CONIRMMDX TEST (MDXHEALTH) FOR DETERMINING NEED FOR REPEAT PROSTATE BIOPSY

Genetic Test Product Brief - ConfirmMDx is intended to help distinguish between patients at low risk for prostate cancer who may forego repeat prostate biopsy from those at high risk who should consider repeat biopsy. ConfirmMDx measures the methylation of GSTP1, APC, and RASSF-1 genes in formalin-fixed, paraffin-embedded tissue samples from men with cancer-negative prostate biopsies.

PROMARK PROTEIN BIOMARKER TEST (METAMARK GENETICS, WALTHAM, MA, USA) FOR ASSESSING PROSTATE CANCER PROGNOSIS

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master's-level medical librarian in ECRI Institute's Health Technology Assessment Information Center. We searched PubMed, EMBASE, and selected web-based resources for guidelines, position statements, and third-party payer policies relevant to this topic and published between Feb 1, 2013 and Feb 26, 2018.

DECIPHER PROSTATE CANCER CLASSIFIER (GENOMEDX BIOSCIENCES, INC.) FOR EVALUATING PROGNOSIS AND INFORMING TREATMENT DECISIONS

Genetic Test Product Brief - Decipher tests require tissue from a formalin-fixed, paraffin-embedded tumor biopsy sample (Decipher Biopsy) or radical prostatectomy (RP) specimen (Decipher RP) and use oligonucleotide microarray technology to measure mRNA expression levels of 22 prostate-specific biomarkers from 19 unique genes.

GENETIC TESTING FOR LYNCH SYNDROME

Genetic Test Hotline Response - Lynch syndrome (LS) is an inherited predisposition to developing colorectal cancer (CRC) and other cancers. Microsatellite instability (MSI) analysis and immunohistochemistry (IHC) of mismatch repair (MMR) proteins are used to screen for LS in tumors of patients with cancer. If screening yields a positive result, LS is diagnosed by testing for germline DNA mutations in MMR genes.

CXBLADDER TRIAGE (PACIFIC EDGE, LTD.) LIQUID BIOPSY TEST FOR EXCLUDING THE LIKELIHOOD OF BLADDER CANCER

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master’s-level medical librarian in ECRI Institute’s Health Technology Assessment Information Center. We searched PubMed, EMBASE, and selected web-based resources for guidelines, position statements, and third-party payer policies relevant to this topic and published between July 1, 2012, and February 2, 2018.

COLARIS (MYRIAD GENETICS, INC.) FOR ASSESSING RISK OF HEREDITARY COLORECTAL AND UTERINE CANCERS

Genetic Test Product Brief - Colaris® is intended to assess an individual's risk of developing hereditary colorectal cancer (CRC) or endometrial cancer. Colaris performs bidirectional Sanger sequencing and large rearrangement testing of mismatch repair genes to detect mutations associated with Lynch syndrome (LS), which increase a patient’s lifetime risk for hereditary cancer.
**4KSCORE TEST (OPKO HEALTH, INC.) FOR ASSESSING RISK OF AGGRESSIVE PROSTATE CANCER BEFORE INITIAL OR REPEAT BIOPSY**

Genetic Test Product Brief - 4Kscore™ is intended to assess the risk of aggressive (high-grade) prostate cancer (Gleason score ≥7) in two categories of patients — men who have undergone prostate cancer screening and in whom prostate cancer is suspected but have not yet had a biopsy or men who have had previous negative biopsy results and are being considered for an additional biopsy.

Jan 15, 2018 - ECRlgene

**FOUNDATIONFOCUS CDXBRA (FOUNDATION MEDICINE, INC.) FOR DETERMINING ELIGIBILITY FOR RUCAPARIB (RUBRACA) TREATMENT FOR OV ...**

Genetic Test Product Brief - FoundationFocus™ CDxBRCA is intended as a companion diagnostic test for rucaparib to detect BRCA1 and BRCA2 mutations in tumors from patients with ovarian cancer who may benefit from treatment with rucaparib.

Jan 11, 2018 - ECRlgene

**MYRISK HEREDITARY CANCER PANEL (MYRIAD GENETICS, INC.) FOR IDENTIFYING INHERITED CANCER RISK**

Genetic Test Product Brief - The myRisk hereditary cancer panel is intended to predict patients' risk for developing these cancers colorectal, endometrial, gastric, hereditary breast and/or ovarian cancer (HBOC), pancreatic, prostate, melanoma. The test uses next-generation sequencing (NGS) techniques to analyze and detect pathogenic variants (PVs) in a panel of 28 genes that were selected because of their putative role in the development of hereditary cancer.

Jan 9, 2018 - ECRlgene

**ENDOPredict (MYRIAD GENETICS, INC.) FOR ASSESSING RISK OF BREAST CANCER RECURRENTCE**

Genetic Test Product Brief - EndoPredict uses the expression profile of 12 genes alone (EP score) or combined with clinical factors of tumor stage and lymph node status (EPclin score) to categorize patients with breast cancer who have undergone surgical resection as being at low or high risk of recurrence and to detect the likelihood distant metastasis 5 or 10 years after surgery.

Jan 5, 2018 - ECRlgene

**GENECEPT ASSAY (GENOMIND, INC.) FOR PREDICTING RESPONSE TO BEHAVIORAL HEALTH MEDICATIONS**

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master’s-level medical librarian in ECRI Institute’s Health Technology Assessment Information Center. We searched PubMed, EMBASE, and selected web-based resources for guidelines, position statements, and third-party payer policies relevant to this topic and published between July 1, 2012, and January 2, 2018.

Jan 2, 2018 - ECRlgene

**MELARIS GENETIC TEST (MYRIAD GENETICS, INC.) FOR ASSESSING RISK OF HEREDITARY MELANOMA**

Genetic Test Product Brief - The Melaris genetic test is intended to help assess a patient's risk for developing hereditary melanoma associated with germline mutations of the cyclin-dependent kinase inhibitor 2A (CDKN2A) gene. Melaris uses bi-directional Sanger sequencing, which is the gold standard for detecting CDKN2A mutations in individuals at risk of hereditary melanoma.

Dec 22, 2017 - ECRlgene

**LIFEKit PREDICT (PRESCIENT MEDICINE) FOR PREDICTING RISK OF OPIOID DEPENDENCY**

Genetic Test Product Brief - The LifeKit Predict test is intended to help physicians identify patients who may be at risk for misusing and becoming dependent on opioid drugs. The test is a variant genotyping assay that uses quantitative PCR (qPCR) and microarray technology to detect single nucleotide polymorphisms (SNPs) in 16 genes that may be associated with an individual's response to opioid medication and predisposition for dependency.

Dec 22, 2017 - ECRlgene
FOUNDATIONONE HEME (FOUNDATION MEDICINE, INC.) GENOMIC PROFILING TEST FOR GUIDING THERAPY FOR BLOOD CANCERS AND SARCOMAS ...

Genetic Test Product Brief - FoundationOne Heme (F1H) test is intended to identify well-established and novel genomic alterations that drive growth of hematologic malignancies (HMs) and sarcomas. These genomic alterations may provide information to assess risk, guide treatment decisions, and enroll patients in clinical trials.

Dec 13, 2017 - ECRIgene

FOUNDATIONONE CDX (FOUNDATION MEDICINE, INC.) GENOMIC PROFILING TEST FOR GUIDING TARGETED THERAPY FOR CANCER

Genetic Test Product Brief - FoundationOne CDx is a genomic profiling test intended to identify actionable genetic alterations that drive cancer growth. The test sequences 315 genes and selected introns from 28 additional genes. Genomic alterations in some of these genes (e.g., ALK, BRAF, EGFR, ERBB2, KRAS) are well-established markers for guiding treatment decisions for certain cancers.

