LABHORIZONS
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New Procedures

Hemophagocytic Lymphohistiocytosis (HLH) Genetic Panel 830203

CPT 81404; 81479

Synonyms Factor IX Genetic Sequencing; Factor VIII Genetic Sequencing; Inversion testing; Von Willbrand Genetic Sequencing

Special Instructions The following genes associated with hemophagocytic lymphohistiocytosis (HLH) are sequenced using Next Generation Sequencing (NGS): *LYST, NLRC4, AP3B1, STX11, PRF1, RAB27A, UNC13D (MUNC13-4), STXBP2, SH2D1A* (*SAP* is protein), and *XIAP (BIRC4)*.

Specimen Whole blood; acceptable alternate: cheek swab (buccal swab)

Volume 3 mL

Minimum Volume 1 mL

Container Lavender-top (EDTA) tube

Collection Invert tube 4 times to ensure adequate mixing.

Storage Instructions Room temperature

Stability

Temperature	Period
Room temperature	1 month

Causes for Rejection Sample contamination

Use Hemophagocytic Lymphohistiocytosis (HLH) is a life-threatening disease where an underlying immune defect or triggering event initiates excessive activation of immune cells (macrophages and lymphocytes) leading to multi-organ dysfunction and failure. Median survival without treatment is less than two months. Treatment of HLH may vary depending on the underlying cause, including whether a genetic cause is detected.

Limitations This test targets all exons and untranslated regions of the selected genes, 25-bp of intronic DNA flanking the exon-intron boundary, plus several additional known variants of interest elsewhere in the genome for sequencing. This test would not detect a causative mutation within promoter regions or elsewhere in the genome that were not specifically targeted. A rare variant that disrupts primer binding during PCR could potentially lead to a false negative. All our reports are based on the current understanding of the genes and disease. This understanding changes over time as new papers are published. We recommend annual follow-up for more current interpretations. This test will not detect inhibitors to F8, F9 or VWF proteins, which are non-hereditary. This test does not detect pseudo-VWD (also called platelet VWD), caused by mutations in *GP1B*.

Methodology Next Generation Sequencing (NGS)

References

Côte M, Ménager MM, Burgess A, et al. Munc18-2 deficiency causes familial hemophagocytic lymphohistiocytosis type 5 and impairs cytotoxic granule exocytosis in patient NK cells. *J Clin Invest.* 2009 Dec;119(12):3765-3773. PubMed 19884660

George MR. Hemophagocytic lymphohistiocytosis: review of etiologies and management. *J Blood Med.* 2014 Jun 12;5:69-86. PubMed 24966707

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Niece JA, Rogers ZR, Ahmad N, Langevin AM, McClain KL. Hemophagocytic lymphohistiocytosis in Texas: Observations on ethnicity and race. *Pediatr Blood Cancer.* 2010 Mar;54(3):424-428. PubMed 19953651

U.S. Food and Drug Administration. FDA approves first treatment specifically for patients with rare and life-threatening type of immune disease [Press Release]. Silver Spring, MD: FDA; Nov. 20, 2018.7

MaterniT21 Genome Add On 452104

CPT 81422; 81479

Special Instructions **This test can only be ordered if MaterniT21 PLUS has been previously performed.**

The following information must be provided with the test request form: patient's date of birth, gestational age, and additional patient demographic information: pregnancy type (singleton), donor egg status and the clinical indications (including advanced maternal age, abnormal ultrasound, history suggestive of increased risk for aneuploidy, positive serum screen, or other indications).

Specimen Whole blood

Volume 10 mL

Container Black-and-tan-top (Streck) tube (whole blood). Sequenom collection kits are available (PeopleSoft No. 116373 379551G-CS-LCA.SEQUENOM-LCA ONLY KIT EA=1/KIT and PeopleSoft No. 116374 549403G-CS-LCA.SEQUENOM-LCA TEST REG STICKERS ST=3/SET).

Collection Only the Sequenom collection kit (PeopleSoft No. 116373) can be used for collection.

Storage Instructions Room temperature. Do **not** refrigerate or freeze. Keep out of direct sunlight. Samples must be shipped to LabCorp in a Sequenom collection kit.

Causes for Rejection Gestational age less than nine weeks; expired or incorrect blood tubes (including nonglass tubes); quantity not sufficient for analysis; received more than seven days from collections; excessive hemolysis; frozen specimens

Use The MaterniT Genome test provides comprehensive chromosome copy number analysis including unbalanced derivatives, and information about deletions or duplications of chromosome material 7 Mb or larger, as well as analysis of seven clinically relevant microdeletions less than 7 Mb in size.

Limitations While the results of these tests are highly accurate, discordant results, including inaccurate fetal sex prediction, may occur due to placental, maternal, or fetal mosaicism or neoplasm; vanishing twin; prior maternal organ transplant; or other causes. Sex chromosomal aneuploidies are not reportable for known multiple gestations. MaterniT Genome assay is not validated for multifetal gestations; multifetal samples are excluded from the resequencing pathway. These tests are screening tests and not diagnostic; they do not replace the accuracy and precision of prenatal diagnosis with CVS or amniocentesis. A patient with a positive test result should be referred for genetic counseling and offered invasive prenatal diagnosis for confirmation of test results. A negative result does not ensure an unaffected pregnancy, nor does it exclude the possibility of other chromosomal abnormalities or birth defects, which are not a

These new/revised publications are now available:

- **GeneSeq®: Cardio flyer (L11182)**
- **Pre-exposure Prophylaxis (PrEP) flyer (L20156)**
- **Specimen Processing Instructions Guide (Centrifugation Collection Instructions) (L18640)**

Please ask your LabCorp service representative for these titles.

part of these tests. An uninformative result may be reported, the causes of which may include, but are not limited to, insufficient sequencing coverage, noise or artifacts in the region, amplification or sequencing bias, or insufficient fetal fraction. These tests are not intended to identify pregnancies at risk for neural tube defects or ventral wall defects. Testing for whole chromosome abnormalities (including sex chromosomes) and for subchromosomal abnormalities could lead to the potential discovery of both fetal and maternal genomic abnormalities that could have major, minor, or no, clinical significance. Evaluating the significance of a positive or a non-reportable result may involve both invasive testing and additional studies on the mother. Such investigations may lead to a diagnosis of maternal chromosome or subchromosomal abnormalities, which on occasion may be associated with benign or malignant maternal neoplasms. These tests may not accurately identify fetal triploidy, balanced rearrangements, or the precise location of subchromosomal duplications or deletions; there may be detected by prenatal diagnosis with CVS or amniocentesis. The abillity to report results may be impacted by maternal BMI, maternal weight, maternal systemic lupus erythematosus (SLE) and/or by certain pharmaceutical agents such as low molecular weight heparin (for example: Lovenox®, Xaparin®, Clexane®, and Fragmin®). The results of this testing, including the benefits and limitations, should be discussed with a qualified healthcare provider. Pregnancy managment decisions, including termination of pregnancy, should not be based on the results of these tests alone. The healthcare provider is responsible for the use of this information in the management of their patient.

This test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration.

Methodology Cell-free DNA is isolated from the sample and analyzed using massively parallel sequencing technology.

References

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MateriT21 Genome Add On Redraw 452114

CPT 81422; 81479

Special Instructions This test can only be ordered if MateriT21 PLUS has been previously performed.

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Specimen Whole blood

Volume 10 mL

Minimum Volume 8 mL

Container Black-and-tan-top (Streck) tube (whole blood). Sequenom collection kits are available (PeopleSoft No. 116373 379551G-CS-LCA.SEQUENOM-LCA ONLY KIT EA=1/KIT and PeopleSoft No. 116374 549403G-CS-LCA.SEQUENOM-LCA TEST REG STICKERS ST=3/SET).

Collection Only the Sequenom collection kit (PeopleSoft No. 116373) can be used for collection.

Storage Instructions Room temperature. Do **not** refrigerate or freeze. Keep out of direct sunlight. Samples must be shipped to LabCorp in a Sequenom collection kit.

Causes for Rejection Gestational age less than nine weeks; expired or incorrect blood tubes (including nonglass tubes); quantity not sufficient for analysis; received more than seven days from collections; excessive hemolysis; frozen specimens

Use The MateriT Genome test provides comprehensive chromosome copy number analysis including unbalanced derivatives, and information about deletions or duplications of chromosome material 7 Mb or larger, as well as analysis of seven clinically relevant microdeletions less than 7 Mb in size.

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Methodology Cell-free DNA is isolated from the sample and analyzed using massively parallel sequencing technology.

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POC Microarray Reflex MCC 489187

CPT 81229

Synonyms Reveal® SNP Microaray-Products of Conception (POC); SNP Array

Special Instructions Pertinent medical findings should accompany the test request form. If prior FISH analysis has been performed, include copy of report. Please direct questions to genetic customer service at 800-345-4363. If reflex test is performed, additional charges/CPT code(s) may apply.

Expected Turnaround Time 14 - 21 days

Specimen Microarray: Preferred nonfixed products of conception (POC)/placental villus biopsy; formalin fixed paraffin embedded (FFPE) tissue (samples received in fixative are subject to additional charge for histopathology processing and reporting); unstained tissue slides.

MCC: Whole blood **or** LabCorp buccal swab kit (buccal swab collection kit contains instructions for use of a buccal swab); (submission of of maternal blood is required for fetal testing)

Volume Microarray: > 2-4 mm(3) tissue; 10 unstained tissue slides **and MCC:** 7 mL whole blood **or** LabCorp buccal swab kit

Minimum Volume MCC: 3 mL whole blood **or** two buccal swabs

Container Microarray: Sterile container containing sterile Ringer's lactate **or** Hanks' balanced salt solution or transport medium provided by the cytogenetics laboratory. (Do **not** use isotonic saline as a transport medium or urine containers for shipping.) Specialized kits are now available for POC microarray testing. To order, please contact your local LabCorp representative (PS No. 89063, catalogue item ID No. 39025G).

MCC: Lavendar-top (EDTA) **or** yellow-top (ACD) tube **or** LabCorp buccal swab kit.

Collection Microarray: Aseptically obtain a small piece of fetal tissue that does not appear necrotic. If specimen is a POC, placental villi or

membranes may be the only fetal-derived tissue available, and an effort should be made to submit these tissues rather than maternal decidua.

Storage Instructions Room temperature

Causes for Rejection **Microarray:** Quantity not sufficient for analysis; necrotic tissue submitted. For formalin fixed paraffin embedded samples/no fetal visualized on pathology report, only a small area is identified on fixed sample as fetal, and is less than 50% of sample.

MCC: Frozen or hemolyzed specimen; quantity not sufficient for analysis; improper container.

Use **Microarray:** This test will detect chromosomal imbalance that could be associated with developmental delay/congenital anomalies. It provides detection of uniparental disomy of any chromosome, the percent and location of homozygosity, including the degree of identity by descent. It will also allow the detection of complete or partial molar pregnancies. A normal female microarray results will reflex to MCC, quality assurance for interpretation of prenatal molecular genetic test results.

Limitations This SNP assay does not detect balanced rearrangements, low-level mosaicism (<10%), marker chromosomes that only contain heterochromatin or tetraploidy. Genotypes in some formalin-fixed tissues are unable to be determined, allowing only genomic dosage to be determined.

This test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration.

MCC: Not applicable innon-maternity. Results for this test are for research purposes only by the assay's manufacturer. The performance characteristics of this product have not been established. Results should not be used as a diagnostic procedure without confirmation of the diagnosis by another medically established diagnostic product or procedure.

Methodology **Microarray:** For nonfixed specimens, SNP microarray analysis is performed using the Cytoscan® HD platform, which uses more than 743,000 SNP probes and 1,953,000 HPCN probes with median spacing of 0.88kb. For fixed specimens, SNP microarray analysis is performed using the Oncoscan® FFPE platform, which uses more than 220,000 SNP probes with a median spacing of 5.0 kb, within the majority of genes.

MCC: Analysis of short tandem repeat markers by polymerase chain reaction (PCR) and capillary electrophoresis.

References

Coppinger J, Alliman S, Lamb A, Torchia BS, Bejjani BA, Shaffer LG. Whole-genome microarray analysis in prenatal specimens identifies clinically significant chromosome alterations without increase in results of unclear significance compared to targeted microarray. *Prenatal Diagn*. 2009 Dec;29(12):1156-1166. PubMed 19795450

Shadravan F. Sizing Precision and Reproducibility Studies of AmpFLP-STR® Kits with ABL Prism® 3100 Genetic Analyzer. Proc AM Acad Forensic Sci. 2001;7:26.

