three separate mutations in the Cystic Fibrosis Transmembrane Receptor (*CFTR*) gene. In addition, the IVS8-5T/7T/9T markers are automatically reflexed as part of the test. All mutations contained in the assay are recommended for testing by the American College of Obstetricians and Gynecologists (ACOG) and the American College of Medical Genetics (ACMG).
	Cystic Fibrosis Genotyping Assay	**Cystic Fibrosis:** Genotype a panel of mutations and variants in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene in genomic DNA isolated from human whole blood specimens. The panel includes mutations and variants recommended by the American College of Medical Genetics (ACMG, 2004) and the American College of Obstetricians and Gynecologists (ACOG, 2005), plus additional multiethnic mutations and variants. It provides information intended to be used for carrier screening in adults of reproductive age, as an aid in newborn screening, and in confirmatory diagnostic testing in newborns and children.
Hematology		
	CEP X SpectrumOrange/ Y SpectrumGreen DNA Probe Kit	Indicated for use as an adjunct to standard cytogenetic analysis for identifying and enumerating chromosomes X and Y in interphase nuclei and metaphase spreads obtained from bone marrow specimens in subjects who received opposite-sex bone marrow transplantation for **chronic myelogenous leukemia (CML), acute myeloid leukemia (AML), myeloproliferative disorder (MPD), myelodysplastic syndrome (MDS), acute and lymphoid leukemia (ALL),** or **hematological disorder not otherwise specified (HDNOS).**
	eSensor Thrombophilia Risk Test	All four thrombophilia-related genetic markers: FV, FII, *MTHFR 677, MTHFR 1298.*
	Factor II (Prothrombin) G20210A Kit	Detection and genotyping of a single point mutation (G to A at position 20210) of the human Factor II gene from DNA isolated from human whole peripheral blood. Detection and genotyping of the Factor II (Prothrombin) G20210A mutation as an aid to diagnosis in the evaluation of patients with suspected thrombophilia.

Drug Name (Brand name)	Test/Kit	Indication
	Factor V leiden Kit	Detection and genotyping of a single point mutation (G to A at position 1691) of the human Factor V gene, referred to as Factor V Leiden mutation. Detection and genotyping of the Factor V Leiden mutation as an aid to diagnosis in the evaluation of patients with suspected **thrombophilia**.
	Illumina VeraCode Genotyping Test for Factor V and Factor II	Detection and genotyping of Factor V Leiden G1691A and Factor II (Prothrombin) G20210A point mutations in DNA obtained from EDTA-anticoagulated human blood samples. It is indicated for use as an aid to diagnosis in the evaluation of patients with suspected thrombophilia.
	INFINITI System	Identify genetic variants for Factor II, Factor V, and *MTHFR* genes.
	Invader Factor V	Detect a single nucleotide substitution mutation, causing a change in the translated protein's amino acid at 506th position from Arginine to Glutamine.
	Invader Factor II	Detect G20210A mutation that is characterized by a guanine to adenine transition at position 20210 in the 3' untranslated region of the Factor II gene.
	Invader *MTHFR* 677	Detect a polymorphism at the 677 position of the gene that causes a Cytosine to Thymine substitution.
	Invader *MTHFR* 1298	Detect a polymorphism at the 1298 position of the gene that causes an Adenine to Cytosine substitution.
	Verigene F5 Nucleic Acid Test Verigene F2 Nucleic Acid Test Verigene MTHFR Nucleic Acid Test	Detection and genotyping of a single point mutation (G to A at position 1691; also known as Factor V Leiden) of the human Factor V gene (*F5*; Coagulation Factor V gene) in patients with suspected **thrombophilia**. Verigene *F2* :(G to A at position 20210) of the human Factor II gene (F2; prothrombin gene), *Verigene MTHFR*: (C to T at position 677) of the human 5,10 methylene-tetra-hydro-folate reductase gene (*MTHFR*).
	Xpert HemosIL FII & FV	Detection of Factor II (FII) and Factor V (FV) alleles. Performed on the Cepheid GeneXpert System, the test is intended to provide rapid results for FII (G20210A) and FV Leiden (G1691A) mutations as an aid in the diagnosis of suspected **thrombophilia**.
Immunology		
	AlloMap® gene signature	**Heart transplantation:** Monitors patient's immune response to heart transplant to guide immunosuppressive therapy.
Budesonide (Entocort®)	Prometheus® IBD Serology 7	**Inflammatory bowel disease:** Identifies subset of patients who will benefit from budesonide.