Dec 7, 2017 - ECRIgene

PROLARIS GENETIC TEST (MYRIAD GENETICS, INC.) FOR DETERMINING PROSTATE CANCER PROGNOSIS

Genetic Test Product Brief - The Prolaris test measures the expression levels of genes involved in prostate cancer cell replication to generate a cell cycle progression (CCP) score. The CCP score ranges from 0 to 10 and scores greater than 3 are considered high risk. Prolaris is intended to assist clinicians in predicting the aggressiveness of a patient's prostate cancer.

Nov 21, 2017 - ECRIgene

ONCOTYPE DX BREAST DCIS ASSAY (GENOMIC HEALTH, INC.) FOR PREDICTING RECURRENCE RISK IN PATIENTS WITH DUCTAL CARCINOMA IN ...

Genetic Test Product Brief - The Oncotype DX Breast DCIS (ductal carcinoma in situ) test is intended to estimate the 10-year breast cancer recurrence risk in patients given a diagnosis of DCIS. The test assays the activity of 12 breast-cancer-related genes using a tumor tissue sample and stratifies patients according to their recurrence risk to aid treatment decision making.

Nov 2, 2017 - ECRIgene

HARMONY CELL-FREE FETAL DNA TEST (ARIOSA DIAGNOSTICS, INC.) FOR PRENATAL SCREENING

Genetic Test Evidence Report - Harmony is a noninvasive prenatal screening test intended to identify pregnancies at high risk of fetal chromosomal abnormality. Harmony analyzes cell-free fetal DNA (cffDNA) circulating in the maternal bloodstream. Harmony can screen for trisomies 13, 18, and 21; the microdeletion 22q11.2; and sex aneuploidies. The intended benefits of cffDNA testing include no or low risk of harm to mother and fetus and increased accuracy compared with other noninvasive prenatal screening tests (i.e., maternal serum testing, ultrasound). Potential disadvantages of cffDNA testing include false test results, need for follow-up diagnostic testing for patients with positive results, and increased cost compared with maternal serum screening.

Oct 31, 2017 - ECRIgene

PROGENSA PCA3 ASSAY (HOLOGIC, INC.) FOR DETERMINING THE NEED FOR REPEAT PROSTATE BIOPSY

Genetic Test Product Brief - The Progensa PCA3 assay is a nucleic acid amplification test intended for use in conjunction with other patient information to help determine whether men 50 years of age or older with 1 or more previous negative prostate biopsies need to undergo repeat biopsy.

Oct 31, 2017 - ECRIgene

SELECTMDX (MDXHEALTH) LIQUID BIOPSY TEST FOR PREDICTING RISK OF AGGRESSIVE PROSTATE CANCER

Genetic Test Product Brief - SelectMDx is a noninvasive, urine-based liquid biopsy assay performed after digital rectal examination to help evaluate a patient's risk of aggressive prostate cancer. The test is intended to reduce
the number of unnecessary prostate biopsies in low-risk patients and to identify those at high risk of aggressive prostate cancer who may benefit from biopsy and earlier detection. The test is not intended to diagnose prostate cancer.

Oct 5, 2017 - ECRigene

CANCERNEXT GENE PANEL (AMBRY GENETICS) FOR ASSESSING CANCER RISK

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master’s-level medical librarian in ECRI Institute’s Health Technology Assessment Information Center. We searched PubMed, EMBASE, and selected web-based resources for guidelines, position statements, and third-party payer policies relevant to this topic and published between July 1, 2012, and July 18, 2017.

Oct 2, 2017 - ECRigene

NETEST (WREN LABORATORIES, LLC) FOR DIAGNOSING AND MONITORING NEUROENDOCRINE TUMORS

Genetic Test Product Brief - NETest is intended to aid in measuring neuroendocrine tumor (NET) disease activity. The test uses a multianalyte analytic algorithm, based on a combination of gene expression data and clinical parameters, to calculate risk of highly active (or aggressive) disease. Thus, the test may differentiate between stable/low activity and highly active disease in patients with NETs.

Sep 28, 2017 - ECRigene

CXBLADDER MONITOR TEST (PACIFIC EDGE, LTD.) FOR MONITORING UROTHELIAL CARCINOMA RECURRENCE

Genetic Test Product Brief - Cxbladder Monitor is a noninvasive, urine-based, liquid biopsy test intended to monitor patients for disease recurrence after diagnosis of urothelial carcinoma (UC). Cxbladder uses quantitative polymerase chain reaction techniques to analyze expression levels of five genes associated with UC and one gene involved in inflammatory responses.

Sep 28, 2017 - ECRigene

BREASTNEXT COMPREHENSIVE TESTING PANEL (AMBRY GENETICS CORP.) TO ASSESS RISK FOR HEREDITARY BREAST AND OVARIAN CANCER

Genetic Test Product Brief - BreastNext uses a blood or saliva sample to measure inherited mutations in 17 genes, including BRCA1 and BRCA2, and assess genetic predisposition to hereditary breast and ovarian cancer (HBOC) in patients suspected to be at high risk based on medical and family history.

Sep 20, 2017 - ECRigene

CORUS CAD (CARDIODX, INC.) GENE EXPRESSION TESTING FOR ASSESSING RISK OF OBSTRUCTIVE CORONARY ARTERY DISEASE

Genetic Test Product Brief - Corus CAD is a blood test that incorporates a patient’s age, sex, and gene expression level into a score termed ASGES to identify patients with chest pain and related symptoms who are unlikely to have obstructive coronary artery disease. Corus CAD is intended to aid in clinical decision making and allow patients to avoid further CAD testing and associated risks.

Sep 18, 2017 - ECRigene

INDICATIONS FOR GENETIC TESTING FOR SPINOCEREBELLAR ATAXIA

Genetic Test Hotline Response - Spinocerebellar ataxias (SCA) are a group of hereditary disorders characterized by degeneration in parts of the brain related to movement control, such as the cerebellum and spinal cord. For many SCAs, genetic testing provides a definitive diagnosis. This report focuses on the clinical indications for pursuing genetic testing for patients suspected of having a SCA.

Sep 15, 2017 - ECRigene

PERCEPTA BRONCHIAL GENOMIC CLASSIFIER (VERACYTE, INC.) FOR ASSESSING SUSPICIOUS LUNG NODULES

Genetic Test Product Brief - The Percepta Bronchial Genomic Classifier is a genetic test intended to help clinicians identify patients with lung nodules who are at low risk for lung cancer after inconclusive results from
bronchoscopy. Being identified as low risk allows patients to avoid more invasive diagnostic procedures, such as lung tissue biopsy, in favor of clinical surveillance of their lesions. Percepta is not indicated for use in individuals who have never smoked.

Sep 15, 2017 - ECRIgene

CXBLADDER DETECT (PACIFIC EDGE, LTD.) LIQUID BIOPSY TEST FOR DIAGNOSING UROTHELIAL CARCINOMA

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master’s-level medical librarian. We searched PubMed, EMBASE, and selected web-based resources for guidelines, position statements, and third-party payer policies relevant to this topic and published between June 1, 2012, and July 6, 2017.

Aug 8, 2017 - ECRIgene

ROSETTA GX REVEAL MICRORNA CLASSIFIER (ROSETTA GENOMICS) FOR EVALUATING CYTOLOGICALLY INDETERMINATE THYROID NODULES

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master’s-level medical librarian in ECRI Institute’s Health Technology Assessment Information Center. We searched PubMed, EMBASE, and selected web-based resources for guidelines, position statements, and third-party payer policies relevant to this topic and published between June 1, 2012, and July 3, 2017.

Aug 8, 2017 - ECRIgene

COBAS EGFR MUTATION TEST V2 (ROCHE MOLECULAR SYSTEMS INC.) TO DETERMINE ELIGIBILITY FOR OSIMERTINIB (TAGRISSO) OR ERLOTINIB ...