Pre-Exposure Prophylaxis (PrEP) HIV Profile, Female, Baseline 245450

CPT 82565; 84702; 86704; 86706; 86780; 86803; 87340; 87389; 87491; 87591

Test Includes *Chlamydia trachomatis; Neisseria gonorrhoeae;* creatinine, serum; eGFR calculation; enzyme immunoassay (EIA) for antigen/antibody screen for HIV with reflex to supplementary differentiation assay for HIV-1 or HIV-2. The antigen/antibody assay detects antibodies to HIV-1 and HIV-2 as well as HIV-1 p24 antigen. Specimens positive by the screening assay but negative by the supplementary antibody typing assay will reflex to qualitative nucleic acid amplification (NAA). This test also includes hepatitis B core antibody, total; hepatitis B surface antibody, qualitative; hepatitis B surface antigen; hepatitis C virus (HCV) antibody with reflex to quantitative real-time PCR; human chorionic gonadotropin (hCG), β-subunit, quantitative, serum; *Treponema pallidum* (syphilis) with reflex to qualitative rapid plasma reagin (RPR) on positives. If reflex testing is performed, additional charges/CPT code(s) may apply.

Special Instructions This profile requires a dedicated, **unopened,** gel-barrier tube and frozen serum pour off tube.

Tests included within this profile may exhibit interference when sample is collected from a person who is consuming a supplement with a high dose of biotin (also termed as vitamin B7 or B8, vitamin H, or coenzyme R). It is recommended to ask all patients who may be indicated for testing about biotin supplementation. Patients should be cautioned to stop biotin consumption at least 72 hours prior to the collection of a sample.

Specimen Serum **and** endocervical or vaginal swab or first-void urine (patient should not have urinated for one hour prior to specimen collection)

Volume 9 mL refrigerated serum, 2 mL frozen serum, **and** one swab (endocervical or vaginal) or 2 mL of a 20 mL to 30 mL urine collection

Minimum Volume 6 mL refrigerated serum (**Note:** This volume does **not** allow for repeat testing), 1 mL frozen serum, **and** one swab (endocervical or vaginal) or 2 mL of a 15 mL urine collection

Container Gel-barrier tube **and** Gen-Probe® APTIMA® swab or APTIMA® urine specimen transport

Collection

Serum specimen: Usual blood collection technique.

Option 1: Gen-Probe® Aptima® Endocervical or Vaginal Swab

Endocervical swab: Remove excess mucus from the cervical os and surrounding mucosa using the cleaning swab (white-shaft swab in the package with red printing). **Discard this swab.** Insert the specimen collection swab (blue-shaft swab in the package with green printing) into the endocervical canal. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling. Withdraw the swab carefully; avoid contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Carefully break the swab shaft at the scoreline; use care to avoid splashing of the contents. Recap the swab specimen transport tube tightly.

Vaginal swab: Care provider specimen: Collect vaginal fluid sample using the Gen-Probe® Aptima® vaginal swab kit by contacting the swab to the lower third of the vaginal wall and rotating the swab for 10 to 30 seconds to absorb fluid. Immediately place the swab into the transport tube and carefully break the swab shaft against the side of the tube. Tightly screw on the cap. ***Patient self-collection:*** Partially open the package of the Gen-Probe® Aptima® vaginal swab kit. Do **not** touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Aptima® swab specimen collection kit. Remove the swab. Carefully insert the swab into the vagina about two inches past the introitus and gently rotate the swab for 10 to 30 seconds, making sure the swab touches the walls of the vagina so that moisture is absorbed by the swab. Withdraw the swab without touching the skin. Immediately place the swab into the transport tube, and carefully break the swab shaft against the side of the tube. Tightly screw on the cap.

Option 2: Urine Specimen: The patient should not have urinated for at least one hour prior to specimen collection. Direct patient to provide a **first-catch urine** (approximately 20 to 30 mL of the initial urine stream) into a urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity; lesser volumes may not adequately rinse organisms into the specimen. Female patients should **not** cleanse the labial area prior to providing the specimen. Add urine to the Aptima® Combo 2 urine collection device. The final volume must be between the two black lines on the device (about 2 mL).

PCR test: Centrifuge sample within 24 hours of collection. Transfer serum to a screw-cap polypropylene transport tube. Ship frozen.

Storage Instructions **Serum:** Gel-barrier tubes refrigerated up to 14 days;
PCR test: Frozen up to six weeks
APTIMA® Swab or Urine: Maintain at room temperature or refrigerate at (2°C to 30°C)

Stability

Temperature	Period
Room temperature	Swab: 60 days, Urine: 30 days (stability provided by manufacturer or literature reference)
Refrigerated	Serum: 14 days (stability provided by manufacturer or literature reference)
Frozen	Serum: 6 weeks (stability provided by manufacturer or literature reference)
Freeze/thaw cycles	Serum: Stable x4 (stability provided by manufacturer or literature reference)

Patient Preparation Patient should not have urinated for one hour prior to specimen collection.

Causes for Rejection Hemolysis; lipemia; received outside of specimen and/or storage and/or labeling requirements; aliquot received for HIV testing; specimen in expired transport or incorrect transport device;

specimens with inappropriate source for test requested; APTIMA® urine transport >30 days from collection; APTIMA® urine transport with incorrect specimen volume; APTIMA® swab transport >60 days from collection; APTIMA® swab specimen without a swab; cleaning swab (white-shaft swab) in APTIMA® swab transport; APTIMA® transport device with multiple swabs

Use Detect HIV infection using fourth-generation HIV antigen-antibody assay; detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae;* serological test for screening for syphilis infection; determine HBV infection status; diagnosis of active hepatitis C virus (HCV) infection; the estimated glomerular filtration rate (eGFR) provides an assessment of the filtering capacity of the kidney; early detection of pregnancy

Limitations Fourth-generation HIV antigen-antibody specimens with repeatedly reactive results must be investigated by additional supplemental tests. A negative test for an individual does not preclude exposure to or infection with HIV-1 and/or HIV-2. Negative results can occur if the quantity of the marker present in the sample is too low for detection by the assay or if the marker is not present during the stage of disease in which a sample is collected. All estimates of GFR based on serum creatinine will be less accurate for patients at the extremes of muscle mass (including frail elderly, critically ill, or cancer patients), those with unusual diets, and those with conditions associated with reduced secretion or extrarenal elimination of creatinine.

Methodology See individual test components.

Pre-Exposure Prophylaxis (PrEP) HIV Profile, Female, Monitor 245438

CPT 82565; 84702; 86780; 87389; 87491; 87591

Test Includes *Chlamydia trachomatis; Neisseria gonorrhoeae;* creatinine, serum; eGFR calculation; enzyme immunoassay (EIA) for antigen/antibody screen for HIV with reflex to supplementary differentiation assay for HIV-1 or HIV-2. The antigen/antibody assay detects antibodies to HIV-1 and HIV-2 as well as HIV-1 p24 antigen. Specimens positive by the screening assay but negative by the supplementary antibody typing assay will reflex to qualitative nucleic acid amplification (NAA). This test also includes human chorionic gonadotropin (hCG), β-subunit, quantitative, serum; *Treponema pallidum* (syphilis) with reflex to qualitative rapid plasma reagin (RPR) on positives. If reflex testing is performed, additional charges/CPT code(s) may apply.

Special Instructions This profile requires a dedicated, **unopened,** gel-barrier tube.

Tests included within this profile may exhibit interference when sample is collected from a person who is consuming a supplement with a high dose of biotin (also termed as vitamin B7 or B8, vitamin H, or coenzyme R). It is recommended to ask all patients who may be indicated for testing about biotin supplementation. Patients should be cautioned to stop biotin consumption at least 72 hours prior to the collection of a sample.

Specimen Serum **and** endocervical or vaginal swab or first-void urine (patient should not have urinated for one hour prior to specimen collection)

Volume 6 mL refrigerated serum **and** one swab (endocervical or vaginal) or 2 mL of a 20 mL to 30 mL urine collection

Minimum Volume 4 mL refrigerated serum (**Note:** This volume does **not** allow for repeat testing) **and** one swab (endocervical or vaginal) or 2 mL of a 15 mL urine collection

Container Gel-barrier tube **and** Gen-Probe® APTIMA® swab or APTIMA® urine specimen transport

Collection

Serum specimen: Usual blood collection technique.

Option 1: Gen-Probe® Aptima® Endocervical or Vaginal Swab

Endocervical swab: Remove excess mucus from the cervical os and surrounding mucosa using the cleaning swab (white-shaft swab in the package with red printing). **Discard this swab.** Insert the specimen collection swab (blue-shaft swab in the package with green printing) into the endocervical canal. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling. Withdraw the swab carefully; avoid contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Carefully break the swab shaft at the scoreline; use care to avoid splashing of the contents. Recap the swab specimen transport tube tightly.

Vaginal swab: Care provider specimen: Collect vaginal fluid sample using the Gen-Probe® Aptima® vaginal swab kit by contacting the swab to the lower third of the vaginal wall and rotating the swab for 10 to 30 seconds to absorb fluid. Immediately place the swab into the transport tube and carefully break the swab shaft against the side of the tube. Tightly screw on the cap. ***Patient self-collection:*** Partially open the package of the Gen-Probe® Aptima® vaginal swab kit. Do **not** touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Aptima® swab specimen collection kit. Remove the swab. Carefully insert the swab into the vagina about two inches past the introitus and gently rotate the swab for 10 to 30 seconds, making sure the swab touches the walls of the vagina so that moisture is absorbed by the swab. Withdraw the swab without touching the skin. Immediately place the swab into the transport tube, and carefully break the swab shaft against the side of the tube. Tightly screw on the cap.

Option 2: Urine Specimen: The patient should not have urinated for at least one hour prior to specimen collection. Direct patient to provide a **first-catch urine** (approximately 20 to 30 mL of the initial urine stream) into a urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity; lesser volumes may not adequately rinse organisms into the specimen. Female patients should **not** cleanse the labial area prior to providing the specimen. Add urine to the Aptima® Combo 2 urine collection device. The final volume must be between the two black lines on the device (about 2 mL).

Storage Instructions **Serum:** Gel-barrier tubes refrigerated up to 14 days

APTIMA® Swab or Urine: Maintain at room temperature or refrigerate at (2°C to 30°C)

Stability

Temperature	Period
Room temperature	Swab: 60 days, Urine: 30 days (stability provided by manufacturer or literature reference)
Refrigerated	Serum: 14 days (stability provided by manufacturer or literature reference)

Patient Preparation Patient should not have urinated for one hour prior to specimen collection.

Causes for Rejection Hemolysis; lipemia; received outside of specimen and/or storage and/or labeling requirements; aliquot received for HIV testing; specimen in expired transport or incorrect transport device; specimens with inappropriate source for test requested; APTIMA® urine transport >30 days from collection; APTIMA® urine transport with incorrect specimen volume; APTIMA® swab transport >60 days from collection; APTIMA® swab specimen without a swab; cleaning swab (white-shaft swab) in APTIMA® swab transport; APTIMA® transport device with multiple swabs

Use Detect HIV infection using fourth-generation HIV antigen-antibody assay; detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae;* serological test for screening for syphilis infection; the estimated glomerular filtration rate (eGFR) provides an assessment of the filtering capacity of the kidney; early detection of pregnancy

Limitations Fourth-generation HIV antigen-antibody specimens with repeatedly reactive results must be investigated by additional supplemental tests. A negative test for an individual does not preclude exposure to or infection with HIV-1 and/or HIV-2. Negative results can occur if the quantity of the marker present in the sample is too low for detection by the assay or if the marker is not present during the stage of disease in which a sample is collected. All estimates of GFR based on serum creatinine will be less accurate for patients at the extremes of muscle mass (including frail elderly, critically ill, or cancer patients), those with unusual diets, and those with conditions associated with reduced secretion or extrarenal elimination of creatinine.

Methodology See individual test components.