	ImmuKnow®	**Post-Transplant Immune Status:** Is an immune cell function assay that detects cell-mediated immunity in an immunosuppressed population.
Oncology		
Afatinib * (Gilotrif®)	therascreen *EGFR* RGQ PCR Kit	**Lung cancer:** Detection of exon 19 deletions and exon 21 (L858R) substitution mutations of the epidermal growth factor receptor *(EGFR)* gene in non-small cell lung cancer (NSCLC) tumor tissue. It is intended to be used to select patients with NSCLC for whom Afatinib is indicated.
	CancerTYPE ID®	Classifies 28 main tumor types and 50 subtypes.
Carboplatin *	ResponseDx: Lung™	**Lung cancer:** Expression profiles and mutations in *ERCC1, TS, EGFR, RRM1, KRAS,* and *EML4-ALK* provide information for the selection of various therapies.

Drug Name (Brand name)	Test/Kit	Indication
	CEP 12 SpectrumOrange Direct Labeled Chromosome Enumeration DNA Probe	**B-cell chronic lymphocytic leukemia:** Detect AT rich alpha satellite sequences in the centromere region of chromosome 12 in conjunction with routine diagnostic cytogenetic testing. It is indicated for use as an adjunct to standard cytogenetic analysis for identifying and enumerating chromosome 12 via fluorescence in situ hybridization (FISH) in interphase nuclei of cells obtained from peripheral blood lymphocytes in patients with B-cell chronic lymphocytic leukemia (CLL).
Cetuximab * (Erbutix®)	therascreen *KRAS* RGQ PCR Kit	Colorectal cancer: Detection of seven somatic mutations in the human *KRAS* oncogene in colorectal cancer (CRC) tissue. It is intended to aid in the identification of CRC patients for treatment with Cetuximab based on a *KRAS* no mutation detected test result.
	ResponseDx: Colon™	**Colon cancer:** Expression profiles and mutations in *ERCC1, TS, EGFR, BRAF, KRAS* provide information for the selection of various therapies.
	Target GI™	**Colon cancer:** Provides information of the expression of key molecular targets—*KRAS, TS,* and *TOPO1*—to guide therapy.
	DAKO *EGFR* PharmDx Kit	**Colorectal cancer:** Identify *EGFR* expression in normal and neoplastic tissue. It detects the *EGFR (HER1)* protein in *EGFR*-expressing cells. It is indicated as an aid in identifying colorectal cancer patients eligible for treatment with Cetuximab.
	ResponseDx: Lung™	**Lung cancer:** Expression profiles and mutations in *ERCC1, TS, EGFR, RRM1, KRAS,* and *EML4-ALK* provide information for the selection of various therapies.
	CompanDx® 31-gene signature	**Breast cancer:** The test predicts "time to event" for metastasis of breast cancer, following surgery or biopsy.
Crizotinib * (Xalkori®)	Vysis *ALK* Break Apart FISH Probe Kit	**Lung cancer:** To detect rearrangements involving the ALK gene via fluorescence in situ hybridization (FISH), in non-small cell lung cancer (NSCLC) tissue specimens to aid in identifying those patients eligible for treatment with Crizotinib.
	CupPrint™	**Multiple cancers:** Determines cancer classification for tumors of unknown primary origin.
Dabrafenib * (Tafinlar®)	THxID™ BRAF Kit	**Melanoma:** Qualitative detection of the *BRAF* V600E and V600K mutations in human melanoma tissue. It is intended to be used as an aid in selecting melanoma patients whose tumors carry the *BRAF* V600E mutation for treatment with Dabrafenib.
	Dako *TOP2A* FISH PharmDx Kit	**Breast cancer:** Detect amplifications and deletions of the *TOP2A* gene in human breast cancer tissue. Deletions and amplifications of the *TOP2A* gene serve as a marker for poor prognosis in high risk breast cancer patients.
Erlotinib * (Tarceva®)	ResponseDx: Lung™	**Lung cancer:** Expression profiles and mutations in *ERCC1, TS, EGFR, RRM1, KRAS*, and *EML4-ALK* provide information for the selection of various therapies.
	Cobas *EGFR* Mutation Test	**Lung cancer:** Qualitative detection of exon 19 deletions and exon 21 (L858R) substitution mutations of the epidermal growth factor receptor (*EGFR*) gene in human non-small cell lung cancer (NSCLC) tumor tissue. It is intended to be used as an aid in selecting patients with metastatic NSCLC for Erlotinib use.