Genetic Test Product Brief - The cobas EGFR Mutation Test version 2 (v2) is a companion diagnostic test that detects mutations in the epidermal growth factor receptor (EGFR) gene from formalin-fixed, paraffin-embedded (FFPE) tumor tissue or cell-free tumor DNA (cfDNA) in a patient’s plasma sample. The test is intended to identify patients with EGFR-positive non-small cell lung cancer (NSCLC) who may benefit from EGFR tyrosine kinase inhibitor (TKI) treatments erlotinib or osimertinib.

Aug 8, 2017 - ECRIgene

CLARITAS CLINICAL EXOME (CLARITAS GENOMICS) TEST FOR DIAGNOSING COMPLEX GENETIC DISORDERS

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master’s-level medical librarian in ECRI Institute’s Health Technology Assessment Information Center. We searched PubMed, EMBASE, and selected web-based resources for guidelines, position statements, and third-party payer policies relevant to this topic and published between June 1, 2012, and June 16, 2017.

Aug 7, 2017 - ECRIgene

ASSUREMDX BLADDER LIQUID BIOPSY TEST (MDXHEALTH) FOR IDENTIFYING PATIENTS AT LOW RISK FOR BLADDER CANCER

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master’s-level medical librarian in ECRI Institute’s Health Technology Assessment Information Center. We searched PubMed, EMBASE, and selected web-based resources for guidelines, position statements, and third-party payer policies relevant to this topic and published between June 1, 2012, and July 20, 2017.

Aug 7, 2017 - ECRIgene

ENVISIA GENOMIC CLASSIFIER (VERACYTE, INC.) FOR DIAGNOSING IDIOPATHIC PULMONARY FIBROSIS

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master’s-level medical librarian in ECRI Institute’s Health Technology Assessment Information Center. We searched PubMed, EMBASE, and selected web-based resources for guidelines, position statements, and third-party payer policies relevant to this topic and published between June 1, 2012, and July 20, 2017.
GEM CANCER PANEL (ASHION ANALYTICS) FOR INFORMING MANAGEMENT OF SOLID TUMORS

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master’s-level medical librarian in ECRI Institute’s Health Technology Assessment Information Center. We searched PubMed, EMBASE, and selected web-based resources for guidelines, position statements, and third-party payer policies relevant to this topic and published between January 1, 2012, and June 21, 2017.

Aug 1, 2017 - ECRIgene

5-FLUOROURACIL (5-FU) TOXICITY AND CHEMOTHERAPEUTIC RESPONSE TEST, 5 MUTATIONS TEST (ARUP LABORATORIES) FOR PREDICTING C ...

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master’s-level medical librarian in ECRI Institute’s Health Technology Assessment Information Center. We searched PubMed, EMBASE, and selected web-based resources for guidelines, position statements, and third-party payer policies relevant to this topic and published between July 1, 2012, and July 27, 2017.

Jul 27, 2017 - ECRIgene

UROVYSION BLADDER CANCER KIT (ABBOTT LABORATORIES, INC.) TO AID DIAGNOSIS AND MONITORING OF BLADDER CANCER

Genetic Test Product Brief - The UroVysion Bladder Cancer Kit is designed to detect aneuploidy for chromosomes 3, 7, 17, and loss of the 9p21 locus via fluorescence in situ hybridization (FISH) in urine specimens from individuals with hematuria who are suspected of having bladder cancer. The results are intended for use in conjunction with, not in place of, current standard diagnostic procedures for initial diagnosis of bladder cancer in patients with hematuria and subsequent monitoring for tumor recurrence in patients with a previous diagnosis.

Jul 27, 2017 - ECRIgene

GENESTRAT (BIODESIX, INC.) LIQUID BIOPSY TEST FOR INFORMING MANAGEMENT OF NON-SMALL CELL LUNG CANCER

Genetic Test Product Brief - The GeneStrat liquid biopsy test analyzes up to six genes associated with non-small cell lung cancer (NSCLC) to help inform whether and which targeted therapy may be indicated for a patient with advanced NSCLC. GeneStrat is also intended to provide for disease monitoring to inform appropriate changes in therapy over time.

Jul 25, 2017 - ECRIgene

PD-L1 IHC 22C3 PHARMDX (AGILENT TECHNOLOGIES, INC.) FOR DETERMINING ELIGIBILITY FOR KEYTRUDA (PEMBROLIZUMAB) THERAPY

Genetic Test Product Brief - PD-L1 IHC 22C3 pharmDx is an immunohistochemistry (IHC) companion diagnostic test intended to help identify patients with non-small cell lung cancer (NSCLC) who are likely to respond to treatment with pembrolizumab (Keytruda®). The assay is a gene-expression test that quantifies expression of programmed death-ligand 1 (PD-L1) in terms of the proportion of tumor cells (from 0% to 100%) that expresses the protein.

Jul 25, 2017 - ECRIgene

PD-L1 IHC 28-8 PHARMDX TEST (AGILENT TECHNOLOGIES, INC.) FOR INFORMING NIVOLUMAB (OPDIVO) TREATMENT DECISIONS FOR MELANO ...

Genetic Test Product Brief - The PD-L1 IHC 28-8 pharmDx is a test intended to aid in identifying patients with non-small cell lung cancer (NSCLC) or melanoma who could benefit from nivolumab (Opdivo®) treatment. The assay is a gene-expression test that detects the PD-L1 protein in tissue obtained from patients' tumors. PD-L1 protein helps tumor cells avoid immune surveillance by binding to the PD-1 receptor on immune cells. Therefore, PD-L1 expression can indicate tumor responsiveness to certain treatments. However, PD-L1 testing is not required to prescribe nivolumab and is therefore considered to be a complementary diagnostic test.

Jul 19, 2017 - ECRIgene
COBAS KRAS MUTATION TEST (ROCHE MOLECULAR SYSTEMS, INC.) FOR DETERMINING ELIGIBILITY FOR ERBITUX (CETUXIMAB) OR VECTIBIX...

Genetic Test Product Brief - The cobas KRAS Mutation test is a qualitative PCR test used to detect KRAS mutations in colorectal cancer (CRC) biopsies from patients with confirmed CRC. The test helps identify patients who harbor wild-type KRAS who may benefit from treatment with anti-epidermal growth factor receptor (EGFR) therapies.

Jul 14, 2017 - ECRIfine

GENESIGHT ANALGESIC (ASSUREX HEALTH, INC.) FOR PREDICTING PAIN MEDICATION RESPONSE

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master's-level medical librarian in ECRI Institute's Health Technology Assessment Information Center. We searched PubMed, EMBASE, and selected web-based resources for guidelines, position statements, and third-party payer policies relevant to this topic and published between June 1, 2012, and June 23, 2017.

Jul 12, 2017 - ECRIfine

ANORA MISCARRIAGE TEST (NATERA, INC.) TO AID IN DETERMINING CAUSE OF PREGNANCY LOSS

Genetic Test Product Brief - The Anora Miscarriage Test is a blood test intended to determine whether a miscarriage (also known as spontaneous abortion) was caused by fetal chromosomal abnormalities, especially in patients who have experienced recurrent miscarriages or have a history of fetal chromosomal abnormalities. Anora uses single-nucleotide polymorphism (SNP)-based chromosomal microarray (CMA) testing to detect certain chromosomal abnormalities.

Jul 10, 2017 - ECRIfine

PROSIGNA BREAST CANCER PROGNOSTIC GENE SIGNATURE ASSAY (NANOSTRING TECHNOLOGIES, INC.) FOR ASSESSING RISK OF BREAST CANC...

Genetic Test Product Brief - Prosigna testing is intended for use in postmenopausal women with hormone receptor-positive (HR+), node-negative (stage I or II), or node-positive (1-3 nodes; stage II) breast cancer treated with adjuvant endocrine therapy. The assay analyzes the expression profile of 50 genes in preserved formalin-fixed paraffin-embedded (FFPE) tissue to aid in assessing the risk of recurrence (ROR) within the next 5 to 10 years when used in conjunction with clinicopathologic information.