Pre-Exposure Prophylaxis (PrEP) HIV Profile, Male, Baseline 245476

CPT 82565; 86704; 86706; 86780; 86803; 87340; 87389; 87491; 87591

Test Includes *Chlamydia trachomatis; Neisseria gonorrhoeae;* creatinine,

serum; eGFR calculation; enzyme immunoassay (EIA) for antigen/antibody screen for HIV with reflex to supplementary differentiation assay for HIV-1 or HIV-2. The antigen/antibody assay detects antibodies to HIV-1 and HIV-2 as well as HIV-1 p24 antigen. Specimens positive by the screening assay but negative by the supplementary antibody typing assay will reflex to qualitative nucleic acid amplification (NAA). This test also includes hepatitis B core antibody, total; hepatitis B surface antibody, qualitative; hepatitis B surface antigen; hepatitis C virus (HCV) antibody with reflex to quantitative real-time PCR; *Treponema pallidum* (syphilis) with reflex to qualitative rapid plasma reagin (RPR) on positives. If reflex testing is performed, additional charges/CPT code(s) may apply.

Special Instructions This profile requires a dedicated, unopened, gel-barrier tube and frozen serum pour off tube.

Tests included within this profile may exhibit interference when sample is collected from a person who is consuming a supplement with a high dose of biotin (also termed as vitamin B7 or B8, vitamin H, or coenzyme R). It is recommended to ask all patients who may be indicated for testing about biotin supplementation. Patients should be cautioned to stop biotin consumption at least 72 hours prior to the collection of a sample.

Specimen Serum **and** urine

Volume 8 mL refrigerated serum, 2 mL frozen serum, **and** 2 mL of a 20 mL to 30 mL urine collection

Minimum Volume 6 mL refrigerated serum (**Note:** This volume does **not** allow for repeat testing), 1 mL frozen serum, **and** 2 mL of a 15 mL urine collection

Container Gel-barrier tube **and** APTIMA® urine specimen transport

Collection

Serum specimen: Usual blood collection technique.

Urine specimen: The patient should not have urinated for at least one hour prior to specimen collection. Direct patient to provide a first-catch urine (approximately 20 to 30 mL of the initial urine stream) into a urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity; lesser volumes may not adequately rinse organisms into the specimen. Add urine to the APTIMA® Combo 2 urine collection device. The final volume must be between the two black lines on the device (about 2 mL).

PCR test: Centrifuge sample within 24 hours of collection. Transfer serum to a screw-cap polypropylene transport tube. Ship **frozen.**

Storage Instructions **Serum:** Gel-barrier tubes refrigerated up to 14 days; **PCR test:** Frozen up to six weeks

APTIMA® Urine: Maintain at room temperature or refrigerate (2°C to 30°C)

Stability

Temperature	Period
Room temperature	Urine: 30 days (stability provided by manufacturer or literature reference)
Refrigerated	Serum: 14 days (stability provided by manufacturer or literature reference)
Frozen	Serum: 6 weeks (stability provided by manufacturer or literature reference)
Freeze/thaw cycles	Serum: Stable x4 (stability provided by manufacturer or literature reference)

Patient Preparation Patient should not have urinated for one hour prior to specimen collection.

Causes for Rejection Hemolysis; lipemia; received outside of specimen and/or storage and/or labeling requirements; aliquot received for HIV testing; specimen in expired transport or incorrect transport device; specimens with inappropriate source for test requested; APTIMA® urine transport >30 days from collection; APTIMA® urine transport with incorrect specimen volume

Use Detect HIV infection using fourth-generation HIV antigen-antibody assay; detect Chlamydia trachomatis and Neisseria gonorrhoeae; serological test for screening for syphilis infection; determine HBV infection status; diagnosis of active hepatitis C virus (HCV) infection; the estimated glomerular filtration rate (eGFR) provides an assessment of the filtering capacity of the kidney

Limitations Fourth-generation HIV antigen-antibody specimens with repeatedly reactive results must be investigated by additional supplemental tests. A negative test for an individual does not preclude exposure to or infection with HIV-1 and/or HIV-2. Negative results can occur if the quantity of the marker present in the sample is too low for detection by the assay or if the marker is not present during the stage of disease in which a sample is collected. All estimates of GFR based on serum creatinine will be less accurate for patients at the extremes of muscle mass (including frail elderly, critically ill, or cancer patients), those with unusual diets, and those with conditions associated with reduced secretion or extrarenal elimination of creatinine.

Methodology See individual test components.

Pre-Exposure Prophylaxis (PrEP) HIV Profile, Male, Monitor 245488

CPT 82565; 86780; 87389; 87491; 87591

Test Includes *Chlamydia trachomatis; Neisseria gonorrhoeae;* creatinine, serum; eGFR calculation; enzyme immunoassay (EIA) for antigen/antibody screen for HIV with reflex to supplementary differentiation assay for HIV-1 or HIV-2. The antigen/antibody assay detects antibodies to HIV-1 and HIV-2 as well as HIV-1 p24 antigen. Specimens positive by the screening assay but negative by the supplementary antibody typing assay will reflex to qualitative nucleic acid amplification (NAA). This test also includes *Treponema pallidum* (syphilis) with reflex to qualitative rapid plasma reagin (RPR) on positives.

Special Instructions This profile requires a dedicated, **unopened,** gel-barrier tube.

Tests included within this profile may exhibit interference when sample is collected from a person who is consuming a supplement with a high dose of biotin (also termed as vitamin B7 or B8, vitamin H, or coenzyme R). It is recommended to ask all patients who may be indicated for testing about biotin supplementation. Patients should be cautioned to stop biotin consumption at least 72 hours prior to the collection of a sample.

Specimen Serum **and** urine

Volume 6 mL refrigerated serum **and** 2 mL of a 20 mL to 30 mL urine collection

Minimum Volume 4 mL refrigerated serum (**Note:** This volume does **not** allow for repeat testing) **and** 2 mL of a 15 mL urine collection

Container Gel-barrier tube **and** APTIMA® urine specimen transport

Collection

Serum specimen: Usual blood collection technique.

Urine specimen: The patient should not have urinated for at least one hour prior to specimen collection. Direct patient to provide a **first-catch urine** (approximately 20 to 30 mL of the initial urine stream) into a urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity; lesser volumes may not adequately rinse organisms into the specimen. Add urine to the APTIMA® Combo 2 urine collection device. The final volume must be between the two black lines on the device (about 2 mL).

Storage Instructions **Serum:** Gel-barrier tubes refrigerated up to 14 days

APTIMA® Urine: Maintain at room temperature or refrigerate (2°C to 30°C)

Stability

Temperature	Period
Room temperature	Urine: 30 days (stability provided by manufacturer or literature reference)
Refrigerated	Serum: 14 days (stability provided by manufacturer or literature reference)

Patient Preparation Patient should not have urinated for one hour prior to specimen collection.

Causes for Rejection Hemolysis; lipemia; received outside of specimen and/or storage and/or labeling requirements; aliquot received for HIV testing; specimen in expired transport or incorrect transport device; specimens with inappropriate source for test requested; APTIMA® urine transport >30 days from collection; APTIMA® urine transport with incorrect specimen volume

Use Detect HIV infection using fourth-generation HIV antigen-antibody assay; detect Chlamydia trachomatis and Neisseria gonorrhoeae; sero-

logical test for screening for syphilis infection; the estimated glomerular filtration rate (eGFR) provides an assessment of the filtering capacity of the kidney

Limitations Fourth-generation HIV antigen-antibody specimens with repeatedly reactive results must be investigated by additional supplemental tests. A negative test for an individual does not preclude exposure to or infection with HIV-1 and/or HIV-2. Negative results can occur if the quantity of the marker present in the sample is too low for detection by the assay or if the marker is not present during the stage of disease in which a sample is collected. All estimates of GFR based on serum creatinine will be less accurate for patients at the extremes of muscle mass (including frail elderly, critically ill, or cancer patients), those with unusual diets, and those with conditions associated with reduced secretion or extrarenal elimination of creatinine.

Methodology See individual test components.

Vitamin B12 Deficiency Cascade 141503

CPT 82607

Synonyms Pernicious Anemia Cascade

Test Includes Vitamin B12 testing is performed on all samples. If Vitamin B12 is <200 pg/mL: Intrinsic Factor Blocking Antibodies and Antiparietal Cell Antibody (APCA) will be performed at an additional charge. If Vitamin B12 is between 200 and 400 pg/mL: Methylmalonic Acid (MMA) will be performed at an additional charge. If Methylmalonic Acid (MMA) is >378 nmol/L: Intrinsic Factor Blocking Antibodies and Antiparietal Cell Antibody (APCA) will be performed at an additional charge.

Specimen Serum

Volume 3 mL

Minimum Volume 2 mL (**Note:** This volume does **not** allow for repeat testing).

Container Red-top tube or gel-barrier tube

Collection If a red-top tube is used, transfer separated serum to a plastic transport tube.

Storage Instructions Store specimen at room temperature

Stability

Temperature	Period
Room temperature	7 days
Refrigerated	7 days
Frozen	14 days
Freeze/thaw cycles	Stable x3

Use Diagnosis of Vitamin B12 Deficiency. Although often used as the first-line screening test for B12 deficiency, serum B12 measurement used in isolation has a generally poor sensitivity and specificity for detection of B12 deficiency.[1,6,19,32] The National Health and Nutrition Examination Survey (NHANES) opted to use the combination of serum total vitamin B12 and methylmalonic acid (MMA) to monitor B12 status in the United States population.[35] In the interest of economy, a number of groups have suggested the use of a sequential selection algorithm for the detection of B12 deficiency.[5,14,33,34] In this approach, a second-line assay (in this case MMA) is performed only when the outcome of the first-line assay (vitamin B12 level) falls in an "equivocal" range.[1,7] It has been suggested that borderline B12 levels (200-400 ng/L) should be followed up with measuring MMA levels.[1] MMA levels below the upper limit of the reference interval (0-378 nmol/L) are strongly suggestive of normal B12 status.

Limitations Ninety per cent of patients with pernicious anemia have gastric parietal cell antibodies, but specificity of this test is poor since they are also found in 15% of elderly subjects.

If IFA results are negative but suspicion for pernicious anemia remains, an elevated serum gastrin level is consistent with the diagnosis.[7]

Mutations in the gene encoding intrinsic factor, can also lead to an inherited form of B12 malabsorption and deficiency, which resembles pernicious anemia, but without autoantibody involvement.[36]

In the presence of discordance between laboratory test result and strong clinical features of B12 deficiency, it remains important to proceed with treatment to avoid neurological impairment.[14]

MMA can increase (300-700 nmol/L) in renal failure and its refractory to B12 administration.[1]

Some patients with gastric atrophy and diminished parietal cell function are not positive for IFA or PCA. Diminished acid secretion caused by gastric atrophy regardless of the etiology can cause increased secretion of gastrin. Elevated gastrin levels can support the diagnosis of PA in antibody negative patients.[24,29] It is important to diagnose hypergastrinaemia arising from loss gastric parietal cells drives development of antral enterochromaffin cell hyperplasia that can further develop into neoplasia and carcinoid syndrome.[1,3,24,30,31]

Additional Information B12 is essential for certain enzymatic reactions that are required for numerous physiologic functions including erythropoiesis and myelin synthesis.[1,2] Impaired DNA synthesis caused by B12 deficiency impacts nuclear maturation of rapidly dividing cells. This affects hematopoiesis and results in the presence of immature and ineffective red cells that are larger than normal (megaloblasts) in a context of severe anemia and pancytopenia. This megaloblastic anemia is characterized by the hypersegmented neutrophils that can be seen on peripheral smears and giant bands in bone marrow. Other rapidly dividing cells of the small-bowel epithelium can be affected resulting in malabsorption and diarrhea.[3] Glossitis is a frequent hallmark of megaloblastic anemia, with the patient experiencing a painful, smooth, red tongue. Ineffective erythropoiesis and associated increased red cell turnover can result in elevation in bilirubin levels, manifesting as jaundice.[3]

B12 deficiency can also produce neurological manifestations including sensory and motor disturbances (symmetric paresthesias, numbness and gait problems), ataxia, cognitive decline leading to dementia and psychiatric disorders. These neurological symptoms often predominate and can frequently occur in the absence of hematological complications.[3,7] In fact, the majority of patients with suspected B12 deficiency do not have anemia.[5-8]