Drug Name (Brand name)	Test/Kit	Indication
5-FU * (Adrucil®)	ResponseDx: Colon™	**Colon cancer:** Expression profiles and mutations in *ERCC1, TS*, *EGFR, BRAF, KRAS* provide information for the selection of various therapies.
	ResponseDx: Lung™	**Lung cancer:** Expression profiles and mutations in *ERCC1, TS, EGFR, RRM1, KRAS*, and *EML4-ALK* provide information for the selection of various therapies.
	ResponseDx: Gastric™	**Stomach cancer:** Expression profiles and mutations in *ERCC1, TS*, and *HER2* provide information for the selection of various therapies.
Gefitinib * (Iressa®)	ResponseDx: Lung™	**Lung cancer:** Expression profiles and mutations in *ERCC1, TS, EGFR, RRM1, KRAS,* and *EML4-ALK* provide information for the selection of various therapies.
Gemcitabine * (Gemzar®)	ResponseDx: Colon™	**Colon cancer:** Expression profiles and mutations in *ERCC1, TS, EGFR, BRAF, KRAS* provide information for the selection of various therapies.
	ResponseDx: Lung™	**Lung cancer:** Expression profiles and mutations in *ERCC1, TS, EGFR, RRM1, KRAS,* and *EML4-ALK* provide information for the selection of various therapies.
	GeneSearch Breast Lymph Node (BLN) Test	**Breast Cancer:** First intra-operative and gene-based test approved for use in the US to detect the spread of breast cancer into the lymph nodes.
Imatinib mesylate * (Gleevec®)	DAKO *C-KIT* PharmDx	**GIST:** Specifically detect the c-kit protein in CD 117 antigen-expressing cells. It is indicated as an aid in the differential diagnosis of gastrointestinal stromal tumors (GIST) for those patients eligible for treatment with Imatinib mesylate.
Irinotecan * (Camptosar®)	Target GI™	**Colon cancer:** Provides information of the expression of key molecular targets—*KRAS, TS,* and *TOPO1*—to guide therapy.
	ResponseDx: Colon™	**Colon cancer:** Expression profiles and mutations in *ERCC1, TS, EGFR, BRAF, KRAS* provide information for the selection of various therapies.
	Invader® *UGT1A1* Molecular Assay	Determines the UGT1A1 *28 genotype as recommended in the label for the chemotherapeutic drug irinotecan, which is approved as a first-line therapy for metastatic colorectal cancer. Patients with a heterozygous-deficient *1 / *28 genotype or homozygous-deficient *28 / *28 genotype have greater risk for severe toxicity when treated with irinotecan therapy.
	MammaPrint	**Breast cancer:** First and only FDA-cleared IVDMIA breast cancer recurrence assay. The unique 70-gene signature of MammaPrint provides you with the unprecedented ability to identify which early-stage breast cancer patients are at risk of distant recurrence following surgery, independent of Estrogen Receptor status and any prior treatment.
	Mammostrat®	**Breast cancer:** Test used for postmenopausal, node negative, estrogen receptor expressing breast cancer patients who will receive hormonal therapy and are considering adjuvant chemotherapy.
	NADiA ProsVue	**Prostate Cancer:** The NADiA ProsVue assay is performed for patients having less than 0.1 ng/mL serum tPSA values (determined by standard-of-care assays that are FDA approved/cleared) in the first sample collected more than 6 weeks after radical prostatectomy. It is indicated for use as a prognostic marker in conjunction with clinical evaluation as an aid in identifying those patients at reduced risk for recurrence of prostate cancer for the eight year period following prostatectomy.

Drug Name (Brand name)	Test/Kit	Indication
	Oncotype DX® 16-gene signature	**Breast cancer:** A 16-gene signature (plus five reference genes) indicates whether a patient has a low, intermediate, or high risk of having a tumor return within 10 years. Low-risk patients may be treated successfully with hormone therapy alone. High-risk patients may require more aggressive treatment with chemotherapy.
	Oncotype DX® 7-gene signature	**Colon cancer:** The seven-gene signature (plus five reference genes) provides a risk score that indicates whether a patient is likely to have a tumor recurrence with stage II colon cancer. Risk levels guide treatment with adjuvant chemotherapy.
Panitumumab * (Vectibix®)	DAKO *EGFR* PharmDx Kit	**Colorectal cancer:** Identify *EGFR* expression in normal and neoplastic tissues and detects the *EGFR (HER1)* protein in *EGFR*-expressing cells. It is indicated as an aid in identifying colorectal cancer patients eligible for treatment with Panitumumab.