Jul 7, 2017 - ECRIfine

FHNEXT (AMBRY GENETICS) FOR DIAGNOSING FAMILIAL HYPERCHOLESTEROLEMIA

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master's-level medical librarian in ECRI Institute's Health Technology Assessment Information Center. We searched PubMed, EMBASE, and selected web-based resources for guidelines, position statements and third-party payer policies relevant to this topic and published between April 15, 2012, and April 14, 2017.

Jun 26, 2017 - ECRIfine

BOND ORACLE HER2 IHC SYSTEM (LEICA BIOSYSTEMS NEWCASTLE LTD.) FOR DETERMINING ELIGIBILITY FOR TRASTUZUMAB (HERCEPTIN) TR...

Genetic Test Product Brief - Human epidermal growth factor receptor 2 (HER2)-targeted therapies, such as trastuzumab, are used to treat patients with HER2-positive breast cancer. The Bond Oracle™ HER2 IHC (immunohistochemical) system is a companion diagnostic test intended to identify the HER2 status of patients with breast cancer for whom treatment with trastuzumab should be considered.

Jun 26, 2017 - ECRIfine

HYPERTROPHIC CARDIOMYOPATHY (HCM) PANEL (GENEDX) FOR DIAGNOSING OR ASSESSING RISK FOR HCM

Genetic Test Product Brief - The hypertrophic cardiomyopathy (HCM) panel is a 25-gene test used to detect pathogenic mutations, deletions, or duplications in genes associated with HCM and additional inherited
cardiomyopathies. The test is intended to confirm a diagnosis of HCM in symptomatic patients and determine the risk of developing HCM in asymptomatic family members.

Jun 22, 2017 - ECRigene

**COLON CANCER LIQUID BIOPSY TEST (BIOCEPT, INC.) FOR INFORMING TREATMENT DECISIONS**

Genetic Test Product Brief - The Biocpet colon cancer liquid biopsy test using the Target Selector platform analyzes both circulating tumor cells and circulating tumor DNA (ctDNA) from patients with colorectal cancer (CRC) to determine the mutation status of the BRAF and KRAS genes. The test is intended to inform targeted therapy recommendations and monitor the response to ongoing therapy.

Jun 19, 2017 - ECRigene

**ANEUVYSIS TEST (ABBOTT LABORATORIES, INC.) FOR DIAGNOSING FETAL CHROMOSOMAL ANEUPLOIDIES**

Genetic Test Product Brief - The AneuVysion kit is a prenatal FISH-based assay that requires a sample of amniotic fluid obtained during amniocentesis. It is intended to aid diagnosis of fetal aneuploidies (abnormal numbers) of chromosomes 13, 18, 21, X, and/or Y in patients judged to be at high risk for carrying a fetus with such abnormalities.

Jun 1, 2017 - ECRigene

**COLVERA (CLINICAL GENOMICS PATHOLOGY, INC.) LIQUID BIOPSY TEST FOR DETECTING RECURRENCE OF COLORECTAL CANCER**

Genetic Test Product Brief - Colvera™ is a blood-based liquid biopsy test intended to detect colorectal cancer (CRC) recurrence in patients undergoing routine follow-up testing. The test measures methylation of two genes that indicate the presence of CRC. Colvera is intended to detect disease recurrence earlier to improve patient survival.

May 25, 2017 - ECRigene

**FOCUS::DLBCL&FL (CANCER GENETICS, INC.) FOR INFORMING MANAGEMENT OF DIFFUSE LARGE B-CELL LYMPHOMA AND FOLLICULAR LYMPHOMA ...**

Genetic Test Product Brief - The FocusDLBCL&FL test uses a next-generation sequencing (NGS) approach to analyze a panel of 45 genes intended to determine patient risk stratification, aid disease management, and aid treatment selection for diffuse large B-cell lymphoma (DLBCL) or follicular lymphoma (FL).

May 25, 2017 - ECRigene

**MAMMAPRINT (AGENDIA, INC.) FOR ASSESSING METASTATIC RISK OF EARLY-STAGE BREAST CANCER**

Genetic Test Product Brief - MammaPrint, a 70-gene expression profiling (GEP) test, is an FDA-approved microarray test that uses a formalin-fixed, paraffin-embedded (FFPE) sample. It is intended to be used in conjunction with standard clinicopathologic factors for determining the 5-year risk for distant metastases and optimal treatment regimens for women with early-stage breast cancer and certain clinical characteristics.

May 3, 2017 - ECRigene

**FOUNDATIONACT (FOUNDATION MEDICINE, INC.) LIQUID BIOPSY GENOMIC PROFILING TEST FOR GUIDING TARGETED THERAPY FOR SOLID TU ...**

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master’s-level medical librarian in ECRI Institute’s Health Technology Assessment Information Center. We searched PubMed, EMBASE, and selected web-based resources for guidelines, position statements and third-party payer policies relevant to this topic and published between May 4, 2012, and May 3, 2017.

Apr 20, 2017 - ECRigene

**ATHEROGXONE (ADMERA HEALTH) FOR AIDING RISK ASSESSMENT AND DIAGNOSIS OF EARLYATHEROSCLEROSIS**
Genetic Test Product Brief - AtheroGxOne is intended to aid in risk assessment and diagnosis of conditions related to early atherosclerosis, including premature coronary artery disease (CAD) in men <50 years and women < 60 years, familial hypercholesterolemia (FH), familial hypertriglyceridemia, mixed hyperlipidemias, and maturity-onset diabetes of the young (MODY).

Apr 18, 2017 - ECRgene

**PDGFRB FISH TEST (ARUP LABORATORIES) FOR DETERMINING ELIGIBILITY FOR GLEEVEC TREATMENT OF MELODYPLASTIC SYNDROME/ MYEL ...**

Genetic Test Product Brief - The platelet derived growth factor receptor β (PDGFRB) fluorescence in situ hybridization (FISH) test is provided by a single reference laboratory and is intended to measure the presence of PDGFRB gene rearrangements in the bone marrow of patients with myelodysplastic syndrome/myeloproliferative disease (MDS/MPD).

Apr 17, 2017 - ECRgene

**PANORAMA CELL-FREE FETAL DNA TEST (NATERA, INC.) FOR PRENATAL SCREENING**

Genetic Test Evidence Report - Panorama (Natera, Inc.) is a noninvasive prenatal screening test intended to identify pregnancies at high risk of fetal chromosomal abnormality. Panorama analyzes DNA from the placenta circulating in the maternal bloodstream with next-generation sequencing.

Apr 13, 2017 - ECRgene

**FAMILIAL HYPERCHOLESTEROLEMIA (INVITAE) FOR DIAGNOSING FAMILIAL HYPERCHOLESTEROLEMIA**

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master’s-level medical librarian in ECRI Institute’s Health Technology Assessment Information Center. We searched PubMed, EMBASE, and selected web-based resources for guidelines, position statements and third-party payer policies relevant to this topic and published between April 14, 2012, and April 13, 2017.

Apr 10, 2017 - ECRgene

**RENALNEXT TEST (AMBRY GENETICS) FOR ASSESSING RISK OF HEREDITARY KIDNEY CANCER**

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master’s-level medical librarian in ECRI Institute’s Health Technology Assessment Information Center. We searched PubMed, EMBASE, and selected web-based resources for guidelines, position statements and third-party payer policies relevant to this topic and published between April 11, 2012, and April 10, 2017.