Emerging evidence indicates that low (though not necessarily deficient) B12 is associated with increased risk of various chronic diseases of ageing including cognitive dysfunction, cardiovascular disease and osteoporosis.[5,6] Dietary vitamin B12 is normally bound to proteins in food and requires release by gastric acid and pepsin in the stomach.[7] In the small intestine, vitamin B12 binds to intrinsic factor (IF) produced by gastric parietal cells. In the ileum, the B12-IF complex binds to specific receptors, which facilitates absorption into the blood. Large amounts of absorbed vitamin B12 are stored in the liver such that any reduction in vitamin B12 intake/absorption may take many years to manifest clinically.[8] Low B12 status, especially in older adults, is rarely attributable to dietary insufficiency[9] and is more typically the result of malabsorption related to atrophic gastritis, inflammatory bowel disease or use of proton pump inhibitors or other gastric acid suppressant drugs.[2,6,7,10-13]

The diagnosis of vitamin B12 deficiency requires consideration of both the clinical state of the patient and the results of laboratory tests. Screening average-risk adults for vitamin B12 deficiency is not recommended.[2] However, testing should be considered in patients with risk factors and/or clinical blood count and serum vitamin B12 level.[2,5,7,14,15] The World Health Organization[16] and the British Committee for Standards in Haematology[14] suggested using 200 pg/mL as a cut-off to define B12 deficiency. In practice, detectable disturbances in metabolic networks consistent with possible deficiency occur at B12 levels as high as 400 pg/mL.[17]

A significant number of B12-deficient patients may be overlooked when serum B12 measurement is used in isolation.[5,17] Further investigation using a second-line test can be useful for serum B12 results that fall within the indeterminate range. The enzyme, methylmalonyl-CoA mutase requires vitamin B12 as a cofactor for the conversion of methylmalonyl-CoA to succinyl-CoA.[5] In vitamin B12 depletion, reduced activity of this enzyme leads to an accumulation of methylmalonyl-CoA which is, in turn, hydrolyzed to methylmalonic acid. Measurement of serum methylmalonic acid provides biochemical evidence of metabolic abnormalities consistent with B12 insufficiency.[2,5,7,10,14,18,19]

In the United States and the United Kingdom, the prevalence of vitamin B12 deficiency has been estimated to be approximately 6% of persons younger than 60 years, and nearly 20% in those older than 60 years.[10] B12 status in the United States has been assessed in the National Health and Nutrition Examination Survey (NHANES).[20] Using NHANES data from 1999 to 2004, the prevalence of B12 status defined as low was estimated to be 2.9%, 10.6% or 25.7% based on serum B12 cut-off values of 200, 300 and

400 pg/mL, respectively.[20] Using these cut-off values, the prevalence of low B12 status increased with age from young adults (19-39 years of age) to older adults (greater than or equal to 60 years of age), and was generally higher in women than than in men (prevalence of 3.3% versus 2.4% with a serum B12 level of <200 pg/mL, respectively).[20] Using increased levels of MMA as a functional indicator of B12 status, the prevalence of low B12 status was 2.3% or 5.8% based on cut-off values of >376 and >271 nmol/L, respectively.[20] The prevalence of increased levels of MMA increased with age and was not different between men and women.[20] Notably, only 50-75% of participants in NHANES with low levels of serum B12 had increased levels of MMA.[20] It should also be noted that modest increases occur with renal failure.[7]

Pernicious Anemia (PA) caused by autoimmune destruction of gastric parietal cells and atrophy of the gastric mucosa is the most common cause of vitamin B12 deficiency.[3,6,7,21] Asymptomatic autoimmune gastritis, a chronic inflammatory disease of the gastric mucosa, precedes the onset of mucosal atrophy by 10-20 years.[22]

With disease progression, an increasing number of the parietal cells that produce hydrochloric acid and intrinisic factor are destroyed.[22] This may present initially as iron deficiency anemia due to loss of gastric acid, which is required for iron absorption.[1,23] Ultimately, diminished production of intrinsic factor together with development of neutralizing antibody against intrinsic factor itself leads to B12 malabsorption.[2,3,10,24] The autoimmune nature of PA is reflected by the presence of autoantibodies against the parietal cell proton pump protein (H/K ATPase) and to intrinsic factor.[3,20,24,25] This condition frequently coexists with other autoimmune disorders including Hashimoto's thyroiditis and type 1 diabetes mellitus.[3,24,29]

Parietal Cell Antibodies (PCA) are present at a high frequency in PA (80%-90%), especially in early stages of the disease and are considered a predictive marker of subsequent gastric mucosa atrophy and its hematologic manifestations.[3,24] In the later stages of the disease, the incidence of PCA decreases due to the progression of autoimmune gastritis and a loss of gastric parietal cell mass, as a result of the decrease in antigenic rate.[26] PCA can precede the clinical symptoms of the gastric disease by several years.[3] PCA are found in 90% of patients with PA, but have low specificity and are seen in various autoimmune disorders.1 Intrinsic Factor Antibodies (IFA) are less sensitive, but are considered highly specific for PA.[3] Studies have reported positivity for IFA in 40%-60% of patients with PA, which rises to 60%-80% with increasing duration of disease.[3,27] The combined assessment of both PCA and IFA increases diagnostic performance, with 73% sensitivity and 100% specificity.[28]

Diminished acid secretion caused by gastric atrophy resulting from autoimmune disease or some other etiology elevates secretion of gastrin. Elevated gastrin levels can support the diagnosis of PA.[24,29] Hypergastrinaemia arising from loss gastric parietal cells drives development of antral enterochromaffin cell hyperplasia that can further develop into neoplasia and carcinoid syndrome.[1,3,24,30,31]

Footnotes

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Service Announcement

LabCorp will add Interpretive Comments for Allergy Component Testing

Effective September 30, 2019, LabCorp will add interpretive comments for allergy component testing to aid in the diagnosis and management of patients with suspected allergy to egg, milk, peanut, cashew nut, hazelnut (filbert), walnut and Brazil nut.

These comments, an enhancement to the allergy component test results, will print automatically on results reports when allergen-specific IgE triggers performance of component testing. The addition of interpretive comments will not affect test numbers or reference intervals.

For more information, please contact allergy customer service at 888-200-5439, ext. 63483, between 8 a.m. and 5 p.m. Monday through Friday.

Updates to the *Directory of Services and Interpretive Guide (DoS)*

Test Name	Test No.	**Field**/Change (Only fields that change are included here.)
***BRAF* Gene Mutation Analysis**	**481030**	**Volume** FFPE tissue block **or** four unstained slides and one matching H&E-stained slide at 5 µM; 5 to 10 mL FNA in CytoLyt container; 3 to 7 mL whole blood, 1 to 2 mL bone marrow **Container** FFPE tissue block **or** slides, lavender-top (EDTA) tube, green-top (sodium heparin) tube, yellow-top (ACD-A) tube, FNA in CytoLyt container **Storage Instructions** Maintain specimen at room temperature. If specimen is to be stored prior to shipment, store at 2°C to 8°C. Store FFPE block or slides, FNA in CytoLyt container at room temperature. **Causes for Rejection** Tumor block containing no tumor; broken or stained slides; specimen does not meet collection criteria; frozen whole blood, marrow, or cell pellet; leaking tube; clotted blood or marrow; grossly hemolyzed specimen or otherwise visibly degraded; contamination by another specimen; specimens containing suspicious foreign material
Breast Cancer Monitor Profile II	**485003**	**Limitations** This profile should not be used as a diagnostic or screening test for cancer. The LASA test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration.
Colorectal Cancer Monitor Profile	**485011**	**Limitations** This profile should not be used as a diagnostic or screening test for cancer. The LASA test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration.
Cytochrome P450 2C9 Genotyping	**511893**	**Use** This test provides genotype information for CYP2C9. **Limitations** This assay detects CYP2C9 alleles *1, *2 and *3. Other alleles are not detected by this assay. This test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration.
Cytochrome P450 2C9 Genotyping Siponimod	**512215**	**Use** CYP2C9 genotype testing is required to determine candidacy and the appropriate maintenance dosage for siponimod before treatment initiation. Siponimod is contraindicated in patients who have a CYP2C9*3/*3 genotype. Refer to the siponimod package insert for more details. **Limitations** This test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration. **References** Siponimod [package insert]. East Hanover, NJ: Novartis Pharmaceutical Corporation; 2019.

Note: Please consult the online Directory of Services and Interpretive Guide at https://www.labcorp.com/tests for the most current test information.

Test Name	Test No.	**Field**/Change (Only fields that change are included here.)
Cytochrome P450 2C19 Genotyping	**511675**	**Specimen** Whole blood **Volume** 7 mL **Minimum Volume** 3 mL **Container** Lavender-top (EDTA) tube or yellow-top (ACD) tube **Causes for Rejection** Frozen specimen; hemolysis; quantity not sufficient for analysis; improper container **Use** The xTAG® CYP2C19 Kit v3 is a qualitative genotyping assay, which can be used as an aid to clinicians in determining therapeutic strategy for the therapeutics that are metabolized by the CYP2C19 gene product. CYP2C19 is involved in the metabolism of drugs including clopidogrel, anticonvulsants, diazepam, omeprazole, tricyclic antidepressants and proton pump inhibitors. The CYP2C19 gene is highly polymorphic. Many alleles of CYP2C19 encode enzymes that have non-functional, decreased or increased enzyme activity compared to wild-type. Depending on the combination of alleles in an individual, drug-metabolizing phenotypes associated with the CYP2C19 enzyme can vary. **Limitations** The kit is not indicated for stand-alone diagnostic purposes. This test is not intended to be used to predict drug response or non-response. Only alleles listed will be identified by this product. Other CYP2C19 alleles, which are rare, or were unknown at the time of release of this product, will not be identified by this product. These other alleles may result in either a *1 call, a no-call, or a call of a genetically related allele included in this kit. The physiological effect of CYP2C19 phenotype depends on individual clinical profile. The co-administration of drugs metabolized by CYP2C19, or other drugs that can act as inducers or inhibitors of CYP2C19, also affects the drug metabolizing phenotype. Other factors include the individual's age, weight, gender, renal and liver function, disease status, and lifestyle factors such as smoking, diet and alcohol consumption. It is important to interpret genotyping test results in the context of an individual's profile. **Methodology** This assay utilizes the Luminex xTAG® CYP2C19 Kit v3 US-IVD. The xTAG® CYP2C19 Kit v3 is an in vitro diagnostic test used to simultaneously detect and identfy a panel of nucleotide varients found within the highly polymorphic CYP450 2C19 gene, located on chromosome 10q24, from genomic DNA extracted from EDTA or citrate anticoagulated whole blood samples. The xTAG® CYP2C19 Kit v3 incorporates multiplex Polymerase Chain Reaction (PCR) and multiplex Allele Specific Primer Extension (ASPE) with a proprietary universal array system on the Luminex platform. **Alleles detected by xTAG® CYP2C19 Kit v3:** *1,*2,*3,*17. The wild-type (WT) allele, CYP2C19 *1, is the most common variant. **Additional Information** Drug-metabolizing phenotypes can be classified according to the level of metabolism: poor metabolizers (PMs), intermediate metabolizers (IMs), extensive metabolizers (EMs), and ultra-rapid metabolizers (UMs). An idividual's phenotype depends on the combination of alleles they have. PMs have little to no CYP2C19 enzyne activity and have two non-functional alleles. EMs are identified as having normal enzyme activity, and are homozygous wild-type for the *1 functional allele. UMs have increased enzyme activity resulting from two gain-of-function alleles or one functional allele and one gain-of-function allele. The *17 allele is the only UM allele identified thus far for CYP2C19. IMs have intermediate enzyme activity resulting from one functional allele and one loss-of-function allele. The consequence of a *17 allele with a loss of function allele may be in between the EM and IM phenotypes and may possibly be substrate dependent. Variations in CYP2C19 enzyme activity can lead to a variety of clinical implications. PMs have reduced enzyme activity and may require alternative therapeutic treatment or adjustment of standard dosage regime to reduce the risk of concentration-dependent side effects, overdose drug toxicity or prolonged therapeutic effect as a result of impaired clearance of drug. If a drug is administered as a prodrug that requires activation by CYP2C19 enzyme, PMs may experience inadequate therapeutic effect if the drug does not reach the therapeutic dose. EMs in general have normal enzyme activity and can be administered CYP2C19-metabolized drugs using standard dosing. EMs who are heterozygous for a varient allele with a non-functional allele may have a modest decrease in enzyme activity. For UMs, rapid metabolism of the drug may lead to inadequate drug efficacy and therapeutic failure, because the drug may not reach the therapeutic serum concentration. For prodrugs like clopidogrel, UMs may be at risk of elevated exposure to active drug metabolites leading to adverse drug reactions. **References** Meyer UA. Pharmacogenetics and adverse drug reactions. *Lancet.* 2000 Nov 11;356(9242):1667-1671. Xie HG, Zou JJ, Hu ZY, Zhang JJ, Ye F, Chen SL. Individual variability in the disposition of and response to clopidogrel: pharmacogenomics and beyond. *Pharmacol Ther.* 2011 Mar;129(3):267-289. xTAG® CYP2C19 Kit v3 US-IVD [package insert]. Luminex; MLD-046-KPI-001 Rev E; 2018.