	ResponseDx: Colon™	**Colon cancer:** Expression profiles and mutations in *ERCC1, TS, EGFR, BRAF, KRAS* provide information for the selection of various therapies.
	Target GI™	**Colon cancer:** Provides information of the expression of key molecular targets—*KRAS, TS,* and *TOPO1*—to guide therapy.
	ResponseDx: Lung™	Lung cancer: Expression profiles and mutations in *ERCC1, TS, EGFR, RRM1, KRAS*, and *EML4-ALK* provide information for the selection of various therapies.
	Pathwork Tissue of Origin Test Kit—FFPE	Measure the degree of similarity between the RNA expression patterns in a patient's tumor and the RNA expression patterns in a database of fifteen tumor types (poorly differentiated, undifferentiated and metastatic cases) that were diagnosed according to then current clinical and pathological practice.
Pemetrexed * (Alimta®)	ResponseDx: Colon™	**Colon cancer:** Expression profiles and mutations in *ERCC1, TS, EGFR, BRAF, KRAS* provide information for the selection of various therapies.
Pertuzumab * (Perjeta®)	HERCEPTEST	**Breast cancer:** To determine *HER2* protein overexpression in breast cancer tissues from patients with metastatic gastric or gastroesophageal junction adenocarcinoma. It is indicated as an aid in the assessment of breast cancer patients for whom Pertuzumab treatment is being considered.
	HER2 FISH PharmDx Kit	**Breast cancer:** Quantitatively determine *HER2* gene amplification in breast cancer tissue and patients with metastatic gastric or gastroesophageal junction adenocarcinoma. It is indicated as an aid in the assessment of breast cancer patients for whom Pertuzumab is being considered.
	MLH1, MSH2, MSH6	**Multiple cancers:** Guides surveillance and preventive treatment based on susceptibility risk for colon and other cancers.
	BRCA1/2	**Breast cancer:** Guides surveillance and preventive treatment based on susceptibility risk for breast and ovarian cancer.
Platinum therapies *	ResponseDx: Colon™	**Colon cancer:** Expression profiles and mutations in *ERCC1, TS, EGFR, BRAF, KRAS* provide information for the selection of various therapies.
	ResponseDx: Gastric™	**Stomach cancer:** Expression profiles and mutations in *ERCC1, TS,* and *HER2* provide information for the selection of various therapies.
	PROGENSA PCA3 Assay	**Prostate cancer:** Detects Prostate Cancer Gene 3 (PCA3) messenger ribonucleic acid (mRNA) in male urine specimens to generate a PCA3 Score. The PCA3 Score is intended for use in conjunction with standard-of-care diagnostic algorithms as an aid in the diagnosis of prostate cancer.

Drug Name (Brand name)	Test/Kit	Indication
Tamoxifen * (Nolvadex®)	Breast cancer IndexSM	**Breast cancer:** Calculates a combined risk analysis for recurrence after tamoxifen treatment for ER-positive, node-negative breast cancer.
Trametenib * (Mekinist®)	THxID™ *BRAF* Kit	**Melanoma:** Qualitative detection of the *BRAF* V600E and V600K mutations in human melanoma tissue. It is intended to be used as an aid in selecting melanoma patients whose tumors carry the *BRAF* V600E or V600K mutation for treatment with Trametinib.
Trastuzumab * (Herceptin®)	Bond Oracle *HER2* IHC System	To determine *HER2* oncoprotein status in **breast cancer** tissue. It is indicated as an aid in the assessment of patients for whom Trastuzumab treatment is being considered.
	HER2 CISH PharmDx Kit	Determine HER2 gene status in **breast cancer** tissue. It is indicated as an aid in the assessment of patients for whom Trastuzumab treatment is being considered.
	HER2 FISH PharmDx Kit	Quantitatively determine *HER2* gene amplification in breast cancer tissue from patients with metastatic gastric or gastroesophageal junction adenocarcinoma. It is indicated as an aid in the assessment of breast and gastric cancer patients for whom Trastuzumab treatment is being considered.
	HERCEPTEST	Semi-quantitative assay to determine *HER2* protein overexpression in breast cancer tissues. It is indicated as an aid in the assessment of **breast and gastric cancer patients** for whom Trastuzumab treatment is being considered.