Apr 7, 2017 - ECRgene

**GYNPLUS TEST (AMBRY GENETICS) FOR ASSESSING RISK OF OVARIAN AND UTERINE CANCER**

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master’s-level medical librarian in ECRI Institute’s Health Technology Assessment Information Center. We searched PubMed, EMBASE, and selected web-based resources for guidelines, position statements and third-party payer policies relevant to this topic and published between April 8, 2012, and April 7, 2017.

Apr 6, 2017 - ECRgene

**BREAST CANCER INDEX TEST (BIOTHERANOSTICS, INC.) FOR ASSESSING METASTATIC RISK AND INFORMING MANAGEMENT OF EARLY-STAGE I ...**

Genetic Test Product Brief - The Breast Cancer Index (BCI) Risk of Recurrence & Extended Endocrine Benefit Test is a gene-expression profiling (GEP) test intended for use in patients with estrogen receptor-positive (ER+), lymph node-negative (LN-), or lymph node positive (LN+) early-stage invasive breast cancer, who are distant recurrence (DR)-free. The BCI Predictive component of the assay reports whether a patient has a high or low likelihood of benefiting from extended (>5 years) endocrine therapy.

Apr 4, 2017 - ECRgene
DECISIONDX-UM (CASTLE BIOSCIENCES, INC.) FOR ASSESSING METASTATIC RISK IN PATIENTS WITH UVEAL MELANOMA

Genetic Test Product Brief - The DecisionDx-UM test is a multigene expression assay intended to predict the risk of metastasis in patients with primary uveal melanoma (UM) who do not show evidence of metastatic disease. DecisionDx-UM uses primary tumor tissue specimens to determine the gene expression profile (GEP) of 15 genes.

Apr 4, 2017 - ECRgene

HHTNEXT TEST (AMBRY GENETICS) FOR SCREENING OR DIAGNOSING HEREDITARY HEMORRHAGIC TELANGIECTASIA

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master’s-level medical librarian in ECRI Institute’s Health Technology Assessment Information Center. We searched PubMed, EMBASE, and selected web-based resources for guidelines, position statements and third-party payer policies relevant to this topic and published between April 5, 2012, and April 4, 2017.

Apr 3, 2017 - ECRgene

HORIZON 4 CARRIER SCREEN (NATERA, INC.) FOR SCREENING CARRIER STATUS FOR AUTOSOMAL RECESSIVE AND X-LINKED GENETIC CONDIT ...

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master’s-level medical librarian in ECRI Institute’s Health Technology Assessment Information Center. We searched PubMed, EMBASE, and selected web-based resources for guidelines, position statements and third-party payer policies relevant to this topic and published between April 4, 2012, and April 3, 2017.

Mar 31, 2017 - ECRgene

ADMARK APP DNA SEQUENCING TEST AND DUPLICATION TEST (ATHENA DIAGNOSTICS, INC.) FOR DIAGNOSING ALZHEIMERS DISEASE

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master’s-level medical librarian in ECRI Institute’s Health Technology Assessment Information Center. We searched PubMed, EMBASE, and selected web-based resources for guidelines, position statements, and third-party payer policies relevant to this topic and published between April 1, 2012, and March 31, 2017.

Mar 30, 2017 - ECRgene

PGLNEXT TEST (AMBRY GENETICS) FOR ASSESSING RISK FOR NEUROENDOCRINE TUMORS

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master’s-level medical librarian in ECRI Institute’s Health Technology Assessment Information Center. We searched PubMed, EMBASE, and selected web-based resources for guidelines, position statements and third-party payer policies relevant to this topic and published between March 31, 2012, and March 30, 2017.

Mar 17, 2017 - ECRgene

TRIO WHOLE EXOME SEQUENCING (BAYLOR COLLEGE OF MEDICINE) FOR DIAGNOSING DEVELOPMENTAL DELAYS

Genetic Test Bibliography - This bibliography provides results of a mediated search conducted by a master’s-level medical librarian in ECRI Institute’s Information Center. We searched PubMed, EMBASE and selected web-based resources for guidelines, position statements and policies relevant to this topic and published between March 19, 2012, and March 17, 2017.

Mar 7, 2017 - ECRgene

TROVERA KRAS MUTATION DETECTION TEST (TROVAGENE, INC.) FOR INFORMING MANAGEMENT OF KRAS-ASSOCIATED CANCERS

Genetic Test Product Brief - The Trovera KRAS Mutation Detection Test is a noninvasive liquid biopsy test that uses a patient’s urine or blood sample to detect mutations in the Kirsten rat sarcoma viral oncogene homolog
(KRAS) gene. It is intended to inform management of patients with KRAS-associated cancers (e.g., colorectal cancer [CRC] or non-small cell lung cancer [NSCLC]), who may not benefit from certain targeted therapies if they are positive for KRAS mutations.

Mar 1, 2017 - ECRIlgene

GPS CANCER TEST (NANTHEALTH, INC.) FOR INFORMING MANAGEMENT OF SOLID TUMORS

Genetic Test Product Brief - The Genomic Proteomic Spectrometry (GPS) Cancer™ Test is intended to identify clinically actionable genomic alterations in patients with solid tumor cancers to inform treatment decisions and improve patient outcomes. The test requires both a formalin-fixed, paraffin-embedded (FFPE) tumor biopsy sample and a blood sample. The test combines whole-genome DNA sequencing, whole-transcriptome mRNA sequencing, and quantitative, mass spectrometry–based proteomics. A proprietary algorithm integrates DNA and mRNA sequencing data and determines associations with cellular signaling pathways.

Feb 28, 2017 - ECRIlgene

PARADIGM CANCER DIAGNOSTIC PCDx TEST (PARADIGM DIAGNOSTICS, INC.) FOR INFORMING MANAGEMENT OF SOLID TUMORS

Genetic Test Product Brief - Paradigm Cancer Diagnostic (PCDx) is a DNA-, mRNA-, and protein-based biomarker test intended to identify actionable molecular alterations in patients with solid tumor cancers to help select targeted therapies, identify clinical trials on such therapies, and potentially improve patient outcomes. PCDx requires a formalin-fixed, paraffin-embedded sample and uses next-generation sequencing and immunohistochemistry (IHC).

Feb 27, 2017 - ECRIlgene

THYROID GENE EXPRESSION CLASSIFIER (AFIRMA) FOR ASSESSING INDETERMINATE THYROID NODULES

Genetic Test Evidence Report - The Afirma Gene Expression Classifier (GEC) is intended to help identify thyroid nodules that are at low risk for malignancy after cytologic analysis from a fine needle aspiration (FNA) biopsy returns an indeterminate result. The test is intended to enable low-risk patients to opt for clinical surveillance and avoid diagnostic thyroid surgery.

Feb 14, 2017 - ECRIlgene

DECISIONDX-MELANOMA (CASTLE BIOSCIENCES, INC.) FOR ASSESSING METASTATIC RISK OF STAGE I OR II CUTANEOUS MELANOMA

Genetic Test Product Brief - The DecisionDx-Melanoma test is a multigene expression assay that analyzes a panel of 31 genes (28 discriminating genes and 3 control genes) that exhibit minimal expression changes in both metastatic and nonmetastatic melanoma cells. It is performed on primary tumor tissue specimens of a patient's cutaneous melanoma tumor. The test is intended to predict the risk of metastasis in patients with stage I, II, or III cutaneous melanoma whose disease has not spread beyond the original tumor.

Feb 6, 2017

ONCOTYPE SEQ LIQUID SELECT (GENOMIC HEALTH, INC.) LIQUID BIOPSY TEST FOR INFORMING MANAGEMENT OF STAGE IV SOLID TUMORS

Genetic Test Product Brief - Oncotype SEQ® Liquid Select is a noninvasive blood-based liquid biopsy test that detects mutations in 17 cancer-associated genes. The test uses next-generation sequencing (NGS) technology to examine cell-free DNA (cfDNA) and detect single nucleotide variations (SNVs), insertions and deletions (indels), gene fusions, and copy number gains.