Note: Please consult the online Directory of Services and Interpretive Guide at https://www.labcorp.com/tests for the most current test information.

Test Name	Test No.	**Field**/Change (Only fields that change are included here.)
Cytochrome P450 2D6/2C19 Genotyping	**511905**	**Specimen** Whole blood **Volume** 7 mL **Minimum Volume** 3 mL **Container** Lavender-top (EDTA) tube or yellow-top (ACD) tube **Causes for Rejection** Frozen specimen; clotted whole blood; hemolysis; quantity not sufficient for analysis; improper container **Use** The xTAG® CYP2D6 Kit v3 is a qualitative genotyping assay, which can be used as an aid to clinicians in determining therapeutic strategy for the therapeutics that are metabolized by the CYP2D6 gene product. CYP2D6 is involved in the metabolism of more than 65 commonly used drugs including β-blockers, antipsychotics, antidepressants, analgesics, and antiarrythmics. The CYP2D6 gene is highly polymorphic. Many alleles of 2D6 encode enzymes that have reduced or no function compared to the wild-type enzyme. Individuals can also have gene rearrangements with more than two copies of the CYP2D6 gene (gene duplication) or absence of both copies (gene deletion). Depending on the combination of alleles in an individual, drug-metabolizing phenotypes associated with the CYP2D6 enzyme can vary. The XTAG® CYP2C19 Kit v3 is a qualitative genotyping assay, which can be used as an aid to clinicians in determining therapeutic stattegy for the therapeutics that are metabolized by the CYP2C19 gene product. CYP2C19 is involved in the metabolism of drugs including clopidogrel, anticonvulsants, diazepam, omeprazole, tricyclic antidepressants and proton pump inhibitors. The CYP2C19 gene is highly polymorphic. Many alleles of CYP2C19 encode enzymes that have non-functional, decreased or increased enzyme activity compared to wild-type. Depending on the combination of alleles in an individual, drug-metabolizing phenotypes associated with the CYP2C19 enzyme can vary. **Limitations** These kits are not indicated for stand-alone diagnostic purposes. These tests are not intended to be used to predict drug response or non-response. Only alleles listed will be identified by these products. Other CYP2D6 or CYP2C19 alleles, which are rare, or were unknown at the time of release of these products, will not be identified by these products. These other alleles may result in either a *1 call, a no-call, or a call of a genetically related allele included in these kits. The physiological effect of phenotype depends on individual clinical profile. The co-administration of drugs metabolized, or other drugs that can act as inducers or inhibitors, also affects the drug metabolizing phenotype. **Methodology** This assay utilizes the Luminex xTAG® CYP2D6 Kit v3 US-IVD and the Luminex xTAG® CYP2C19 Kit v3 US-IVD. The xTAG® CYP2D6 Kit v3 is a device used to simultaneously detect and identify a panel of nucleotide varients found within the highly polymorphic CYP2D6 gene located on chromosome 22 from genomic DNA extracted from EDTA and citrate anticoagulated whole blood samples. This kit can also identify gene rearrangements associated with the deletion (*5) and duplication genotypes. The xTAG® CYP2D6 Kit v3 incorporates multiplex Polymerase Chain Reaction (PCR) and multiplex Allele Specific Primer Extension (ASPE) with Luminex's proprietary Universal Tag sorting system on the Luminex® 100/200™ xMAP® platform. Alleles detected by the xTAG® CYP2D6 Kit v3: *1, *2, *3, *4, *5, *6, *7, *8, *9, *10, *11, *15, *17, *29, *35, *41, and DUP (duplication). The *1 allele is the most common allele in all ethnicities. The xTAG® CYP2C19 Kit v3 is an in vitro diagnostic test used to simultaneously detect and identify a panel of nucleotide variants found within the highly polymorphic CYP450 2C19 gene, located on chromosome 10q24, from genomic DNA ectracted from EDTA or citrated anticoagulated whole blood samples. The xTAG® CYP2C19 Kit v3 incorporates mutiplex Polymerase Chain Reaction (PCR) and multiplex Allele Specific Primer Extension (ASPE) with a proprietary universal array sorting system on the Luminex® platform. Alleles detected by xTAG® CYP2C19 Kit v3: *1, *2, *3, *17. The wild-type (WT) allele, CYP2C19*1, is the most common variant. **Additional Information** The combination of alleles contributes to the individual's phenotype. Drug-metabolizing phenotypes have been classified into groups, from the lowest level of metabolism to the highest level of metabolism: poor metabolizers (PMs), intermediate metabolizers (IMs), normal/extensive metabolizers (NMs/EMs), rapid metabolizers (RMs), and Ultra-rapid extesive metabolizers (UMs). Variations in enzyme activity can lead to a variety of problems in clinical practice. PMs develop a higher serum concentration of drug, which may lead to increased risk of concentration-dependent side effects. They may also experience drug toxicity or other adverse drug reactions, or prolonged therapeutic effect because of impaired clearance of drug. If a drug is administered as a pro-drug that requires biotransformation to an active form, PMs may experience inadequate therapeutic effect if the drug does not reach the therapeutic dose. IMs may experience some of these same problems to a lesser extent. For UMs, rapid metabolism of the drug may lead to inadequate drug efficacy and therapeutic failure, because the drug may not reach the therapeutic serum concentration. For pro-drugs, UMs may be at higher risk of adverse drug reactions and side effects. **References** Caudle KE, Dunnenberger HM, Freimuth RR, et al. Standardizing terms for clinical pharmacogenetic test results: consensus terms from the Clinical Pharmacogenetics Implimentation Consortium (CPIC). *Genet Med.* 2017 Feb;19(2):215-223. Shimada T, Yamazaki H, Mimura M, Inui Y, Guengerich FP. Interindividual variations in human liver cytochrome P-450 enzymes involved in the oxidation of drugs, carcinogens and toxic chemicals: studies with liver microsomes of 30 Japanese and 30 Caucasians. *J Pharmacol Exp Ther.* 1994 Jul;270(1):414-423. Wilkinson GR. Drug metabolism and variability among patients in drug response. *N Engl J Med.* 2005 May 26;352(21):2211-2221. xTAG® CYP2D6 Kit v3 US-IVD [package insert]. Luminex; MLD-030-KPI-001 Rev G; 2018. xTAG® CYP2C19 Kit v3 US-IVD [package insert]. Luminex; MLD-046-KPI-001 Rev E; 2018.

Note: Please consult the online Directory of Services and Interpretive Guide at https://www.labcorp.com/tests for the most current test information.

Test Name	Test No.	**Field**/Change (Only fields that change are included here.)
Cytochrome P450 2D6 Genotyping	**511230**	**Specimen** Whole blood **Volume** 7 mL **Minimum Volume** 3 mL **Container** Lavender-top (EDTA) tube or yellow-top (ACD) tube **Causes for Rejection** Frozen specimen; hemolysis; quantity not sufficient for analysis; improper container **Use** The xTAG® CYP2D6 Kit v3 is a qualitative genotyping assay, which can be used as an aid to clinicians in determining therapeutic stategy for therapeutics that are metabolized by the CYP2D6 gene product. CYP2D6 is involved in the metabolism of more than 65 commonly used drugs including β-blockers, antipsychotics, antidepressants, analgesics, and antiarrythmics. The CYP2D6 gene is highly polymorphic. Many alleles of 2D6 encode enzymes that have reduced or no function compared to the wild-type enzyme. Individuals can also have gene rearrangements with more than two copies of the CYP2D6 gene (gene duplication) or absence of both copies (gene deletion). Depending on the combination of alleles in an individual, drug-metabolizing phenotypes associated with the CYP2D6 enzyme can vary. **Limitations** This kit is not indicated for stand-alone diagnostic purposes. This test is not indicated to be used to predict drug response or non-response. Only alleles listed will be identified by this product. Other CYP2D6 alleles, which are rare, or were unknown at the time of release of this product, will not be identified by this product. These other CYP2D6 alleles my result in either a *1 call, a no-call, or a call of a genetically related allele included in this kit. The CYP2D6 phenotype depends on enviromental factors in addition to the CYP2D6 genotype. These factors include the individual's age, size and gender, renal and liver function, disease status, and lifstyle factors such as smoking, some foods, and alcohol consumption. The co-administration of drugs metabolized by the CYP2D6, or other drugs that can act as inducers or inhibitors of CYP2D6 also affect the drug-metabolizing phenotype. **Methodology** This assay utilizes the Luminex xTAG® CYP2D6 Kit v3 US-IVD. The xTAG® CYP2D6 Kit v3 is a device used to simultaneously detect and identify a panel of nucleotide variants found within the highly polymorphic CYP2D6 gene located on chromosome 22 from genomic DNA extracted from EDTA and citrate anticoagulated whole blood samples. This kit can also identify gene rearrangements associated with the deletion (*5) and duplication genotypes. The xTAG® CYP2D6 Kit v3 incorporates multiplex Polymerase Chain Reaction (PCR) and multiplex Allele Specific Promer Extension (ASPE) with Luminex's proprietary Universal Tag sorting system on the Luminex® 100/200™ xMAP® platform. Alleles detected by the xTAG® CYP2D6 Kit v3: *1, *2, *3, *4, *5, *6, *7, *8, *9, *10, *11, *15, *17, *29, *35, *41, and DUP (duplication). The *1 allele is the most common allele in all ethnicities. **Additional Information** Drug-metabolizing phenotypes have been classified into groups, from the lowest level of metabolism to the highest level of metabolism: poor metabolizers (PMs), intermediate metabolizers (IMs), normal metabolizers (NMs), rapid metabolizers (RMs), and ultra-rapid extensive metabolizers (UMs). The combination of alleles contributes to the individual's phenotype. For CYP2D6, categories of alleles include: normal function (*1, *2, *35), reduced function (*9, *10, *17, *29 and *41), non-functional (*3, *4, *5, *6, *7, *8, *11 and *15), and increased function resulting from gene duplication. The combination of inherited alleles is a diplotype. There is no standard approach to convert diplotypes into predicted phenotype, and more importantly, predictions may not absolutely correlate to the observed phenotype. However, the Clinical Pharmacogenetics Implementation Consortium (CPIC) guidelines describe a frequently referenced model for assigning activity scores to diplotypes and subsequently predict a phenotypic metabolic classification. Variations in CYP2D6 enzyme activity can lead to a variety of problems in clinical practice. PMs develop a higher serum concentration of drug, which may lead to increased risk of concentration-dependent side effects. They may also experience drug toxicity or other adverse drug reactions, or prolonged therapeutic effect because of impaired clearance of drug. If a drug is administered as a pro-drug that requires biotransformation to an active form, PMs may experience inadequate therapeutic effect if the drug does not reach the therapeutic dose. IMs may experience some of these same problems to a lesser extent. For UMs, rapid metabolism of the drug may lead to inadequate drug efficacy and therapeutic failure, because the drug may not reach the therapeutic serum concentration. For pro-drugs, UMs may be at higher risk of adverse drug reactions and side effects. **References** Caudle KE, Dunnenberger HM, Freimuth RR, et al. Standardizing terms for clinical pharmacogenetic test results: consensus terms from the Clinical Pharmacogenetics Implimentation Consortium (CPIC). *Genet Med.* 2017 Feb;19(2):215-223. Gaedigk A, Sangkuhl K, Whirl-Carrillo M, Klein T, Leeder JS. Prediction of CYP2D6 phenotype from genotype across world puplications. 2017 Genetics in Medicine. *Genet Med.* 2017 Jan;19(1):69-76. Meyer UA. Pharmacogenetics and adverse drug reactions. *Lancet.* 2000 Nov 11;356(9242):1667-1671. Shimada T, Yamazaki H, Mimura M, Inui Y, Guengerich FP. Interindividual variations in human liver cytochrome P-450 enzymes involved in the oxidation of drugs, carcinogens and toxic chemicals: studies with liver microsomes of 30 Japanese and 30 Caucasians. *J Pharmacol Exp Ther.* 1994 Jul;270(1):414-423. Wilkinson GR. Drug metabolism and variability among patients in drug response. *N Engl J Med.* 2005 May 26;352(21):2211-2221. xTAG® CYP2D6 Kit v3 US-IVD [package insert]. Luminex; MLD-030-KPI-001 Rev G; 2018.
Cytochrome P450 3A4/3A5 Genotyping	**504155**	**Use** This test provides genotypes for CYP3A4 and CYP3A5. **Limitations** This assay detects CYP3A4 alleles *1 and *22, and CYP3A5 alleles *1, *3, *6, *7. Other alleles are not detected by this assay. This test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration.