	INFORM *HER-2/NEU*	**Breast cancer:** Determines the qualitative presence of Her-2/Neu gene amplification in human breast tissue. It is indicated for use as an adjunct to existing clinical and pathologic information currently used as prognostic indicators in the risk stratification of breast cancer in patients who have had a priori invasive, localized breast carcinoma and who are lymph node-negative.
	INFORM *HER2* DUAL ISH DNA Probe Cocktail	Intended for use in determining *HER2* gene status by enumeration of the ratio of the *HER2* gene to Chromosome 17. It is indicated as an aid in the assessment of patients for whom Trastuzumab treatment is being considered.
	INSITE *HER-2/NEU* KIT	Semi-quantitative detection of over-expression of *HER-2/NEU (I.E., C-ERBB-2)* in normal and neoplastic tissue. It is indicated as an aid in the assessment of breast cancer patients for whom Trastuzumab therapy is being considered.
	PATHVYSION *HER-2* DNA Probe Kit	To detect amplification of the *HER-2/NEU* gene human breast cancer tissue. It is indicated as an aid in the assessment of patients for whom Trastuzumab treatment is being considered.
	PATHWAY ANTI-*HER-2/NEU* (4B5) Rabbit mAb	Intended for laboratory use for the semi-quantitative detection of *C-ERBB-2* antigen in neoplastic tissue. It is indicated as an aid in the assessment of breast cancer patients for whom Trastuzumab treatment is being considered.
	ResponseDx: Gastric™	**Stomach cancer:** Expression profiles and mutations in *ERCC1, TS,* and *HER2* provide information for the selection of various therapies.
	SPOT-LIGHT *HER2* CISH Kit	Quantitatively determine *HER2* gene amplification in breast carcinoma tissue. It is indicated as an aid in the assessment of patients for whom Trastuzumab treatment is being considered.

Drug Name (Brand name)	Test/Kit	Indication
Vemurafenib * (Zelboraf®)	Cobas® 4800 *BRAF* V600 Mutation Test	**Melanoma:** Detects the *BRAF* V600E mutation in human melanoma tissue. It is designed to help select patients for treatment with Vemurafenib.
	Vysis CLL FISH Probe Kit	**B-cell lymphocytic leukemia:** Detect deletion of the LSI TP53, LSI ATM, and LSI D13S319 probe targets and gain of the D12Z3 sequence in peripheral blood specimens from untreated patients with B-cell chronic lymphocytic leukemia (CLL).
	Vysis *EGR1* FISH Probe Kit	**Acute Myeloid Leukemia:** Detect deletion of the LSI EGR1 probe target on chromosome 5q in bone marrow specimens and to be used, in addition to cytogenetics, other biomarkers, morphology and other clinical information, at the time of acute myeloid leukemia (AML) diagnosis as an aid in determining prognosis. Deletion of chromosome 5q has been associated with an unfavorable prognosis in AML patients.
	Vysis UroVysion Bladder Cancer Recurrence Kit	**Bladder cancer:** Detect aneuploidy for chromosomes 3, 7, 17, and loss of the 9p21 locus via fluorescence in situ hybridization (FISH) in urine specimens from persons with hematuria suspected of having bladder cancer.
Psychology		
	GeneSightRx®	**Psychiatric disorders:** Genetic variants *(CYP1A2, CYP2D6, CYP2C19,* serotonin transporter gene SLC6A4, serotonin 2A receptor gene *5HTR2A)* in this test may affect a patient's ability to metabolize, tolerate or respond to 26 psychotropic medications.
Resperidone (Risperdal®) Olanzapine (Zyprexa®)	PhyzioType PIMS	**Psychiatric disorders:** Predicts risk of psychotropic-induced metabolic syndrome, based on a patient's combinatorial genotype for 50 genes.
Rheumatology		
Etanercept (Enbrel®) Infliximab (Remicade®)	PsoriasisDx™	**Psoriatic arthritis:** This sequencing-based assay detects the presence of gene variant *MICA-A9*, indicative of an increased risk of psoriatic arthritis. Identification of risk could guide monitoring and early treatment with TNF-alpha antagonists.

This list reflects commonly used or available products as of May 2014. Some products, for which the FDA recommends or requires pharmacogenomic testing or which have pharmacogenomic information in their label, are listed at the FDA's Web site (http://www.fda.gov/Drugs/ScienceResearch/ResearchAreas/Pharmacogenetics/ucm083378.htm). Other listed products that are novel, and/or that address large populations, have been identified via web sites and public announcements.