Jan 26, 2017 - ECRIlgene

TROVERA EGFR MUTATION DETECTION TEST (TROVAGENE, INC.) FOR INFORMING MANAGEMENT OF EGFR-ASSOCIATED DISORDERS

Genetic Test Product Brief - The Trovera® EGFR Mutation Detection Test is a noninvasive liquid biopsy test that uses a patient's urine or blood sample to detect mutations in the epidermal growth factor receptor (EGFR) gene.
It is intended to inform patient management of individuals with the mutations (e.g., patients with non-small cell lung cancer [NSCLC]).

Jan 25, 2017 - ECRIgene

GUARDANT360 (GUARDANT HEALTH) LIQUID BIOPSY TEST FOR INFORMING MANAGEMENT OF ADVANCED SOLID TUMORS

Genetic Test Product Brief - Guardant360™ is a liquid biopsy test that uses a patient's blood sample to detect point mutations/single nucleotide variants in 73 genes by analyzing cell-free DNA (cfDNA), also known as circulating tumor DNA (ctDNA). The test is intended to inform management of patients with advanced or metastatic solid tumor cancers, including breast, colorectal, and lung cancer.

Jan 18, 2017 - ECRIgene

ONCOTYPEDx AR-V7 NUCLEUS DETECT (ALSO CALLED EPIC AR-V7) LIQUID BIOPSY TEST (GENOMIC HEALTH/EPIC SCIENCES, INC.) TO PRED ...

Genetic Test Product Brief - Metastatic castration-resistant prostate cancer (mCRPC) that expresses the androgen-receptor splice variant 7 (AR-V7) is known to be resistant to androgen inhibitors used to treat prostate cancer. The OncotypeDX AR-V7 Nucleus Detect (also called Epic AR-V7) liquid biopsy test is intended to detect AR-V7 in circulating tumor cells (CTCs) from a patient's blood sample and determine whether patients will have resistance to treatment with androgen synthesis inhibitors and whether an alternative, such as taxane-based chemotherapy, should be considered.

Jan 6, 2017 - ECRIgene

THYGENX ONCOGENE PANEL PLUS THYRAMIR MICRONA CLASSIFIER (INTERPACE DIAGNOSTICS, LLC) FOR EVALUATING CYTOLOGICALLY INDET ...

Genetic Test Product Brief - ThyGenX® Oncogene Panel and ThyraMIR™ microRNA Classifier are complimentary genetic tests intended to aid diagnosis of thyroid nodules for which cytopathology analysis after fine needle aspiration (FNA) biopsy yields an indeterminate result (lesion classified as neither benign nor malignant). The test panels' results are intended to be used together with other available clinical information to inform patient management.

Jan 5, 2017 - ECRIgene

STOOL DNA–BASED SCREENING TEST (COLOGUARD) FOR DETECTING DNA AND HEMOGLOBIN BIOMARKERS ASSOCIATED WITH COLORECTAL CANCER ...

Genetic Test Evidence Report - Cologuard® (Exact Sciences, Madison, WI, USA) is a multitarget stool DNA–based colorectal cancer (CRC) screening test for patients age 50 years or older who are at average risk for CRC. To undergo testing with Cologuard, a patient receives a prescription from a primary care provider, collects a stool sample at home, and ships the sample to the manufacturer for analysis.

Dec 14, 2016 - ECRIgene

GENETIC TESTING FOR SCREENING OR DIAGNOSING VON HIPPEL-LINDAU SYNDROME

Genetic Test Hotline Response - Von Hippel-Lindau (VHL) syndrome is a rare genetic disorder characterized by abnormal growth of tumors and cysts in various parts of the body. Tumors can be benign or cancerous and occur throughout life, although most often during young adulthood. Molecular genetic testing for VHL gene mutations is used to confirm VHL syndrome.

Dec 1, 2016 - ECRIgene

PROOVE OPIOID RESPONSE (PROOVE BIOSCIENCES, INC.) FOR PREDICTING CLINICAL RESPONSE AND OPTIMAL DOsing OF OPIOID MEDICATI ...

Genetic Test Product Brief - The Proove® Opioid Response test is intended to evaluate genetic markers to determine whether a patient will be a good or poor responder to opioid medications and to inform the best dosages to prescribe for a patient.
Nov 30, 2016 - ECRIgene
VERISTRAT (BIODESIX, INC.) FOR PREDICTING RESPONSE OF ADVANCED NON-SMALL CELL LUNG CANCER TO EGFR TYROKINASE INHIBITOR T...
Genetic Test Product Brief - VeriStrat® serum-based proteomic test is intended to help physicians determine whether patients with advanced non-small cell lung cancer (NSCLC) should receive treatment with epidermal growth factor receptor tyrosine kinase inhibitors or single-agent chemotherapy. The test is also intended to predict overall disease aggressiveness.

Nov 28, 2016 - ECRIgene
TROVERA BRAF (TROVAGENE, INC.) LIQUID BIOPSY TEST FOR INFORMING MANAGEMENT OF BRAF-ASSOCIATED DISORDERS
Genetic Test Product Brief - The Trovera® BRAF Mutation Detection Test is a noninvasive liquid biopsy test that uses a patient's urine or blood sample to detect mutations in the v-raf murine sarcoma viral oncogenes homolog B1 (BRAF) gene. It is intended to inform patient management of individuals with the mutations.

Nov 1, 2016 - ECRIgene
BRCA1 AND BRCA2 GENE TESTING FOR ASSESSING RISK OF BREAST AND OVARIAN CANCER
Genetic Test Hotline Response - Individuals at high risk for BRCA gene mutations are candidates for BRCA genetic testing. This includes individuals with family members who have, or have had, breast or ovarian cancer and/or who are known to harbor BRCA mutations. Testing for BRCA mutations is complex. More than 1,200 BRCA1 and BRCA2 mutations are known. Thus, a comprehensive analysis of either gene requires full-gene DNA sequencing.

Oct 25, 2016 - ECRIgene
EPI PROCOLON TEST (EPIGENOMICS AG) FOR COLORECTAL CANCER SCREENING
Genetic Test Product Brief - Epi proColon® is a PCR-based assay intended to detect methylated DNA from the SEPT9 tumor suppressor gene in blood plasma as a biomarker for colorectal cancer (CRC) screening. The test is targeted toward patients who are unwilling or unable to undergo CRC screening by colonoscopy.

Oct 25, 2016 - ECRIgene
PROOVE OPIOID RISK (PROOVE BIOSCIENCES, INC.) FOR ASSESSING RISK OF OPIOID MISUSE
Genetic Test Product Brief - The Proove® Opioid Risk Test (previously known as Narcotic Risk test) is intended to help physicians identify patients who may be at risk for misusing opioid drugs and becoming addicted. The test is a variant genotyping assay that uses quantitative PCR (qPCR) to detect 12 single nucleotide polymorphisms (SNPs) in genes that may be associated with an individual's response to opioid medication and predisposition for dependency COMT, DBH, DRD1, DRD2, DRD4, GABRG2, HTR2A, MTHFR, OPRK1, OPRM1, SLC6A3, and SLC6A4.

Oct 1, 2016 - ECRIgene
COUNSELING OF INDIVIDUALS AND FAMILIES AT RISK FOR HUNTINGTON’S DISEASE
Genetic Test Hotline Response - Huntington’s disease (HD) is an inherited neurologic disorder that causes involuntary movements, severe emotional disturbance, and cognitive decline. No treatment for HD is available. Significant emotional and ethical issues surround its diagnosis and the detection of the disease-causing gene in asymptomatic patients.