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Test Name	Test No.	**Field**/Change (Only fields that change are included here.)
Diabetes Risk–Asymptomatic Adults	**090400**	**Container** **Hemoglobin A1c:** lavender-top (EDTA) tube; green-top (lithium heparin) tube; or gray-top (sodium fluoride) tube **Glucose, Plasma:** gray-top (sodium fluoride) tube or green-top (lithium heparin) tube
α-Fetoprotein (AFP), Maternal Serum for Open Spina Bifida	**010801**	**Container** Gel-barrier tube **Collection** Collect in serum separator tube with gel barrier. Allow blood to clot, avoiding hemolysis. Separate serum from cells by centrifugation. Transport spun tube to testing laboratory. Pour-off is not advised. Maternal serum specimens must be drawn prior to amniocentesis to avoid contamination with fetal blood.
α-Fetoprotein (AFP) Tetra Profile	**017319**	
***FGFR* Mutation Analysis, Urothelial Cancer**	**489124**	**Causes for Rejection** • Specimen does not meet all of the above criteria for sample type, container, minimum volume, collection and storage. • Specimens containing suspicious foreign material. • No tumor tissue in FFPE block or slides. • Broken or stained slides. • Fixative other than formalin. • If total non-necrotic tumor tissue area per slide is determined to be <5mm2 (i.e. >20 unstained slides are required to obtain the required tumor tissue input).
First Trimester Screen With Nuchal Translucency	**017500**	**Container** Gel-barrier tube **Collection** Collect in serum separator tube with gel barrier. Allow blood to clot, avoiding hemolysis. Separate serum from cells by centrifugation. Transport spun tube to testing laboratory. Pour-off is not advised. Maternal serum specimens must be drawn prior to amniocentesis to avoid contamination with fetal blood.
Fragile X, PCR and Southern Blot Analysis	**511655**	**Methodology** Polymerase chain reaction (PCR) followed by capillary electrophoresis and Southern blot analysis performed on all samples at the same time. **Fragile X syndrome:** DNA is amplified by the polymerase chain reaction (PCR) to determine the size of the CGG repeat region within the *FMR1* gene. PCR products are generated using a fluorescence labeled primer and sized by capillary gel electrophoresis. If indicated, Southern blot analysis is performed by hybridizing the probe StB12.3 to EcoRI- and EagI- digested DNA. The analytical sensitivity of both Southern blot and PCR analyses is 99% for expansion mutations in the *FMR1* gene. Reported CGG repeat sizes may vary as follows: +/- one for repeats less than 60, and +/- two to four for repeats in the 60 - 120 range. For repeats greater than 120, the accuracy is +/- 10%. If 55-90 trinucleotide repeats are detected in carrier screening females, a PCR assay targeting AGG sequences within the CGG repeats is performed to assess the number and position of AGG interruptions.
Fragile X Syndrome, PCR With Reflex to Southern Blot	**511919**	
GeneSeq®: Cardio-Early-onset Coronary Artery Disease/Familial Hypercholesterolemia Profile	**451416**	**Test Includes** This test covers all coding nucleotides of 7 genes: *ABCA1, APOA2, APOC3, LDLR, LDLRAP1, PCSK9,* and *PON2;* plus at least two and typically 10 flanking intronic nucleotides upstream and downstream of each coding exon, covering the conserved donor and acceptor splice sites, as well as typically 10 flanking nucleotides in the 5′ and 3′ UTR. This test also covers the region of *APOB* where all disease associated mutations have been found (within a 200-nucleotide region in exon 26 of *APOB*). **Methodology** Mutation analysis is performed using the Agilent Sure Select XT® enrichment method and the Illumina® next-generation sequencing platform. Regions of interest include all exons and splice junctions for each gene and limited regions for the following: *APOB* (556bp of exon 26) and *MED12* (c.3020A>G). Sequencing reads are aligned with the hg19 build of the human genome reference sequence. Analytical sensitivity is based on the depth of coverage across the regions of interest and is provided separately for each gene. Greater than 98% of target bases are synonymous variants not previously recorded at greater than or equal to 20x coverage. Sanger sequencing is used to confirm mutation identity and analyze regions with low coverage. Variants are reported using numbering and nomenclature recommended by the Human Genome Variation Society (HGVS). Variants known to be benign and synonymous variants not previously recorded in our internal variant data bases are not reported.
GeneSeq®: Cardio-Familial Aortopathy Profile	**451432**	**Test Includes** This test covers all coding nucleotides of 10 genes: *ACTA2, COL3A1, FBN1, MYLK, MYH11, SLC2A10, SMAD3, TGFB2, TGFBR1, TGFBR2,* and the *MED12* (c.3020>G) variant, plus at least two and typically 10 flanking intronic nucleotides upstream and downstream of each coding exon, covering the conserved donor and acceptor splice sites, as well as typically 10 flanking nucleotides in the 5′ and 3′ UTR. **Methodology** Mutation analysis is performed using the AgilentSure Select XT® enrichment method and the Illumina® next-generation sequencing platform. Regions of interest include all exons and splice junctions for each gene and limited regions for the following: *APOB* (556bp of exon 26) and *MED12* (c.3020A>G). Sequencing reads are aligned withthe hg19 build of the human genome reference sequence. Analytical sensitivity is based on the depth of coverage across the regions of interest and is provided separately for each gene. Greater than 98% of target bases are synonymous variants not previously recorded at greater than or equal to 20x coverage. Sanger sequencing is used to confirm mutation identity and analyze regions with low coverage. Variants are reported using numbering and nomenclature recommended by the Human Genome Variation Society (HGVS). Variants known to be benign and synonymous variants not previously recorded in our internal variant data bases are not reported.

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Test Name	Test No.	Field/Change (Only fields that change are included here.)
GeneSeq®: Cardio-Familial Arrhythmia Profile	**451412**	**Test Includes** This test covers all coding nucleotides of 29 genes: *ANK2, AKAP9, ATP1B1, CACNA1C, CACNB2, CASQ2, CAV3, DSC2, DSG2, DSP, GPD1L, JUP, KCNE1, KCN2E2, KCNH2, KCNJ2, KCNQ1, LIG3, NOS1AP, NPPA, PKP2, PLN, RYR2, SCN1B, SCN4B, SCN5A, SNTA1, TGFB3,* and *TMEM43;* plus at least two and typically 10 flanking intronic nucleotides upstream and downstream of each coding exon, covering the conserved donor and acceptor splice sites, as well as typically 10 flanking nucleotides in the 5′ and 3′ UTR. **Methodology** Mutation analysis is performed using the Agilent Sure Select XT® enrichment method and the Illumina® next-generation sequencing platform. Regions of interest include all exons and splice junctions for each gene and limited regions for the following: *APOB* (556bp of exon 26) and *MED12* (c.3020A>G). Sequencing reads are aligned with the hg19 build of the human genome reference sequence. Analytical sensitivity is based on the depth of coverage across the regions of interest and is provided separately for each gene. Greater than 98% of target bases are synonymous variants not previously recorded at greater than or equal to 20x coverage. Sanger sequencing is used to confirm mutation identity and analyze regions with low coverage. Variants are reported using numbering and nomenclature recommended by the Human Genome Variation Society (HGVS). Variants known to be benign and synonymous variants not previously recorded in our internal variant data bases are not reported.
GeneSeq®: Cardio-Familial Cardiomyopathy Profile	**451422**	**Test Includes** This test covers all coding nucleotides of 48 genes: *ABCC9, ACTC1, ACTN2, ALMS1, APOA1, BAG3, CAV3, CSRP3, CTF1, DES, DNAJC19, DSC2, DSG2, DSP, DTNA, EMD, EYA4, FKTN, GLA, JUP, LAMP2, LDB3, LMNA, MYBPC3, MYH6, MYH7, MYL2, MYL3, MYLK2, PLN, PKP2, PRKAG2, RBM20, RYR2, SCN5A, SGCD, TAZ, TCAP, TGFB3, TMEM43, TMPO, TNNC1, TNNI3, TNNT2, TPM1, TTR, TTN,* and *VCL,* plus at least two and typically 10 flanking intronic nucleotides upstream and downstream of each coding exon, covering the conserved donor and acceptor splice sites, as well as typically 10 flanking nucleotides in the 5′ and 3′ UTR. **Methodology** Mutation analysis is performed using the Agilent Sure Select XT® enrichment method and the Illumina® next-generation sequencing platform. Regions of interest include all exons and splice junctions for each gene and limited regions for the following: *APOB* (556bp of exon 26) and *MED12* (c.3020A>G). Sequencing reads are aligned with the hg19 build of the human genome reference sequence. Analytical sensitivity is based on the depth of coverage across the regions of interest and is provided separately for each gene. Greater than 98% of target bases are synonymous variants not previously recorded at greater than or equal to 20x coverage. Sanger sequencing is used to confirm mutation identity and analyze regions with low coverage. Variants are reported using numbering and nomenclature recommended by the Human Genome Variation Society (HGVS). Variants known to be benign and synonymous variants not previously recorded in our internal variant data bases are not reported.
GeneSeq®: Cardio-Familial Congenital Heart Disease Profile	**451402**	**Methodology** Mutation analysis is performed using the Agilent Sure Select XT® enrichment method and the Illumina® next-generation sequencing platform. Regions of interest include all exons and splice junctions for each gene and limited regions for the following: *APOB* (556bp of exon 26) and *MED12* (c.3020A>G). Sequencing reads are aligned with the hg19 build of the human genome reference sequence. Analytical sensitivity is based on the depth of coverage across the regions of interest and is provided separately for each gene. Greater than 98% of target bases are synonymous variants not previously recorded at greater than or equal to 20x coverage. Sanger sequencing is used to confirm mutation identity and analyze regions with low coverage. Variants are reported using numbering and nomenclature recommended by the Human Genome Variation Society (HGVS). Variants known to be benign and synonymous variants not previously recorded in our internal variant data bases are not reported.
GeneSeq®: Cardio-Gene Specific Sequencing	**452053**	**Name** Changed from "GeneSeq®: Cardio Gene Specific Sequencing, NGS" **Test Includes** Full gene sequencing for any one of the following genes: following genes: A*2ML1, ABCA1, ABCC9, ACTA2, ACTC1, ACTN2, ALMS1, AKAP9, ANK2, APOA1, APOA2, APOC3, ATP1B1, BAG3, BRAF, CACNA1C, CACNB2, CASQ2, CAV3, CBL, CHD7, COL3A1, CSRP3, CTF1, DES, DNAJC19, DSC2, DSG2, DSP, DTNA, EMD, EYA4, FBN1, FKTN, GATA4, GLA, GPD1L, HRAS, JUP, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, KRAS, LAMP2, LDB3, LDLR, LDLRAP1, LIG3, LMNA, LZTR1, MAP2K1, MAP2K2, MRAS, MYBPC3, MYH11, MYH6, MYH7, MYL2, MYL3, MYLK, MYLK2, NF1, NRAS, NKX2–5, NOS1AP, NPPA, PCSK9, PKP2, PLN, PON2, PRKAG2, PTPN11, RAF1, RASA2, RBM20, RIT1, RRAS, RYR2, SCN1B, SCN4B, SCN5A, SGCD, SHOC2, SLC2A10, SMAD3, SNTA1, SOS1, SOS2, SPRED1, TAZ, TBX5, TCAP, TGFB2, TGFB3, TGFBR1, TGFBR2, TMEM43, TMPO, TNNC1, TNNI3, TNNT2, TPM1, TTR, TTN,* and *VCL*. Partial sequencing is performed for *APOB* (556bpof exon 26) and *MED12* (c.3020A>G). **Use** Full gene sequencing is available for all the genes included in any of the GeneSeq®: Cardio profiles: GeneSeq®: Cardio-Familial Arrhythmia Profile (451412); GeneSeq®: Cardio-Familial Cardiomyopathy Profile (451422); GeneSeq®: Cardio-Noonan Syndrome/RASopathies Profile (451441); GeneSeq®: Cardio-Familial Aortopathy Profile (451432); GeneSeq®: Cardio-Early-onset Coronary Artery Disease/FamilialHypercholesterolemia Profile (451416); GeneSeq®: Cardio-Familial Hypercholesterolemia Profile (452040); and GeneSeq®: Cardio-Familial Congenital Heart Disease Profile (451402). **Methodology** Mutation analysis is performed using the Agilent Sure Select XT® enrichment method and the Illumina® next-generation sequencing platform. Regions of interest include all exons and splice junctions for each gene and limited regions for the following: *APOB* (556bp of exon 26) and *MED12* (c.3020A>G). Sequencing reads are aligned with the hg19 build of the human genome reference sequence. Analytical sensitivity is based on the depth of coverage across the regions of interest and is provided separately for each gene. Greater than 98% of target bases are synonymous variants not previously recorded at greater than or equal to 20x coverage. Sanger sequencing is used to confirm mutation identity and analyze regions with low coverage. Variants are reported using numbering and nomenclature recommended by the Human Genome Variation Society (HGVS). Variants known to be benign and synonymous variants not previously recorded in our internal variant databases are not reported.

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Test Name	Test No.	Field/Change (Only fields that change are included here.)
GeneSeq®: Cardio-Familial Hypercholesterolemia Profile	**452040**	**Test Includes** This test covers all coding nucleotides of 3 genes: *LDLR, LDLRAP1* and *PCSK9,* plus at least two and typically 10 flanking intronic nucleotides upstream and downstream of each coding exon, covering the conserved donor and acceptor splice sites, as well as typically 10 flanking nucleotides in the 5' and 3' UTR. This test also covers the region of the *APOB* where all disease associated mutations have been found (within a 200-nucleotide region in exon 26 of *APOB*). **Methodology** Mutation analysis is performed using the Agilent Sure Select XT® enrichment method and the Illumina® next-generation sequencing platform. Regions of interest include all exons and splice junctions for each gene and limited regions for the following: *APOB* (556bp of exon 26) and *MED12* (c.3020A>G). Sequencing reads are aligned with the hg19 build of the human genome reference sequence. Analytical sensitivity is based on the depth of coverage across the regions of interest and is provided separately for each gene. Greater than 98% of target bases are synonymous variants not previously recorded at greater than or equal to 20x coverage. Sanger sequencing is used to confirm mutation identity and analyze regions with low coverage. Variants are reported using numbering and nomenclature recommended by the Human Genome Variation Society (HGVS). Variants known to be benign and synonymous variants not previously recorded in our internal variant data bases are not reported.
GeneSeq®: Cardio-Noonan Syndrome/ RASopathies Profile	**451441**	**Name** Changed from "GeneSeq®: Cardio Noonan Syndrome and Related Conditions Profile" **Test Includes** This test covers all coding nucleotides of 20 genes: *A2ML1, BRAF, CBL, HRAS, KRAS, LZTR1, MAP2K1, MAP2K2, MRAS, NF1, NRAS, PTPN11, RAF1, RIT1, RRAS, RASA2, SHOC2, SOS1, SOS2,* and *SPRED1,* plus at least two and typically 10 flanking intronic nucleotides upstream and downstream of each coding exon, covering the conserved donor and acceptor splice sites, as well as typically 10 flanking nucleotides in the 5' and 3' UTR. **Methodology** Mutation analysis is performed using the Agilent Sure Select XT® enrichment method and the Illumina® next-generation sequencing platform. Regions of interest include all exons and splice junctions for each gene and limited regions for the following: *APOB* (556bp of exon 26) and *MED12* (c.3020A>G). Sequencing reads are aligned with the hg19 build of the human genome reference sequence. Analytical sensitivity is based on the depth of coverage across the regions of interest and is provided separately for each gene. Greater than 98% of target bases are synonymous variants not previously recorded at greater than or equal to 20x coverage. Sanger sequencing isused to confirm mutation identity and analyze regions with low coverage. Variants are reported using numbering and nomenclature recommended by the Human Genome Variation Society (HGVS). Variants known to be benign and synonymous variants not previously recorded in our internal variant data bases are not reported.
Glucose, Plasma	**001818**	**Container** Gray-top (sodium fluoride) tube or green-top (lithium heparin) tube
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus,* NAA and Human Papillomavirus (HPV) (Aptima®)	**193157**	**Limitations** Failure to obtain adequate ectocervical, endocervical, or vaginal cell population is suboptimal for evaluation. Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination and may lead to unsatisfactory Pap results. The use of the liquid-based cytology specimen for multiple tests may limit the volume available for Pap reprocessing or HPV testing. A negative result does not exclude the possibility of an HPV infection since very low levels of infection or sampling error may produce a false-negative result. This test detects only the 14 most common high-risk HPV types. Testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* requires special procedures to be used in the processing of the cytology specimen; therefore, testing for these organisms cannot be added on after the specimen has been submitted. The liquid-based cytology specimen must be processed for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* testing.
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus/ Trichomonas,* NAA and Human Papillomavirus (HPV) (Aptima®)	**199328**	**Limitations** Failure to obtain adequate ectocervical, endocervical, or vaginal cell population is suboptimal for evaluation. Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination and may lead to unsatisfactory Pap results. The use of the liquid-based cytology specimen for multiple tests may limit the volume available for Pap reprocessing or HPV testing. A negative result does not exclude the possibility of an HPV infection since very low levels of infection or sampling error may produce a false-negative result. This test detects only the 14 most common high-risk HPV types. Testing for *Chlamydia trachomatis, Neisseria gonorrhoeae,* and *Trichomonas vaginalis* requires special procedures to be used in the processing of the cytology specimen; therefore, testing for these organisms cannot be added on after the specimen has been submitted. The liquid-based cytology specimen must be processed for *Chlamydia trachomatis, Neisseria gonorrhoeae,* and *Trichomonas vaginalis* testing.
Gynecologic Pap Test (Image-guided), Liquid-based Preparation With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U With Reflex to HPV Genotypes 16 and 18,45	**199340**	**Limitations** Failure to obtain adequate ectocervical, endocervical, or vaginal cell population is suboptimal for evaluation. Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination and may lead to unsatisfactory Pap results. The use of the liquid-based cytology specimen for multiple tests may limit the volume available for Pap reprocessing or HPV testing. A negative result does not exclude the possibility of an HPV infection since very low levels of infection or sampling error may produce a false-negative result. This test detects only the 14 most common high-risk HPV types. When reflex conditions are met, HPV type 16 and type 18,45 testing is performed.

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Test Name	Test No.	**Field**/Change (Only fields that change are included here.)
HLA A CWD Resolution	**167331**	**Specimen** Whole blood **or** buccal swabs **Volume** 7 mL whole blood **or** four buccal swabs **Minimum Volume** 3 mL whole blood **or** four buccal swabs **Container** Lavender-top (EDTA) tube **or** four buccal swabs in a sealed envelope (buccal swab kit). When submitting buccal swabs, please use a buccal swab kit provided by LabCorp. To obtain the buccal swab kit, please telephone 800-533-1037.
HLA A High Resolution	**167377**	
HLA A Intermediate Resolution	**167267**	
HLA A,B,C Intermediate Resolution	**167116**	
HLA A,B,C Profile (High Resolution)	**176088**	
HLA B CWD Resolution	**167352**	
HLA B High Resolution	**167391**	
HLA B Intermediate Resolution	**167292**	
HLA C High Resolution	**167405**	
HLA C Intermediate Resolution	**167316**	
HLA DPB1 High Resolution	**167323**	
HLA DQB1 High Resolution	**167232**	
HLA DQB1 Intermediate Resolution	**167190**	
HLA DRB1 CWD Resolution	**167147**	
HLA DRB1 High Resolution	**167167**	
HLA DRB1 High Resolution, DRB3,4,5 Intermediate Resolution	**176082**	
HLA DRB1 Intermediate Resolution	**167259**	
HLA DRB3,4,5 High Resolution	**167357**	
HLA DR1/3/4/5, DQ Intermediate Resolution	**167120**	
HLA DR15 (DR2) Immunosuppressive Response Association in Myelodysplastic Syndrome (MDS)	**167100**	**Synonyms** DR15; Immunosuppressive Response; MDS; Myelodysplastic Syndrome **Use** Determine the presence of DR15 antigen.
IFNL3 (IL28B) Genotyping (rs12979860)	**480630**	**Name** Changed from "Interleukin 28B (*IL28B*) Polymorphism (rs12979860)" **Use** This assay is used for genotyping IL-28B rs12979860. **Limitations** *IL28B* genotype should be interpreted in the context of other clinical factors. This assay detects only a single base change in the *IL28B* gene (single nucleotide polymorphism rs12979860 C/T). No other polymorphisms are detected by this assay. Rare sequence polymorphisms close to rs12979860 may interfere with the genotype results of this assay. **Methodology** Real-time polymerase chain reaction (PCR) with allele-specific TaqMan® probes is used to detect a single nucleotide polymorphism (SNP) (rs12979860 C/T) on chromosome 19q13. The rs12979860 SNP maps 3 kilobases upstream of the IL28B gene (OMIM 607402), which encodes the type III interferon-λ3.