Sep 30, 2016 - ECRIgene
BIOSPECIFX BIOMARKER TEST (HELOMICS CORP.) FOR INFORMING MANAGEMENT OF SOLID TUMORS
Genetic Test Product Brief - The BioSpeciFx® biomarker test is a laboratory-developed test consisting of a group of molecular assays intended to determine the chemosensitivity and chemoresistance of a patient's tumor and the association of these biomarkers with patient prognosis. It is intended to aid patient management in deciding treatment regimens for various solid tumors.
GENETIC TESTING FOR PMP22 FOR CHARCOT-MARIE-TOOTH DISEASE TYPE 1A

Genetic Test Hotline Response - Charcot-Marie-Tooth (CMT) disease subtypes (e.g., type 1A) are categorized on the basis of genetic variants in causative genes, so molecular genetic testing plays an essential role in making a differential diagnosis for patients with CMT. Establishing a diagnosis of CMT1A requires a genetic analysis of the PMP22 gene.

PHARMACOGENETIC TESTING TO GUIDE TREATMENT OF CHRONIC PAIN

Genetic Test Hotline Response - Increased knowledge of the role genetics plays in drug metabolism has ushered in an era of pharmacogenetic testing to guide treatment of many conditions, including chronic pain. Many studies have sought to identify and examine genetic characteristics in people that might be associated with inadequate responses to various pain medications, including opioids.

GENETIC TESTING FOR PREDICTING THE RISK OF HUNTINGTON’S DISEASE

Genetic Test Hotline Response - Huntington's disease (HD) is an inherited autosomal dominant disorder characterized by involuntary movements (chorea), progressive dementia, and psychological disturbances (e.g., depression, psychosis, irritability). It is caused by an increased number of cytosine-adenine-guanine (CAG) repeats in the huntingtin (HTT) gene, called repeat expansion.

HARMONY PRENATAL TEST (ARIOSA DIAGNOSTICS) FOR DETERMINING RISK OF FETAL ANEUPLOIDY (TRISOMY 13, 18, 21; X AND Y ANEUPLO ...
IMMUNOASSAY PANELS FOR DETECTING TUMOR-ASSOCIATED ANTIGENS AND AUTOANTIBODIES ASSOCIATED WITH LUNG CANCER

Genetic Test Evidence Report - Immunoassay panel blood tests that detect tumor-associated antigens (TAAs) and TAA-targeted autoantibodies are intended to aid in early lung cancer diagnosis for asymptomatic patients at high risk. These tests may also aid in risk stratification for indeterminate lung nodules. TAAs and their autoantibodies are potential biomarkers for lung cancer that may be present in the blood months to years before patients are symptomatic.

OVERA MULTIVARIATE BIOMARKER TEST (VERMILLION, INC.) FOR ASSESSING RISK OF MALIGNANCY OF AN OVARIAN MASS

Genetic Test Product Brief - The second-generation Overa® multivariate biomarker test (also called OVA1 Next Generation test, OVA2, and multivariate index assay second generation) is intended to aid in assessing whether an ovarian mass in a patient for whom surgery is planned has a low or high likelihood of being malignant.

THERASCREEN KRAS RGQ PCR KIT (QIAGEN N.V.) FOR DETERMINING ELIGIBILITY FOR VECTIBIX OR ERBITUX TREATMENT FOR COLORECTAL ...

Genetic Test Product Brief - The therascreen® KRAS RGQ PCR kit is intended to detect 7 somatic mutations in codons 12 and 13 of the human KRAS oncogene to help identify patients with colorectal cancer (CRC) harboring wild-type KRAS who are eligible for treatment with panitumumab (Vectibix®) or cetuximab (Erbitux®).

COBAS® 4800 BRAF V600 MUTATION TEST TO DETERMINE ELIGIBILITY FOR VEMURAFENIB (ZELBORAF) THERAPY FOR METASTATIC MELANOMA

Genetic Test Product Brief - The cobas 4800 BRAF V600 mutation test is a companion diagnostic test intended to aid in selecting patients with metastatic melanoma whose disease harbors the BRAFV600E mutation and who are eligible for treatment with the BRAF-inhibitor vemurafenib (Zelboraf®).

ONCOTYPE DX COLON CANCER ASSAY (GENOMIC HEALTH, INC.) FOR PREDICTING RECURRENCE OF COLON CANCER

Genetic Test Product Brief - The Oncotype DX colon cancer assay uses a preserved formalin-fixed, paraffin-embedded (FFPE) biopsy tissue sample from a patient with stage II or III colon cancer to analyze the expression profile of 12 genes, determine cancer recurrence risk after surgical resection of the tumor, and predict disease response to chemotherapy.

BRACANALYSIS TEST (MYRIAD GENETICS, INC.) FOR ASSESSING RISK OF HEREDITARY BREAST AND OVARIAN CANCER

Genetic Test Product Brief - The BRACAnalysis® test is intended to confirm the presence of mutations in the breast cancer susceptibility genes, BRCA1 and BRCA2, to assess a patient's risk of developing hereditary breast or ovarian cancer (HBOC). The test comes in two forms Comprehensive BRACAnalysis and Integrated BRACAnalysis.

VYSIS ALK BREAK APART FISH TEST (ABBOTT MOLECULAR) FOR DETERMINING ELIGIBILITY FOR XALKORI (CRIZOTINIB) TREATMENT FOR NO ...
Genetic Test Product Brief - The Vysis ALK Break Apart FISH (fluorescence in situ hybridization) Probe Kit is a companion diagnostic test used in patients with non-small cell lung cancer (NSCLC) to determine whether they have the ALK (anaplastic lymphoma receptor tyrosine kinase) gene rearrangement, which would make them appropriate candidates for treatment with the ALK inhibitor crizotinib.

May 1, 2016 - ECRIgene

COLOPRINT (AGENDIA, INC.) FOR DETERMINING RISK OF RECURRENCE FOR COLON CANCER

Genetic Test Product Brief - ColoPrint® 18-gene colon cancer recurrence assay is intended to predict the 5-year recurrence risk in patients with stage II colon cancer. ColoPrint combines clinical and histopathologic factors to stratify patients as having either low or high risk of colon cancer recurrence.

May 1, 2016 - ECRIgene

FAMILY PREP SCREEN (COUNSYL, INC.) FOR SCREENING CARRIER STATUS FOR MULTIPLE GENETIC DISEASES

Genetic Test Product Brief - The Family Prep Screen assesses DNA samples for the presence of genetic variants associated with heritable diseases. It is intended to identify adults who carry clinically relevant genetic mutations associated with 1 or more of the 110 inherited genetic diseases to inform reproductive decisions.

Apr 1, 2016 - ECRIgene

RISK OF OVARIAN MALIGNANCY ALGORITHM (ROMA) (FUJIREBIO DIAGNOSTICS, INC.) FOR ASSESSING RISK OF MALIGNANCY OF AN OVARIAN...

Genetic Test Product Brief - The ROMA™ test is intended to stratify premenopausal and postmenopausal women who have an ovarian mass as having low or high likelihood for ovarian malignancy upon surgery. The test uses a single serum sample and combines the results of two in vitro diagnostic assays (HE4 EIA, ARCHITECT CA 125 II™) and a patient's menopausal status into a numeric score intended to predict the risk of having ovarian cancer upon surgery to remove the ovarian mass.

Apr 1, 2016 - ECRIgene

PANEXIA (MYRIAD GENETICS, INC.) FOR DETECTING RISK OF HEREDITARY PANCREATIC CANCER

Genetic Test Product Brief - Panexia® is a genetic test intended to provide information about inherited risk for pancreatic cancer. Panexia detects mutations in the BRCA2 and PALB2 genes, both known to be associated with pancreatic cancer. A healthcare provider can use Panexia test results to plan an individualized strategy for patient management.

Apr 1, 2016 - ECRIgene

PROMETHEUS IBD SGI DIAGNOSTIC (PROMETHEUS LABORATORIES, INC.) FOR DIFFERENTIATING INFLAMMATORY BOWEL DISEASE FROM NON-IN...