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Test Name	Test No.	Field/Change (Only fields that change are included here.)
Inheritest® Carrier Screen, Ashkenazi Jewish Panel (48 Genes)	**451920**	**Methodology** **Next generation sequencing (NGS):** Genomic regions of interest are selected using the Agilent® SureSelect-tXT® hybridization capture method for target enrichment and sequenced via the Illumina® next generation sequencing platform. Sequencing reads are aligned with the human genome reference GRCh37/hg19 build. Targeted regions are sequenced to at least 200X mean base coverage with a minimum of 99% of bases at > or = 20X coverage. Analytical sensitivity is estimated to be >99% for single nucleotide variants and small insertions/deletions (<5 bp). **Alpha-thalassemia:** Analysis of the alpha-globin (HBA) gene cluster is performed by multiplex ligationdependent amplification (MLPA). Variants included in the analysis are the Constant Spring non-deletion variant and the following deletions: -alpha3.7, -alpha4.2, -alpha20.5, --SEA, --FIL, --THAI, --MED, and the HS-40 regulatory region. This MLPA analysis does not detect other variants in the alpha-globin genes or variants in the beta-globin gene and may not detect the co-occurrence of a deletion and a duplication. Analytical sensitivity is estimated to be >99% for the targeted variants. **Spinal muscular atrophy:** DNA is amplified by real-time polymerase chain reaction (PCR). The number of copies of exon 7 of *SMN1* is assessed relative to internal standard reference genes. A mathematical algorithm calculates 0, 1, 2 and 3 copies with statistical confidence. If one copy of *SMN1* is detected, primer and probe binding sites are sequenced to rule out variants that could interfere with copy number analysis. If no copies of *SMN1* are detected, *SMN2* copy number is assessed by digital PCR analysis relative to an internal standard reference gene. Copy number analysis cannot detect carriers with either 2 or, very rarely, 3 copies of *SMN1* and no copies of *SMN1* on the other chromosome. **Fragile X syndrome:** DNA is amplified by the polymerase chain reaction (PCR) to determine the size of the CGG repeat region within the *FMR1* gene. PCR products are generated using a fluorescence labeled primer and sized by capillary gel electrophoresis. If indicated, Southern blot analysis is performed by hybridizing the probe StB12.3 to EcoRI- and EagI- digested DNA. The analytical sensitivity of both Southern blot and PCR analyses is 99% for expansion mutations in the *FMR1* +/- one for repeats less than 60, and +/- two to four for repeats in the 60 - 120 range. For repeats greater than 120, the accuracy is +/- 10%. If 55-90 trinucleotide repeats are detected in carrier screening females, a PCR assay targeting AGG sequences within the CGG repeats is performed to assess the number and position of AGG interruptions. Pathogenic and likely pathogenic variants are reported after confirmation by Sanger sequencing or an appropriate technology. Non-deletion variants are specified using the numbering and nomenclature recommended by the Human Genome Variation Society (HGVS, http://www.hgvs.org). Variants of uncertain significance and benign variants are not reported. Variant classification is consistent with ACMG standards and guidelines.[1] Detailed variant classification information is available upon request.
Inheritest® Carrier Screen, Comprehensive Panel (144 Genes)	**451950**	
Inheritest® Carrier Screen, Society-guided Panel (14 Genes)	**451960**	
Inheritest® Core Panel	**451964**	**Methodology** **CFplus:** DNA is isolated from the sample and tested for the 97 CF mutations listed. Regions of the *CFTR* gene are amplified enzymatically and subjected to a solution-phase multiplex allele-specific primer extension with subsequent hybridization to a bead array and fluorescence detection. Some mutations are then specifically identified by bidirectional dideoxysequencing. **Fragile X syndrome:** DNA is amplified by the polymerase chain reaction (PCR) to determine the size of the CGG repeat region within the *FMR1* gene. PCR products are generated using a fluorescence labeled primer and sized by capillary gel electrophoresis. If indicated, Southern blot analysis is performed by hybridizing the probe StB12.3 to EcoRI- and EagI- digested DNA. The analytical sensitivity of both Southern blot and PCR analyses is 99% for expansion mutations in the *FMR1* gene. Reported CGG repeat sizes may vary as follows: +/- one for repeats less than 60, and +/- two to four for repeats in the 60 - 120 range. For repeats greater than 120, the accuracy is +/- 10%. If 55-90 trinucleotide repeats are detected in carrier screening females, a PCR assay targeting AGG sequences within the CGG repeats is performed to assess the number and position of AGG interruptions.
Integrated 1	**017100**	**Container** Gel-barrier tube **Collection** Collect in serum separator tube with gel barrier. Allow blood to clot, avoiding hemolysis. Separate serum from cells by centrifugation. Transport spun tube to testing laboratory. Pour-off is not advised. Maternal serum specimens must be drawn prior to amniocentesis to avoid contamination with fetal blood.
Integrated 2	**017170**	
Lactic Acid Dehydrogenase (LD)	**001115**	**Causes for Rejection** Plasma specimens collected in EDTA, oxalate, or citrated tubes; gross hemolysis; gross bacterial contamination; improper labeling **Methodology** Enzymatic, colorimetric, UV
Leukemia/Lymphoma Monitor Profile)	**485029**	**Limitations** This profile is not useful as a screening or diagnostic test for leukemia or lymphoma. The LASA test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration.

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Test Name	Test No.	Field/Change (Only fields that change are included here.)
Lipid-associated Sialic Acid (LASA)	**100313**	**Reference Interval** 8 - 23 mg/dL **Limitations** This test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration.
Lipid-associated Sialic Acid (LASA) (Serial Monitor)	**480129**	**Test Includes** This test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration.
Liver Cancer Monitor Profile	**485060**	**Limitations** This profile should not be used as a diagnostic or screening test for cancer. The LASA test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration.
Lung, Adenocarcinoma Monitor Profile	**485078**	
Lung, Small-cell Cancer Monitor Profile	**485177**	**Limitations** This profile should not be used as a diagnostic or screening test for cancer. The LASA test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration. The results of the NSE test are labeled for research purposes only by the assay's manufacturer. The performance characteristics of this assay have not been established by the manufacturer. The result should not be used for treatment or for diagnostic purposes without confirmation of the diagnosis by another medically established diagnostic product or procedure. The performance characteristics were determined by LabCorp.
Lysosomal Acid Lipase (LAL) Deficiency	**402300**	**Special Instructions** When submitting whole blood, specimen must arrive at the testing laboratory within 4 days of collection. **Storatge Instructions** ***Whole blood:*** Refrigerated transport must arrive at testing facility within 4 days of collection. ***Dried blood spot:*** Maintain specimen at room temperature.
MaterniT Genome	**451941**	**Special Instructions** The following information must be provided with the test request form: patient's date of birth, gestational age, and additional patient demographic information: pregnancy type (singleton), donor egg status and the clinical indications (including advanced maternal age, abnormal ultrasound, history suggestive of increased risk for aneuploidy, positive serum screen, or other indications).
MaterniT21 Genome NO Gender	**452106**	
Measles (Rubeola) Antibodies, IgG	**096560**	**Reference Interval** • Negative: <13.5 AU/mL • Equivocal: 13.5-16.4 AU/mL • Positive: >16.4 AU/mL
Measles (Rubeola) Antibodies, IgM	**160218**	**Name** Changed from "Rubeola Antibodies, IgM" **Reference Interval** • Negative: <0.91 ISR • Equivocal: 0.91-1.09 ISR • Positive: >1.09 ISR
Melanoma Monitor Profile	**485037**	**Limitations** This profile should not be used as a diagnostic or screening test for cancer. The LASA test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration. The results of the NSE test are labeled for research purposes only by the assay's manufacturer. The performance characteristics of this assay have not been established by the manufacturer. The result should not be used for treatment or for diagnostic purposes without confirmation of the diagnosis by another medically established diagnostic product or procedure. The performance characteristics were determined by LabCorp.
Neuroblastoma Monitor Profile	**485052**	
Neuron-specific Enolase (NSE)	**140624**	**Limitations** NSE is not a screening test. Results of this test are labeled for research purposes only by the assay's manufacturer. The performance characteristics of this assay have not been established by the manufacturer. The result should not be used for treatment or for diagnostic purposes without confirmation of the diagnosis by another medically established diagnostic product or procedure. The performance characteristics were determined by LabCorp.
Neuron-specific Enolase (NSE) (Serial Monitor)	**480137**	**Limitations** Results of this test are labeled for research purposes only by the assay's manufacturer. The performance characteristics of this assay have not been established by the manufacturer. The result should not be used for treatment or for diagnostic purposes without confirmation of the diagnosis by another medically established diagnostic product or procedure. The performance characteristics were determined by LabCorp.
Ovarian Cancer Monitor Profile III	**485110**	**Limitations** This profile should not be used as a diagnostic or screening test for cancer. The LASA test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration.
Pancreatic Cancer Monitor Profile	**485086**	

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Test Name	Test No.	Field/Change (Only fields that change are included here.)
pH, Stool	**010991**	**Reference Interval** pH: 0 to 6 months: 4.5–5.5; >6 months: 7.0–7.5
Prenatal Noonan Syndrome	**451890**	**Test Includes** This test covers all coding nucleotides of 19 genes: *A2ML1, BRAF, CBL, HRAS, KRAS, LZTR1, MAP2K1, MAP2K2, MRAS, NRAS, PTPN11, RAF1, RIT1, RRAS, RASA2, SHOC2, SOS1, SOS2,* and *SPRED1*, plus at least two and typically 10 flanking intronic nucleotides upstream and downstream of each coding exon, covering the conserved donor and acceptor splice sites, as well as typically10 flanking nucleotides in the 5′ and 3′ UTR. **Methodology** Mutation analysis is performed using the Agilent Sure Select XT® enrichment method and the Illumina® next-generation sequencing platform. Regions of interest include all exons and splice junctions for each gene and limited regions for the following: *APOB* (556bp of exon 26) and *MED12* (c.3020A>G). Sequencing reads are aligned with the hg19 build of the human genome reference sequence. Analytical sensitivity is based on the depth of coverage across the regions of interest and is provided separately for each gene. Greater than 98% of target bases are synonymous variants not previously recorded at greater than or equal to 20x coverage. Sanger sequencing is used to confirm mutation identity and analyze regions with low coverage. Variants are reported using numbering and nomenclature recommended by the Human Genome Variation Society (HGVS). Variants known to be benign and synonymous variants not previously recorded in our internal variant databases are not reported.
Renin Activity, Plasma	**002006**	**Patient Preparation** In order to facilitate interpretation of test results, the patient should be taken off medications for at least three weeks prior to sample collection (see Limitations for details). Dietary sodium levels during the period prior to testing can affect renin levels. Sodium restriction tends to cause an increase in renin activity, while supplementation can result in lower values. A 24-hour urine sodium determination from a sample collected on the day before a renin test can be used to assess sodium intake. Since patient posture prior to collection affects renin levels, it is recommended that the patient be ambulatory for at least 30 minutes before blood collection.1 If inpatients are physically able, they should be asked to ambulate for 30 minutes before blood is drawn for renin activity.
Rituximab and Anti-Rituximab Antibody, *Dose*ASSURE™ RTX	**504355**	**Specimen** Serum **Container** Gel-barrier tube, red-top tube, or serum transfer tube **Collection** Serum must be separated from cells within 45 minutes of venipuncture. Submit serum in a plastic transport tube. To avoid delays in turnaround time when requesting multiple test on frozen samples, **please submit separate frozen specimens for each test requested.**
Sequential 1	**017700**	**Container** Gel-barrier tube **Collection** Collect in serum separator tube with gel barrier. Allow blood to clot, avoiding hemolysis. Separate serum from cells by centrifugation. Transport spun tube to testing laboratory. Pour-off is not advised. Maternal serum specimens must be drawn prior to amniocentesis to avoid contamination with fetal blood.
Sequential 2	**017750**	
Serum Integrated 1	**017200**	
Serum Integrated 2	**017270**	
Uterine Cancer Monitor Profile	**485136**	**Limitations** This profile should not be used as a diagnostic or screening test for cancer. The LASA test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration.

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CPT Code Updates

Test Name	Test No.	CPT(s)
GeneSeq®: Cardio-Familial Aortopathy Profile	**451432**	81410
GeneSeq®: Cardio-Familial Cardiomyopathy Profile	**451422**	81439
GeneSeq®: Cardio-Familial Hypercholesterolemia Profile	**452040**	81401; 81406(x2); 81479
GeneSeq®: Cardio-Noonan Syndrome/RASopathies Profile	**451441**	81442
Gene Sequencing, Hemophilia-Complete	**830129**	81238; 81406; 81407; 81408
Holter Cardiologist Overread	**019331**	93227
PlateletGenex Functional Defect Panel	**830153**	81404; 81406; 81408; 81479
Prenatal Noonan Syndrome	**451890**	81442

Deleted Procedures

Deleted Tests	Test No.	LabCorp Offers	Test No.
Clopidogrel CYP2C19 Genotyping	**511710**	Cytochrome P450 2C19 Genotyping	511675
Gene Sequencing, ADAMTS-13	**824840**	Gene Sequencing, ADAMTS-13	825252
Gene Sequencing, aHUS	**825178**	Gene Sequencing, aHUS	825212
Gene Sequencing, Dysfibrinogenemia	**824839**	Gene Sequencing, Dysfibrinogenemia	830113
Gene Sequencing, Hemophilia-Complete	**824833**	Gene Sequencing, Hemophilia-Complete	830129
Gene Sequencing, VWD-Complete	**824841**	Gene Sequencing, VWD-Complete	830195
Opioid CYP2D6 Genotyping	**511380**	Cytochrome P450 2D6 Genotyping	511230
Plasminogen Gene Sequencing	**824837**	Plasminogen Gene Sequencing	830145
PlateletGenex Functional Defect Panel	**824842**	PlateletGenex Functional Defect Panel	830153
PlateletGenex Thrombocytopenia Panel	**824834**	PlateletGenex Thrombocytopenia Panel	830160
Tamoxifen P450 2D6 Genotyping	**511280**	Cytochrome P450 2D6 Genotyping	511230
Warfarin (P450 2C9 and VKORC1)	**511460**	Please contact your LabCorp representative for testing options.	

The CPT codes listed are in accordance with the current edition of Current Procedural Terminology, a publication of the American Medical Association. CPT codes are provided for the convenience of our clients; however, correct coding often varies from one carrier to another. Consequently, the codes presented here are intended as general guidelines and should not be used without confirming with the applicable payer that their use is appropriate in each case.

LOINC® Map. The Logical Observation Identifiers Names and Codes (LOINC®) corresponding to the individual LabCorp published assays is updated on a regular basis at www.labcorp.com.

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