Genetic Test Product Brief - The test measures the levels of 17 serologic, genetic, and inflammatory biomarkers using multiple analytic technologies, including enzyme-linked immunosorbent assay (ELISA), chemiluminescent assay, indirect immunofluorescent assay (IFA), and polymerase chain reaction (PCR)/single nucleotide polymorphism (SNP) assays. A Smart Diagnostic Algorithm is used for inflammatory bowel disease (IBD) prediction and differentiation.

Apr 1, 2016 - ECRIgene

CYTOSCAN DX ASSAY (AFFYMETRIX, INC.) FOR DETECTING CHROMOSOMAL VARIATIONS ASSOCIATED WITH DEVELOPMENTAL DELAY AND INTELL...

Genetic Test Product Brief - The CytoScan® Dx Assay is intended to aid diagnosis of children’s developmental delay and intellectual disability, congenital anomalies, and dysmorphic features with a high-resolution genome-wide analysis of genetic aberrations. According to the manufacturer, CytoScan analyzes the whole genome in a single assay.

Apr 1, 2016 - ECRIgene
CANCERTYPE ID (BIOTHERANOSTICS, INC.) TO AID IN DETERMINING TUMOR TYPE OF CANCERS OF UNKNOWN PRIMARY ORIGIN
Genetic Test Product Brief - CancerTYPE ID® is intended for use with standard clinical and pathologic assessment to classify tumor tissue of origin and subtype in patients with cancer of unknown primary origin.

Apr 1, 2016 - ECRIgene

ONCOTYPE DX BREAST CANCER ASSAY (GENOMIC HEALTH, INC.) FOR PREDICTING LONG-TERM RISK OF BREAST CANCER RECURRENCE
Genetic Test Product Brief - The Oncotype DX® breast cancer assay analyzes the expression profile of 21 genes and is intended to determine the 10-year recurrence risk of early-stage, invasive breast cancer and to predict disease response to chemotherapy so that those who would not benefit can avoid chemotherapy.

Mar 1, 2016 - ECRIgene

GENETIC TESTING FOR MANAGING INHERITED CARDIAC CHANNELOPATHIES
Genetic Test Hotline Response - Inherited cardiac channelopathies involve variations in the structure and function of ion-transferring channels in the heart and can result in sudden cardiac death. Multiple genetic tests have been developed to detect gene mutations thought to be associated with inherited cardiac channelopathies. Techniques used include polymerase chain reaction, denaturing high-performance liquid chromatography, DNA sequencing, next-generation sequencing, and whole-exome sequencing.

Mar 1, 2016 - ECRIgene

ONCOTYPE DX PROSTATE CANCER ASSAY (GENOMIC HEALTH, INC.) FOR PREDICTING AGGRESSIVENESS OF PROSTATE CANCER
Genetic Test Product Brief - The Oncotype® DX Prostate Cancer Assay is intended to predict the likelihood of aggressive prostate cancer in patients with a diagnosis of very low, low, and low-intermediate risk, determined by National Comprehensive Cancer Network criteria. The test is meant to predict a patient’s likelihood of having favorable pathology results at the time of prostate biopsy.

Mar 1, 2016 - ECRIgene

GENETIC TESTING FOR HYPERTROPHIC CARDIOMYOPATHY
Genetic Test Hotline Response - More than 1,500 mutations that may cause hypertrophic cardiomyopathy (HCM) have been identified. Most of these mutations are in one of the genes that encode different components of the sarcomere (the functional unit of muscle tissue). About 90% of the mutations are identified in four genes MYH7, MYBPC3, TNNT2, TNNI3. Genetic testing may help confirm the HCM diagnosis, differentiate the causes of HCM, and identify at-risk family members.

Mar 1, 2016 - ECRIgene

PANCRAGEN (INTERPACE DIAGNOSTICS, LLC) FOR ASSESSING CYSTS TO DETERMINE RISK FOR PANCREATIC CANCER
Genetic Test Product Brief - PancraGEN™ (previously known as PathFinderTG®-Pancreas) is a molecular test intended to aid diagnosis of pancreatic cysts and assess risk of pancreatic cancer by combining genetic analysis with other clinical and imaging information. The test analyzes DNA from cystic fluid; sequencing is done on a portion of the KRAS gene to determine the presence of cancer-related mutations.

Mar 1, 2016 - ECRIgene

ARRAY-BASED COMPARATIVE GENOMIC HYBRIDIZATION FOR SCREENING OR DIAGNOSING DEVELOPMENTAL DISORDERS IN FETUSES, INFANTS, A ...
Genetic Test Hotline Response - DNA microarray-based comparative genomic hybridization (CGH or aCGH) is a technology that can assess the copy number of thousands of genes at once. Microarrays can be either "targeted" or "whole genome." Whole-genome microarrays contain probes spanning the entire human genome; targeted
arrays contain probes specific to only those DNA segments of interest, such as known mutations that cause a particular disease.

Mar 1, 2016 - ECRIfene

**PRECISETYPE HEA MOLECULAR BEADCHIP TEST (BIOARRAY SOLUTIONS, LTD.) FOR RED BLOOD CELL ANTIGEN TYPING**

Genetic Test Product Brief - PreciseType™ HEA (human erythrocyte antigen) Molecular BeadChip Test is a high-throughput, in vitro diagnostic (IVD) assay intended to help detect single nucleotide polymorphisms (SNPs) of red blood cell (erythrocyte) antigens in donor blood and patients receiving blood transfusions. It is intended to provide additional information for determining donor-recipient blood compatibility.

Jan 1, 2016 - ECRIfene

**ARRAY-BASED COMPARATIVE GENOMIC HYBRIDIZATION FOR SCREENING OR DIAGNOSING CLINICAL CONDITIONS**

Genetic Test Hotline Response - Array-based comparative genomic hybridization (aCGH) using DNA microarray is designed to allow clinicians to identify many genetic variations to inform clinical practice. This technique relies on the ability of single-stranded DNA molecules to hybridize with a specific complementary DNA sequence.

Nov 1, 2015 - ECRIfene

**GENESIGHT PSYCHOTROPIC PHARMACOGENOMIC TESTING (ASSURERX HEALTH, INC.) FOR GUIDING MEDICATION SELECTION FOR PATIENTS WITH...**

Genetic Test Product Brief - The GeneSight® Psychotropic test is intended to analyze genetic information related to eight genes to predict a patient’s metabolism of, and treatment response to, 38 medicines approved by the U.S. Food and Drug Administration for treating various psychiatric disorders, such as major depression.

Jun 1, 2015 - ECRIfene

**GENETIC TESTING FOR DEVELOPMENTAL DISABILITIES, INTELLECTUAL DISABILITY, AND AUTISM SPECTRUM DISORDER**

Genetic Test EPC Report - Genetics research in recent decades has discovered numerous genetic variants that help explain the etiology of developmental disabilities (DDs). Genetic tests (e.g., array comparative genomic hybridization, sequencing) are rapidly diffusing into clinical practice for diagnosing DDs or, more often, for determining their genetic etiology. An urgent need exists for a better understanding of these tests and their clinical utility.

May 1, 2015 - ECRIfene

**OOPHORECTOMY AND MASTECTOMY FOR PREVENTING BREAST AND OVARIAN CANCER IN BRCA1/2 GENETIC MUTATION CARRIERS**

Genetic Test Hotline Response - Hereditary breast and ovarian cancer syndrome is inherited in an autosomal dominant fashion. Mutations in either the BRCA1 or BRCA2 gene have been identified as the cause. The proteins coded by these genes assist in repair of damage to DNA. Women who inherit these mutations have a significantly increased risk of developing breast and/or ovarian cancer. Prophylactic mastectomy and oophorectomy are intended to prevent cancer in women with these mutations.

Updated: 3/20/2018